

Does the Radiofrequency Procedure for Fecal Incontinence Improve Quality of Life and Incontinence at 1-Year Follow-Up?

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PURPOSE: Fecal incontinence is a socially isolating disease that causes physical and psychologic distress. Radiofrequency delivered to the anal canal is a surgical modality for fecal incontinence that has been noted to be safe and potentially effective. The aim of this study was to evaluate improvement in fecal incontinence and quality of life after the radiofrequency procedure at 1-year follow-up.

METHODS: After institutional review board approval, patients with fecal incontinence for at least 3 months were prospectively recruited between March 2003 and June 2004. Patients enrolled in the study underwent the Secca procedure. The Cleveland Clinic Florida Fecal Incontinence Score and the Fecal Incontinence Quality of Life Questionnaire were completed at the first visit and then at 12-month follow-up. Wilcoxon signed rank test was used to analyze the difference between baseline and follow-up.

RESULTS: A total of 24 patients (23 females) were enrolled in the study, and 16 were available at the 12-month follow-up visit. The main causes of fecal incontinence were either idiopathic or included obstetric injury, aging, and trauma from previous anorectal surgeries. The mean operative time was 45.5 ± 8.3 minutes, and the mean number of radiofrequency lesions in the anal canal was 65.5 ± 13.8 . There were 3 self-

limited episodes of postoperative bleeding and 1 instance of constipation that was resolved with laxatives. There were no delayed complications. The mean Cleveland Clinic Florida Fecal Incontinence Score improved from a mean of $15.6 (\pm 3.2)$ at baseline to $12.9 (\pm 4.6)$ at 12 months ($P = .035$). The mean Fecal Incontinence Quality of Life Questionnaire score improved in all subsets except for the depression subscore.

CONCLUSION: Radiofrequency is a safe, minimally invasive tool for treating patients with fecal incontinence. Improvement in fecal incontinence and quality of life was maintained at 12 months without delayed morbidity. The actual significance of this improvement is yet to be determined.

KEY WORDS: Fecal incontinence; Incontinence score; Radiofrequency; Incontinence; Quality of life.

There are many treatment options for fecal incontinence (FI) depending on the cause and the severity.¹⁻³ The approach usually begins with dietary measures, fiber supplements, antitmotility agents, pelvic muscle exercises, and biofeedback.^{4,5} Surgical options may be offered to patients with sphincter defects and those without defects who fail to respond to initial conservative therapy. Surgical modalities include sacral nerve stimulation, injection of bulking agents, graciloplasty, dynamic graciloplasty, gluteoplasty, implantation of an artificial bowel sphincter, or antegrade colonic enema conduit construction.^{1,6-9} Some of these modalities, such as sacral nerve stimulation, injectable bulking agents, and dynamic graciloplasty, are not approved for use in the United States. Radiofrequency energy (RFE) delivered to the anal canal is a surgical modality used to treat FI that is reported to be safe and effective.¹⁰⁻¹²

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For the last 2 decades, RFE has been used for various disease states, such as prostatic hypertrophy,¹³ gastroesophageal reflux disease,^{14,15} sleep apnea syndrome,^{16,17} ablation of hepatic tumors,¹⁸ spinal lesions,¹⁹ renal tumors,¹⁸ and joint capsule instability.¹ The development of the Secca procedure (Curon Medical Inc, Sunnyvale, CA) made it possible to deliver temperature-controlled RFE to the anorectal junction to treat fecal incontinence. In 1999, RFE was used for the first time to treat fecal incontinence in Mexico.² The radiofrequency generator uses heat generated by a high-frequency alternating current that flows from 4 electrodes causing frictional movements of ions and tissue heating. Temperature-controlled radiofrequency is a modified technology in which constant temperature monitoring and feedback are used to control the amount of energy delivered to tissue, with a simultaneous cooling of the surface tissue. The first clinical trial conducted by Takahashi et al¹⁰ showed the feasibility, safety, and efficacy of the concept of RFE delivery for treatment of fecal incontinence. The 10 patients included in the study had FI of various origins and reported significant improvement in their Cleveland Clinic Florida Fecal Incontinence (CCF-FI) scores.⁶ A more recent report showed the initial results of a multicenter open-label trial that included 50 patients.⁹ The mean procedure duration was 36.9 ± 9.2 minutes, and efficacy was measured by CCF-FI score. The mean score improved in a steady, gradual manner at 1-, 3-, and 6-month follow-up.

The purpose of the present article was to evaluate the 1-year results of RFE (Secca) in patients with FI at 3 institutions using the CCF-FI score and quality of life questionnaire to evaluate outcomes. Hereafter, RFE will denote the Secca method of deliverance of radiofrequency energy.

PATIENTS AND METHODS

Patients were prospectively recruited between March 2003 and June 2004. After institutional review board approval was obtained, all Cleveland Clinic Hospitals (including Cleveland, Weston, and Naples) participated in recruiting patients for the study. All subjects gave informed consent before the procedure. All patients who presented with FI of at least 3-month duration and had failed conservative management and/or prior surgery were included. For this study, FI was defined as uncontrolled loss of liquid or solid stool that interfered with daily activities. Exclusion criteria were inflammatory bowel disease, active anal fissure, constipation or chronic diarrhea, collagen vascular diseases, anal fistula or perianal sepsis, pelvic irradiation, pregnancy, history of laxative abuse, or unstable psychiatric disorder.

During the screening visit, all patients provided a health history and underwent physical examination including proctologic evaluation. The CCF-FI⁶ and Fecal Incontinence Quality of Life Questionnaire (FIQL)¹³ scores

were obtained at baseline and at 12 months after the procedure.

Procedure

RFE was performed in the endoscopy unit or the ambulatory surgery center. Patients received a cleansing enema before the procedure. Prophylactic antibiotics were administered and chosen by the individual surgeon. Patients were positioned in the prone jackknife position with the buttocks laterally taped for enhanced visualization. A standard electrocautery dispersive electrode (ground pad) was placed on the patient's buttock or lower back and was connected to the 4-channel RFE generator. Patients received intravenous sedation and local anesthesia consisting of a perianal injection of lidocaine or bupivacaine with epinephrine. Digital examination and anoscopy were performed, and the thickness of the rectovaginal septum was evaluated in female patients to determine the proximal extent for the anterior RFE.

The device was positioned under direct visualization within the anal canal aligned at the dentate line, after which the needles were deployed into the tissue. The RFE generator delivered energy (465 kHz, 2–5 W) at each needle electrode for 90 seconds. Power was automatically stopped to the electrode when the temperature exceeded 85°C. In addition, the mucosa was constantly cooled by chilled water (45 mL/min) at the base of each needle. The therapeutic goal was to create thermal lesions in the muscle while preserving the mucosal integrity via surface irrigation. Once the needles were inserted into the anal sphincter, each needle caused 4 thermal lesions to be formed. In all 4 quadrants, additional sets were created in the region from 2 cm below to 1.5 cm above the dentate line. No special wound care or diet was necessary, and no postoperative antibiotics were used.

Statistical Analysis

Data were analyzed by one of the authors (R.A.P.) with the assistance of a statistician using the Statistical Analysis System software (SAS Institute Inc, Cary, NC). Continuous outcomes from the CCF-FI score and FIQL were evaluated by computing the difference between baseline and 12-month follow-up using the Wilcoxon signed-rank test. For the demographic data, the *t* test was also applied, and values were expressed in mean \pm SD and ranges. A *P* value less than .05 was considered statistically significant.

RESULTS

A total of 24 patients were enrolled in the study (23 females, 1 male) and underwent RFE. Attempts were made to contact all patients for follow-up, but only 16 were available. The main causes of FI were either idiopathic or included obstetric injury, aging, and trauma from previous

anorectal surgeries. These 16 patients had a mean age of 72.8 (range, 53–84) years. The mean duration of FI symptoms was 8.6 (range, 3–31) years, and the mean age at FI onset was 64.2 (range, 45–78) years.

All female patients had vaginal deliveries; 4 deliveries (17.4%) required use of forceps and 8 (34.8%) were accompanied by an episiotomy. A history of hemorrhoidectomy was present in 1 patient, and no prior fistula surgeries had been performed. Previous overlapping anal sphincter repairs for FI had been performed in 3 patients (13%).

Before enrolling in the study, 16 patients (66.7%) had been treated with dietary modifications, including both high-fiber and low-residue diets. Twenty patients (83.3%) had daily psyllium fiber supplements added to their diets. All patients had received antidiarrheal agents including codeine, diphenoxylate, and loperamide. Four (16.7%) patients underwent at least one biofeedback session. For 1 year after the procedure, all patients were maintained on their respective low-residue or high-fiber diets. Antidiarrheal agents were used as needed, but data were not captured regarding their use.

The mean treatment time was 45.5 ± 8.3 (range, 26–65) minutes and the number of radiofrequency lesions in the anal canal varied from 31 to 80, with a mean of 65.5 ± 13.8 . The radiofrequency procedure was well tolerated.

There were 4 patients who experienced complications related to the preparation for the procedure: one patient orally ingested the enema and became nauseated and vomited; one had a mild allergic reaction to the prophylactic antibiotic therapy with metronidazole and levofloxacin; one had abscess formation at the local anesthetic site that was resolved successfully with drainage; and one had a urinary tract infection.

There were 4 patients who experienced complications related to RFE, of whom 2 presented with minimal bleeding within days after the procedure; in each case, the bleeding spontaneously resolved. The third patient had diarrhea and bleeding that resolved, and the fourth patient reported constipation after the procedure that resolved with laxatives.

Fecal Incontinence Score Evaluation

Eight of the initial 24 patients were lost to follow-up, leaving 16 patients available for the 12-month analysis. The initial CCF-FI score was 15.6 ± 3.2 at baseline, which improved to a mean score of 12.9 ± 4.5 ($P = .035$) at 12 months. Figures 1 and 2 show the scores from the initial visit compared with the 12-month follow-up. The CCF-FI score indicated that 4 patients (25%) had worsening of their fecal incontinence and 2 patients (12.5%) had no improvement. Of the 10 patients (62.5%) with improvement, 2 (12.5%) had 50% or more improvement in the CCF-FI score at 12-month follow-up, and 7 (43.8%) had 20% or more improvement. There were 6 patients who improved

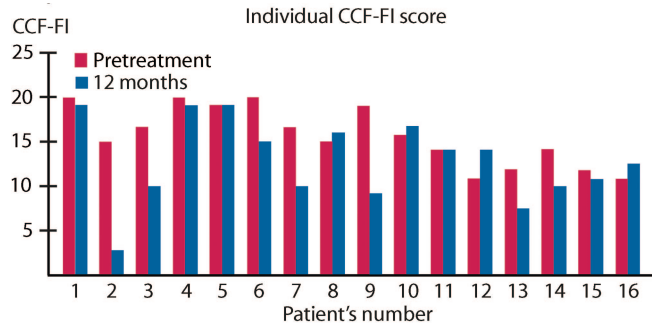


FIGURE 1. Individual fecal incontinence score (Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score) at baseline and 12 months.

to a score below 10. Overall, 10 of 16 patients had a score less than 15, indicating moderate fecal incontinence.^{11,12,20} The mean CCF-FI score was reduced from severe to moderate incontinence 1 year after radiofrequency treatment.

Fecal Incontinence Quality of Life Score

Of 4 subsets of the FIQL score, 3 revealed a significant improvement at 1-year follow-up (Table 1 shows the FIQL scores at baseline and 1-year follow-up). The depression component was the only subscale that trended toward improvement but did not reach significance ($P = .58$).

DISCUSSION

RFE has been shown to be a safe outpatient procedure for the treatment of FI.^{10,21,22} In this study, both the CCF-FI score and 3 of 4 subsets of the FIQL had statistically significant improvement at 1 year.

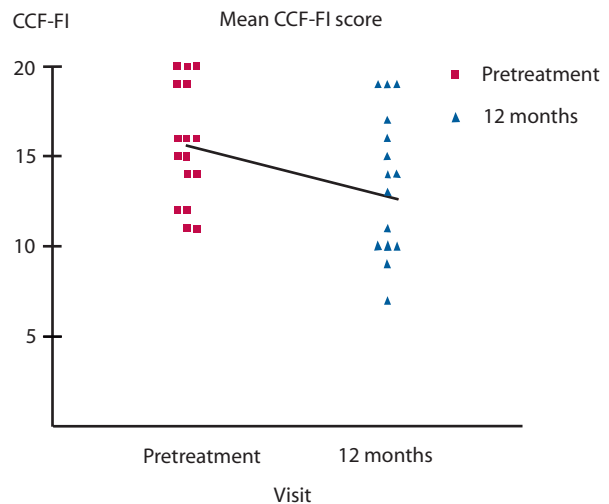


FIGURE 2. Mean fecal incontinence score at baseline and 1-year follow-up.

TABLE 1. FIQL: comparison of subsets at baseline and 12 months

FIQL subscale	At baseline, mean ± SD	At 12 mo, mean ± SD	P
Lifestyle*	2.6 ± 0.85	3.0 ± 0.9	.0035
Coping*	1.6 ± 0.4	2.2 ± 1.0	.0095
Depression	2.5 ± 0.7	2.8 ± 0.8	.058
Embarrassment*	1.3 ± 0.4	2.2 ± 1.0	.0005

FIQL = Fecal Incontinence Quality of Life Questionnaire.

*Significant improvement.

Takahashi et al¹⁰ reported good maintenance of the efficacy of the RFE at 2-year follow-up. Repeating the radiofrequency treatment may be one of the choices to potentially increase the efficacy in cases of procedure failure, as suggested by these authors. Takahashi et al²³ later presented their results of 5-year follow-up in 19 patients with a significant improvement of the CCF-FI score, from a mean of 14.4 to 8.3, and the FIQL score in all of the subsets. There were no long-term complications. The series from Takahashi et al is the longest follow-up study published to date, which also presented the most favorable results for the RFE. Another prospective study with 8 patients was performed by Kim et al.²⁴ At 6-month follow-up after RFE, suboptimal outcomes were reported. FI measured by the Fecal Incontinence Severity Index showed no improvement. FIQL score showed improvements only in the embarrassment scale. The authors also documented a significantly higher complication rate versus that seen in this and other studies. Inclusion of patients with chronic constipation and previous pelvic irradiation (which are exclusion criteria for most RFE studies) may be a negative factor toward poor outcomes in the study of Kim et al.

In the present study, improvement in FIQL score in all components except for depression point toward a positive impact on quality of life for patients treated with RFE for FI. The significant improvement of the CCF-FI score in the present series was also encouraging, especially after review-

ing the sustained results obtained by Takahashi et al²³ with a longer follow-up. In addition, Lefebure et al²⁵ prospectively analyzed 15 patients at 12 months after RFE and observed significant improvement in the CCF-FI score.

Critical analyses of all published studies treating FI with RFE have failed to demonstrate complete resolution of FI. In this study, it is unclear what the significant mean improvement in CCF-FI score from 15.6 to 12.9 really implies because the majority of patients continued to have moderate FI. Although it could reflect some form of placebo effect, alternatively, impairment of daily life caused by FI may be so negative that a minor improvement may be important to these patients. The improvement in 3 of 4 quality of life subscales may indicate that even this modest improvement in FI translated into improvements in daily life. Comparing all studies using RFE for FI, Takahashi et al¹⁰ at 1-year follow-up had the best improvement, as mean CCF-FI score decreased from 13.8 to 7.3. Their subsequent 5-year follow-up analysis²³ showed a relative attrition of their results with a CCF-FI score of 8.26. Efron et al²¹ in a multicenter study showed an improvement in the CCF-FI score from 14.5 to 11.1 at 1 year, which is similar to this study. Lefebure et al²⁵ also reported a similar significant improvement of CCF-FI score, from 14.07 to 12.33 at 1 year. Table 2 compares FI and FIQL scores for all published RFE studies for FI. Ideally, a prospective randomized trial with a larger number of patients would be necessary to explore what improvement means and how RFE relates to quality of life.

Early postoperative complications have included mainly minor rectal bleeding and anal pain for most series in 10% to 45% of patients. Nearly all were self-limited.^{10,21,24-26} Anal pain was sometimes noted and usually resolved within 1 week of the procedure. A study from Efron et al²¹ reported on 50 patients; 2 of these patients experienced severe procedural-related ulcerations, which led to modifications to the device. In the current study, there were 3 self-limited episodes (12.5%) of bleeding and 1 episode (4.2%) of constipation that resolved with laxatives.

TABLE 2. Comparison of FI scores and FIQL subscales among published studies of RFE

Reference	Year	FI score	FIQL subscale			
			Lifestyle	Coping	Depression	Embarrassment
Takahashi et al ¹⁰	2002	13.8–7.3*	2.3–3.3*	1.7–2.7*	2.4–3.4*	1.5–2.4*
Efron et al ²¹	2003	14.5–11.1*	2.5–3.1*	1.9–2.4*	2.8–3.3*	1.9–2.5*
Felt-Bersma et al ²⁶	2007	18.3–11.5 ^a	NA	NA	NA	NA
Takahashi et al ²³	2008	14.37–8.26*	2.43–3.15*	1.73–2.6*	2.24–3.15*	1.56–2.51*
Lefebure et al ²⁵	2008	14.07–12.33*	2.3–2.05	1.77–1.82	1.92–2.33*	2.49–1.62
Kim et al ²⁴	2009	35.1–25.6 ^b	2.64–2.65	2.35–2.35	2.55–2.77	2.25–2.46
This study	2010	15.6–12.9*	2.6–3.0*	1.6–2.2*	2.5–2.8	1.3–2.2*

FI = fecal incontinence; FIQL = Fecal Incontinence Quality of Life Questionnaire; RFE = radiofrequency energy; NA = not available.

*Significant improvement.

^aVaizey score.

^bFecal Incontinence Severity Index.

The precise mechanism of action of RFE is unknown. No consistent changes in anal manometry or anorectal ultrasound have been reported.^{24–26} Takahashi et al¹⁰ reported significantly reduced maximum tolerable volumes at 1-year follow-up, but this finding has not been confirmed by others.

Available nonsurgical options for the management of FI include dietary modification, fiber supplementation, antidiarrheal medications, and biofeedback. The available surgical options (besides sphincter repair) include implantation of an artificial bowel sphincter, graciloplasty, dynamic graciloplasty, and sacral nerve stimulation. These procedures are associated with significant morbidity, and only the artificial bowel sphincter and nonstimulated graciloplasty can be offered in the United States. Two minimally invasive procedures are described for FI: (1) injection of bulking agents, which is also not available to date in the United States, and (2) RFE. Until more options become available for FI in the United States, the data support considering use of RFE in appropriate patients.

The current study was limited by loss of follow-up of 33% of patients, an overall small sample size, and a lack of physiologic study data. However, these factors should not impact on patient results.

CONCLUSION

RFE is a safe, minimally invasive treatment that should be considered for those patients who fail medical management of FI. This therapy may also be offered to appropriate patients who seek FI treatment but do not desire to undergo more invasive procedures. The results of the present study show significant improvement in the tool used to measure FI and in the 3 of 4 subsets of the quality of life tool at 1 year after RFE. As shown in this study, the importance of significant improvement in CCF-FI score is unclear when the follow-up score still reflects moderate FI. Future studies are needed to provide more insight into the clinical relevance of what degree of improvement truly translates into improvement in quality of life.

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