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Targeted Electromyographic Biofeedback With Endoanal Electrostimulation for Anal Incontinence

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Abstract

Purpose. Anal incontinence (AI) is a disabling condition with a variable response to conservative physical therapies. We assess the utility of combining electromyographic biofeedback with endoanal electrostimulation targeted to the weakest areas of the pelvic floor using the MAPLe® probe (Multiple Array Probe Leiden Novuqare). *Methods*. Patients with AI unresponsive to conservative measures were assessed before and after treatment with anorectal manometry (ARM), electromyography (EMG), Wexner Continence Scoring, Visual Analog Scoring (VAS), FIQL and SF-12 quality of life determination. *Results*. Of 29 patients in the final analysis, there was an improvement in the mean Wexner continence score from 13.59 to 8.03 and a concomitant improvement in the reported VAS from 3.45 to 6.72. Both Wexner continence and VAS scores were maintained during follow-up. Maximum voluntary manometric contraction significantly improved from 91.76 mmHg to 110.33 mmHg with no changes in resting pressure. The EMG values (μV) that significantly improved included the average and peak resistance, the average general voluntary contraction, and the average and peak voluntary contraction for both the external anal sphincter and the puborectalis. In the FIQL, behavior, depression and shame domains improved after treatment and during follow-up with lifestyle improvements detected at 6 and 12 months. Physical and mental components of the SF-12 improved at 6 and 12 months. *Conclusions*. Targeted electromyographic biofeedback and endoanal electrostimulation using MAPLe® probe in AI patients sustainably improves objective ARM and EMG parameters along with subjective reporting of continence severity, VAS, and quality of life.

Keywords

anal incontinence, biofeedback and endoanal electrostimulation, multiple array probe leiden novuqare, electromyography

Introduction

Anal incontinence (AI) is a physically and psychologically disabling condition resulting in a significant impairment in patient quality of life and a considerable social health burden.[1] AI management begins with conservative measures aimed at diet and improving the impact of AI on well-being. This is followed with simple medication designed to reduce the number and consistency of stools. Treatment then typically progresses to pelvic floor rehabilitation techniques which include biofeedback, electrostimulation, or posterior tibial neuromodulation. Surgical treatment is customarily reserved as the last option and includes sacral nerve stimulation, sphincter reconstruction or muscle transpositions.[2] Surface electromyography (EMG) has increasingly been used for diagnosis in urogynecology and proctology[3-5] with biofeedback therapy and electrostimulation demonstrating

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proven worth in the management of AI patients.[6,7] Despite these good reported outcomes, the studies are heterogeneous and because there is often limited detail outlining particular biofeedback and electrostimulation protocols, it is difficult to reproduce these results. To date, no article has been published using the MAPLe® device as a therapeutic method for AI, only 2 publications and a trial registered in 2019 (UK trial NCT03969069 "Assessment of Faecal Incontinence with MAPLe®") focus on its diagnostic utility.[8,9]

We present the outcome of a selected group of AI patients managed with an intensive protocol based on electromyographic biofeedback and endoanal electrostimulation specifically targeted to the weakest area of the pelvic floor using the MAPLe® system.

Material and Methods

Patient Cohort and Assessment

The conduct of this study was approved by the local institutional Ethics Committee. Patients included in the study were diagnosed with AI at the Coloproctology Unit of the Clinica Cemtro (Madrid), a University-affiliated tertiary referral center. Adult patients who presented between February 2018 and December 2019 with AI and who were unresponsive to conservative measures including dietary change and medications contributed to the study. Patients <18 years of age and those with a congenital anorectal malformation, malabsorption syndrome or an intellectual disability that precludes them from adequately answering a function questionnaire were excluded from the analysis. All data were collated by consultant colorectal surgeons with patients providing a detailed medical history and undergoing a thorough anorectal examination with recording of pre-treatment endoanal ultrasonography (Hitachi HI Vision, Avius) and 7-channel water-perfused anorectal manometry (ARM) (Solar GI MMS, Laborie Canada).

The protocol of biofeedback and electrostimulation was designed by colorectal surgeons and included ten 30-min sessions of treatment once or twice a week with follow-up manometry. Functional outcome was assessed with the Wexner incontinence scale[10] combined with a Visual Analogue Scale (VAS) which described the subjective perception of the severity of incontinence, indicating their bother (0 = the worst imaginable, 10 = none at all).[11] Quality of life (QoL) assessments were made using the SF-12 health-related QoL instrument and the Fecal Incontinence Quality of Life (FIQL) questionnaire. The SF-HRQoL (12v1) questionnaire is a modification of the short-form health survey SF-36 covering the same domains but with fewer questions.[12] The SF-12v1 rates the physical and the mental health status with separate scoring 2 domains, the Physical Component Summary Score (PCS) and the Mental Component Summary (MCS) Score. The FIQL questionnaire includes 29 questions that rate lifetsyle, behavior, depression/self-perception and shame as separate domains.[13] Functional scores and QoL assessments were performed before and immediately after biofeedback therapy and at 6 months and a year following completion of treatment.

The MAPLe® Device

The working endoanal probe (MAPLe® Multiple Array Probe Leiden Novuqare) consists of 24 high-definition electrodes which measure EMG signals for the different sides and levels of the pelvic floor musculature.[8] The system was developed for electromyographic registration and electrostimulation of the anal canal and individual muscles including the external anal sphincter (EAS) and the component parts of the levator ani (puborectalis, pubococcygeus and iliococcygeus). The electrodes are situated at 6 levels (rings 1-6) with 4 corresponding plates (front, back, left and right). The treating surgeon ensures the correct placement and orientation of the probe with the most caudal electrode located at the level of the EAS. Optimal probe deployment permits identification and targeting of the weakest individual muscles with the electrodes switching from diagnostic to therapeutic elements capable of low frequency electrostimulation. The MAPLe® system is operated through an iPad app with a visual representation of the entire pelvic floor via a high-definition interface that can also be viewed by the patient. The screen image provided appears as a circle with 6 rings where the center of the circle represents the uppermost (proximal) electrodes and the outermost circles the lowermost (distal) electrodes, as shown in Figure 1. This allows instant visualization of the different muscles on different sides and at variable depths with the muscle activity level displayed either in color or grayscale. The image permits the therapist to select the rings or plates that can be targeted and followed during biofeedback treatment. The screen image, shown in Figure 2, also provides the muscle activity of the patient, represented graphically vs time for repeat contracting/resting training protocols.

Description of the Biofeedback with Electrostimulation Protocol

From our initial previous experience, we developed a customized therapeutic protocol of 10 sessions used once or twice weekly depending upon patient availability. Each session was designed to last 30 min and was structured into 3 discrete segments (pre-stimulation, stimulation and post-stimulation) with the EMG recorded as μV. The pre-stimulatory phase records the average muscle activity at rest over 60 s followed by

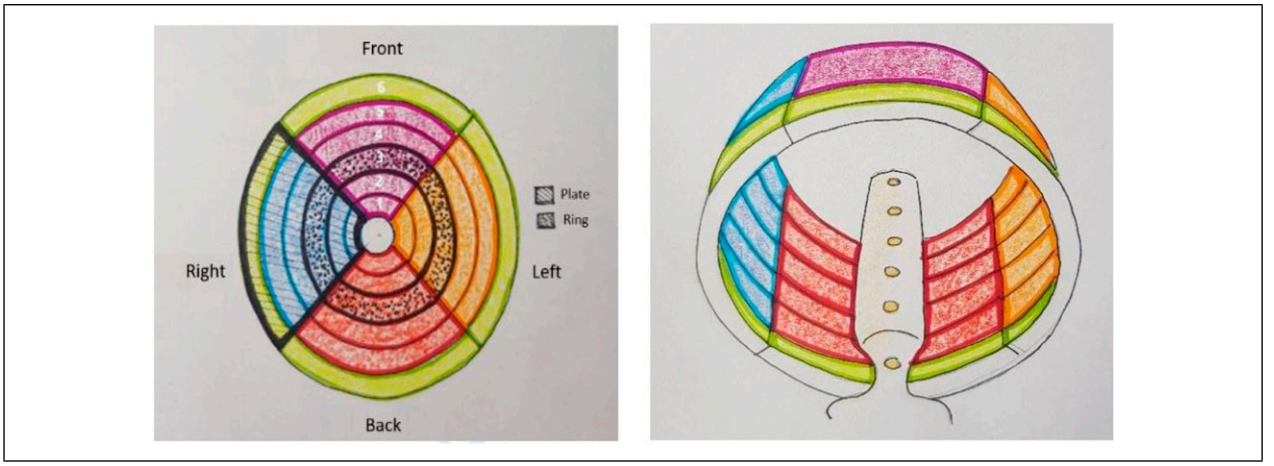

Figure 1. A sectorial image (plates and rings) is provided by the MAPLe® electrodes for muscle activity at different muscle orientations and depths.

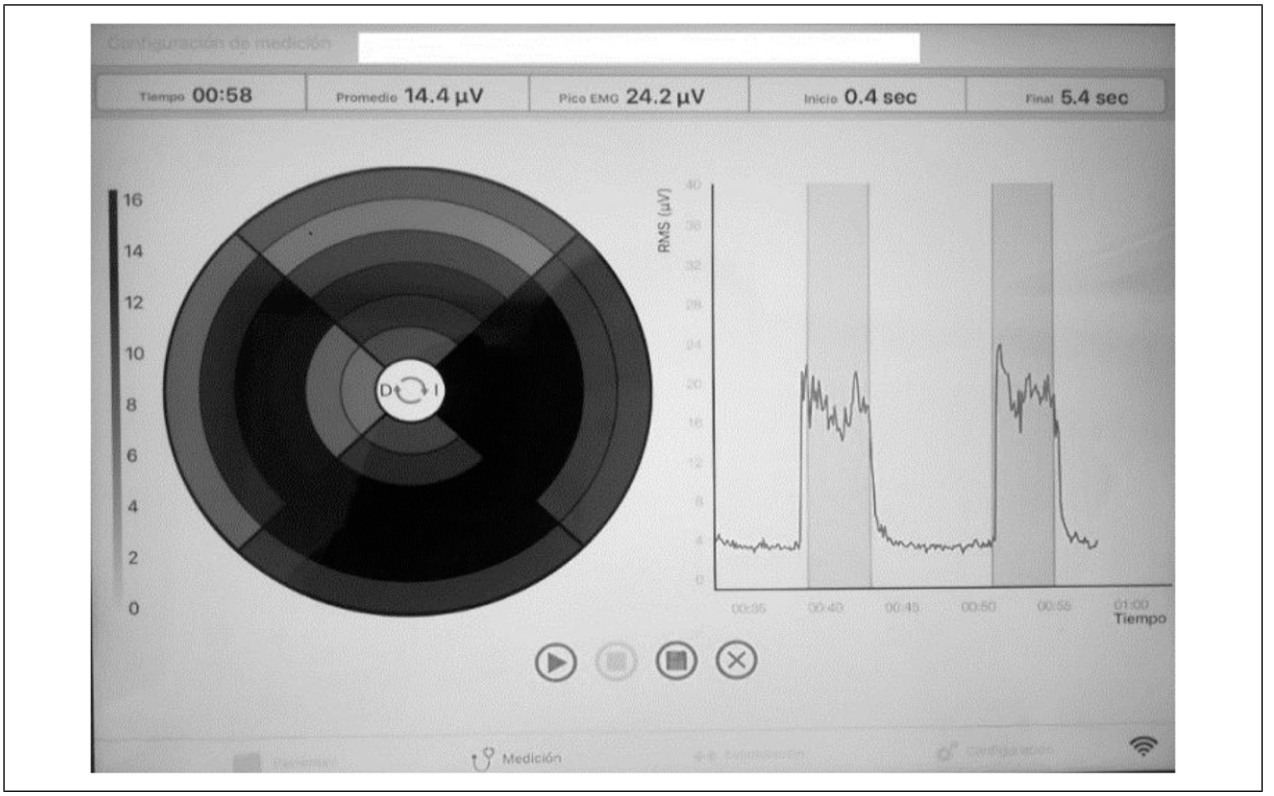

Figure 2. Screen view with the pelvic floor representation and the bar chart. The grey bars indicate to the patient when they must contract. Each bar is preceded by a "beep" sound that indicates to the patient when to start the contraction. The line in the bar chart represents the contraction and resting activity of the patient.

a resistance phase where two 15 s contractions are performed with a 10 s rest between. The average and peak EMG values are recorded. After this the voluntary contraction is measured as an average and peak EMG value for 5 contractions which each last 4 s with an 8 s rest between. This final part of the pre-stimulatory phase is conducted 4 times and is performed firstly with all of the rings selected and then a second time focusing on rings 3 and 4 (representing puborectalis activity). The measurement is made the third time by concentrating on ring 6 which equates with the EAS and the fourth measurement studies the rings and plates in what we refer to as a 'specific assessment' corresponding to those areas identified as weak at rest and during contraction.

The stimulatory phase lasts 10 min and is a symmetrical biphasic waveform with a gradual on and off cycle. This uses a pulse of 4 s of activity and 8 s of rest, a width of 350 μs and a frequency of 35 Hz. The treatment is focused on the rings or plates that are identified with the greatest weakness (the 'specific assessment' areas with lower registered voltages) and the intensity of the wave is steadily increased until the patient feels the vibration. The post-stimulattion phase is repeat the same exercises as in pre-stimulation phase. A 5-min period of freestyle 'training' is also included at completion of the post-stimulation recording where patients can practice the exercises with visual feedback of the contraction waveforms. Patients are provided with information sheets regarding supplementary Kegel exercises which they should perform daily at home.

Statistical Analysis

Analysis was performed with the SPSS v. 21.0 (Chicago, Ill) software package for Windows. Variables are reported as frequencies and percentages. Comparisons were made with the Student's t-test. Mann-Whitney test and Fisher's exact test are used to determine factors predictive of response and multivariate analysis is performed for relevant independent variables. The Odds Ratio (OR) and 95% CI are reported with P values <.05 considered significant.

Results

Thirty-three patients meet all the inclusion criteria for the treatment, 6 males, 27 females with a mean overall age of 58.1 ± 14.7 years. The median duration of incontinence prior to consultation was 2 years (range 1-5 years). There were 11 (28.9%) of the patients who had undergone prior anorectal surgery, 2 with a previous hysterectomy and 3 after specific rectal surgery (transanal minimally invasive surgery, transanal endoscopic microsurgery and a low anterior resection). There was one patient after a laparoscopic ventral rectopexy and one following a laparoscopic prostatectomy. Twenty four of the 27 women (88.9%) were parous with a mean parity of 2.2 and there were 8 women (33.3%) who had sustained a perineal tear in childbirth.

The Bristol stool consistency was >5 in 17 (56.1%) of the cases with urge incontinence reported in 27 (92.4%) of the cohort. Both the IAS and the EAS were intact on anal endosonography in 12 (36.4%) of the patients with defects in both sphincter muscles in 9 (27.8%). There was an isolated IAS defect in 6 (18.2%) of the cases and another 6 (18.2%) had an isolated EAS defect.

After commencement of the management schedule, 4 patients abandoned the treatment (COVID-19 related) leaving 29 patients in the final analysis. Table 1 shows a consistent improvement in both the Wexner score and the VAS in the immediate period after treatment and a maintenance of those improvements out to 12 months of follow-up ($P < .001$).

Significant differences were noted in the ARM values with an improvement of the Maximal Squeeze Pressure (MSP) from a preoperative value of 91.76 mmHg to a postoperative mean of 110.33 mmHg ($P < .01$). This was unaccompanied by any significant change in the Maximun Resting Anal Pressure (MRAP) (Pre-treatment 47.45 ± 16.54 mmHg vs. Post-treatment 48.87 ± 17.62 mmHg). In 82.8% of cases the EAS contractile response was the weakest area evident, and this was principally targeted for treatment. Table 2 shows the MAPLe® electromyographic data with significant differences noted in most measurable parameters including the average and peak resistance, the average voluntary contraction, the average and peak voluntary EAS contraction (corresponding to ring 6) and the average voluntary puborectalis contraction (corresponding to rings 3-4). Both the average and peak stimulated contractions of the targeted areas showed progressive increases ($p < .001$).

There were significant changes noted in the coping, depression and embarrassment domains of the FIQL after treatment with an extension of reported improvement to the lifestyle domain after 6 and 12 months of follow-up, as shown in Table 3. Changes in the measured physical and mental components of the truncated SF-12v1questionnaire where a significant effect in both component scores was not found in the immediate post-treatment period but was achieved during follow-up.

Patients were divided into 4 discrete groups according to whether they had a combined IAS and EAS injury, isolated sphincter damage or no evidence of sphincter injury. In comparing these groups no differences were noted in any of the measured parameters (Wexner Score, ARM or EMG) nor was there any effect of prior anorectal surgery or the presence of an obstetric sphincter tear.

Those patients with improvement in the Wexner scale and VAS ≥5 were regarded as clinical responders. Using this definition, this resulted in 24 responders (83%) and 5 non-responders. A univariate analysis was conducted in order to determine factors predictive of response where the analysis included patient age, gender, a prior history of anorectal surgery, a prior obstetric tear, duration of incontinence, the preliminary Wexner or VAS Score and the pre-treatment manometric or EMG variables. A significant effect predictive of response was noted with the pre-treatment manometric MSP and with a range of pre-treatment EMG variables, shown in Table 4. In multivariate analysis only the pre-treatment manometric MSP remained on logistic regression as an independent predictor of a clinical response to electrostimulation. For every one-point increase in the manometric MSP, there was an OR for being a responder of 1.048 (95% CI = 1.003-1.095; $P = .035$).

Table 1. Mean Pre- and post-procedural Wexner and VAS scores in the patient cohort (n = 29).

	Pre	Immediate Post	6 months	12 months	*P* Value
Mean Wexner score (SD)	13.59 (4.43)	8.03 (2.52)	8.07 (2.48)	7.38 (3.27)	<.001
Mean VAS (SD)	3.45 (2.71)	6.72 (2.66)	7.03 (2.75)	7.55 (2.35)	<.001

Abbreviations: Pre, Pre-treatment; Immediate Post, Measurments made immediately after treatment completion; VAS, Visual Analogue Scale; SD, Standard deviation.

Table 2. MAPLe® electromyography: The effects of sessional treatment.

	1° Session	10° Session	P Value
Average resistance (μV)	16.024	21.331	.019
Peak resistance (μV)	27.138	35.593	.001
Average voluntary contraction (μV)	15.621	19.255	<.001
Average EAS voluntary contraction (μV)	11.397	14.799	<.001
Peak EAS voluntary contraction (μV)	21.207	29.245	<.001
Average voluntary puborectalis contraction (μV)	16.934	20.400	<.001
Average targeted contraction (μV)	12.064	15.645	<.001
Peak targeted contraction (μV)	22.961	33.096	<.001

Table 3. Changes in the measured FIQOL and SF-12 during treatment.

Scale	Domain	Pre	Immediate Post	P Value	6 months	12 months	P Value
FIQL	Lifestyle	29.31	30.62	.196	32.69	33.31	.011
	Coping	21.07	23.24	.023	25.45	26.90	<.001
	Depression	19.69	21.03	.038	23.34	24.86	<.001
	Embarrassment	7.21	8.28	.004	9.24	9.79	<.001
SF-12	Physical Health (PCS)	41.472	44.015	.072	45.838	45.571	.025
	Mental Health (MCS)	43.997	44.597	.693	48.704	49.062	.012

Abbreviations: PCS, Physical Component Summary Score; MCS, Mental Component Summary Score.

Table 4. Significant factors predictive of a treatment response on univariate analysis (Improvement in the Wexner and VAS Score ≥5 points).

Pre-treatment Manometry (mmHg)	Maximal Squeeze Pressure
Pre-treatment EMG parameters (μV)	Average resting pressure
	Average resistance
	Average voluntary contraction
	Average EAS voluntary contraction
	Peak EAS contraction
	Average puborectalis contraction

The treatment was well tolerated in the cohort with one patient complaining of pain during stimulation. In this case the pain resolved spontaneously after cessation of the stimulation and the patient continued the treatment and remain pain-free.

Discussion

This prospective study describes the functional outcome of patients presenting with AI who underwent a short intensive 10-session treatment course of combined biofeedback and electrostimulation targeting identifiable areas of pelvic floor weakness with the Multiple Array Probe Leiden (MAPLe®). The treatment and EMG assessment were accompanied by significant improvement in the mean post-treatment Wexner continence and VAS scores which were maintained out to 12 months after stimulation. This VAS has not been traditionally studied during combined treatment. A diminished EAS contractile response was identified as the weakest area that could be targeted with the therapy. The functional gain was accompanied by significant increases in MSP on conventional manometry and correlative increases in electromyographic recordings of resistance and voluntary contractile effort across the puborectalis and EAS musculature. Patients who experienced functional improvements reported positive responses on their quality-of-life assessments. On multivariate logistic regression analysis,

the pre-treatment MSP was an independent predictor of treatment response.

The data examining the effect of biofeedback regimes on the parameters of social functioning in incontinence sufferers are limited[14,15] with some general outcome comparisons made with different forms of electrostimulation.[6,16,17] Biofeedback has evolved over time and has become an established and effective conservative measure in the hierarchy of management of patients with AI where it is routinely used prior to consideration of surgical interventions or neuromodulation implants.[18] There have been significant technical advances in the monitoring of treatment which have developed from simple visual manometric traces and auditory signals during pelvic floor training to the current EMG probes capable of detecting voltages within active muscle groups. This latter approach has been supplemented by audio-visual signalling and interactive touch screens. Most available systems are, however, not optimized for biofeedback registration as they regard the pelvic floor musculature as a single entity. This contrasts with the MAPLe® device used in our study which separately identifies the component pelvic muscles with a feedback screen, providing a visual representation of the anal canal and permitting an easier and more effective learning and training process.

As far as we are aware there are currently no studies which have assessed the utility of EMG biofeedback with electrostimulation by integrating clinical outcome (Wexner and VAS scales), manometry, EMG recordings and QoL parameters.

Our improvement noted in the mean Wexner of 5,56 points is equivalent to that previously reported.[19-21] There remains debate, however, concerning the mechanism of action of electrostimulation, the optimal stimulation frequency required and whether patient reported QoL criteria should be the primary outcome measure as opposed to previously validated continence scoring.[22]

In our cohort there was a significant increase in the manometric MSP after treatment, but this was not accompanied by any effect on the MRAP. These findings are in keeping with those independently reported by Terra et al.[23] and by Kuo and colleagues[21] where most of the reported EMG improvements reflect changes in either resistance or voluntary contraction. In our patients a range of pre-treatment contractile EMG values and the manometric MSP correlated with a treatment response but after multivariate analysis only the pre-treatment MSP remained as an independent prognostic variable. In comparison, when patients were separated into partial responders, good responders and non-responders by Boselli et al.[20] there was a predictive value for response on univariate analysis of MRAP, MSP, the pre-treatment Wexner score and patient age. None of these parameters, however, remained as independent predictors after logistic regression multivariate analysis.

Studies typically report functional outcomes immediately following treatment; however, more prolonged follow-up is needed in order to determine the durable benefit of therapy. As in our study, Sun et al.[24] followed 126 AI patients with sphincter lesions through biofeedback and electrical stimulation showing that although there was some deterioration of function out to 24 months that the final results were still better than the pre-treatment values.

Few studies examine the effects of combined biofeedback and electrostimulation on quality of life. Our findings showed an ultimate improvement in all FIQL domains with similar results to those reported by Schwandner et al.[25] Our patient cohort also demonstrated substantial improvements in the SF-12 score, including mental and physical well-being during the follow-up after treatment.

Even though muscle strengthening should address all the structures involved, the smooth muscle of the IAS is not amenable to such voluntary training. Moreover, physical therapies tend to target fast-twitch (Type II) rather than slow-twitch (Type I) fibres with the latter forming the bulk of the striated muscle of the pelvic floor and therefore also largely unaffected by these exercises.[26] It is these slow-twitch and smooth muscle fibres that are potentially responsive to electrostimulation. The optimal current necessary for stimulation remains to be decided representing a balance between the frequency and the responsiveness of the slow-twitch fibres and the potential for the induction of pain during treatment. In this regard these desired slow-twitch fibres tend to be recruited last with the lower frequencies (up to 35 Hz) and when amplitudes ranging between 200-300 μsec are used. The current strength needed to reach these fibres may, however, be intolerable for some patients.[27,28]

Overall, it is important that the protocols employed be shown to be highly effective so that a positive continence response is achieved with the fewest number of treatment sessions. Our treating surgeons designed the protocol based upon our own prior experience with biofeedback therapy[29] as well as that suggested in the available literature.[23] This amounted to 2 sessions a week with a total of 10 sessions and a duration of 2-3 months. In contrast with Schwandner who proposes a longer program of 6[25] and 9 months,[19] with 2 sessions a day.

Conclusion

In summary, the MAPLe® system provides a unique opportunity to target and support pelvic muscles that are initially identified as weak, its novel biofeedback screen allows an easier and more effective learning and training process. This preliminary study of biofeedback combined

with endoanal electrostimulation shows a sustained improvement in subjective continence scoring (Wexner and VAS scales) and in patient-reported quality of life, with objective improvements in manometry and electromyographic variables, including resistance, voluntary squeeze pressure and contractile EAS and puborectalis response. Future controlled studies with larger patient numbers will better establish the benefits of combining biofeedback with electrostimulation.

Author Contributions

Study conception and design: L. Martín Prieto, I. Pascual Migueláñez JM. Fernández Cebrián.
Acquisition of data: Martínez Puente MC, L. Martín Prieto, M. Fernández Rodríguez.
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Drafting of manuscript: L. Martín Prieto
Critical revision of manuscript: I. Pascual Migueláñez, JM. Fernández Cebrián, Martínez Puente MC, JA. Pascual Montero.

Declaration of Conflicting Interests

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