



## ORIGINAL ARTICLE

# OUTCOME & PREDICTORS OF SUCCESS OF BIOFEEDBACK FOR PATIENTS WITH SPASTIC PELVIC FLOOR SYNDROME

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### Abstract

**Aim:** The study was undertaken to determine outcome and to identify predictors of success of biofeedback for patients with spastic pelvic floor syndrome.

**Patients & Methods:** The study was done on 50 patients (35 females & 15 males) with a mean age of  $30 \pm 10$  years & a mean duration of constipation of 5 years. History, physical examination & barium enema excluded constipation secondary to organic causes. Then a series of tests of colonic & pelvic floor functions were performed before & after biofeedback treatment: colon- transit time, anorectal manometry  $\pm$  EMG & defecography. Patients were treated on a weekly basis (average of  $7 \pm 2$  sessions). Parameters included use of cathartics, number of spontaneous bowel movements per week, number of biofeedback sessions, results of anorectal physiology testing & patient satisfaction.

**Results:** The median number of spontaneous bowel movements per week before treatment was zero. Thirty five patients had complete success, 11 patients showed partial success and 4 patients had no improvement. Neither patient age, sex, symptom at initial assessment, nor duration of symptoms significantly affected outcome. Good indicators of success were ability to expel the balloon & to relax the pelvic floor early in the sessions. Also, the motivated patient who wants to continue the sessions, to cooperate & to spend time with the therapist was the most important predictive factor of success.

**Conclusion:** Biofeedback is an attractive treatment option as other therapies are associated with considerable morbidity for patients with spastic pelvic floor syndrome

**Keywords:** Anorectal manometry, defecography, colon transit, biofeedback.

### INTRODUCTION

Chronic constipation is a common and distressing complaint, which may be secondary to many diseases, or may also be of functional origin.<sup>(1)</sup> For diagnosing functional defecation disorders, there must be 2 or more of 6 symptoms present for the last 3 months; straining,

lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal obstruction / blockage or manual maneuvers to facilitate defecation on more than 25% of bowel movements or less than 3 bowel movements per week.<sup>(2)</sup>

For normal evacuation to take place there must be

adequate relaxation of the puborectalis muscle & pelvic floor, allowing straightening of the anorectal angle and passage of the faecal bolus. Subsequent relaxation of the external anal sphincter muscles makes evacuation possible. Failure of relaxation may result in obstructed defaecation. This condition has been ascribed many synonyms including spastic pelvic floor syndrome.<sup>(3)</sup>

Various surgical and medical treatments for spastic pelvic floor syndrome have been tried with partial success but considerable morbidity.<sup>(4)</sup> Spastic pelvic floor syndrome is a behavioral disorder because there are no associated morphological or neurological abnormalities & consequently biofeedback training has been recommended as a behavioral therapy for such disorder.<sup>(5)</sup> Although most groups restricted the use of biofeedback to patients with normal transit & paradoxical pelvic floor contraction during straining, the technique has a wide therapeutic benefit & may be applied & give good results even in patient with slow colonic transit.<sup>(6)</sup> In behavioral therapy (Biofeedback) information about a physiologic process (contraction & relaxation of a muscle) is converted into a simple visual or auditory signal to enable the patient to learn to control the disordered function.<sup>(7)</sup> Almost in most centers a simple visual or auditory EMG or pressure signals of sphincter activity is feedback to the patient. Most techniques also use a method of simulated evacuation, such as the expulsion of a balloon to demonstrate to the patient normal coordination for successful expulsion.<sup>(8)</sup> A good patient – therapist relationship is essential.<sup>(9)</sup> Success rate in most series is between 60 & 90 % using these techniques.<sup>(10)</sup>

The aim of the study was to review a 5-year experience with biofeedback for patients with constipation due to spastic pelvic floor syndrome and to identify factors that may predict a successful outcome.

## PATIENTS AND METHODS

Patients referred to our center with idiopathic constipation diagnosed as (SPFS) have long standing symptoms unresponsive to laxatives & dietary changes. The study was done in the anorectal laboratory, Gastroenterology Center, Mansoura University from 2006 to 2011. There were 35 females & 15 males, their mean age was  $30 \pm 10$  (range 15-55) & mean duration of constipation of 5 years. 45 patients were associated with normal colon transit & 5 patients with slow colonic transit.

Patients were assessed clinically using a specially designed questionnaire including age of onset, bowel frequency, precipitation factors, use of laxatives, urinary symptoms, gynecologic history or previous anorectal surgery. The patients fulfilled Rome criteria for dyschezia & spastic pelvic floor syndrome.<sup>(3)</sup>

History, physical examination & barium enema were done to exclude constipation secondary to organic

causes. Proctologic examination was done to exclude anal fissure, piles, rectal prolapse. Then, a series of tests of colonic & pelvic floor functions were performed before & after biofeedback treatment:

**Colon- transit study:** Patients ingested radioopaque markers and followed (by serial plain x-ray) during their journey in the colon & rectum. If 80% of markers stayed in the colon or rectum more than 4 days it is considered as slow transit.

**Anorectal manometry:** 8-lumen (circumferentially arranged) pressure catheter with a terminal balloon connected to an infusion pump, polygraph ID & a computer monitor was used. Anorectal measurements included functional anal canal length, pressures within the anal canal during rest (resting pressure), squeeze (squeeze pressure) & on straining. Rectoanal inhibitory reflex (relaxation of the sphincter & drop of pressure within the anal canal on inflation of the rectal balloon) is also obtained. Rectal sensation was tested by gradually inflating the rectal balloon to test the first rectal sensation, the urge to defecate & the maximum tolerable volume. Increased pressure within the anal canal during straining was considered as the paradoxical contraction (SPFS) (Fig. 1).

Finally we asked the patient to defecate the balloon which indicates coordination of muscles of the anorectum & pelvic floor. The balloon expulsion is a simple procedure to identify impaired evacuation and is considered normal if a water filled balloon placed in the rectum could be expelled in less than 60 seconds. Sitting position is better to mimic a habitual defecatory maneuver.

**EMG of the external sphincter:** Surface EMG electrode was used to assess myoelectric activity at rest, on squeezing & straining. A reproducible increase in myoelectrical activity during straining was considered as the paradoxical contraction.

**Defecography:** Visualizing the dynamics of defecation (at rest, on squeeze & on straining) after injection of barium paste into the anorectum. Prolonged emptying (>40 seconds) or incomplete emptying is considered abnormal. Paradoxical contraction, lack of a measurable increase in the anorectal angle, rectocele, rectal prolapse & intussusception were also assessed.

Finally, diagnosis of SPFS was based on the presence of straining, feeling of incomplete evacuation or facilitate defecation digitally associated with manometric & defecography evidence of inappropriate contraction or failure to relax the pelvic floor muscles during attempts to defecate.

**Biofeedback training:** Biofeedback training was performed on a twice weekly basis for an average of  $7 \pm 2$  sessions lasting 20-30 minutes supervised by a certified biofeedback therapist. At the first session, the anatomy & physiology of the pelvic floor were explained to the

patient with the objectives of biofeedback. In the pressure-based training we used the same 8-lumen catheter & the subjects were allowed to view the manometric recordings & instructed to look for changes in the pressure tracings, thereby visualizing the location and function of the pelvic floor muscles with specific attention to the responses of the anal sphincters during squeezing & straining. The patients were taught to be conscious of a balloon distending the rectum, to relax the pelvic floor, to improve rectoanal coordination without increasing pelvic floor muscle activity, to strain effectively & try to expel the balloon at the end of the procedure. Patients were taught squeeze-relax exercises and encouraged to practise these manoeuvres at home. Patients continued biofeedback sessions until they had control of the pelvic floor musculature as demonstrated by anorectal manometry ± EMG, and had a reduction in the use of cathartics and resolution of the constipation as indicated by the diary.

At each biofeedback session the therapist tries to achieve good rapport with the patient to facilitate good understanding & collaboration. This includes gaining an appreciation about the patient's personal life & psychological factors which may be relevant.

Outcome was divided into three categories. Patients were deemed to have complete success if they passed three or more spontaneous bowel movements per week without the aid of cathartics or digitation. Partial success was defined as the passage of fewer than three spontaneous bowel movements per week with a reduced dependence on assistance. Patients who had no improvement in either of these parameters were graded as failed. Finally patients, who did not adequately complete the study were withdrawn.

**Statistical analysis:** Non-normal data were expressed as median & full range. Normal data were expressed as mean ± standard deviation. Student's T-test was used to compare the treatment results and the Chi-square test was used for comparison of proportions.  $P < 0.05$  was considered statistically significant.

## RESULTS

A total of 50 patients attended the study. There were (35♀ & 15♂) with a mean age of  $30 \pm 10$  years & the mean duration of constipation symptoms was 4 years. Patients were treated on a weekly basis by an average of  $7 \pm 2$  sessions. They were all assessed after the end of biofeedback therapy. The median time of follow-up was 24 months. The follow-up interview took place after a mean period of  $3.0 \pm 1.2$  years. One fifth of patients (10 patients) were recorded as having possible relevant psychological factors especially anxiety & attributed them as a precipitating event or condition as such stress makes the pelvic floor more tense & rigid which by time cannot relax on defecation. No previous abdominal or anorectal surgery in all patients. 4 patients had experienced constipation since childhood. No patient had spontaneous bowel movements per week before the

commencement of biofeedback therapy. Forty two patients used at least one cathartic per day and only 8 denied cathartic use. 12 patients reported the use of digitation to achieve evacuation as those patients have the desire to defecate but unable to evacuate (outlet obstruction). The median number of spontaneous bowel movements per week before treatment was zero. At the end of treatment, 46 of the 50 patients reported a subjectively overall improvement. 35 patients had complete success (three or more spontaneous bowel movements per week with discontinuation of cathartics).

This is because spastic pelvic floor syndrome is a functional disorder ( abnormal function of a normal muscle ) which could be retreated by biofeedback training to come back to normal relaxation of the anal sphincters & pelvic floor with the incoming stool mimicked by the inflated balloon in the rectum 11 patients had partial success (fewer than three spontaneous bowel movements per week with continued use of cathartics), but no straining & the patients feel satisfaction & complete evacuation even with the aid of laxatives . Four patients had no improvement and such patients were referred to a psychiatrist for psychotherapy as there may be a hidden cause making them tense & no response to treatment (Table 1) shows the prevalence of symptoms before & after biofeedback in the study group. The most common findings were difficult evacuation, hard stool, and laxative dependence.

Table 2 shows that the number of patients reporting fewer than 3 bowel movements per week reduced both immediately after biofeedback and at follow-up. Similarly, symptoms of dyschezia (need to strain, feeling of incomplete evacuation & need to digitate) were reported less frequently after biofeedback and at follow-up than at the time of referral. All patients underwent both a transit study and defecography to differentiate slow transit constipation from outlet obstruction. Five patients had slow colonic transit & 45 patients with normal colonic transit. However patients with slow colonic transit and pelvic floor dyssynergia gained benefit, and this may be due to improved psychological status of the patient which affect the hormonal environment in the gut & helps movements of the colon, but the number of patients is too small to draw a conclusion.

**Predictive Factors:** Age & gender were not a predictive factor of outcome. Also, no symptom at initial assessment or duration of symptoms appeared predictive of patient satisfaction. On the other hand, patients helped by biofeedback received more than 5 sessions while those not initially improved received less than 4 sessions. So, we have to wait & give more sessions for a successful outcome as the disorders is a functional one which means abnormal function of a normal muscle so by patency we can obtain good results. All patients showed manometric evidence of

inappropriate contraction or failure to relax the pelvic floor muscles during attempts to defecate at referral time (seen as persistent elevation of the manometric trace instead of relaxation on bearing down as in normals). Ability to relax the pelvic floor early in the course of training was a good indicator of success as this means cooperative patient & good patient- physician relationship. (Table 3) (Figs. 2a,2b). Mean values obtained for the maximum resting pressure & mean squeeze pressure are slightly higher than normal because the muscles are tense & spastic but non-significant.

First sensation, urge sensation & maximum tolerable volume were all in the normal range for our laboratory, both at referral & after biofeedback without any significant difference & are not of predictive value.

However, urge sensation to volume distension was higher after biofeedback compared with before because of irritability of the rectum in such patients but non-significant (Table 3). The balloon expulsion test was pathologic in all patients (i.e cannot defecate the balloon on bearing down) but improved significantly after biofeedback & is a good predictive factor of success especially if occurring early in the sessions, as it means good coordination of the anal sphincter complex & the pelvic floor. However, the most important factor of predictive value was the motivated patient who wants to continue the sessions, to cooperate & to spend time with the therapist & to correct the underlying psychological abnormality & this is a good proof of a higher control of CNS & the disorder is a functional one that can come back to normal.

**Table 1. Presentations before & after biofeedback (BF).**

Symptoms	Patients before BF No (%)	1 month after BF No (%)	6months after BF No (%)
Difficult evacuation	50 (100%)	20 (40%)	5 (10%)
Hard stools	45 (90%)	25 (50%)	4 (8%)
Need for digitations	12 (24%)	5 (10%)	2 (4%)
Sense of incomplete emptying	35 (70%)	13 (26%)	6 (12%)
Laxative dependence	43 (86%)	21 (42%)	5 (10%)

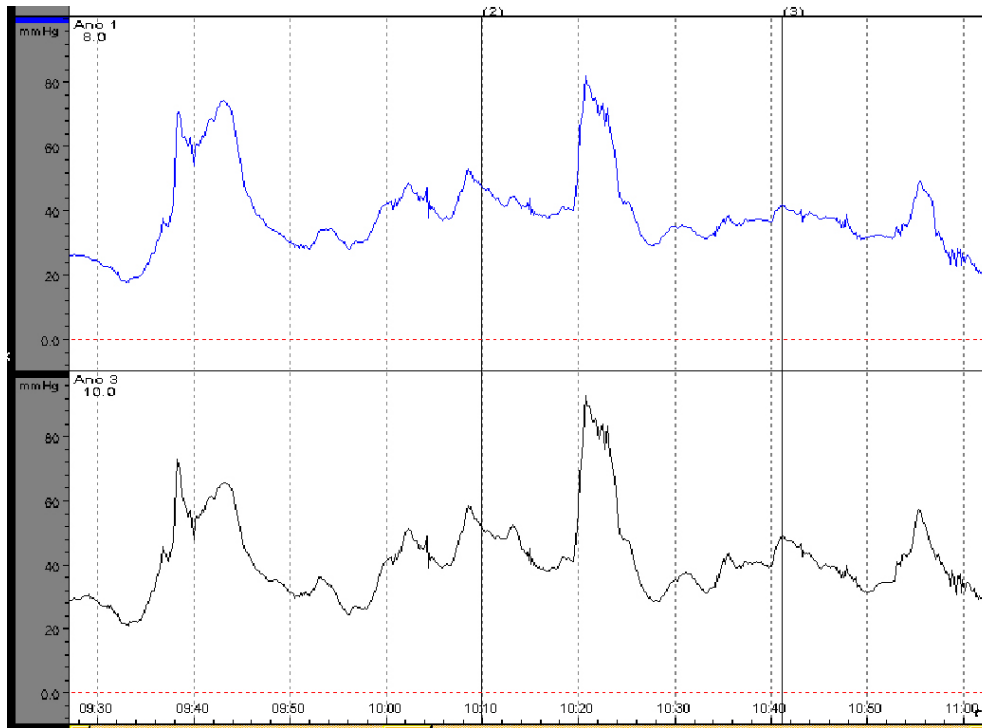
**Table 2. Need for enemas& bowel frequency before & after BF.**

	At referral	1 month after BF	p-value	6 month after BF	p-value
Bowel frequency (<3/week)	50 (100%)	7 (4%)	< 0.0001	3 (6%)	< 0.0001
Use of enemas	28 (56%)	12 (24%)	< 0.0005	4 (8%)	< 0.001

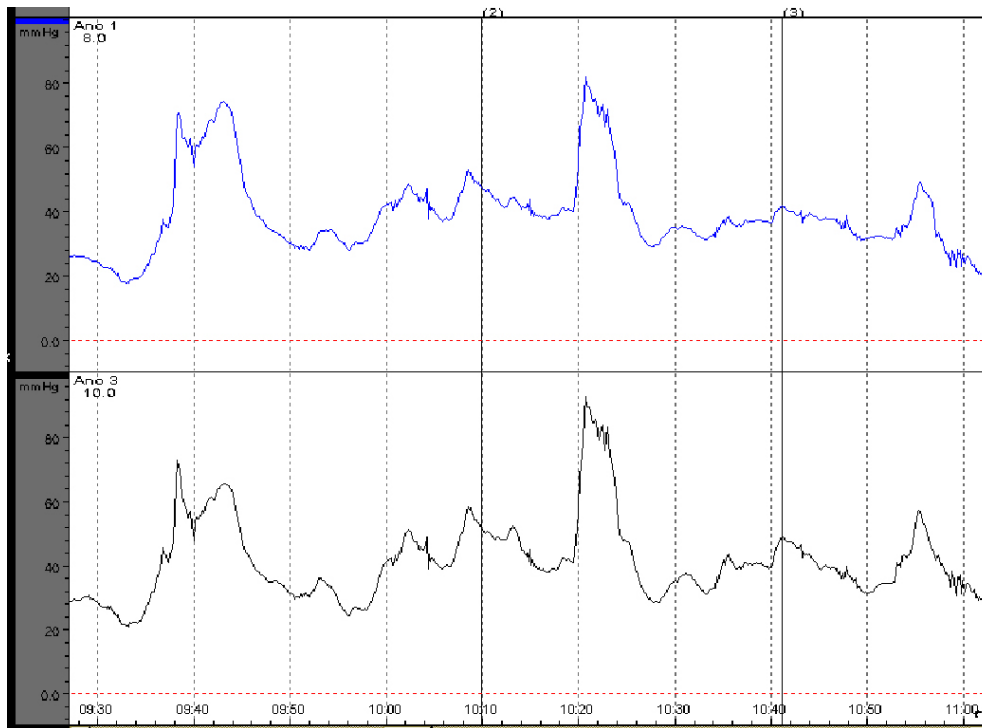
**Table 3. Anorectal tests at referral & after biofeedback.**

	At referral	After biofeedback	P-value
Inappropriate contraction of pelvic floor	50	5	< 0.001
Maximum resting pressure (mmHg)	75 ± 20	60 ± 25	Ns
Maximum squeeze pressure (mmHg)	140 ± 25	150 ± 20	Ns
First sensation (C.C)	45 ± 15	50 ± 10	Ns
Urge to defecate (C.C)	130 ± 15	125 ± 20	Ns
Maximum tolerable volum	170 ± 30	180 ± 20	Ns
Failed balloon expulsion	50	4	< 0.001

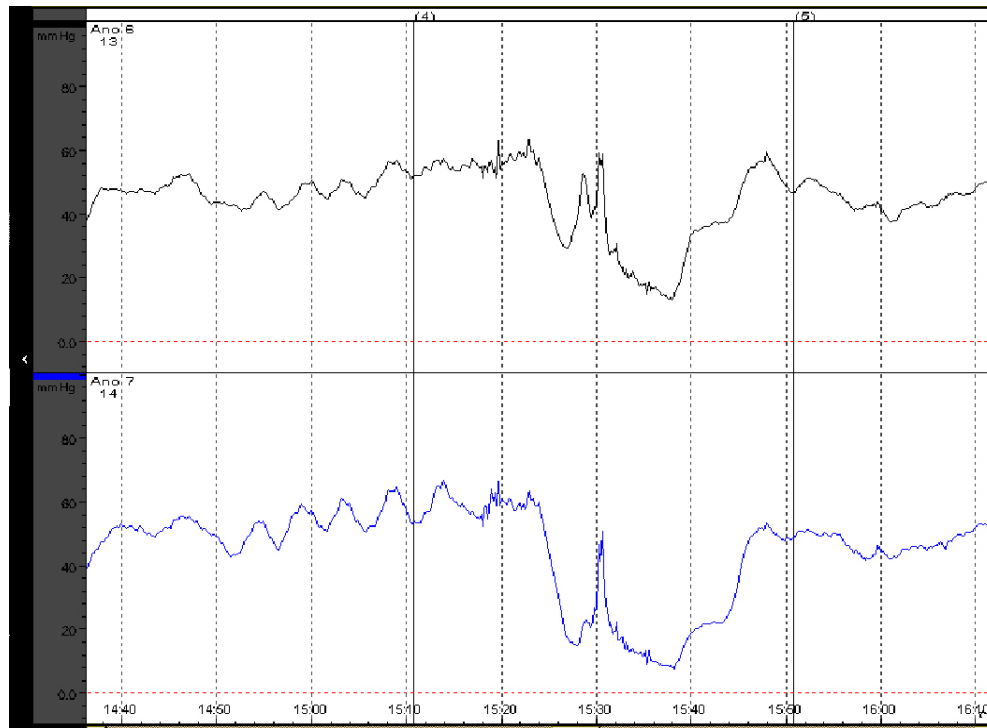
**Ns:** non-significant.



**Fig 1. Anorectal manometry on straining: Persistent elevation of pressures within the anal canal on bearing down instead of normal relaxation to allow defecation.**



**Fig 2a. Straining before biofeedback showing failure of relaxation of anal sphincter on straining.**



**Fig 2b. Straining after biofeedback showing successful relaxation of anal sphincter & pelvic floor on straining.**

## DISCUSSION

Biofeedback has been employed in the treatment of obstructed defaecation with success rates ranging between 65 and 100%.<sup>(11)</sup> Safety makes biofeedback an attractive treatment option as other therapies are associated with considerable morbidity. Improvement was supported by an increase in bowel frequency & decreased use of laxatives or digital facilitation.

Methods of biofeedback therapy varied widely between centers but no difference was described when EMG-based biofeedback was compared to manometry-based biofeedback or when visual or auditory feedback was given.<sup>(12)</sup> Some authors have used manometry to display sphincter pressures in an attempt to retrain pelvic floor, while other investigators use surface EMG electrodes placed on the external sphincter and buttocks.<sup>(13)</sup>

Bleijenberg and Kuijpers demonstrated the superiority of EMG-based biofeedback over manometric biofeedback.<sup>(14)</sup> The frequency and length of treatment sessions also varies widely. Some units prefer inpatient protocols whereas other use daily<sup>(15)</sup> or weekly<sup>(16)</sup> outpatient sessions. So, the results are difficult to compare as biofeedback protocols vary considerably between institutions.

In our anorectal laboratory we used manometry-based biofeedback with visual feedback which was convenient

both to the patient and to the therapist in a twice weekly sessions each lasting 30-45 minutes.

Patients had symptoms of dyschezia (straining, feeling of incomplete evacuation after defecation or having to facilitate defecation digitally by pressing in or around the anus on least 25% of bowel movements) & manometric evidence of paradoxical contraction or failure to relax the pelvic floor muscles when attempting defecation. Meanwhile organic lesions were excluded by colonoscopy or barium enema. Hirschsprung's disease was excluded by anorectal manometry & all of our patients showed intact rectoanal inhibitory reflex.

Stratifying patients by age did not reveal any significant difference in outcome. Some authors have shown that patients who have had symptoms for many years are particularly resistant to treatment,<sup>(17)</sup> but again stratification of patients by duration of symptoms failed to reveal any differences in the rate of success.

Patients with slow-transit subjectively improved and their bowel frequency increased. Koutsmanis et al., 1994 showed that these patients can normalize their measured transit time with biofeedback.<sup>(10)</sup>

The median number of spontaneous bowel movements per week before treatment was zero. 35 patients had complete success (three or more spontaneous bowel movements per week with discontinuation of

cathartics), 11 patients had partial success (fewer than three spontaneous bowel movements per week with continued use of cathartics) and 4 patients had no improvement. Our high success rate may be due to the fact that all of our patients ended the therapy with motivation. Dahl et al.<sup>(13)</sup> reported an overall success rate of 50 per cent at 6 months' follow-up, whereas Loening-Baucke<sup>(18)</sup> reported overall success in only 37 per cent of patients after 12 months' therapy.

Although age, sex and duration of symptoms did not influence outcome, willingness to comply with treatment protocols was the most important predictor of success.

The ideal patient for biofeedback must be willing to spend as much time as necessary alleviating the symptoms. Such cooperation will be met with a high success rate.

A small group of patients experienced initial benefit which was not sustained & such patients were offered the opportunity of a "booster" session at a later date.

Neither patient age or duration of symptoms was indicative of outcome in our patients as also shown by Karlbom et al.<sup>(9)</sup> The study demonstrated greater psychological morbidity (depression, anxiety) than age matched healthy control which influence gut function via autonomic efferent neural pathways.

Manometry was used to identify patients with spastic pelvic floor syndrome. It allows the therapist to work on recto-anal coordination and rectal sensory perception to improve the patient defecatory function. The majority had corrected this anomaly at the end of training as seen by balloon expulsion & relaxation of the pelvic floor.

Rectal sensory perception was improved & lower thresholds for urge sensation to rectal distension.

In conclusion patients with spastic pelvic floor syndrome gain much benefit from biofeedback in the long term without the risk of other methods. Until a better therapy emerges biofeedback remains a morbidity free, low-cost & effective outpatient therapy for well-motivated patients complaining of functional constipation & diagnosed as spastic pelvic floor syndrome.

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