

## [Safety and Effectiveness of Temperature-Controlled Radiofrequency Energy Delivery to the Anal Canal \(Secca Procedure\) for the Treatment of Fecal Incontinence.](#)

Efron JE, Corman ML, Fleshman J, Barnett J, Nagle D, Birnbaum E, Weiss EG, Nogueras JJ, Sligh S, Rabine J, Wexner SD. Dis Colon Rectum. 2003 Dec;46(12):1606-16; discussion 1616-8.

**PURPOSE:** This multicenter study evaluated the safety and efficacy of radio-frequency energy delivery to the anal canal for the treatment of fecal incontinence.

**METHODS:** Fifty patients at five centers were enrolled. All reported fecal incontinence at least once per week for three months, and medical and/or surgical management failed to help their symptoms. At baseline and six months, patients completed questionnaires (Cleveland Clinic Florida Fecal Incontinence score [0-20], fecal incontinence-related quality of life, Short Form-36, and visual analog scale) and underwent anorectal manometry, endoanal ultrasound, and pudendal nerve terminal motor latency testing. On an outpatient basis using local anesthesia, radio-frequency energy was delivered via an anoscopic device with multiple needle electrodes (Secca® system) to create thermal lesions deep to the mucosa of the anal canal.

**RESULTS:** Forty-three females and seven males (aged 61.1 + 13.4 (mean + standard deviation); range 30-80 years) were treated. Mean duration of fecal incontinence was 14.9 years. Treatment time was 37 + 9 minutes. At six months, the mean Cleveland Clinic Florida Fecal Incontinence score improved from 14.5 to 11.1 (P<0.0001). All parameters in the Fecal Incontinence Quality of Life scales were improved (lifestyle (from 2.5-3.1; P<0.0001); coping (from 1.9-2.4; P<0.0001), depression (from 2.8-3.3; P=0.0004); embarrassment (from 1.9-2.5; P<0.0001)). Responders, as assessed by a systematic referenced analog scale, reported a median 70 percent resolution of symptoms. The mean Short Form-36 social function improved from 64.3 to 76 (P=0.003). There were no changes in endoanal ultrasound or pudendal nerve terminal motor latency assessment, or in anal manometry. Complications included mucosal ulceration (one superficial, one with underlying muscle injury) and delayed bleeding (n=1).

**CONCLUSION:** This multicenter trial demonstrates that radio-frequency energy can be safely delivered to the lower rectum and anal canal. The Secca® procedure significantly improved the Cleveland Clinic Florida Fecal Incontinence score and the overall quality of life for most patients having undergone the procedure.