Biofeedback for functional anorectal disorders is a specialized biofeedback application with a 30-year history. This article summarizes the nature of the disorders that are responsive to this treatment, the techniques used, current status of the evidence of efficacy, and some of the latest research work that is rapidly strengthening the empirical case for the value of anorectal biofeedback.

Biofeedback has been used to treat disorders in the lowest parts of the human intestinal tract, the anus and rectum, for three decades. Over this extensive time, a large number of published research reports on these clinical applications has accumulated. Most of these studies have provided indications that this treatment modality is effective for anorectal problems. However, limitations related to the size and design of many of the trials have hindered anorectal biofeedback from achieving the recognition and general acceptance for insurance coverage that might be expected from the ample evidence of therapeutic impact (Palsson, Heymen, & Whitehead, 2004). Those difficulties may soon be alleviated, however. For one thing, through the labor of many investigators the quantity of empirical data finally seems to be achieving critical mass. Equally important, researchers are now recognizing and systematically plugging the holes in the body of evidence that allow conclusive decisions about the value of these specialized applications of biofeedback. This is evidenced by the fact that several studies recently published, or nearing completion, are among the best designed and most important in this field to date.

In this article, we will briefly describe the nature of the functional anorectal disorders that lend themselves to biofeedback, discuss the present status of the evidence for biofeedback in their treatment, and highlight some of the latest positive developments in this domain.

What Are the Functional Anorectal Disorders?

In the current Rome II diagnostic system, which provides the most widely recognized criteria for diagnosing and classifying functional gastrointestinal disorders, three anorectal disorders are recognized: functional fecal incontinence (FI), functional anorectal pain, and pelvic floor dyssynergia (PFD; Whitehead et al., 2000). As indicated by their designation as “functional” disorders, these three disorders have in common symptoms thought to involve abnormalities in anal and rectal physiological functioning, and they are conversely by definition not thought to result from anatomical or biological pathology.

PFD (also called outlet obstruction constipation, anismus, or spastic pelvic floor syndrome) is a type of chronic constipation that results from inappropriate use of the muscles of the pelvic floor that facilitate defecation—especially the puborectalis muscle and external anal sphincter. Instead of relaxing these muscles during defecation attempts, the patients paradoxically contract them, thereby inadvertently inhibiting defecation. The symptoms of PFD commonly include straining and incomplete or blocked evacuation, but definite diagnosis requires physiologic confirmation of the abnormal defecation dynamics through surface electromyographic (SEMG), manometric (pressure), or radiologic testing.

Functional FI is defined by the Rome II criteria as recurrent uncontrolled passage of fecal material in an individual with a developmental age of at least 4 years. FI is associated with fecal impaction, diarrhea, or nonstructural anal dysfunction (Whitehead et al., 2000). Etiology of FI is varied, often complex, and can involve disturbed intestinal motility (diarrhea, constipation, or both); poor compliance of the rectal wall; impaired sensation in the rectum; or weakened pelvic floor muscles.

Functional anorectal pain is a problem that generally comes in one of two different variants, each with its own name and quite different in regard to symptom duration, frequency, and intensity (although they may co-exist in the same patient). Levator ani syndrome presents as a dull or indistinct feeling of uncomfortable pressure or pain in the upper part of the rectum. To be diagnosable, according to the Rome II criteria, it must be experienced for at least 20 minutes at a time and be present for 12 or...
more weeks out of the past year (Whitehead et al., 2000). Proctalgia fugax, on the other hand, is defined by sudden and intense anal or lower rectal pain that lasts from a few seconds to a few minutes, and it rarely occurs more than five times a year. It is the only anorectal disorder reported predominantly by males. The causes of both types of functional anorectal pain are largely unknown.

It is important to recognize that although these three disorders are considered to result principally from problems in the anorectal physiological functioning, in clinical reality multiple other causal influences often play a substantial role in creating and maintaining them. These may include anatomical, physiological, and behavioral factors, as well as side effects of the other co-morbid medical conditions. For example, in patients with pelvic floor dys-synergia, the constipation experienced can be partly the result of co-existing abnormally slow propagation of bowel contents through the colon, diagnosable by radiographically assessing the travel time of radio-opaque markers or radioisotopes through the colon. It can also be aggravated by a variety of medications, inadequate fluid intake, lack of fiber in the diet, lack of physical activity, or high levels of psychological distress. Similarly, the clinical symptoms of functional FI can be partly the result of obstetric trauma or anatomical conditions like rectal prolapse, or a side effect of chronic diarrhea. Biofeedback is generally most likely to be effective when the primary causes of the problem are disturbed or impaired physiological functioning that may be corrected through training for muscle strengthening or more skillful use of the anorectal muscles involved. However, it must also be noted that biofeedback can often succeed to some degree even when physical pathology or medical or psychological comorbidities contribute to the problem.

The clinical picture that presents for anorectal biofeedback intervention is complicated even further by the fact that more than one functional anorectal disorder can be co-present in the patient and be causally interdependent. In particular, one of the common causes of episodic functional FI is “overflow incontinence” from buildup of fecal matter in the rectum due to PFD constipation.

**Biofeedback Approaches to Anorectal Disorders**

Anorectal biofeedback is a specialized form of biofeedback designed expressly to intervene in and correct the abnormal physiological activity observed in functional anorectal disorders. Biofeedback for PFD uses visual or auditory feedback from electromyographic (EMG) sensors, anal canal pressure sensors, or a combination of the two to teach patients to relax their pelvic floor muscles while simultaneously generating a mechanical propulsive force by applying a downward intra-abdominal pressure (the so-called Valsalva maneuver). Biofeedback for FI varies in its approach, buttressing one or more key functions that maintain continence. Most common, at least in published reports (see review by Heymen, Jones, Ringel, Scarlett & Whitehead, 2001) is some version of coordination training (Engel, Nikoomanesh, & Schuster, 1974), where patients learn to coordinate or synchronize pelvic floor muscle response to intrarectal distention by simultaneously using pressure feedback from intrarectal balloon distension and pressure feedback from pelvic floor muscle contraction. Other FI biofeedback techniques include strength training of the anal sphincter with the aid of EMG or intracanal pressure feedback, and sensory training, where patients improve their ability to detect small rectal distentions. Unlike PFD and FI, anorectal pain is not reliably characterized by a measurable pattern of physiological dysfunction. The three prospective studies that reported success in biofeedback for anorectal pain (reviewed in Palsson et al., 2004) all used external anal sphincter pressure feedback for training.

No particular biofeedback approach has shown clear superiority in the treatment of anorectal disorders. However, a meta-analysis of PFD treatment (Heymen, Jones, Scarlett, & Whitehead, 2003) has suggested that pressure feedback yields superior outcomes on the average compared with EMG feedback. Another meta-analysis (Heymen et al., 2001) found conversely that for FI treatment, EMG feedback does better than pressure feedback within the strength-training approach to FI treatment, whereas it found no difference between coordination and strength training in the treatment of that condition.

In clinical practice, anorectal biofeedback training is typically combined with multiple other therapeutic interventions. These may include balloon defecation practice in the clinic, patient education, pelvic floor home exercises, laxatives, fiber supplements, enemas, or the use of EMG home training devices. The number of biofeedback sessions used in clinical treatment can range from one to 12 sessions. Many studies show that high rates of symptom improvement can be achieved with as few as three to four treatment sessions.

**Why Use Biofeedback?**

Functional anorectal disorders are relatively common conditions. Population prevalence estimates are 12%–19% for
chronic constipation (Higgins & Johanson, 2004), about half of which may involve PFD. FI with significant accidental passage of fecal material is present in about 1% of the population, but milder cases are seen in 7% of the population (Drossman et al., 1993; Nelson, Norton, Cautley, & Furner, 1995). The two types of functional anorectal pain affect 6.6%–14% of the general population (Drossman et al., 1993; Panitch & Schofferman, 1975). All of these disorders are associated with significant emotional effects and quality of life impairment, but FI, in particular, can have grave consequences for patients. FI symptoms, especially when severe, often limit life activities and mobility, lead to social isolation and difficulty with intimate relationships, impair self-esteem, and cause depression (Burnett, Whitehead, & Drossman, 1998; Miner, 2004).

Conventional approaches to medical management leave about half of patients with functional FI and PFD, and most of those with functional anorectal pain, left without satisfactory symptom relief (Whitehead et al., 2000; Whitehead, Wald, & Norton, 2001). Since all three conditions are chronic, with symptoms that are likely to remain unabated for years, biofeedback is an attractive option for helping those who do not improve from standard medical treatment. Since biofeedback is inexpensive, is without adverse side effects, and often produces therapeutic results that last for years, it compares favorably to almost any other intervention that might be considered for these patients (typically additional drugs or surgery).

How Effective Is Biofeedback for Anorectal Disorders?

In 2004, we conducted a comprehensive efficacy review of the published literature on anorectal biofeedback, at the request of the Association of Applied Psychophysiology and Biofeedback (AAPB), and presented our findings in the September 2004 issue of *Applied Psychophysiology and Biofeedback* (Palsson et al., 2004). Our systematic examination of the world empirical literature in this domain since 1975 revealed a total of 74 qualifying studies that provided data on clinical outcomes. Thirty-eight of these were PFD trials, 33 were FI treatment studies, and only three concerned treatment of functional anorectal pain. Our review identified significant shortcomings in much of this literature. Many of the studies were too small for conclusive results, or they employed weak designs; only 20% were controlled trials, and of those, not nearly all randomized patients to groups. Furthermore, the conditions treated were often heterogeneous in nature or poorly evaluated or described, and methods used to assess outcome varied greatly. Nonetheless, we were able to come up with a way to summarize the overall pattern of the data in this considerable body of work in a way that we believe was meaningful and objective, and an impressive pattern of results emerged.

Because most of the studies did not use nonbiofeedback control groups, this would normally preclude conclusion about any advantage of biofeedback over standard medical care alone. However, because several studies of biofeedback for FI and PFD used standard medical treatment as comparison groups, we were able to pool patients from all applicable studies of each disorder and use a $\chi^2$ test to statistically compare the relative success rate of biofeedback vs standard medical care for these two conditions, respectively. We found that biofeedback treatment added substantially to the likelihood of successful treatment outcome compared with standard medical care alone for both PFD (62.4% vs 45.0% success; a total of 1,107 vs 233 patients) and FI (67.2% vs 35.9%; 1,170 vs 87 patients). These comparisons are summarized in the Figure. These observations provide strong indication of substantial benefits from the availability of biofeedback as an adjunct management option for these disorders.

Second, it was notable that the reported success rates from biofeedback treatment were quite high in the vast majority of studies. Success rates above 50% were reported in 25 of the 26 uncontrolled studies for FI (one additional study did not report success rate), 23 of 29 uncontrolled studies for PFD, and two of three studies on anorectal pain treatment. These high rates of therapeutic response are particularly impressive in light of the fact that a lot of the patients were enrolled in these trials.
specifically because they had proven unresponsive to standard medical treatment.

However, uncontrolled studies do not control for spontaneous improvement unrelated to the study intervention, nor can they exclude the possibility that the observed improvements are placebo responses resulting from expectancy of benefit from receiving a new and different treatment. Only well-controlled randomized trials can conclusively eliminate such confounds and therefore be vital. This has been the Achilles’ heel of this research domain. Not only are the controlled studies conducted to date too few, but the ones that have been published have often left a lot to be desired—for example, by using samples that are so small that they lack power for detecting veritable outcome differences between groups, or by treating very heterogeneous patient conditions in the same study. Only two of the five controlled trials for FI, and three out of eight for PFD, showed some advantage for biofeedback in our review. In the case of PFD, moreover, we did not find a single comparison of biofeedback vs standard medical care in adult patients.

In our review, we applied the recently developed standard AAPB/Society for the Study of Neuronal Regulation treatment efficacy ratings (AAPB, 2002) to this literature. Using these clear and objective guidelines conscientiously, we concluded that biofeedback for PFD in children qualified for the Level 4–efficacious rating, and that adult PFD treatment warranted a rating of Level 3–probably efficacious. FI treatment rated Level 3–probably efficacious, but biofeedback treatment for anorectal pain, which has been poorly investigated to date, could only be assigned Level 2–possibly efficacious. These ratings show well both the strong promise of anorectal biofeedback and the work that still remains to be done to determine, with full scientific certainty, the value of biofeedback for anorectal disorders.

**What Is New in This Area of Work?**

There is presently a lot of active effort by investigators to improve the quality of the research and the knowledge base in anorectal biofeedback. Since we completed our review only 1 year ago, several new studies have reached the finish line. They generally have more sophisticated designs and methodologies, and often more adequate sample sizes, compared with earlier work.

One of these recently completed studies was conducted by our own group at the University of North Carolina–Chapel Hill. It is a randomized placebo-controlled trial of biofeedback for PFD. The main results were presented by Steve Heymen at the Annual Meeting of the American College of Gastroenterology in October 2005 (Heymen et al., 2005), but have not been published yet in full form. Our team found, in this trial of 117 PFD patients, that the treatment outcome for biofeedback was superior, substantially and with statistical significance (70% success rate), compared with the groups treated with diazepam (23%) or placebo medication (38%), although all three groups received thorough education in symptom self-management (with fiber, adequate water intake, scheduled voiding attempts, etc.) and were trained to do pelvic floor exercises.

Another randomized controlled trial for PFD was reported in May 2005 by Rao et al. (2005) at the Annual Meeting of the American Gastroenterological Association. These investigators studied 77 patients and found biofeedback to result in a significantly higher response rate than a group receiving sham biofeedback/relaxation treatment (88% vs 48%), but did not find biofeedback superior to a medical treatment regimen that included laxatives, diet adjustment, and exercise. A third trial, by Chiarioni, Salandini, and Whitehead (2005), studied 52 patients who had slow gut transit on physiological tests and compared biofeedback treatment response in those patients who also had PFD to those who only had slow transit constipation. Seventy-one percent of patients in the PFD group responded to treatment, but only 8% in the slow transit–only group, demonstrating that biofeedback treatment benefits in constipation treatment are specific to addressing the particular physiological dysfunction that PFD represents.

Other substantial trials are now fast approaching completion, including a large controlled study of biofeedback for FI that our group is finishing in the next few months. The new level of research sophistication in this field, and the scale of the present effort, leave little doubt that anorectal biofeedback practitioners will soon have a far stronger empirical case to present than ever before.

**References**


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