CASE STUDY ONE

History

A 71-year-old female with a 15-year history of mixed urinary incontinence (urgency and frequency) was referred to the clinic for evaluation and treatment. She had episodes of urgency, frequency, nocturia, and daytime incontinence; she wore pads all day and night. She rarely made it to the bathroom on time and changed her clothes multiple times during the day; however, she did feel like she emptied her bladder after each void.

Her history included a bladder tuck and rectocele repair for incontinence 15 years ago. Recently, she had a tension-free vaginal tape implanted, but since that procedure, her incontinence has recurred, and her urgency has increased. She tried medications in the past, both amitriptyline and oxybutynin, and developed an allergy to both drugs, which were then discontinued.

Urodynamics/Testing

A cystoscopy was performed that showed a normal bladder. A routine urinalysis was negative, as was the culture of her urine. Results of a urodynamic study demonstrated a total cystometric bladder capacity of 200 mls with no post-void residual. The abdominal leak point pressure was 200 mls; there was no urine leak with valsalva or cough. During filling, she had detrusor pressures of 139 mls of H2O. Detrusor instability was first noticed at 155 mls. Urge incontinence was first noted at 200 mls, with a detrusor pressure of 28 cm of H2O. These results were consistent with a small capacity bladder and detrusor instability with urge incontinence. The test results indicated that she was a candidate for InterStim® therapy.

Goals and Expectations

The InterStim therapy goals and expectations were discussed with the patient; ultimately, they were to decrease her urgency, frequency, incontinence, and nocturnal episodes (50% or greater). The patient was comfortable with the goals and wanted to proceed. She went home to watch the video and read the pamphlets about this treatment before making her decision.

Surgical Procedures

A month later, she decided to have the InterStim implant and was given a date for 1st and 2nd stage procedures. Pre-operative testing included a cardiolo-
The 1st stage operation was performed on August 10, 2005, and on the fifth day post-procedure, another set of diaries was started. At the end of the 1st stage, the diaries were reviewed. Her baseline diaries indicated that she had 15 voids per day, with multiple incontinent episodes and urgency associated with each episode. She wore a pad all the time and had to change her clothes multiple times both day and night. The second set of diaries showed improvement in the degree of urgency, a decrease to 5 voids per day, a drastic decrease in incontinent episodes, and that she was pad-free on two days. It was not as effective at night; she had to wear a pad overnight with at least one episode of bed wetting at night. The decision was made to move the battery to her left side. She underwent a surgical procedure in January 2006; the battery was moved to the left side, but the lead was not moved. After surgery, she maintained an improvement of 75% to 80%, and the pain around the battery was gone. This patient was very satisfied with the results and InterStim therapy.

**CASE STUDY TWO**

**History**

A 33-year-old female with significantly decreasing bladder function since the birth of her last child eight years ago was referred to the clinic in December 2002 for urinary tract infections. Her history included an unknown bladder procedure that caused her to have a suprapubic catheter placed for several months. After the suprapubic catheter was removed, she was admitted into the hospital for a severe urinary tract infection and urinary retention with overflow incontinence. The bladder volume index (BVI) in the hospital showed residuals of 300 to 350 mls. She was taught how to do clean, intermittent catheterizations four times a day and was sent home with a return appointment in one month.

**Urodynamics**

One month later, the pain was worse, and it was difficult for the patient to move around or sleep at night. The decision was made to move the battery to her left side. She returned to the clinic for a urodynamic test, which showed a total cystometric capacity of 370 mls. Valsalva and cough leak point pressures were negative, and there was no detrusor instability. The voiding study demonstrated complete inability to pass any urine; voided volume was zero, and there were no voluntary contractions. The urethral sphincter was active during voiding attempts. Findings were consistent with detrusor failure and a small capacity bladder.

**Programming/Success**

The neurostimulator battery was programmed on the day the battery was placed, using the N’Vision® programmer. Mapping results were that the number 0 electrode was negative, the number 3 electrode was positive, the pulse width was 210, and the rate was 14 (patient preference). She did not like cycling because she wanted to feel the sensation all the time. There was a soft start of 15 seconds, so any time the device was turned off and then on, there would be a 15-second incremental ramping to her normal amplitude. She described the stimulation as a light tapping on the right side of her body, midway between her rectum and vagina; it was very comfortable. The neurostimulator battery was turned off for 5 days post-implant. The patient was taught how to use the patient programmer Model 3031A and was asked to turn the battery on 5 days later, allowing surgical healing. The patient returned to the clinic one month later for a post-operative check to discuss symptom relief and to tweak the program if necessary. She was very happy with her program and parameters, and she felt her symptoms were 75% to 80% better. She was pad-free during the day but still had an occasional episode of bed wetting at night. No device parameters were changed.

**Post-Operative Complication**

What makes this patient interesting is that within three months, she developed severe pain around the neurostimulator battery. She was unable to move around without pain at the site. First, the neurostimulator was turned off for five days to see if the pain would subside. It did not make any difference; the pain was persistent. Multiple changes in the programming did not help; impedances had not changed. A low pelvic X-ray was ordered to see if the lead had migrated, but it was in the same area. There was no swelling over the site, but her physical examination indicated tenderness around the battery. The tests were inconclusive. It was decided to wait one more month and see if there was improvement.

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Goals and Expectations

InterStim therapy goals and expectations were discussed with the patient; ultimately, the goals were to decrease the number of catheterizations per day and to be able to voluntarily void. A realistic expectation for this patient was that she may have to catheterize one time or more a day. She was happy with these expectations. On return home, she watched the patient video and reviewed the pamphlets, and she was asked to return in one month.

Surgical Procedure

One month later, the patient decided to have the InterStim implant and was scheduled for 1st and 2nd stage procedures. Pre-operative testing included a chest X-ray and blood work that were within normal limits. An appointment with an anesthesiologist was made. She was taught how to use the external stimulator box and performed a return demonstration. She started a set of diaries for three full days and nights that documented times and amounts of the catheterizations.

In March 2003, she had the 1st stage of the InterStim therapy. After this procedure, there were multiple phone calls to discuss how the stimulator was working, the comfort of the sensations, and whether she needed to make any changes to the external box. Within 10 days, she was voiding on her own with catheterized residuals of less than 100 mls; the overflow incontinence was gone. During the test, catheterizations were decreased to once a day. At the end of the test, she was catheterizing every morning for 100 to 125 mls and had a regular voiding pattern during the day. She was not waking up at night to void. She was very happy with the test and continued the morning catheterization. One week later, she returned to have the 2nd stage procedure, the placement of a permanent neurostimulator battery. Model 3023 was placed in her right hip.

Programming/Success

The InterStim device was programmed using the N’Vision programmer on the day of surgery and left on to maximize her therapy. Programming started by mapping the electrodes that ended with the case positive, negative 2, pulse width 240, rate of 17 (patient preference). She liked cycling (20 seconds on and 8 seconds off), with a 4-second soft start. The sensation she felt was a light flutter in her vaginal area. She was taught how to use the patient programmer and did a return demonstration before she was discharged from the recovery room. The five-day waiting period to afford healing with the device off was waived because her treatment had been so successful and there was concern that she might not be able to empty her bladder. She has been very happy with this treatment and it continues to be successful.

Conclusion

These two patients illustrate the successful use of the InterStim implant, and both patients are very happy with their outcomes. It is very important to make sure patients have realistic goals and expectations in order to have successful outcomes. This treatment improves the quality of life for those who choose to have the device implanted, and it is rewarding to experience their success.