

Brakes Put on SURx System for Stress Incontinence

BY BETSY BATES

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TUCSON, ARIZ. — The SURx radiofrequency system for treating stress urinary incontinence is no longer being marketed, following recognition by CooperSurgical Inc. that “the product is much more technique-dependent than we had hoped it would be,” a company official revealed in a telephone interview.

“It turns out this is a very technique-dependent procedure that requires [application of energy at] just the right depth, just the right exposure, and just the right amount of endopelvic fascia [to be successful],” said Loren Smith, vice president of marketing for the Trumbull, Conn.-based surgical device company.

“There are a few dozen really strong supporters of the product, and for them, we make the product available. They are highly trained, very skilled surgeons and have gotten excellent results. They want to continue to use it, and more power to them,” Mr. Smith said.

After CooperSurgical purchased the SURx company in late 2003, it launched a number of intensive, hands-on training sessions for surgeons. It soon became evident

that incorrect placement or application of energy was a common problem, he added.

“It became too time-consuming and costly to really do the—not literal, but figurative—hand-holding required for surgeons to become comfortable enough to have consistent results, patient after patient.”

A few small studies presented at recent urogynecology meetings began to hint at inconsistent success rates with radiofrequency bladder neck suspension for the treatment of stress urinary incontinence (SUI) or mixed urinary incontinence, prompting an investigation into the current status of SURx radiofrequency devices that could be used transvaginally or laparoscopically for minimally invasive SUI treatment.

For example, more than half of patients were considered treatment failures within 6 weeks of undergoing laparoscopic application of radiofrequency energy to the pubocervical fascia at the level of the urethrovaginal junction in a study reported at the annual meeting of the Society of Gynecologic Surgeons.

Among 24 women who had failed conservative treatment for stress incontinence, 14 demonstrated objective and/or subjective incontinence by 6 weeks and 9 opted

to undergo additional procedures. Just six patients were subjectively cured and four subjectively “improved,” defined as “rare SUI,” at 6 weeks.

Dr. Michael D. Vardy and Dr. Vincent Lucente independently stopped offering the SURx procedure after evaluating results at their respective institutions, Mount Sinai School of Medicine in New York and the Institute for Female Pelvic Medicine and Reconstructive Surgery in Allentown, Pa.

In addition to serving as fellowship director in the division of female pelvic medicine and reconstructive surgery at Mount Sinai, Dr. Vardy directs female pelvic medicine and reconstructive surgery at Englewood (N.J.) Hospital and Medical Center.

The Vardy/Lucente study referenced a prior report from the University of Rochester (N.Y.) of poor success rates after using a transvaginal approach to SURx radiofrequency ablation for SUI.

Presented at the 2005 American Urogynecologic Society meeting in Atlanta, the Rochester study noted that among 15 patients, 1 was continent, 4 obtained greater than 50% improvement, and 10 were unimproved postoperatively.

The results of both studies are at odds with previous reports of 70%-81% success

rates with radiofrequency bladder neck suspension. For example, a 2002 study from the Geisinger Medical Center in Danville, Pa., found that 76 of 94 (81%) of women were “continent or improved” 12 months after radiofrequency bladder neck suspension (*J. Urol.* 2002;167:141-5).

In a review article, Dr. Roger Dmochowski and Dr. Rodney A. Appell of Vanderbilt University Medical Center, Nashville, Tenn., reported “treatment success”—defined as cured or improved—in 70 of 96 patients (73%) who completed a 12-month follow-up examination after transvaginal radiofrequency therapy (*Curr. Urol. Rep.* 2003;4:350-5).

The same article cited the Geisinger study as further evidence for its conclusion that radiofrequency application “results in reproducible tissue effects, which have provided substantial improvement for women with genuine stress urinary incontinence, with minimal short-term and essentially no long-term complications.”

Dr. Vardy, contacted by e-mail, said he believes the uneven history of SURx radiofrequency treatment of SUI is “typical of industry-sponsored research.” Inconsistent outcome measures make it difficult to interpret data from such studies, he said. ■



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