



EDCO FORUM[®]

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 13 NUMBER 3

SEPTEMBER 2006

REPRINT

THE RENESSA[®] SYSTEM

A New Non-Surgical Solution for Female Stress Urinary Incontinence

Stress urinary incontinence (SUI) is the most common type of urinary incontinence and affects as many as 15 million women in the United States. SUI impacts women of all ages, including approximately 25 percent of women between the ages of 30-59, and is highly prevalent in those who have had at least one vaginal delivery. The primary cause of SUI is inadequate support of the bladder, resulting in bladder outlet hypermobility. While not a life-threatening disorder, SUI can diminish a woman's quality of life, often restricting participation in professional and social activities for fear of leakage. Despite the daily discomfort and distress caused by SUI, most women ignore their symptoms and do not seek professional help because of fear or embarrassment (1). Some even accept SUI as a natural part of aging or childbirth. Conversely, despite the prevalence of SUI, physicians often do not inquire of their patients whether they might experience symptoms.

Novasys Medical, Inc. (Newark, CA), a company dedicated to the development of innovative therapies in women's health, has recently launched the **Recessa[®] System**, a novel, non-surgical approach to treat female SUI due to bladder outlet hypermobility. The Recessa procedure, a catheter-based treatment that uses radiofrequency (RF) energy to increase bladder outlet resistance, offers women a unique treatment for SUI that can be performed in a physician's office or other

outpatient setting. The Recessa treatment has a rapid and comfortable recovery with minimal post-procedure limitations. This treatment has an excellent safety profile and has been shown to be well tolerated with high patient satisfaction.

The 20-30 minute procedure can be performed by a urologist, urogynecologist or gynecologist using local anesthesia with oral sedation. A single-use transurethral probe is positioned within the bladder, and a small



balloon is inflated to maintain the probe in its proper position. RF energy from a compact generator is delivered for 60 seconds to four small needle electrodes deployed from the probe into the submucosal tissue of the bladder neck and proximal urethra. The resulting controlled, low-temperature heating of tissue targets within the lower urinary tract denatures the collagen in tissue at multiple small sites. Upon healing, the now

microscopic alterations in submucosal collagen do not change urethral luminal caliber or cause stricture. The treatment is associated with a safety profile comparable to that of a brief bladder catheterization (2). No visualization of the treatment site is required. The procedure requires no incisions, bandages or dressings, and women can safely resume most activities within 24 hours. Upon healing, the treated tissue is firmer, increasing resistance to involuntary leakage at times of heightened intra-abdominal pressure, such as coughing, sneezing or during exercise,

thereby reducing or eliminating SUI episodes.

A multi-site, randomized, controlled US clinical trial demonstrated that the majority of women who underwent the Renessa treatment experienced a significant improvement in quality of life measures at 12 months post-treatment. Seventy-six percent of treated women experienced a reduction in daily incontinence episodes; 58 percent eliminated the need for incontinence pads; and 35 percent were completely dry (cured). In addition, a retrospective follow-up study in 26 women was conducted 3-4 years after they had the Renessa treatment. Fifty-six percent of these women have >50 percent reduction in Incontinence Episode Frequency (IEF)—exactly the same as at one year. Satisfaction with the treatment and willingness to refer the treatment to a friend remain high.

With other currently available surgical and non-surgical SUI therapies, many patients and physicians have concerns about safety, recovery, compliance, and effectiveness. Behavioral and bio-feedback therapies often require multiple treatments over weeks or months and are plagued by limited success. Some surgical treatments have demonstrated adequate success, but are associated with patient discomfort, high costs, and

perioperative morbidity. Furthermore, some women who have undergone a surgical treatment report continued leaking and surveys have shown that many women are not interested in a surgical therapy (3). The Renessa System represents an approach that could be considered one of the least invasive, yet most effective, treatments available.

What attracted Denise Elser, MD, Illinois Urogynecology, Ltd. (Oaklawn, IL), to the Renessa treatment was that it “presented a great option for some ladies who are not surgical candidates, such as the older patients who may be afraid of surgery because they have other medical problems and maybe ought not to have anesthesia or surgery, or the young patients who started having kids at a young age or have bad tissue and have incontinence that's unbearable. I'm not causing tissue destruction or putting in a device that's going to block future treatments for this young patient.” About two-thirds of Dr. Elser's patients returned with great results, and reported that they had little or no pain.

Rodney A. Appell, MD, Department of Urology, Baylor College of Medicine (Houston, TX), finds that the Renessa treatment is “quite unique. This procedure has the positive aspects of being able to be performed in 20 minutes

under local anesthesia in a doctor's office with a markedly significant improvement rate that has durability for at least one year.” As for convenience and recovery, Dr. Appell notes, “patients can get up and leave at the end of the procedure. There are no catheters and no bleeding—just a follow-up office visit for a checkup.”

These physicians and others performing the Renessa treatment have extensive experience in diagnosis and treatment of SUI, and often perform urodynamics or other sophisticated diagnostic testing to identify patients who are potential candidates for the Renessa treatment. To learn more about how the Renessa treatment may benefit your patients, or to find a physician to whom you can refer your patients, call toll free 1-866-784-4777, e-mail info@novasysmedical.com, or visit the company's Web site at www.novasysmedical.com.

References:

1. Fultz NH, *et al.*, Burden of stress urinary incontinence for community-dwelling women. *Am J Obstet Gynecol* 2003;189:1275-82
2. Appell, RA, *et al.*, The need for “sham treatment” arms in medical device clinical trials for adequate safety evaluation. American Urogynecologic Society Annual Meeting (presentation), 2004.
3. Robinson, D, *et al.*, Department of Urogynaecology, Kings College Hospital, What women want—Their interpretation of the concept of cure. Abstract presented at IUGA 2002 and ICS 2002 Annual Meetings.