

## The Secca Procedure for the Treatment of Fecal Incontinence: Definitive Therapy or Short-Term Solution\*

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The treatment of fecal incontinence by means of radiofrequency energy is based on the concept that collagen deposition and subsequent scarring may increase one's ability to recognize and retain stool and permit improved continence. The procedure is undertaken on an outpatient basis. Individuals may be considered candidates even if they have a potentially reparable defect since the technique does not limit one to the application of a subsequent procedure. Clearly, those for whom other treatment methods have failed and those who have no other reasonable option in the management of their fecal incontinence should be considered for this procedure. Preliminary results are quite encouraging, and the results of a prospective, sham-controlled, randomized clinical trial are awaited.

A five-center study, in which the senior author participated, involved 50 patients (43 women) with fecal incontinence, all of whom were failures of medical or surgical management.<sup>7</sup> Inclusion criteria included incontinence for stool at least once per week for 3 months. At baseline and at 6 months, the patients completed CCF-FI and the FIQL questionnaires as well as a social function questionnaire (SF-36). All subjects underwent anorectal manometry, pudendal nerve terminal motor latency, and anorectal ultrasound testing at baseline and 6 months. At 6 months, the mean CCF-FI score had improved from 14.5 to 11.1 ( $p < 0.0001$ ). All parameters in the FIQL were improved ( $p < 0.001$ ). There was an overall statistically significant improvement in the days with fecal incontinence, the days with gas incontinence, the incidence of pad soiling, the days with urgency, and the days with fear of fecal incontinence. With the exception of one center's data, no objective changes were noted in physiologic studies with the exception that resting anal sphincter length increased by 25% ( $p = 0.019$ ). Complications included mucosal ulceration (one superficial, one with underlying muscle injury) and delayed bleeding (one).

**COMMENT:** There is certainly a gap between nonoperative treatment of fecal incontinence and that of surgery. The Secca procedure is intended to offer a less-invasive option for the management of anal incontinence as compared with surgical alternatives. The Secca System received clearance from the US Food and Drug Administration in early 2002 for the treatment of fecal incontinence. While it is no longer considered an investigational approach there is a unique study currently being undertaken—that of a prospective, randomized, sham-controlled United States trial, in which the Secca procedure is compared with a placebo, anoscopic treatment. This is the only clinical trial of its kind that will meaningfully assess the outcome of any of the interventional options for the treatment of fecal incontinence. Regarding the Secca procedure and the currently available results, there is a favorable risk/benefit ratio when compared with alternative treatments. The Secca procedure is a minimally invasive, ambulatory procedure, and patients may return to normal activities within 48 hours. With respect to individuals who are potential candidates, it could be considered as first-line therapy for those with fecal incontinence, since "no bridges are burned." That is not to say that someone with a reparable sphincter defect would be better served by RF treatment, simply that it is believed that this approach would not preclude a subsequent operation. It should also be considered following a procedure or a treatment that has had less than satisfactory results or in someone who cannot tolerate an operation. Finally, it may certainly be offered as a "last resort" to a patient for whom there is no alternative except fecal diversion. While progress has been made in the areas of requisite training and case of use, a clearer treatment algorithm for the management of fecal incontinence is still required.