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Long-term outcome of anorectal biofeedback for treatment of fecal incontinence

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Abstract

Background: Long-term outcome data for anorectal biofeedback (BF) for fecal incontinence (FI) is scarce. Our aims were to describe the long-term symptom profile, quality of life, and need for surgery in FI patients following BF.

Methods: One hundred and eight consecutive female patients with FI who completed an instrumented BF course were identified for long-term follow-up. In 61 of 89 contactable patients, outcome measures were assessed at short-term (end of BF), mid-term (9 months median), and long-term (7 years median) follow-up after treatment.

Key Results: Long-term response rate (50% or more reduction in FI episodes/wk compared to before BF and not requiring surgical intervention) was seen in 33/61 (54%) patients. Thirteen of these had complete continence. Improvement was seen at short, mid, and long-term follow-up for patients' satisfaction and control of bowel function. In contrast, fecal incontinence severity index and quality of life measures, which improved in short and mid-term, were no different from baseline by long-term follow-up. Patients classified as short-term responders were far more likely to display a long-term response compared to short-term non-responders (68% vs 18%, $P < .001$).

Conclusions & Inferences: Long-term symptom improvement was observed in more than half of FI patients at 7 year post BF follow-up. Quality of life improvements, however, were not maintained. Patients improving during the initial BF program have a high chance of long-term improvement, while patients who do not respond to BF should be considered early for other therapies.

KEYWORDS
biofeedback, fecal incontinence, long-term outcome

1 | INTRODUCTION

Fecal incontinence (FI) is a common and debilitating condition with enormous social and economic consequences.[1,2] First line treatment options include conservative measures to normalize underlying stool form and bowel habit with bulking agents and/or laxatives, use of suppositories or enemas to enhance rectal emptying, and use of loperamide on a regular or as needed basis.[3] Patients that are still symptomatic may be offered anorectal biofeedback (BF) therapy, either focused at improving anal muscle strength and endurance, or a more comprehensive program involving sensory training and anorectal coordination exercises.[4] Other treatment options include neuromodulation, delivered either by posterior tibial nerve stimulation (PTNS) or sacral nerve stimulation (SNS).

Evidence for effectiveness of neuromodulation, in particular SNS, is quite robust, including short and long-term follow-up data,[5] but similar evidence for BF (especially long term) remains scant. In particular, well-designed studies have shown good

short-term and mid-term (up to 1 year) benefit with BF in patients with FI,[6,7]; however similar data for long-term outcomes of BF are still limited.

As fecal incontinence is a chronic debilitating disorder, more common in women, real life data regarding the long-term effect of treatment is of crucial importance for guiding both patients and health care providers in decision-making. Our aims, therefore, were to describe the long-term symptom outcomes, quality of life measures, and the need for surgery or SNS in female patients with FI following a standard course of anorectal biofeedback therapy.

Key Points

- Short-term efficacy data are available for anorectal biofeedback (BF) in fecal incontinence (FI). Our key question was to assess long-term outcomes.
- Long-term symptom improvement was seen in over half of FI patients at 7 years. Quality of life improvements, however, were not maintained. End of BF treatment non-responders have a poor long-term outcome.
- BF has long-lasting beneficial effects in FI. However, patients who do not respond initially should be considered early for other therapies.

2 | MATERIALS AND METHODS

A prospective study was performed in a Neurogastroenterology Unit in a major tertiary referral center. One hundred and eight consecutive female patients reporting FI episodes at least once weekly who completed BF at least 18 months prior were included in the study and, of these, 61 were able to be contacted and agreed to take part in the study. All patients satisfied Rome III criteria for fecal incontinence.[8] The longest period of follow-up was 13 years from completion of treatment. On initial evaluation before BF, all patients completed the Rome Integrative Questionnaire[8] and the Hospital Anxiety and Depression (HAD) scale.[9] Medication use, past surgery, concurrent medical conditions, and bowel pattern were recorded using a structured questionnaire. Patients completed a 7-day stool diary, a modified SF-36 quality of life questionnaire,[10] and underwent a physician assessment. Stool diaries were maintained throughout the BF program. A further physician assessment was performed at the end of treatment documenting major, moderate, or minor improvement; no improvement; or worsening of bowel dysfunction.

The Fecal Incontinence Severity Index (FISI)[11] was calculated before and after treatment. A 10-cm visual analog scale (VAS) was also used before and after treatment for (i) impact of bowel dysfunction on quality of life (score anchors: 0 = no impact; 10 = most impact), (ii) satisfaction with bowel movements (score anchors: 0 = very dissatisfied; 10 = very satisfied), and (iii) feeling of control over bowel function (score anchors: 0 = no control; 10 = complete control).

2.1 | Anorectal physiology testing

After clinical assessment, all patients underwent comprehensive anorectal function studies, as previously described in detail.[12] Complete physical examination including rectal examination was performed in all patients. Anorectal manometry (ARM) was performed using a 7-lumen water-perfused manometry catheter with 0.5 cm spaced sideholes and a compliant balloon (Dentsleeve International, Mississauga, Ontario, Canada). The catheter was connected to calibrated pressure transducers and data from the pressure transducers were displayed in digital form (Neomedix, Sydney, Australia). Each study assessed the following parameters: (i) resting anal sphincter pressure, (ii) maximum anal sphincter squeeze pressure and duration of maximum anal squeeze pressure (sustained squeeze), (iii) rectal pressure on strain and concomitant anal relaxation or paradoxical contraction (iv) anal pressure on cough, (v) rectal sensory thresholds for first sensation, urge and maximum tolerated volumes, and (vi) balloon expulsion recorded as time taken to expel from the rectum, a party balloon tied at the end of a section of intravenous tubing and inflated with 50 mL of warm water, while seated on a private toilet.

2.2 | Anorectal biofeedback treatment

Patients were referred for BF after failing conservative treatment including diet and bulking therapy and having symptoms for at least 6 months. The BF protocol consisted of 30-60 minute weekly sessions, for 6 weeks, with a Gastroenterologist-supervised Nurse Specialist. The protocol comprised of (i) education regarding the anatomy of normal defecation, (ii) advice on correct toilet positioning, (iii) diaphragmatic breathing, (iv) biofeedback involving manometric and surface electromyography (EMG) (Neomedix, Sydney, Australia) for quick, sustained and half maximum anal squeezes, (v) urge resistance training, and when appropriate also, (vi) manometric-based biofeedback aiming to normalize rectal pressure with strain and optimize recto-anal coordination, (vii) rectal sensory training, and (viii) balloon expulsion training. Only patients who completed the full 6 sessions of BF were included in this study.

2.3 | Mid and long-term follow-up

Follow-up at 6 and 12 months after completing the program consisted of repeat BF and repeat documentation of FISI, number of FI episodes/wk and VAS scores. For patients attending both these BF reinforcement sessions, mid-term follow-up data were taken from the 12-month session.

A long-term follow-up questionnaire was sent to all patients at a minimum of 18 months from completion of BF. This included

all outcome data above, and repeated SF36 and HAD, rating of symptom change since BF (improved, stabilized, or worsened) and whether they would recommend BF therapy to patients with similar bowel symptoms. Follow-up phone calls were made to non-repliers and an option to answer the questionnaires verbally was offered.

2.4 | Outcome measures

The main outcome measure was whether or not participants experienced a reduction of at least 50% in weekly FI episodes compared to baseline (before BF). Other outcome measures were the degree of change in FISI score and VAS scores relative to baseline. In calculating these variables, the baseline score was subtracted from scores assessed at (i) end of treatment (short-term), (ii) 6-12 month follow-up (mid-term), and (iii) at least 18 months of follow-up (long-term). Physician assessment of change in bowel dysfunction was categorized as "major or moderate improvement" vs "mild, no improvement or worsening of symptoms."

Patients were defined as "short term responders" if they showed a 50% or greater reduction in the number of FI episodes per week at the end of the BF program compared to before the program (baseline). "Long-term responders" were defined as those exhibiting the same reduction in FI episodes at the time of the long-term follow-up, again compared to before the program, without undergoing any surgical intervention (including SNS) aimed at improving FI. The study protocol was approved by the Royal North Short Hospital Human Research Ethics Committee and written informed consent was obtained from all patients.

2.5 | Statistical analysis

Following descriptive analysis of participant characteristics, we examined, for all followed-up participants, at short-term, mid-term, and long-term follow-up, the main outcome measure (improvement of at least 50% in weekly FI episodes without surgical intervention). For all three time periods, we also examined the degree of difference from baseline in other key outcomes (eg, FISI and VAS). As distributions of these outcomes were often non-normal, non-parametric Wilcoxon sign rank tests were used for all comparisons to baseline. Subsequently, in a series of pairwise analyses (largely correlational analyses using Spearman's rho), and in a multivariate logistic regression using backwards selection, we sought to identify predictors of whether or not an improvement of at least 50% in weekly FI episodes was recorded at long-term follow-up.

Due to minor changes in questionnaires over time, occasional incomplete documentation, and focusing of resources on long-term follow-up, some missing data were present. Missingness was minimal at baseline, end of treatment and long-term follow-up, where the largest missing n for any analyzed variable was 5, 9, and 3, respectively, but, at mid-term follow-up, incomplete data were pronounced (largest missing n for any variable was 31). Importantly, missing values were unrelated to any variable of interest in the study and can therefore be considered missing at random and potentially missing completely at random and will therefore not induce any statistical bias.

Statistical analyses were performed using Stata Statistical Software (Release 15. College Station, TX: StataCorp LP). A two-sided P value of less than .05 was considered to be statistically significant.

3 | RESULTS

3.1 | Participant characteristics

Of the 108 patients, 19 were uncontactable for long-term follow-up. Of the 89 contactable patients, 61 (69% response rate) agreed to answer the long-term follow-up questionnaires. Baseline characteristics and end-of-treatment outcomes were not different between the patients who agreed to participate and those who declined or were uncontactable (Table S1), with the exception of end-of-treatment FISI scores which were worse in study participants (16 vs 12; P = .04).

Sixty-one patients (mean age 61±7 years, all female) were thus included in this study. Mean duration of FI symptoms before commencing BF was 6 years (range 0.5-35). Twenty-four (42%) patients reported no urge before FI episodes and 10 (16%) patients had isolated soiling. Thirty-four (56%) patients had a prior obstetric history of a complicated vaginal delivery. Other baseline characteristics and anorectal physiology are shown in Table 1.

3.2 | Short-term, mid-term, and long-term responses to biofeedback

3.2.1 | Short-term (end of BF program) results

Upon completion of the BF program, 44/61 patients (72%) were short-term responders. As is indicated in Table 2, significant improvements, compared to baseline, were seen in all outcome measures including mean number of FI episodes/week, FISI, and VAS scores for impact on QOL, control of bowel function, and satisfaction with bowel movement. Physician assessment, performed at the end of treatment, categorized 47 patients (78%) as moderate or significant improvement.

3.2.2 | Mid-term results

Median time to mid-term reinforcement sessions was 9 months (mean 8.6 ± 4.9 months). Six patients (10%) did not arrive for either of these sessions and data was incomplete for 4 additional patients who did attend these sessions. As is shown in Table 2, a sustained and significant improvement in all outcome measures was still present at this time point, with 39/51 (76%) of patients still having a 50% or more reduction in FI episodes/week compared to before BF treatment.

TABLE 1 Baseline characteristics and anorectal physiology before biofeedback of all patients included in long-term follow-up (N = 61)

	Long-term (median 7 y) follow-up cohort N = 61
Age-mean, y (SD)	61 (7)
Duration of FI symptoms-mean, y (SD)	6 (8)
FI episodes/wk-mean (SD)	4.6 (4.8)
FISI-mean (SD)	25 (9)
Constipation or IBS-C[a] (Rome)-n (%)	18 (30%)
At least some loose stools (Bristol 6 or 7)-n (%)	24 (40%)
Actively taking loperamide-n (%)	20 (33%)
Actively taking fiber supplements-n (%)	21 (34%)
HAD anxiety score-mean (SD)	6 (4)
HAD anxiety abnormal (>7)-n (%)	22 (37%)
HAD depression score-mean (SD)	3 (2)
HAD depression abnormal (>7)-n (%)	2 (3%)
SF36-mental health-mean (SD)	74 (16)
SF36-pain-mean (SD)	70 (24)
SF36-emotional role-mean (SD)	80 (34)
SF36-physical function-mean (SD)	79 (18)
SF36-physical role-mean (SD)	65 (39)
SF36-social-mean (SD)	78 (29)
SF36-vitality-mean (SD)	55 (22)
Maximal anal resting pressure-mean; mm Hg (SD)	48 (14)
Maximal anal pressure on squeeze-mean; mm Hg (SD)	117 (42)
Duration of squeeze-mean; seconds (SD)	25 (6)
Able to hold sustained anal squeeze >20 s; n (%)	51 (84%)
Anal pressure on cough-mean; mm Hg (SD)	124 (33)
Anal cough-anal squeeze pressure, mm Hg, mean (SD)	7 (39)
Rectal pressure on strain; mm Hg, mean (SD)	54 (22)
Inadequate (<40 mm Hg) rectal pressure on strain; n (%)	16 (28%)
Anal relaxation on strain present; n (%)	6 (10%)
First sensation-mean; mL (SD)	49 (27)
Urge sensation-mean; mL (SD)	111 (48)
Maximum tolerated volume-mean; mL (SD)	179 (63)
Mean time to rectal balloon expulsion; s, mean (SD)	28 (50)
Unable to expel rectal balloon (<60 s)-n (%)	8/61 (13%)

[a]Irritable bowel syndrome—constipation predominant.

3.2.3 | Long-term results

Median time to long-term follow-up was 7 years (mean 6.3 ± 2.6 years). Six patients required surgical interventions including SNS implantation (n = 2), rectal prolapse repair (n = 2), pudendal nerve release (n = 1), and SNS implantation followed by a colostomy (n = 1). As is shown in Table 2, overall, 33/61 (54%) of patients displayed a long-term response; 13 of these responders (39%) had complete continence. Fifty patients (81%) reported that symptoms of FI have either stabilized or improved since completion of the BF program. Although improvements in VAS control and satisfaction numerically worsened compared to end of treatment and mid-term, they were still significantly better than before BF. In contrast, FISI scores and VAS QOL were no longer better at this time point compared to before BF. No differences were seen in HAD or SF-36 scores at long-term follow-up compared to scores before biofeedback treatment. 81% of patients at 7 years from end of treatment said they would recommend BF to patients with similar symptoms.

3.3 | Predicting long-term response to biofeedback

In seeking to predict long-term response, we conducted a pairwise (ie, correlational) analysis of how each baseline (before treatment), and end-of-treatment (short-term) indicator was related to change scores (long-term minus baseline) in number of weekly FI episodes, VAS responses, FISI score, HAD responses, and SF-36 responses. None of the baseline variables predicted long-term response. A subsequent multivariate analysis was performed in which long-term response status served as the outcome variable and the predictors were: (i) end of treatment VAS scores, (ii) end of treatment FISI scores, (iii) end of treatment weekly FI episodes, (iv) amount of short-term change in (i) to (iii), (v) whether or not the participant attended all visits, and (vi) number of days between end of treatment and long-term follow-up. The analysis revealed only one significant predictor of increased response probability: greater reduction in weekly FI episodes from pre-treatment to end of treatment (OR = 0.58, 95% CI = 0.37-0.89, P = .01, n = 58).

To determine whether improvements in other outcome measures were similarly related to reductions in FI episodes, we compared all outcome measures at the different follow-up time points in two subgroups differentiable with respect to FI episodes: (i) short-term responders (n = 44) and (ii) short-term non-responders (n = 17). Compared to short-term responders, short-term non-responders were less likely to attend mid-term reinforcement sessions (29% vs 3%, P = .01, n = 61; in all comparisons across groups that follow here, the P value is from a Kruskal–Wallis test or, in cases where both the predictor and outcome are categorical, Chi-square tests or Fisher's exact tests). For those non-responders who did attend the mid-term sessions, although weekly FI/episodes showed improvement (4.5 vs 2.3, P = .03, n = 11), no benefit was seen in FISI score or any of the VAS outcome measures compared to baseline (Figure 1, P = NS for all comparisons). Short-term responders, in contrast, displayed continued benefit at mid-term follow-up (P < .001 for all outcome measures).

TABLE 2 End of treatment, mid-term and long-term outcomes in all patients completing biofeedback (n = 61)

	Baseline (before BF)	Short-term (end of BF)	Mid-term (median 9 mo)	Long-term (median 7 y)
FI episodes/wk-mean (SD)	4.6 (4.9)	1.9 (2.8)[c]	1.7 (2.5)[c]	2.3 (2.9)[c]
FISI-mean (SD)	24.5 (8.9)	15.8 (8.3)[c]	13.1 (12.6)[c]	21.1 (11.5)
Control over bowel movements; mean (SD)[a]	3.2 (2.0)	7.0 (1.9)[c]	7.4 (1.6)[c]	5.3 (2.6)[c]
Patients' satisfaction with bowel movements; mean (SD)[a]	3.5 (2.2)	6.9 (1.9)[c]	7.2 (2.2)[c]	6.5 (2.7)[c]
Effect of bowel dysfunction on quality of life; mean (SD)[b]	5.5 (2.5)	3.7 (2.4)[c]	3.5 (2.5)[c]	5.6 (2.5)
HAD depression score-mean (SD)	2.9 (2.1)			3.4 (2.8)
HAD anxiety score-mean (SD)	6.2 (3.6)			5.8 (3.9)

[a]Using visual analog scale (0-10), with lower scores indicating worse severity.
[b]Using visual analog scale (0-10), with higher scores indicating worse severity.
[c]$P < .001$.

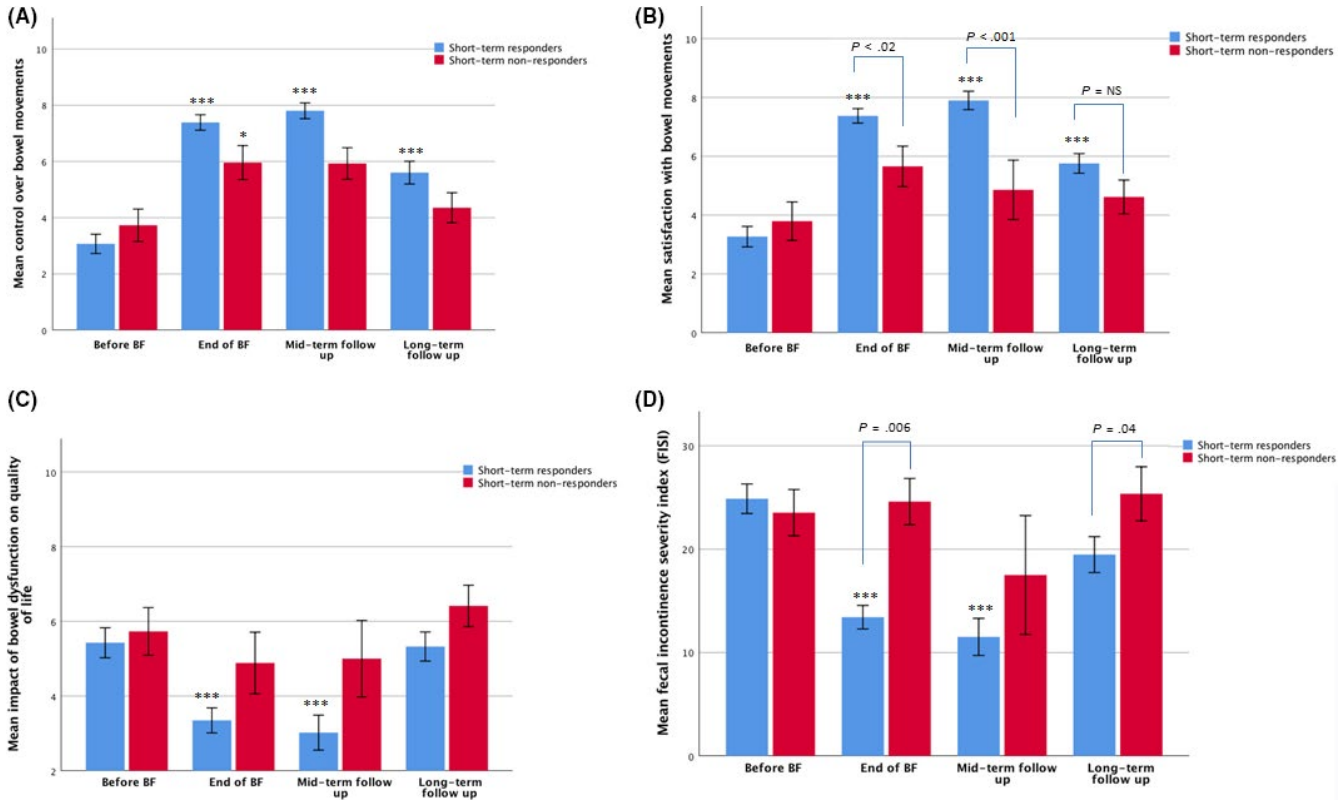

FIGURE 1 Visual analog scores for short-term responders vs short-term non-responders for (A) control (B) satisfaction and (C) effect of bowel dysfunction on quality and (D) fecal incontinence severity score before BF, at the end of BF, and at mid and long-term follow-up (median 7 y). Mean value ±1 SEM is displayed. *$P < .05$; **$P < .01$; ***$P < .001$

As shown in Figure 2, at long-term follow-up, differences between the groups were even more pronounced. 30/44 (68%) of short-term responders displayed a long-term response compared to only 3/17 (18%) of short-term non-responders ($P < .001$ for difference). There was a trend for short-term non-responders to report a worsening of symptoms since completion of BF compared

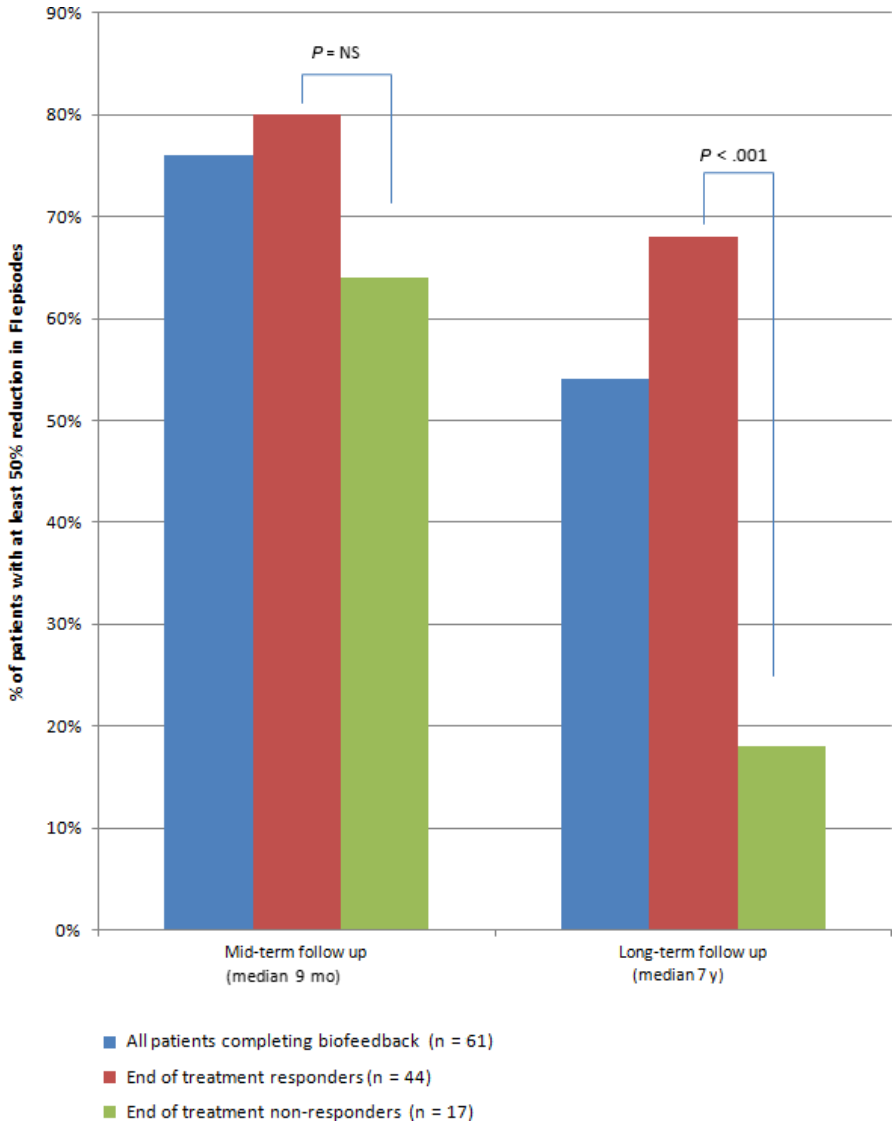

FIGURE 2 Mid- and long-term response rate (defined as at least 50% reduction in FI episodes/wk compared to baseline without undergoing any surgical intervention) in all patients, end of treatment responders and end of treatment non-responders

to short-term responders (35% vs 12%, respectively; $P = .06$). Three patients in each subgroup required surgical intervention following BF ($P = NS$ for difference between groups).

At long-term follow-up, VAS for satisfaction and control was still significantly better than before BF in the short-term responders, but not in the short-term non-responders (Figure 1A,B). There was a trend for FISI change from baseline to indicate greater improvement in short-term responders compared to long-term responders ($P = .06$). No difference in the proportion of patients still using loperamid and/or fiber was noted between the subgroups. VAS-QOL scores, SF-36 scores and HAD did not differ between the two subgroups at long-term follow-up, and were unchanged compared to baseline (full data not shown). In univariate analyses in the short-term responders, longer time from end of treatment to follow-up was associated with worse patients' satisfaction at long-term ($\rho = -.3$, $P = .04$, n = 38) and worse SF-36 scores with respect to physical role ($\rho = -.4$, $P = .01$, n = 39) and vitality ($\rho = -.3$; $P = .04$, n = 39). This was not the case in multivariate analyses involving backwards selection (full analysis not shown).

4 | DISCUSSION

This study provides strong evidence for the long-term durability of anorectal biofeedback treatment in patients with fecal incontinence, especially in patients who have improved during the treatment course itself. 68% of short-term responders were defined as long-term responders at 7 years of follow-up, the longest duration of follow-up reported to date. Patients also showed sustained benefit in their ability to control bowel function and their rated satisfaction with bowel movements. In contrast, the short and mid-term improvements in patients' quality of life measures following BF were no longer evident at long-term follow-up.

Our study findings are that a relatively short-term behavioral intervention can have long-lasting effects, without any ongoing treatment sessions for many years in between the BF course and the assessment time point. If anything, our study may have underestimated the potential long-lasting benefits of biofeedback for several reasons. Firstly, in view of our study having a particularly long period of follow-up (7 years, twice that of most other studies) and

the fact that our analysis suggests a worse outcome with longer periods of follow-up, we may have prejudiced our results to showing a lower long-term response rate than would have been found if we had a shorter mean follow-up. In addition, our study reflects much of the natural history of decline in anorectal function with age thus contributing to seemingly reduced effect of treatment over time. Secondly and importantly, the patients who did not participate in our study (they either declined or were uncontactable), had a higher short-term response rate, indicating a bias toward finding a negative outcome for biofeedback (as short-term response predicts long-term response). It was impressive; however, that 81% of patients said they would recommend the BF course to other patients with similar symptoms.

A major obstacle in comparing our results with previous long-term follow-up studies is the heterogeneity of biofeedback methods, scoring systems, outcome measures and time to follow-up. Pager et al.[13] have reported the single previous cohort comparable in size to our current report, albeit at a shorter duration of follow-up. Different methods were used for BF (manometric, ultrasound, and non-instrumented) focusing only on anal muscle exercises, and using less stringent outcome measures. These investigators reported improvements in 75% of patients at 42 months of follow-up, with a "catch-up" benefit in short-term treatment failures. This may be in line with our overall 54% long-term response rate, using stricter outcome measures and a follow-up period twice in length. The overwhelming outcome data in our study suggest that most short-term non-responders would expect a worse long-term outcome, arguing against a significant "catch-up" benefit.

Lacima et al.[14] reported results of a comprehensive instrumented BF program for FI. Using a strict outcome criteria of 75% or more improvement in FI episodes/week they reported a 80% long-term (5 years) response rate, albeit in a small sample size (n = 31 compared to our study n = 61). All other studies with long-term (up to 4 years) follow-up have included even smaller cohorts, with most,[15-17] but not all,[18] demonstrating a sustained benefit but deterioration in symptoms with time.

To the best of our knowledge, the only study examining long-term improvement in quality of life measures following BF for FI is the study by Pager et al.[13] In contrast to their findings, we did not find a sustained improvement in QOL measures at long-term follow-up. This might be due to our longer follow-up period and might support a time-dependent decline in quality of life related to FI, as suggested by the association of worse SF-36 components with longer time to follow-up in our univariate analysis.

There are almost no studies evaluating the natural history of fecal incontinence over time. Lacima et al.[14] included a control arm of patients with FI who did not undergo BF for their symptoms, and showed that 53% of these patients had no improvement or worsening of symptoms at 5 years, somewhat similar to our 35% of non-responders reporting a worsening of symptoms after a median period of 7 years. In contrast, only 12% of short-term responders reported worsening of symptoms at long-term follow-up, emphasizing again the lasting benefit of the BF program.

One of the major challenges in delivering BF for patients with FI is lack of validated pre-treatment predictors for success. In contrast to BF for functional defecation disorders,[19] prioritizing patients with FI is difficult,[20] and it is our common practice to offer BF to all patients with bothersome FI. Furthermore, as BF is a prerequisite for SNS insurance coverage eligibility in Australia, and PTNS is not widely available, BF is the first line treatment choice in almost all our patients with FI. Our findings thus support a practice of prognostication through a BF treatment trial, much akin to the 2-week temporary electrode placement period of SNS. Patients responding to the BF treatment course should then be encouraged to attend BF reminder sessions and assured about their overall good long-term prognosis. On the other hand, our findings also suggest that better follow-up and treatment (eg, earlier and greater utilization of SNS) should be made possible for BF treatment failures.

Our study is not without limitations. Firstly, we were not able to contact all patients but the reply rate for those contacted was satisfactory (69%). In addition, comparing the groups revealed that non-repliers had slightly better short-term outcomes than our study cohort, leading to a potential bias toward underestimating the long-term value of BF. Secondly, completing the SF36 at short and mid-term endpoints and/or using a validated questionnaire such as the FI-QOL may have shed more light on why no long-term benefits in QOL were observed. Thirdly, we did not include a control, untreated group as we believe it inappropriate not to offer BF for patients with bothersome FI. Lastly, we did not assess whether patients were continuing to carry out BF exercises in the long-term, although previous studies have failed to show this factor as meaningful.[14]

In conclusion, in this the longest term follow-up period reported to date of BF in FI, we provide useful and important information for management of patients. Specifically, patients who improve during the BF program, have a nearly 70% chance of maintaining significant symptom improvement 7 years later. Those patients who do not respond initially to BF treatment are unlikely to subsequently respond and should be considered early in their management course for other therapies.

DISCLOSURES

None.

AUTHOR CONTRIBUTIONS

YM, AM, MJ, and JK planned the study; YM and AA collected all data; MJ and AE conducted all statistical analysis and YM, AE, AM, and JK interpreted the data and jointly drafted the manuscript. All authors reviewed and approved the final draft submitted.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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