



## Original Article

# Influence of sphincter defect on biofeedback outcomes in patients with fecal incontinence



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## ABSTRACT

**Objective:** to evaluate the effect of sphincter defect (SD) on biofeedback (BF) response in patients with fecal incontinence.

**Methods:** two hundred and forty-two patients with fecal incontinence undergoing BF as exclusive treatment were identified from a BF database. Patients were evaluated with fecal incontinence score (Cleveland Clinic Florida – Fecal Incontinence Score, CCF-FI) and anorectal physiology tests. The pre- and immediate post-treatment outcomes were obtained from the chart, and the long-term outcomes by CCF-FI score that was sent by mail.

**Results:** 242 patients underwent BF for fecal incontinence. 143 (59.1%) underwent ultrasonography, 43 (30.1%) of whom had sphincter defect detected on US. The immediate outcomes were not affected by the presence of absence of SD. The second CCF-FI questionnaire was mailed after a mean of 6.1 years after treatment. 31 (57.4%) exhibited improvement, 4 (7.4%) remained unchanged, and 19 (35.2%) had worsening function, which was significantly inferior in patients with SD ( $p=0.021$ ). Electromyography demonstrated increased electrical activity in the contraction phase after BF in both groups.

**Conclusions:** the majority of patients experience improvement in fecal incontinence after BF. However, patients with SD detected on US prior to treatment seem to have worse function at long term.

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## Influência do defeito esfinteriano na resposta ao biofeedback em pacientes com incontinência fecal

## RESUMO

**Objetivos:** avaliar a influência do defeito esfinteriano (DE) na resposta ao biofeedback (BF) em pacientes com incontinência fecal.

**Métodos:** 242 pacientes com incontinência fecal, submetidos exclusivamente ao BF como forma de tratamento, foram selecionados. Os pacientes foram submetidos ao escore de

## Palavras-chave:

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Defeito esfinteriano  
Ultrassom endoanal

incontinência fecal (Cleveland Clinic Flórida-Escore de Incontinência Fecal, CCF-IF) e testes de investigação da fisiologia anorretal. O pré e pós-tratamento imediato foram obtidos do prontuário e para avaliação a longo prazo foi enviado o CCF-IF pelo correio.

**Resultados:** 242 pacientes realizaram BF. 143 (59,1%) realizaram ultrassom e em 43 (30,1%) foi evidenciado DE. Os resultados imediatamente após o BF não foram afetados pela presença ou ausência de DE. O segundo questionário foi enviado pelo correio com tempo médio de 6,1 anos após término do BF. 31 (57,4%) melhoraram, 4 (7,4%) permaneceram inalterados e 19 (35,2%) pioraram, mas nos pacientes com DE a melhora foi significativamente inferior ( $p = 0,021$ ). A eletromiografia demonstrou melhora na atividade elétrica na fase de contração em ambos os grupos.

**Conclusões:** houve melhora clínica na maioria dos pacientes com incontinência fecal após o BF. Entretanto, pacientes com DE detectados ao US antes do tratamento, apresentaram piores resultados a longo prazo.

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## Introduction

Fecal incontinence (FI) is defined as recurrent and uncontrollable loss of fecal material for at least 1 month in an individual at least 4 years of age.<sup>1</sup> Due to the lack of a standardized definition, the prevalence of this disease is difficult to determine.<sup>2</sup> The prevalence rate varies from 2% to 17% of the general population and is higher in women, the elderly, and the disabled.<sup>3</sup> In the United States, FI affects up to 20% of the adults and over 50% of the residents in nursing homes<sup>4</sup> and is the second leading cause of hospitalization in these institutions.<sup>5</sup> In Australia, FI affects up to 72% of the individuals residing in nursing homes for the elderly.<sup>6</sup>

When surgical correction is not indicated, other therapeutic modalities, such as biofeedback (BF), become necessary. Several studies have demonstrated that the success rate of BF in patients with FI varies between 40% and 100%.<sup>1,7-10</sup> However, despite over 25 years of positive results published in the literature, there have been no adequately controlled trials.<sup>8</sup> Furthermore, studies on the influence of anatomical defect of the sphincter muscles on BF in FI patients have not been reported in the literature. This treatment option may, when properly evaluated, abrogate the need for surgical procedures and contribute to potential benefits, such as an improved degree of continence and quality of life. The aim of this study was to evaluate the influence of SD on BF in patients with fecal incontinence.

## Patients and methods

This study included patients with fecal incontinence who underwent BF therapy between 1989 and 2001. Subjects were included regardless of race. All patients received BF as exclusive treatment. Prior to BF patients were subjected to investigatory anorectal physiology tests, evaluation of comorbidities, and application of an assessment questionnaire for the degree of fecal incontinence, developed by Jorge & Wexner<sup>11</sup> and known as the Cleveland Clinic Florida – Fecal Incontinence score (CCF-FI). Patients were followed up in the office upon completion of BF therapy. The pre- and immediately post-treatment data were obtained from the chart.

Long-term outcomes were obtained by CCF = FI that was sent by mail in 2001. Patients who did not respond to the CCF-FI in 30 days were contacted by phone, and their score was reported during the call. Patients who underwent any other type of treatment for fecal incontinence including surgical repair, radiofrequency or injectables procedures were excluded from the study. This study was approved by the Ethics Committee of the Cleveland Clinic Florida.

### Anal manometry

An infusion catheter was used in anorectal manometry with 8 flexible channel sensors and an outer diameter of 4.4 mm. All eight channels were located in the same cross-section along the catheter and separated by an angle of 45°. A low-compliance hydraulic infusion system was used (Arnoldorfer Inc., Greendale, Wisconsin, USA) with an infusion of 0.5 mL/min/channel of distilled water. The catheter for each channel had an internal diameter of 0.8 mm. This system was used to measure the resting anal pressure and squeeze anal pressure in mmHg before BF. All data were recorded and analyzed using Polygram™ V6.4 (Synectics Medical Inc., Irving, Texas, USA).

### Electromyography (EMG)

To perform surface EMG, the endoanal EMG sensor (100–200 Hz) coupled to SRS Orion 8600 equipment (Self Regulation Systems Biotechnologies, Strafford, PA) was used. This test was conducted at the Cleveland Clinic Florida and also at home using a portable unit. Electrical activity was measured during the resting and contraction phases in mV before and after BF.

### Endoanal ultrasound (US)

The endoanal US was performed with the patient in the left lateral position using Bruel and Kjaer model 3535 equipment (Naerum, Denmark) and a rectal sensor 1850. The rotational transducer (10 MHz, focal length 2–4.5 cm) was jacketed with a plastic sonolucent cone (outer diameter 1.7 cm) filled with degassed water to maintain acoustic contact. Images were

obtained along the anal canal to determine the extent of any SD along the longitudinal axis. Any clear gap in the hypoechoic ring representing the internal anal sphincter was considered a defect, whereas defect in the external anal sphincter was detected as a hypoechoic area in relation to the mixed echo of the rest of the muscle. A cicatrix was considered a detected alteration in the ultrasound of the same anatomical region. The degree of the defect was not noted in the US report.

### Biofeedback

During BF, an electromyography catheter was used. Patients were instructed to observe any changes in the pattern of pressure, visualizing the location and function of the pelvic floor muscles, especially the response of the external anal sphincter during contraction. On each trial, the patient was encouraged to increase the amplitude and duration of the contraction of this muscle during a session lasting 60 min. The patient underwent BF one to two times per week, totalling a maximum of 10 sessions.

### Statistical analysis

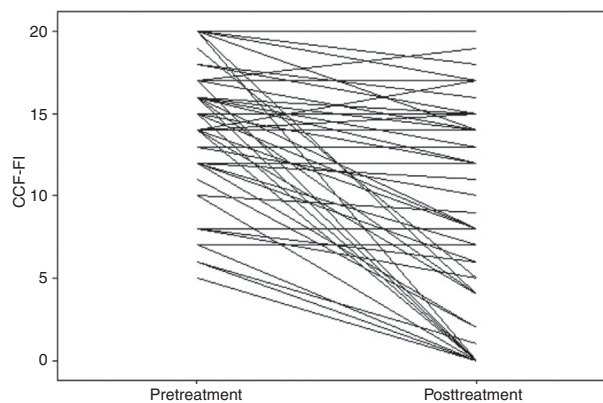
The data were analyzed using descriptive (mean, standard deviation, median, minimum, and maximum) and inferential statistical calculations. To compare the range of manometric values and CCF-FI scores obtained before and after BF, one sample t tests were used for the “before and after” difference of variables with normal distributions, and the Wilcoxon nonparametric (Wilcoxon signed rank) test was used for non-normally distributed variables. For comparisons of factors with more than two categories, the Kruskal–Wallis test with Bonferroni correction was used in cases of significance. For comparisons between the groups with and without defect, the t test for two independent samples and the Kruskal–Wallis test were applied to normally and non-normally distributed cases, respectively. The level of significance was  $\alpha=0.05$ , which equates to a  $p$  value  $\leq 0.05$ . The R-x64 2.13.0 software (The R Foundation for Statistical Computing <http://www.r-project.org/>) was used for the analysis.

## Results

242 patients (74.8% females) of a mean age of  $70.5 \pm 14.0$  (10–100) years were included in the study. 143 (59.1%) patients underwent ultrasound, 43 (30.1%) of whom had sphincter defect or cicatrix detected on US (21 only External Sphincter, 09 only Internal Sphincter and 13 in both), with no difference with regard to gender. The patients underwent approximately  $5.4 \pm 4.4$  of BF sessions.

### CCF-FI score

Sixty-six patients had available CCF-FI score before (mean CCF-FI: 15; 6–20) and immediately after BF treatment (mean CCF-FI: 11; 5–20). Of the 66 patients, 45 (68.2%) exhibited improvement, 18 (27.3%) remained unchanged, and 3 (4.5%) experienced deterioration (Fig. 1). Comparing this score before



**Fig. 1 – Change in fecal incontinence score (CCF-FI) before and after biofeedback.**

and after BF for patients with and without SD no significant difference was found.

After a mean time of 6.1 years of 54 patients (median 72 years) responded to the CCF-FI via mail or after telephone contact. The mean CCF-FI score of this group before treatment was 13 (5–20) and after was 10 (3–20). Of these 54 patients, 31 (57.4%) had improvement, 4 (7.4%) remained unchanged, and 19 (35.2%) had worsening function at long term (Fig. 2).

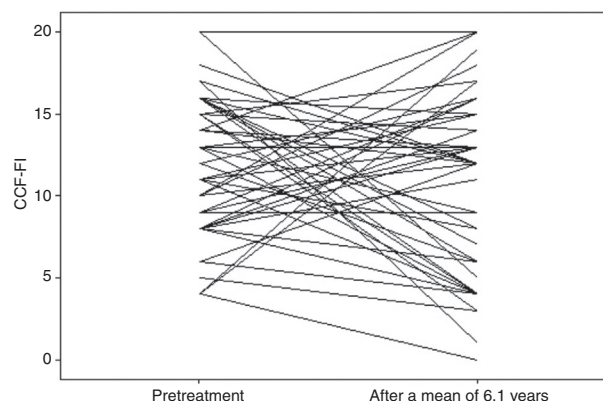
At a mean time of 6.1 years of BF patients without defect had significantly better function than those with defect, specifically of the external sphincter ( $p=0.02$ ) (Table 1).

### Anorectal manometry

Anorectal manometry was performed prior to BF. The comparison between pressure gradients at rest and during squeeze in patients with and without SD revealed no significant differences (Table 2).

### Anal electromyography

There was no difference in electromyographic findings in patient with or without a defect prior to treatment. Interestingly here was a statistically significant improvement during



**Fig. 2 – Change in the fecal incontinence scores (CCF-FI) before and after a mean of 6.1 years of biofeedback.**

**Table 1 – Results of fecal incontinence scores (CCF-FI) according to the presence or absence of SD: before vs. after biofeedback and before vs. after a mean of 6.1 years of biofeedback.**

Biofeedback	Defect	N	Mean	SD	Median	P
Before	Ab	24	13.50	4.30	14.00	0.90 <sup>ns</sup>
	Pr	17	15.41	4.06	16.00	
After-i	Ab	24	8.71	6.72	8.00	
	Pr	17	10.29	7.12	12.00	
Before	Ab	69	13.52	4.10	14.0	0.02
	Pr	38	13.08	4.77	14.0	
After-t	Ab	60	10.63	5.40	12.0	
	Pr	28	13.73	4.48	14.0	

Pr, presence; Ab, absenc; SD, standard deviation; After-i, after biofeedback; After-t, after mean time of 6.1 years; ns, no significant difference.

$p = 0.90$  by Kruskal-Wallis.

$p = 0.02$  by t test for two independent samples.

**Table 2 – Results of anorectal manometry for anal pressure at rest (R) and during squeeze (S) in mmHg before biofeedback according to the presence or absence of SD.**

Variable	Defect	N	Median	P
R	Ab	82	38.0	0.16 <sup>ns</sup>
	Pr	33	33.0	
S	Ab	82	43.0	0.58 <sup>ns</sup>
	Pr	33	40.0	

Pr, presence; Ab, Absence; ns, no significant difference.

Rest: 40–70 mmHg, Squeeze: 80–120 mmHg.

the contraction phase immediately after BF ( $p = 0.000$ ), in both patients with and without defect (Table 3).

## Discussion

The results of this study demonstrated the influence of SD on BF in patients with FI after an average time of 6.1 years.

Clinical improvement was observed in the majority of patients both immediately after BF and after an average time of 6.1 years. Whereas the presence or absence of SD did not influence the immediate outcomes, after a mean of 6.1 years, significantly better results were obtained in patients without SD.

The anorectal manometric findings obtained before BF revealed that patients with and without SD exhibited sufficient muscular conditions to indicate this type of treatment. Anal electromyography revealed a significant increase in electrical activity during the contraction phase immediately after BF, indicating a satisfactory response of the sphincter muscle; patients exhibited improvements in muscle tone regardless of the presence or absence of SD. Regarding the manometric findings collected prior to BF, no significant differences between the pressure gradients at rest and during squeeze were observed in patients with and without SD. These results may be due to the lack of patients whose length, thickness, and angle of defect are large. In this study, regardless of the absence of major SD in patients with FI, BF can be considered a viable treatment option.

Although anal manometry is widely used to evaluate sphincter function, its correlation with ultrasound findings in patients with FI is unknown.<sup>12</sup> Pucciani et al.<sup>13</sup> found an increase in pressure values after the rehabilitation of FI patients with and without SD. However, these authors included in the treatment of these patients other therapeutic options, such as pelvo-perineal kinesiotherapy, BF, volumetric rehabilitation, and electrostimulation, hindering comparison with the results of this study, in which only FI patients treated with BF were studied.

Anal EMG analysis only revealed significant differences between the values obtained before and after BF in the contraction phase, suggesting that the response of the sphincter muscles to BF, measured by electrical activity, was satisfactory. The results (rest and squeeze) before and immediately after BF in patients with and without SD were not significantly different, indicating an improvement in muscle tone regardless of the presence or absence of the defect. These EMG data therefore reinforce the possibility of BF use for FI patients, as mentioned by some authors.<sup>14,15</sup>

**Table 3 – Results of anal electromyography at rest and during contraction (in mV) before and after biofeedback (BF) according to the presence or absence of SD.**

	Phases	BF	SD	N	Mean	SD1	P	
All	Rest	Before	–	54	2.11	1.72	0.28 <sup>ns</sup>	
		After	–	90	2.19	1.67		
	Contraction	Before	–	54	7.25	5.83		
		After	–	90	9.13	6.65		0.00
According to the presence or absence of SD	Rest	Before	Ab	72	2.07	1.93	0.17 <sup>ns</sup>	
			Pr	33	2.14	1.17		
		After	Ab	60	2.38	1.72		
			Pr	28	1.96	1.11		
	Contraction	Before	Ab	72	7.34	6.89		0.41 <sup>ns</sup>
			Pr	33	7.19	4.18		
		After	Ab	60	9.79	6.84		
			Pr	28	10.05	6.87		

Pr, presence; Ab, absence; SD1, standard deviation; SD, sphincter defect; ns, no significant difference.



Comparing the results obtained in patients with postpartum FI subjected to BF and BF with electrical stimulation, Mahony et al.<sup>16</sup> reported an improvement in continence in both groups, as evidenced by increased electrical activity in the contraction phase measured by anal EMG. Furthermore, the addition of electrical stimulation did not achieve better results than BF alone. In the literature, the results of studies on electrical stimulation associated with other types of treatment in patients with FI, such as physical exercise, BF, sacral nerve stimulation<sup>17</sup> and radiofrequency,<sup>18</sup> are contradictory.<sup>19</sup>

The evaluation of the degree of FI revealed an improvement in the CCF-FI score in most patients, both immediately after BF (68.2%) and after a mean time of 6.1 years (57.4%), representing clinical improvement and hence quality of life improvement.

The score immediately after BF remained unchanged in 27.3% of the cases and increased in 4.5% of the cases. In such cases, other therapeutic options may be indicated according to the characteristics of each FI patient.

It is noteworthy that for 35.2% of the patients who responded to the CCF-FI via mail or telephone after a mean time of 6.1 years, there was an increase in this score, representing clinical worsening. One of the factors that may explain this result is the advanced age (median 72 years) of these patients because FI is a common condition in the elderly.<sup>20</sup> Thickening, collagen changes, and reduction of muscular strength occur in the external sphincter muscle with advancing age, which decrease the capacity for bulky fecal retention due to changes in rectal elasticity and distension sensitivity.<sup>21,22</sup>

In the analysis of the CCF-FI score before and immediately after BF, no significant difference was observed between patients with and without SD. The existence or absence of SD did not influence clinical improvement after BF.

Studies of sphincter function should be associated with clinical aspects as, in some patients without FI, a defect may exist that can be detected by ultrasound.<sup>23,24</sup> Pucciani et al.<sup>13</sup> found that in FI patients with and without SD undergoing four types of treatment, including BF, those with the defect exhibited worse FI severity scores than those without. However, comparison with the results of the present study is difficult because the index used by these authors only evaluated information about FI, whereas the CCF-FI score comprises clinical data concerning quality of life.

Rieger et al.<sup>14</sup> found that patients with SD may also benefit from BF. However, these authors did not analyze the physiological aspects of this musculature (anorectal manometry and anal EMG) and therefore could not confirm that the BF result improved function. According to Ferrara et al.<sup>25</sup> the physiology of FI remains relatively unknown.

In this research, functional and FI symptomology of FI patients with and without SD were analyzed in an integrated manner, demonstrating that this treatment is a useful option before opting for surgery. It is important to note that even if the patient does not become continent, the improvement in muscle tone may also contribute to the next treatment option. The limitations of this study include patients having a mean age of 70 years at the time of examination. Trying to understand when the result is not bad if biofeedback was effective or whether it is due to natural aging of the sphincter becomes even harder. Terms would also be interesting to measure the angle of the defect. This would help to analyze the results. If it

were made a prospective analysis it would also be interesting. However, more long term research is necessary, despite the influence of aging, to ascertain the factors that can improve the quality of life of FI patients.

## Conclusion

This study demonstrated that SD influences the biofeedback results after an average time of 6.1 years in patients with fecal incontinence. Anal electromyography revealed a significant increase in electrical activity in the contraction phase after biofeedback, indicating a satisfactory response of the sphincter musculature regardless of the presence or absence of SD. The presence or absence of sphincter defect did not significantly alter clinical improvement immediately after biofeedback, but after 6.1 years, significant better results were obtained in those patients without SD.

## Conflicts of interest

The authors declare no conflicts of interest.

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