Diseases of the Colon & Rectum

Extracorporeal Magnetic Stimulation of the Pelvic Floor: Impact on Anorectal Function and Physiology. A Pilot Study

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PURPOSE: This study was designed to investigate the effect of extracorporeal magnetic stimulation on anorectal function and physiology. METHODS: A pilot study comparing the physiology of ten incontinent (9 females) and five continent (4 females) patients with and without perineal magnetic stimulation (10 Hz and 50 Hz) was performed. The ten incontinent patients were treated with two sessions weekly for five weeks of perineal magnetic stimulation. At treatment completion, precontinent and postcontinent scores and resting and squeeze anal pressure were compared. Patients also reported symptom improvement and satisfaction on a linear analog scale. RESULTS: The patients' mean age was 57 years. Sitting resting and squeeze anal pressures were significantly greater than lying pressures ($P = 0.007$, 0.047). Both 10-Hz and 50-Hz stimulation effected a significant increase in anal pressures compared with the baseline resting pressure ($P = 0.005$). The baseline squeeze pressures were significantly higher than the stimulated pressures compared with 50-Hz pressures ($P = 0.022$). After six weeks of treatment, there was a statistically significant increase in resting and squeeze anal pressures and a significant decrease in continence scores ($P = 0.007$, $P = 0.008$, $P = 0.017$). The mean percentage subjective improvement was 16 percent, and the mean patient satisfaction score was 3.3, positively correlating with an improvement in the continence score. CONCLUSIONS: Extracorporeal magnetic stimulation results in a significant increase in anal resting pressure irrespective of pretreatment continence. Although the subjective improvement in continence after treatment is small, there is a significant improvement in both resting pressures and patient continence scores. [Key words: Extracorporeal magnetic stimulation; Anorectal function]

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Fecal incontinence affects between 7 and 15 percent of the general population.[1,2] Current therapies provide symptomatic improvement in up to 70 percent of patients, but the treatments often are invasive and the physiologic effects are inconsistent.[3,4]

Magnetic stimulation induces an electric field sufficient to produce neural membrane polarization. From urologic studies, this membrane polarization stimulates efferent pudendal nerve activity, resulting in increased urethral closing pressures and reduced detrusor instability.[5,6] Thus far, the effect of magnetic stimulation on anorectal function has been assessed only with sacral nerve electromagnetic stimulation, which requires radiologic positioning and is limited by patient body mass.[7] Unfortunately, the results have been inconsistent.[8] Extracorporeal magnetic innervation is a noninvasive means of delivering magnetic stimulation without x-ray exposure. Using this technology, we have reassessed the effect of pelvic floor magnetic stimulation on anorectal function and symptoms of fecal incontinence.

PATIENTS AND METHODS

Ten patients (9 females; mean age, 62 years) were recruited from patients referred for anorectal physiology to investigate symptoms of fecal incontinence. Inclusion required a history of one or more episodes per month of incontinence to solid feces. Patients also were required to have an intact internal anal sphincter on endoanal ultrasound. Five patients (4 females; mean age, 48 years) with normal continence were recruited as controls. Exclusion criteria for both groups included any implantable devices, recent surgery, pregnancy, and any history of cardiac arrhythmia. A complete obstetric and surgical history was obtained from all patients, and a Wexner continence score was completed.

Anorectal manometry was performed with a stationary, six-radial channel, water-perfusion catheter with computer acquisition and analysis of data (Neomedix, Sydney, Australia). The cranial distance between the six manometry channels was 0.75 cm, such that the pressure was measured from 0.75 to 3.75 cm from the anal verge. The sixth channel measured rectal pressure. The normal ranges for resting and squeeze pressure with the patient lying in the left-lateral position in our laboratory are 60 to 100 $cmH_2 0$.

Patients were initially asked to lie in the left-lateral position. An anorectal manometry catheter was then inserted and the position in the anal canal confirmed with manometry. In particular, the first channel was required to be in the anal canal as evidenced by a resting pressure > zero. All treatment patients underwent formal manometric assessment of resting and squeeze pressures. The catheter was taped to the buttock and the patient carefully positioned on the chair (Neocontrol®, Neotonus, Marietta, GA). The position of the catheter within the anal canal was again confirmed with manometry. A baseline resting and squeeze pressure in the sitting position was recorded for all patients.

Technique of Extracorporeal Magnetic Stimulation

The patient was asked to sit upright in the chair with both feet on the floor. The electromagnetic pulse was generated in the external unit and then transmitted to the base-plate in the seat. The generator created pulses of 275 μs. The frequency was commenced at 10 Hz, and the amplitude was slowly increased until the patient was aware of the stimulation. The patient was asked to adjust the position of their perineal area over the stimulating focus. The strength of the stimulation was slowly increased toward 100 percent of the maximum. Patients reported their maximum tolerated level of stimulation and the treatment was applied at this setting. Stimulation at a frequency of 10 Hz was applied for five seconds followed by five seconds rest for a total of ten minutes. Patients were given a two-minute rest period during which anal resting pressure and a voluntary squeeze pressure were recorded. A second ten-minute period then proceeded with 50-Hz administered, again in five-second on/off cycles. At the completion of this, a further two minutes was allowed to elapse before taking a final resting and squeeze anal pressure measurement.

The treatment cohort then underwent a five-week course of twice weekly, 20-minute sessions. Stimulation was provided at dual frequencies as above, at the maximum tolerated stimulation. During the treatment sessions, continuous anorectal monitoring was not performed. Patients kept a bowel diary throughout the treatment period. At the completion of treatment, patients underwent repeat anorectal physiology and a linear analog bowel function improvement and patient satisfaction score. The linear analog scores required the patient to rate subjective symptom improvement and their satisfaction with the change from zero (no improvement and completely dissatisfied) to ten (symptom resolution and complete satisfaction). From the bowel diaries, an accurate Wexner continence score was calculated. All protocols were approved by South Eastern Area Health Service Ethics Committee.

Statistical Analysis

Nominal data were assessed with a chi-squared test. Paired nonparametric scaled data were assessed with the signed Wilcoxon log rank-sum test. Unpaired data were analyzed by using the Mann-Whitney test. *P* value of 0.05 (two-tailed) was considered significant.

RESULTS

Patients were matched across the groups for age, parity, obstetric injury, and previous perineal surgery. In the treatment group, five patients had a tear or an episiotomy and four patients had undergone previous anal surgery: two hemorrhoidectomies, and two internal sphincterotomies. All patients had intact anal sphincters on endoanal ultrasound. Significantly more patients in the treatment group had undergone a hysterectomy and reported symptoms of urinary incontinence (Table 1). The mean baseline continence score in the treatment group was 14. These continence scores did not correlate with baseline lying or sitting resting or squeeze pressures.

There was a significant increase in both the maxi-

Table 1.
Patient Demographics

	Treatment (n = 10)		*P* Value	Control (n = 5)	
	Pre-treatment	Post-treatment	Treatment *vs.* Control	Pre-treatment	
Age (yr)	62 ± 17		0.45	48 ± 10	
Parity	6 parous median 2		0.62	3 parous median 1	
Obstetric injury	5		0.7	3	
Hysterectomy	5		0.04	0	
Previous surgery	4		0.3	1	
Urinary incontinence	4		0.03	1	
			Treatment Group Only		Control Group Only
Continence score	14 ± 3.5	12 ± 4	0.017	0	
MARP (lying)	64 ± 32	85 ± 39	0.007		
Squeeze (lying)	138 ± 91	170 ± 88	0.008		
MARP (sitting)	123 ± 47		0.007[a]	105 ± 19	
Squeeze (sitting)	195 ± 98		0.047[a]	216 ± 39	
10 Hz (sitting)	156 ± 60		0.005[b]	141 ± 25	0.043[b]
50 Hz (sitting)	144 ± 57		0.005[b]	126 ± 26	0.042[b]
Continence score	14 ± 3.5	12 ± 4		0	

MARP = maximum anal resting pressure.
All anal pressures are measured in cmH_20.
[a]Lying compared with sitting pressure.
[b]Stimulated pressure compared to baseline sitting pressure.

mum resting and squeeze pressures when the patient was seated on the chair compared with lying pressures. The resting pressure increased by a mean of 59 cmH_20 and the squeeze by a mean of 57 cmH_20 (*P* = 0.007, *P* = 0.047, respectively).

The resting and squeeze pressures in the following paragraphs are all sitting pressures. Quantitative values are given in Tables 1 and 2.

In both the treatment and control groups, baseline squeeze pressures were significantly greater than the baseline resting pressures (*P* = 0.005, *P* = 0.043, respectively). Comparing the treatment and control groups, the treatment group baseline resting and squeeze pressures were significantly lower than the control group pressures (*P* = 0.04, *P* = 0.014, respectively). The treatment group continence scores also were significantly greater than those of the control group (*P* = 0.002). All patients tolerated the treatment without reported discomfort at a maximum stimulation > 80 percent.

Applying 10-Hz magnetic stimulation resulted in a significant increase in the anal pressure in the treatment group compared with the baseline resting pressure (*P* = 0.005). The mean increase was 32 (median, 42) cmH_20. Only one patient had a pressure increase of < 10 cmH_20. In three patients the increase was greater than the baseline squeeze pressure. However, in the other seven patients the baseline squeeze pressure was higher than the pressure generated with 10-Hz stimulation but the difference was not significant (*P* = 0.103; Fig. 1).

In the control group, 10-Hz stimulation raised anal pressures in all patients. The mean pressure increase was 36 (median, 55) cmH_20, which was statistically significant (*P* = 0.043). The pressure increase with 10-Hz stimulation was significantly less than the increase with a voluntary squeeze (*P* = 0.043).

Applying 50-Hz magnetic stimulation resulted in a significant increase in the anal pressure in all patients in the treatment group compared with the baseline resting pressure (*P* = 0.005). The mean increase was 21 (median, 27) cmH_20. The pressure increases were significantly less than those generated by the patient during a voluntary anal squeeze (*P* = 0.022). Furthermore the mean increase in pressure was significantly less with 50-Hz stimulation than 10 Hz (*P* = 0.023).

In the control group, 50 Hz significantly raised anal pressure by a mean of 21 (median, 34) cmH_20 compared with the resting pressure (*P* = 0.042). The resultant pressure was again significantly less than baseline squeeze pressure (*P* = 0.043).

The anal pressures measured in the treatment group with 10-Hz and 50-Hz stimulation were greater than the pressures measured in the control group, although the differences were not statistically significant (*P* = 0.06). Given the higher baseline measurements in the control group, the absolute increase was significantly greater in the treatment group (*P* = 0.03).

Table 2.
Treatment Group Pressures (cmH$_2$0), Incontinence Scores, Improvement Scores, and Satisfaction Scores

Patient	MARP Lying	Sq Lying	MARP Sitting	Sq Sitting	10 Hz	50 Hz	MARP Lying Post	Sq Lying Post	Pre ICS	Post ICS	Improvement Score (%)	SAT Score (0–10)
1	49	85	107	128	146	132	109	145	15	15	20	4
2	43	53	102	115	114	109	42	59	18	13	10	3
3	111	135	159	210	235	165	147	197	8	4	50	8
4	37	83	81	122	86	82	78	123	18	15	0	1
5	76	117	155	168	195	189	79	141	19	17	10	1
6	68	164	64	92	74	77	95	164	11	11	0	0
7	38	67	66	128	97	82	42	71	11	8	10	5
8	63	276	134	343	174	169	71	303	14	12	10	4
9	126	321	159	339	202	184	142	330	16	16	0	0
10	32	79	206	302	232	249	44	162	14	10	50	7

MARP = maximum anal resting pressure; Sq = squeeze; Post = posttreatment; Pre = pretreatment; ICS = incontinence score; SAT = satisfaction.

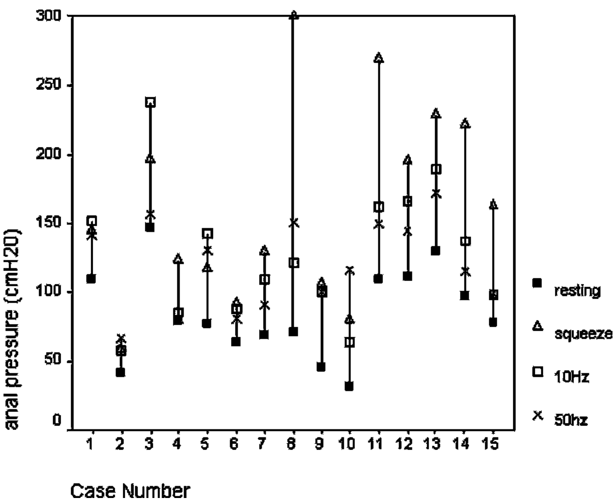

Figure 1. Individual patient resting, squeeze, 10-Hz, and 50-Hz anal pressures (cmH$_2$0). Patients 1 to 10 are treatment patients; Patients 11 to 15 are controls.

In all control patients, the voluntary squeeze pressures were greater than the pressures generated by 10-Hz stimulation, and the 10-Hz pressures were greater than the pressures generated with 50-Hz stimulation.

In the treatment group, seven patients generated voluntary squeeze pressures that were higher than the 10-Hz pressure and eight generated pressures greater than the 50-Hz pressure. Furthermore in nine of ten treatment patients, the pressures generated with the 10-Hz stimulation were greater than the pressures generated with 50-Hz stimulation.

At the completion of six weeks' treatment, there was a significant decrease in the continence scores from 14 to 12 (P = 0.017). There was a significant increase in the lying maximum anal resting pressure (P = 0.007). The mean increase was 21 cmH$_2$0, which is a 37 percent increase from the baseline resting pressure. There was a significant increase in the voluntary lying squeeze pressure with a mean increase of 32 cmH$_2$0 or 23 percent from baseline (P = 0.008). The mean subjective improvement reported was 16 (range, 0–50) percent. The mean patient satisfaction score was 3.3 (range, 0–8). Both of these subjective scores positively correlated with the posttreatment incontinence score (P = 0.048, P = 0.01, respectively) but not the anal resting or squeeze pressures (P > 0.89).

DISCUSSION

Extracorporeal magnetic stimulation applied *via* a chair apparatus has been reported to improve objective and subjective measures of urinary incontinence.[9,10] Before this study the effects of extracorporeal perineal magnetic stimulation on fecal continence and anorectal manometry had not been described. The frequency of stimulation also had not been previously investigated.

Noninvasive sacral magnetic stimulation has been shown to activate large sacral nerve fibers, which *via* the pudendal nerves, innervate the striated sphincters and pelvic floor muscles.[11] Morren *et al.*[7] demonstrated a median increase of 12 mmHg in anal resting pressure with 5-Hz sacral nerve magnetic stimulation. Sheriff *et al.*[12] suggested that 20-Hz sacral nerve magnetic stimulation was required for maximum anal sphincter response. However, there are likely to be significant differences in the stimulation provided by a perineal electrode compared with a sacral electrode.

First, perineal stimulation would be unlikely to penetrate to the sacral nerve roots hypothesized to augment pelvic floor contraction. Conversely, perineal stimulation may be more likely to circumvent the problem of proximal pudendal neuropathy, which resulted in Morren failing to stimulate a response in 25 percent of fecal incontinence patients.[7] Second, Fall[13] suggested that the equivalent of 50-Hz to 100-Hz electric sacral stimulation would be required to stimulate the pudendal nerves, much greater than the frequency required to generate a contraction if supplied *via* the perineum. Finally, pudendal nerve stimulation alone does not explain the manometric changes seen in this study over time.

The pudendal nerve supplies the striated pelvic floor muscles, including the external anal sphincter. However, these muscles are responsible for < 10 percent of the anal resting pressure,[14] which we have shown significantly increase over time. It is possible that perineal stimulation results in polarization of the peripheral small fibers of the pelvic floor generating an action potential both in the pudendal nerves, as evidenced by the immediate increase in anal pressure, and the sympathetic nerves, as evidenced by the increase in resting pressure over time. During pelvic electromyography, a sustained increase in tonic activity of the sphincteric motor unit has been documented.[13] However, whether this effect is because of modification of synapses, a local change of amount of signal or to rerouting of pathway systems within the central nervous system is speculative. The neurophysiology of perineal magnetic stimulation is less clear. We chose to investigate the effects of 10 Hz and 50 Hz based on the urologic data, suggesting that 10 Hz was required to inhibit detrusor instability and, therefore, possibly rectal hypersensitivity and at least 20 Hz for external urethral meatus contraction and, therefore, anal sphincter contraction.[5] Further investigation is required; however, our results would suggest that 10 Hz effects the greatest response on the anal sphincter complex. It may have been that anal sphincter fatigue resulted in a reduction in the response seen with 50-Hz stimulation. Against this, the final 10-Hz trace for each patient resulted in higher pressures than the first 50-Hz trace, although there was a two-minute rest period between the two stimulation periods. The same decrease was not seen with the subsequent 50-Hz stimulations.

The mean pressures generated were no greater than the patient's squeeze pressure for 10-Hz or 50-Hz stimulation in the control group. However, in the treatment group, three patients had anal pressures generated that were greater than their squeeze pressures. There were no factors specific to these patients to explain the different response. Furthermore, the chair was able to induce squeeze pressures in the treatment group that were not significantly different from those of the control group, although the baseline squeeze pressures were significantly different for the two groups. The sphincter complex in incontinent patients was capable of contracting as strongly as the patients with normal continence. If pelvic floor exercises are able to improve anal pressures and anal continence,[15] our results would suggest that the chair may result in a further improvement as evidenced by the decrease in continence scores posttreatment.

CONCLUSIONS

Extracorporeal magnetic stimulation is noninvasive and is tolerated well by patients. The major limiting factor is cost. The chair apparatus alone costs $40,000AUS (U.S. $30,000) and a complete course of treatment costs $80AUS (U.S. $60).

Furthermore, there is no data on the long-term effect of the treatment for urinary or fecal incontinence. However, our results would suggest that although patient perceived improvement after six weeks of treatment is small, there is a statistically significant increase in resting and squeeze anal pressures and a statistically significant reduction in baseline continence scores.

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