

The Renessa[®] Treatment for SUI

Expanding the Continuum of Care and Enhancing Your Practice

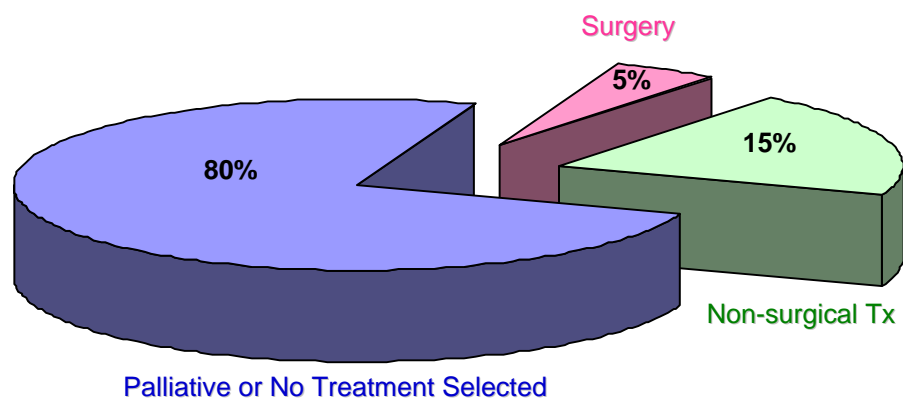
By: Craig McCoy, DO, FACOG

Stress Urinary Incontinence – A Common Problem

Physicians treating women with pelvic floor disorders understand that stress urinary incontinence (SUI) is a common problem. But exactly how common is it? SUI affects an estimated 15 million women in the U.S., 30 million women worldwide.¹ In 85% of SUI patients, the condition is caused by bladder outlet hypermobility. SUI affects women of all ages, including approximately 25% of women age 30-59 years, particularly those who have delivered at least one baby vaginally.

SUI is the most common form of urinary incontinence (UI) and occurs much earlier than the other types (urge and mixed urinary incontinence), representing 50% to 60% of all UI patients among women younger than 75.

Although SUI is treatable and even curable in some cases, only about half of women with SUI mention their condition to their doctor. Of those who do speak to their physicians, 20% actually pursue some form of treatment, partly due to the embarrassing stigma associated with the condition, or because many patients mistakenly believe that SUI is a normal result of aging or childbirth. Of those women who speak to their physician, 5% are willing or able to undergo a surgical procedure, another 15% choose conservative therapies such as pelvic floor muscle training, biofeedback, pessaries, or urethral bulking agent injections. Unfortunately, 80% choose to do nothing – managing their symptoms with diapers and pads, or restricting the kinds of activities that result in leaks.



While not a life-threatening condition, SUI can severely affect a woman's quality of life, and is associated with a wide range of co-morbidities such as urinary tract infections, depression, sleep disturbance, inactivity and weight gain, and sexual dysfunction. Most women live with

their condition, opting to self treat by using diapers or pads, making frequent trips to the bathroom, limiting fluid intake and reducing physical activity. They delay medical treatment due to concerns over the lack of effective non-surgical treatment options and the risks of surgery, including complications and extended recovery periods

1. Health Research International Report, 2005
National Association for Continence Media Report, 2006

Treatment Options

A wide variety of surgical and non-surgical treatments are available for SUI. When women do seek treatment for their SUI symptoms, first-line therapies are typically lifestyle modifications, such as weight loss or limiting caffeine intake, and physical and behavioral techniques, such as pelvic floor muscle retraining (Kegel exercises), bladder retraining, biofeedback, electrical stimulation, or the use of vaginal pessaries. These therapies can be effective, although it may take time to see results and outcomes are highly dependent on a patient's understanding, training, motivation, and persistence. When these conservative treatments fail to provide the relief desired, surgery is often recommended.

While percutaneous slings are the least invasive and the most commonly performed surgical procedure for SUI, they are not without risks. Surgery is associated with a 13%–17.1% average overall complication rate. The most common complications include bladder injury (5-15%), vaginal sling extrusion (6%), infection (4.4%), urinary/renal complications (4.3%) and bleeding (2.8%), resulting in extended hospitalization. (*Neurourol Urodyn* 2005; 24:659-65; *Obstet Gynecol* 2003; 101:671-6).

Recently, the FDA issued a Public Health Notification to healthcare providers regarding serious complications of the use of surgical mesh to treat SUI and pelvic organ prolapse (POP), stating that FDA “has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI.... The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence.” (FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence. October 21, 2008)

In addition to concern about complications, working women and women who care for small children are often too busy to take time off for surgery and recovery. For those who may want to have more children, surgery is typically not an option. In fact, studies have shown that most women:

- Select their initial SUI treatment based on invasiveness, not on likelihood of cure.
- Want a minimally invasive treatment (non-surgical, safe, rapid recovery, etc.) as their initial therapy.
- Expect an improvement in their quality of life, not necessarily a cure: “...patients prefer a minor procedure with a lower risk of complications and are content to accept a lower success rate.”

(Robinson, Anders et al; *What women want – Their interpretation of the concept of cure.* IUGA 2002 and ICS 2002 Annual Meetings)

Until recently, there have been limited effective treatment options for women who have failed conservative therapy, but who do not want, or cannot have, an invasive surgical procedure. Urethral bulking agents have less risk than surgery, but often require multiple treatments. Further, they are indicated for intrinsic sphincter deficiency, which represents only about 15% of cases of SUI, with the other 85% related to bladder outlet hypermobility.

The Renessa[®] treatment was introduced in 2005 and offers women with SUI due to hypermobility and their physicians a safe and effective non-surgical office-based treatment option for women who have tried conservative therapies with limited success but are unwilling or unable to accept the risks, complications and recovery time associated with surgery. The Renessa treatment delivers low temperature radiofrequency energy to heat small submucosal tissue targets in the bladder neck and proximal urethra via a 21F balloon-tipped disposable transurethral probe. The heat denatures collagen in the tissue, and upon healing the tissue is less compliant, increasing resistance to leaks during times of increased intra-abdominal pressure. The procedure is performed in a physician's office using local anesthesia with or without an oral anxiolytic such as Valium or Ativan. Total procedure time is approximately 30 minutes.



The Renessa treatment has been extensively studied, including a U.S. multicenter randomized controlled trial with 12 month prospective follow-up and 3+ year retrospective follow-up. One year outcomes include:

- 76% reported a reduction in incontinence episodes
- 59% reported reduction in daily episodes by at least half
- 73% reported a reduction in leak severity
- 67% reported improvement in quality of life
- 58% were able to eliminate pad use
- more than a third were completely dry

(Appell, et al. Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence. *NeuroUrol and Urodynamics* 25:331-336, 2006.)

At 40-48 months, 81% of patients who had reported an improvement over baseline at 12 months were still responding at 3+ years post-treatment. The procedure is very safe; no serious adverse events have been reported to date.

(Appell, et al. Nonsurgical, radiofrequency collagen denaturation for stress urinary incontinence: retrospective three-year evaluation. *Expert Review of Medical Devices* 4,4:455-461, 2007)

My experience has been consistent with the data from these clinical trials. To date I have tracked the outcomes of 24 patients. Patients were assessed through telephone calls by the nurse or by me in the office. The primary assessment was leakage episodes; patients were asked if their symptoms had improved $\geq 25\%$, $\geq 50\%$, or not at all. Results revealed that 16 (66.6%) patients experienced $\geq 50\%$ improvement, and 18 (75%) experienced $\geq 25\%$ improvement. Four patients (16%) reported no improvement, and no patient reported worsened symptoms. No adverse events were reported. An abstract describing these results has been submitted to two professional societies for presentation at their annual clinical meetings.

Office-Based Procedures = Economic Benefits to Your Practice

Physicians who routinely perform in-office procedures understand the economic benefits and improved efficiency vs. procedures performed in an outpatient surgery center. In the management of SUI patients, a time and motion study reveals that the estimated time a physician spends on evaluation and treatment is up to twice as much for a surgical sling procedure compared to treating a patient with Renessa. The following table illustrates the results of that study:

Estimated Time Typically Spent on Patient Evaluation and Surgical Treatment versus In-Office Renessa for Stress Urinary Incontinence

Evaluation/Treatment Step	Time Spent (min)	
	Surgical Treatment	Nonsurgical Renessa
In-office visit	20–30	20–30
Follow-up visit to review patient’s bladder diary	10–20	10–20
Urodynamic studies–cystoscopy	30	30
Pre-procedure discussion with patient (consent)	15–30	15–30
Operative procedure (sling)	15–30	n/a
Renessa procedure	n/a	20–30
Down time between cases	30–45	n/a
Post-procedure care (90-day global)*	15–30	15–30
Total time	2.3–3.6h+	1.8–2.8h

*Management of complications adds significantly to the time a physician must spend with a patient, with more serious complications requiring more time. Many of these additional hours are expended during the 90-day global period, so no additional reimbursement is provided for that additional time.

(Baum, N. *Economics of Treating Stress Urinary Incontinence*; white paper, May 2007)

And not only are office procedures more efficient in terms of physician time (no waiting around for operating room set-up, no driving to the surgery center or hospital, no waiting for anesthesia to finish up a prior case), offering an in-office procedure such as Renessa can bring more (particularly younger) patients to your practice! In my experience, when women learn that there is a safe and effective non-surgical treatment option that can reduce or even eliminate their incontinence episodes, they are more willing to seek treatment for their condition.

Real-World Experience: Practice Enhancement with Renessa

By conducting inexpensive promotion and advertising about Renessa in local newspapers and radio, I have attracted a significant number of new patients to my practice. On average, I have gained 15 new patients *per month*. All of these are not candidates for Renessa, of course, however all of them receive an evaluation and most get a diagnostic work-up consisting of a cystoscopy and urodynamics. Those who do go on to receive treatment, may have a Renessa procedure, or a sling procedure, or even prolapse repair. Patients with urge incontinence may be treated with percutaneous tibial nerve stimulation (Urgent PC®), and occasionally, InterStim®. All of these diagnostic and therapeutic procedures generate revenue for my practice. Some physicians may believe that offering Renessa will reduce their sling procedures. My experience has been exactly the opposite --- by making women aware that there is a new non-surgical treatment option available, new patients come to my practice and some of these will receive slings.

Below is a simple model showing the potential revenue impact of incorporating Renessa into a practice and conducting some local promotional activities, based on my experience:

Diagnosis and Treatment	Average In-Office Reimbursement per patient (est.)	New Patients per Month from Local Marketing	Annual Revenue
Initial office visit/ History and Physical	\$ 200	15	\$ 3,000
Urinalysis	\$ 15	15	\$ 225
Urine Culture	\$ 5	15	\$ 75
Cystoscopy	\$ 200	15	\$ 3,000
Urodynamics	\$ 800	15	\$ 12,000
Follow-up visit/consultation after 3 months	\$ 150	15	\$ 2,250
One-year follow-up	\$ 150	15	\$ 2,250
	\$ 1,520		\$ 22,800
Renessa treatment for appropriate patients - less cost of disposable probe (assume 25% of new patients)	\$ 1,000	3.75	\$ 3,750
Incremental monthly revenue			\$ 26,550

My advertising expenses have been quite modest – only about \$1000 per month -- so the economic benefits to my practice have been significant.

The Bottom Line

My revenue has increased significantly since incorporating the Renessa treatment into my practice. The procedure is very easy to discuss with my patients; my experience is consistent with the studies – women are looking for non-surgical options. And for the right patients, Renessa offers new hope that they can enjoy their daily lives and activities with less worry about embarrassing leaks. For the practice, Renessa can clearly become an important element of practice enhancement.

About Dr. Craig McCoy

Central Missouri Women's Healthcare

Dr. McCoy is a board certified Obstetrician and Gynecologist and Fellow of the American College of Obstetricians and Gynecologists practicing in the central Missouri town of Marshall . He practices general Obstetrics and Gynecology and has established himself as a regional expert in the management and treatment of pelvic support issues and female urinary incontinence. He serves as a consultant for Uroplasty, Novasys Medical and Boston Scientific. Dr. McCoy and his staff are also actively involved in the advancement of women's health through research. Currently they are participating in two nationwide multicenter randomized prospective studies involving urinary incontinence. It is the goal of Dr. McCoy and his staff to continue to bring new and cutting edge technology to the women of central Missouri.

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