

# My Experience with the Renessa® Non-surgical Treatment for SUI

Nancy Little, MD, FACS

## Introduction

One of the newest and least invasive treatments for female stress urinary incontinence (SUI) is the Renessa® treatment, a non-surgical in-office procedure for SUI due to bladder outlet hypermobility. Renessa is an option for women who have tried conservative therapies such as Kegel exercises or biofeedback with limited success, but who are not candidates for, or who do not desire, a surgical procedure. In this paper, I will describe my own experiences with this innovative therapy, and what I have learned in the last three and a half years since incorporating it into my urology practice.

## My Experience

I began offering the Renessa treatment in January 2006, and have treated over seventy patients since then. My outcomes have been consistent with those described in the published literature<sup>1,2</sup>; approximately 75% of patients experience an improvement in symptoms. Shortly after treating my initial patients, I decided to have the Renessa treatment myself. I was a typical SUI patient: a busy working mother of three who was unwilling and unable to take time off for a surgical procedure. I was looking for something more definitive than Kegel exercises that would result in a reduction in my leak episodes. My experience as a patient has been very positive. Personally, I am about 75-80% improved and I am very pleased with that. This personal experience offers me a unique opportunity to talk to my SUI patients about the Renessa treatment.

## Presenting the Options to Patients

As a urologist specializing in female incontinence, I offer a wide spectrum of treatment options for SUI, including conservative therapies, bulking, and sling surgery in addition to Renessa. After a diagnostic workup that usually includes urodynamics testing and cystoscopy (I always do urodynamics testing before performing any intervention or procedure), I present all appropriate options to my patients and allow them to make the decision that is right for them. I have found that most women are looking for a less invasive option which gives them an opportunity for an improvement in their symptoms, with minimal risk of complications, and with minimal downtime. These women are seeking an

improvement, not necessarily a cure. Studies have shown that this is true of many SUI patients<sup>3</sup>.

## Patient Selection & Setting Expectations

In the three and a half years since incorporating the Renessa treatment into my practice, I have recognized that proper patient selection and setting appropriate patient expectations are absolutely critical to successful outcomes and satisfied patients. I use the following criteria in determining if a patient is an appropriate candidate for the Renessa procedure:

- Patient is leaking enough to require 1-2 incontinence pads (not panty liners) per day. The Renessa treatment is **not** an appropriate option for women with mild symptoms, for example, those who only need a mini-pad or panty liner a day. In these mild incontinence patients, I recommend watchful waiting.
- No prolapse.
- No ISD. I use a combination of bladder capacity and leak point pressure to determine if the patient has sphincter deficiency.
- No significant urgency requiring treatment. This can usually be determined based on patient history, confirmed by urodynamics testing.

In counseling my patients, I ask them what sort of outcome they are looking for. If a woman wants the best possible chance of being completely dry, and is willing and able to undergo surgery, then Renessa is not an appropriate option for her; she should have surgery. However, if the patient is looking for improvement, not necessarily complete dryness, and she fits the criteria described above, then Renessa may be the treatment of choice. I tell my patients that our goal with Renessa is to make them better, not to cure them. Many women with busy schedules and family and work obligations prefer this more conservative option over surgery.

## During Treatment – Tips & Techniques

I tell my Renessa patients to plan to be in the office for about an hour, but that actual treatment time is about 15-20 minutes. Prior to beginning treatment, I check her urine sample to rule out a UTI, and confirm normal voiding, including performing a bladder scan to verify proper emptying.

To ensure patient comfort, before administering a local periurethral block, I first numb the injection site with a small amount of Lidocaine jelly at the three and nine o'clock positions on the "dimples" at the urethral meatus. Other topical anesthetics such as EMLA cream can also be used. I then insert a Lidocaine-soaked Q-tip into the urethra to act as a guide for the injection angle, and mark the angle with a line on the patient's leg to help me maintain the probe at the exact angle of the urethra during the actual treatment.

The block consists of 10cc of 2% Lidocaine without Epinephrine. Using a 25 gauge 1¼" needle, I inject 5cc bilaterally, at the three and nine o'clock positions, inserting the needle all the way to the hub to ensure delivery of the anesthetic as close to the bladder neck as possible. I inject *very slowly* – taking approximately 30 to 60 seconds on each side. I tell my patients to let me know if they experience discomfort. Discomfort is rare, and when it occurs I administer additional Lidocaine at the bladder neck using the same technique. Although I offer an anxiolytic such as Valium to patients who may be a little anxious, I prefer not to do this as it requires that someone drive the patient home.

After the block has taken effect – it's best to wait at least 8-10 minutes – the bladder is drained using a soft red rubber Robinson urinary catheter. Then 30cc of sterile water is instilled into the bladder prior to beginning the application of radiofrequency energy. I use a very small glass pipette and gravity to very slowly instill the 30cc of water. This technique minimizes the risk of bladder contractions or urgency which can be caused by too rapid infusion of fluid into the bladder. Feelings of urgency before the treatment even begins can cause patients to become unnecessarily anxious.

## Post-Procedure Considerations

Patients can return to their normal daily activities the same or the next day, with minimal restrictions – but they should refrain from heavy lifting and sexual intercourse for 7 days. My follow-up protocol:

- Schedule a routine follow-up visit for 30 days post-treatment.
- Prescribe three days of an antibiotic – typically Cipro or Levaquin, to prevent post-procedure UTIs.
- Recommend Pyridium as needed post-treatment to address any dysuria.
- Advise my patients that in the 2-3 week period post-treatment, they may experience some urgency and frequency and that they may feel as if they are "worse" than before the treatment. I tell them that this is common and that it will resolve itself over time, but if it is too bothersome, then they should call me and I can prescribe anticholinergic medication to help them get through this period.
- Occasionally patients will experience hematuria in the days immediately following treatment; in this situation I ask them to come in so I can check for UTI, and then reassure them that this is a temporary side effect that will resolve within a short period of time.
- There is the potential for patients to experience worsening incontinence following the procedure, requiring the use of more pads, so I advise patients of this possibility, although I have not personally seen this in my practice. I tell patients if they do experience urgency symptoms that they perceive as worsening incontinence, and this is not improved with the use of anticholinergic medication, then to contact me and I will schedule a visit immediately.
- Above all, I advise my patients to be patient. It can take up to three to six months for the collagen denaturation and healing process and the full effect of the treatment to take place.

In terms of durability, I tell my patients we do not yet know how long the treatment effect will last. However, retrospective data from the original pivotal trial and my own experience suggest that it can last at least three to four years. Patients occasionally ask if a retreatment can be performed if they don't experience the desired outcome the first time or if the effect wears off over time. Although this has not been studied prospectively, a registry may provide data on the safety and effectiveness of retreatments in the future.

## Conclusion

The Renessa treatment can be an excellent option for your moderate to severe SUI patients who have failed conservative therapy but who cannot have or do not desire a surgical procedure. In the past there have been limited therapeutic options for these women, and as physicians specializing in female incontinence, we owe it to our patients to present them with all appropriate options – particularly those like Renessa which offer the potential for improvement without the risks and extended recovery time associated with surgery.

## About Nancy Little, MD, FACS

Dr. Little is in private practice in Lodi, California. She completed her residency in urology at Duke University Medical Center, followed by a fellowship in neurourology, female urology and reconstructive surgery with Dr. Shlomo Raz at UCLA. She is a Fellow of the American College of Surgeons and a member of the American Urological Association and the Society for Urodynamics and Female Urology.

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## About the Renessa Procedure

The Renessa System, developed by Novasys Medical, is a non-surgical approach to treat stress urinary incontinence (SUI) due to bladder outlet hypermobility. The Renessa treatment uses a small probe similar in size to a Foley catheter which a physician passes through the urethra. The actual treatment time is approximately 20-30 minutes and is performed using local anesthesia in the physician's office during a 45 minute to 1 hour office visit. The Renessa procedure uses low power radiofrequency energy to generate controlled heat at low temperatures in tissue targets within the submucosa of the bladder neck and proximal urethra. The heat denatures collagen in the tissue at multiple small treatment sites. Upon healing, the treated tissue is less compliant, increasing resistance to involuntary leakage at times of heightened intra-abdominal pressure, thereby reducing or eliminating SUI episodes. There are no incisions, bandages or dressings required. Recovery is rapid and comfortable, with minimal post-procedure limitations. The Renessa System was cleared by the FDA in 2005, and over 2500 patients have been treated to date.

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<sup>1</sup> Appell, RA. Transurethral Collagen Denaturation for Women With Stress Urinary Incontinence. *Current Urology Reports* 9:5,373-379, 2008

<sup>2</sup> Elser D, Mitchell G, Miklos J, Nickell K, Cline K, Winkler, H, Wells WG. Nonsurgical Transurethral Collagen Denaturation for Stress Urinary Incontinence in Women: Twelve-Month Results From a Prospective Long-term Study. *Journal of Minimally Invasive Gynecology* 6:1; 56-62, Jan/Feb 2009

<sup>3</sup> Robinson D, Anders K, Cardozo L, et al. What women want: their interpretation of cure. *Neurourol Urodynamics*.2002;21(4):429. Abstract 115

<sup>4</sup> Appell RA, Singh G, Klimberg I, Graham C, Juma S, Wells G, Kanellos A, Reilley S. Nonsurgical, radiofrequency collagen denaturation for stress urinary incontinence: retrospective three-year evaluation. *Expert Review of Medical Devices* 4,4:455-461, 2007

## Managing Side Effects – General Guidelines & Practical Considerations

The Renessa procedure has an excellent safety profile; compared to other incontinence procedures, complications are rare and are typically mild and resolve quickly. The below guidelines provide suggestions of how to manage the complications that have been seen with Renessa.

- *Urinary tract infection.* Risk can be significantly reduced by the administration of prophylactic antibiotics, as described above. If a UTI does occur, treat according to your established practice protocol.
- *Dysuria.* Typically transient; all patients should have Pyridium available post-procedure.
- *Urgency or frequency.* Typically transient; can be managed with anticholinergics. Make sure patient understands that these medications may take up to two weeks to take effect.
- *Urinary retention.* To minimize the risk, ensure that patient can void prior to leaving the office after the procedure, and that she continues to drink fluids and void regularly upon returning home.
  - If retention does occur, a single catheterization usually addresses it. It is not advisable to insert an indwelling catheter post-treatment.
- *Transient pain or discomfort.* Can be managed with over the counter analgesics.
- Persistent pelvic/lower urinary tract pain. This is very rare. Patient should be seen immediately and evaluated.
- *Hematuria.* Check urine for UTI, if culture is positive, treat according to standard practice protocol. If negative, reassure patient that this will resolve within a few days.
- *Worsening urinary incontinence* – patient is wearing significantly more pads or diapers than before the treatment. ***If a patient complains of this, do not wait – see the patient as soon as possible- and perform a comprehensive work-up including urodynamics.***
  - May be caused by UTI, overflow incontinence or urgency symptoms caused by detrusor instability. If so, treat as described above.
  - If these causes have been ruled out, and it appears that the patient now has a low leak point pressure similar to LSD, the following management techniques can be considered to treat the non-hypermobility related symptoms:
    - A pessary may help to create more coaptation of the urethra.
    - Urethral bulking agents.
    - A sling can be considered for appropriate surgical candidates.

## Author Disclosure

Dr. Little is a trainer and consultant for Novasys Medical, Inc. She has no financial interest in the company.