

SECCA[®] Procedure for the Treatment of Fecal Incontinence: Results of Five-Year Follow-Up

ORIGINAL
CONTRIBUTION

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PURPOSE: This study evaluated the long-term (5-year) durability of radiofrequency energy delivery for fecal incontinence.

METHODS: This was an extension of the follow-up from our original prospective study in which patients who suffered from fecal incontinence were treated with the SECCA[®] system for radiofrequency energy delivery to the anal canal muscle. The Cleveland Clinic Florida Fecal Incontinence Scale (0–20), fecal incontinence-related quality of life score, and Medical Outcomes Study Short-Form 36 were administered to five years. Differences between baseline and follow-up were analyzed by using paired *t*-test.

RESULTS: A total of 19 patients were treated and followed for five years, including 18 females (aged 57.1 (range, 44–77) years). The mean duration for fecal incontinence was 7.1 (range, 1–21) years. At five-year follow-up, the mean fecal incontinence score had improved from 14.37 to 8.26 ($P < 0.00025$) with 16 patients (84.2 percent) demonstrating >50 percent improvement. All fecal incontinence-related quality of life scores improved, including lifestyle (2.43 to 3.15; $P < 0.00075$), coping (1.73 to 2.6; $P < 0.00083$), depression (2.24 to 3.15; $P < 0.0002$), and embarrassment (1.56 to 2.51; $P < 0.0003$). The social function component of the Short-Form 36 improved from 38.3 to 60 ($P < 0.05$). There was a trend toward improvement in the mental component summary of the Short-Form 36 from 38.1 to 48.14. There were no long-term complications.

CONCLUSIONS: Significant and sustained improvements in fecal incontinence symptoms and quality of life are seen at five years after treatment with the SECCA[®] system.

This treatment should be considered for patients suffering from fecal incontinence not amenable to surgery and who have failed conservative management.

KEY WORDS: Fecal incontinence; SECCA; Radiofrequency; Sphincter injury; Anal canal; Less invasive colorectal surgery.

Fecal incontinence (FI) is a socially debilitating disease that affects between 2 and 8 percent of U.S. adults.^{1–3} It is believed that even at this high level, the prevalence of the disease is underreported because patients are reluctant or unwilling to discuss their problems or seek treatment because they believe that surgery (colostomy) is their only option for treatment.^{4–7} Dependent on etiology, traditional first-line treatment for FI includes dietary modifications, Kegel exercises, biofeedback, or pharmacologic management.^{5,8} Surgical management, often overlapping sphincter repair, can be offered to patients who have incomplete response to conservative treatment or who have a visible anatomic defect.^{4,6} Other surgical options are available, including graciloplasty, but are usually limited in application because of their invasive nature. More recently new technologies, including sacral nerve stimulation and artificial bowel sphincter implantation have been investigated.^{9–11} There remains a dearth of options available for patients who have failed early management and do not want to consider major surgery for treatment of their fecal incontinence. Radiofrequency energy delivery to the anal junction (SECCA[®] procedure) has been investigated and demonstrated early positive clinical results with minimal complications. However, results have been limited to 6-month to 24-month reports.^{12–15} The purpose of this study was to evaluate and report the long-term (5-year) durability of the SECCA[®] system as an update to data presented at two years.

Reprints are not available.

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PATIENTS AND METHODS

As reported previously, patients were recruited from a pool of patients who presented to the Department of GI Motility Disorders at our center.^{12,13} All patients enrolled had experienced FI for at least three months, had at least one FI episode per week, and had attempted but were dissatisfied with one or more conservative management approaches. Subjects were generally healthy with an ASA score of I-III, ages 18 to 80 years. Exclusion criteria included: previous FI surgery, inflammatory bowel disease, Crohn’s disease, collagen vascular disease, active anal fissure, fistula or abscess, constipation or chronic diarrhea as sole contributor to FI, abnormal blood coagulation or active use of anticoagulant or antiplatelet therapy, previous pelvic irradiation, pregnancy, history of laxative abuse, or unstable psychiatric disorder(s).

Study Design

This was a single-center study involving two cohorts of patients: ten in the first series previously published,^{12,13} and nine in the second series. Institutional Review Board approval was obtained, and all subjects underwent informed consent. A complete history and physical examination was performed along with anoscopy. All subjects completed the fecal incontinence grading scale (Wexner),⁴ the fecal incontinence quality of life (FIQL),³ and the Medical Outcomes Short-Form 36 (SF-36)¹⁶ to establish a baseline.

Procedure

The SECCA® (Curon Medical, Fremont, CA) procedure was performed by a single investigator (TT) and delivered as previously described.^{12,13} The only change in protocol was that the second series of patients received treatment at four levels (vs. 5 in the first series) for a total of 60 (vs. 80) individual treatment sites.

Follow-Up

All subjects were interviewed in our offices and completed the Wexner, FIQL, and SF-36 questionnaires at 1, 2, 3, 6, 12, 24, and 60 months.

Statistical Analysis

Data were analyzed by using SAS software (SAS Institute, Inc., Cary, NC). Continuous outcomes from the Wexner, FIQL, and SF-36 were evaluated by computing the difference between the baseline and follow-up values and applying the Wilcoxon’s signed-rank test. One tail paired *t*-test also was applied to the mean change from baseline to follow-up. Intention to treat was not required because all subjects and corresponding data were available for all follow-ups at 12, 24, and 60 months. A Number Needed to Treat (NNT) analysis was evaluated between the first and

second series of patients to ensure no differences and pool ability. Repeated measures analysis was performed to demonstrate changes within follow-up intervals.

RESULTS

A total of 19 patients were treated (18 females; 94.7 percent; Table 1). The mean Cleveland Clinic Fecal Incontinence (CCF-FI) Scores improved significantly from 14.37 to 8.26 ($P < 0.00025$; Fig. 1) at five years. There was a small initial difference between the two series but the NNT was 60 to demonstrate a difference, thus the data were pooled. Sixteen patients (84 percent) demonstrated a >50 percent reduction in their CCF-FI score at five-year follow-up. Analysis for the Wexner score shows results significant by 2 months with a plateau to 60 months. There was no statistical difference in CCF-FI scores from 24 to 60 months ($P =$ not significant). Individual patient analysis demonstrated that one patient with a moderate initial response had a decrease in their CCF-FI score from 24 to 60 months. All others who had exhibited significant 24-month improvement maintained or improved in their CCF-FI scores.

Mean FIQL scores improved significantly from baseline to five-years in all four categories: Lifestyle 2.43 to 3.16 ($P < 0.00075$), Coping 1.73 to 2.6 ($P < 0.00083$), Depression 2.24 to 3.15 ($P < 0.0002$), and Embarrassment 1.56 to 2.51 ($P < 0.0003$; Fig. 2). There was no change in results between the two-year and five-year follow-up.

The mean social function of the SF-36 scores improved significantly from 36 to 60 ($P < 0.05$). There was a trend toward improvement in the mental component summary (MCS) of the SF-36, whereas the physical component summary (PCS) did not change during the follow-up period (Fig. 3). Perioperative complications included delayed bleeding in six patients with one requiring anoscopy and suture ligation to control bleeding. No patient required transfusion. There were no long-term complications.

Table 1. Patient demographics (N=19)

Male/female ratio	1/18		
	Mean	Range	SD
Age (yr)	57.1	44–77	9.48
Age at onset (yr)	49.2	26–67	11.36
Years with FI	7.9	1–21	6.12
Vaginal delivery	15 (mean 2)		
Forceps	3		
Episiotomy	9		
Hemorrhoid surgery	5		
Other surgery (rectal, anal, colon)	7		

FI = fecal incontinence; SD = standard deviation.

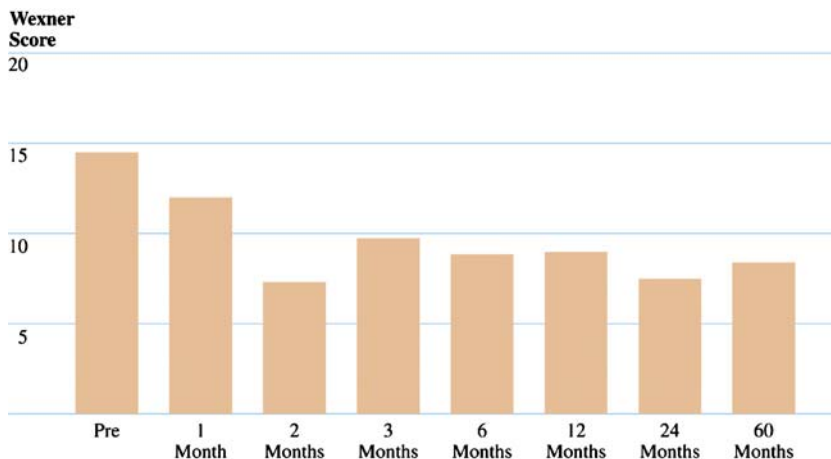


FIGURE 1. The mean Wexner score improved significantly from baseline to five-year follow-up ($P < 0.00025$) with no change in outcomes from 12 to 24 to 60 months ($P =$ not significant).

DISCUSSION

In this study of the five-year results of the Secca device for the treatment of fecal incontinence, we demonstrated significant improvement in the CCF-FI, FIQL, and SF-36 scores. The results show that the procedure outcomes are lasting with significant improvement from baseline reported by 12 months, with no overall decrement in effect from 12 to 24 to 60 months. However, there was a change noted in the CCF-FI score in one patient from 24 to 60 months. Analysis shows that the majority (84 percent) of patients demonstrated a significant clinical response; those who did not respond clearly delineated in their lack of initial clinical response (CCF-FI score) by 12 months. There were limited improvements in AR manometry.¹² However, the significant improvements reported in patient’s rectal sensation may be an important

key in the management of FI because patients may be better able to sense, and thus manage, their bowel contents on a timely basis.

These data are reported for a group of patients with long-standing fecal incontinence confirmed by standardized survey scores who had failed standard, conservative measures for managing their incontinence. This is important, because the current options available to treat fecal incontinence are limited to lifestyle management, medical therapy, biofeedback, and surgery. Conservative measures have limited success, and in the case of biofeedback, often will necessitate sequential treatments to maintain the limited results. A recent study by Norton *et al.*¹⁷ has confirmed this limited utility even in patients suffering from mild FI. For patients who failed early therapy, surgery may be offered to individuals as an option. The most common surgery for correction of FI is

FIGURE 2. The mean Fecal Incontinence Quality of Life (FIQL) scores improved significantly for all four measures from baseline to five-year follow-up ($P < 0.00075$) with no change in outcomes from 12 to 24 to 60 months ($P =$ not significant).

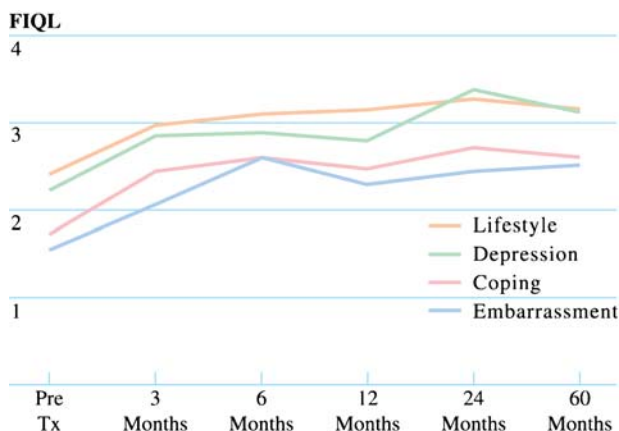
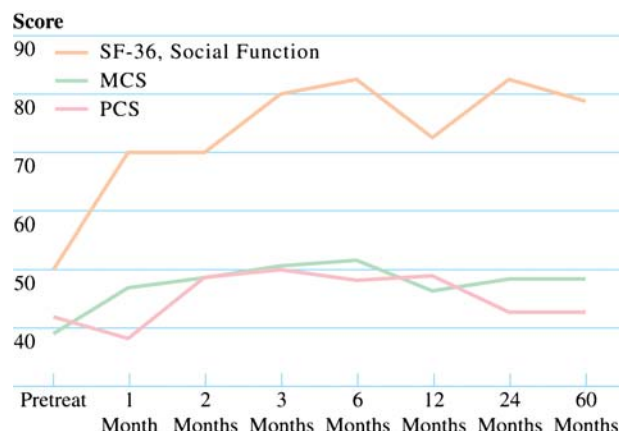


FIGURE 3. The mean Short Form-36 (SF-36) improved significantly from baseline ($P < 0.05$). The MCS (Mental Component Summary) showed a trend toward improvement, whereas the PCS (Physical Component Summary) showed no improvement ($P =$ not significant).



the overlapping sphincter repair, which is most often used in patients with visible defects.¹⁸ Although this surgery may be effective, perioperative complications are reported in 24 percent of cases and the durability may be modest.¹⁹

Other techniques that are being evaluated to alleviate FI include sacral nerve stimulation and the artificial bowel sphincter. Both showed promising early experience, yet complications associated with these implants have occurred frequently and include infection, extrusion, and pain.²⁰ There are minimal long-term data available on these devices.

The safety and efficacy of the SECCA® device has been previously reported. The efficacy was assessed and reported utilizing widely used FI instruments, including the Cleveland Clinic Fecal Incontinence Score, FIQL, and SF-36. In a small cohort of patients, the procedure has shown durability to 24 months. In a larger patient population, Efron *et al.*¹⁴ have demonstrated positive short-term outcomes. Analysis of the response after the SECCA® procedure shows that some patients showed minor worsening of symptoms in the first few weeks after the procedure, after which time progressive improvement was noted from 1 month to as many as 12 months in parallel with normal healing. In these reports no long-term complications were noted, no significant pain incurred, and the recovery process was considered uneventful. The procedures were performed on an outpatient basis under local anesthesia without hospitalization or general anesthesia required. The present study demonstrates that SECCA® provides significant and long-term clinical improvement in the majority of patients. Given the current lack of treatment options outside of conservative, questionably successful management and surgery, patients have been relegated to few treatment options other than suffering and managing with the costly mix of social limitations and diapers. Given the current report, we believe that SECCA® may provide those patients suffering from FI, dissatisfied with medical or conservative therapies, and unwilling or unable to undergo surgical intervention, an option for viable long-term treatment. This is in accord with the recently published treatment algorithm by Khaikin and Wexner²¹ for the management of fecal incontinence. We recognize that limitations of this study include the small number of patients and lack of a control arm. However, given the pronounced clinical improvement in standardized measures, the “do or do not” improve nature of the response and continued stability of outcomes from baseline to 12, 24, and 60 months, the results are encouraging.

CONCLUSIONS

Radiofrequency energy delivery, using the SECCA® device, into the anal canal muscle is a new modality that, in this study has safely provided five-year improvement in Wexner, FIQL scores, and patient quality of life on an

outpatient basis. Although not all patients improve, the majority can expect significant clinical response with minimal risk. Furthermore, there are no “bridges burned” by providing the SECCA® early in the treatment spectrum for patients suffering from fecal incontinence. Further studies will help elucidate responder vs. nonresponder criteria to enhance clinical outcomes.

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