

New Approaches, New Devices for Pelvic Floor Therapy

Four years ago, pelvic floor therapy was barely on the radar screen for IC patients. But now, most physicians who specialize in IC recognize that a significant number of IC patients have pelvic floor dysfunction (PFD) and that physical therapy can make a big difference in pain and other symptoms.

Many physical therapists are now trained to treat the type of PFD that is more typical of IC than of incontinence, and more insurers are reimbursing for the therapy, at least in part.

That could be the happy ending to this story, but the story is far from finished. New devices, new therapies, and new approaches are coming on the scene to treat PFD. A noninvasive interferential therapy device programmed for IC pain is getting an enthusiastic reception, a device similar to sacral neuromodulation devices is undergoing testing, botulinum toxin A (Botox) injections are being tried, and even physical therapy is undergoing a revolution.

Be Your Own PT

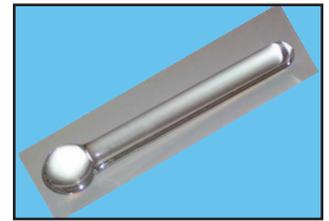
A leader in that revolution is Marilyn Freedman, PT, of Great Neck, New York. Her revolutionary idea is to turn you into your own best physical therapist—fast. In many ways, that's a boon for IC patients, especially for those who are housebound, without insurance, or with an insurer that reimburses little or nothing for physical therapy. Learning to do it yourself can help put physical therapy within your financial reach, allow you to get treatment every day, and give you the power to treat yourself. Freedman starts teaching patients right away in her first two-hour session.

“The people who we help become responsible for their own therapy—those are the ones who really get better,” said Freedman. What's more, patients themselves “are often better therapists than I will ever be because they get to know their own body very well. I'm more than happy for you to come in three times a week, but it's a waste of your money, and you're not going to get better as quickly.”

Although Freedman is always available for advice, tune-ups, and treatments patients can't do themselves, her patients average only six visits before they're treating themselves effectively. Some do it in three, or even just one.

Freedman collaborated with David Wise, PhD, coauthor of *A Headache in the Pelvis*, to develop many of the techniques she uses. The work includes skin rolling, external massage, internal massage, biofeedback, electrical stimulation, exercise for aerobic activity, stretching, visceral mobilization, core stabilization, and paradoxical relaxation.

- **Skin Rolling.** Skin rolling is one of her first lessons and something patients can do without aids. Rolling superficial to deeper tissue from below the ribcage all around the body to above the knees encourages blood flow and more normal neuromuscular feedback.
- **External Massage.** To work out trigger points in external muscles, patients can use a Thera Cane, sometimes with a tennis ball on the end of it.
- **Internal Massage.** Patients also learn internal massage of the pelvic floor through the vagina and the rectum with their finger. For those who aren't flexible enough or whose fingers are too short, Freedman teaches them to use the EZ Magic instrument. This curved device has the right design for internal massage, she said, although when a partner needs to use one for the patient, she recommends the straight EZ Fit for control. Another reason Freedman prefers



When patients need assistive devices, Marilyn Freedman, PT, recommends the Thera Cane for external massage and EZ Magic (patent pending) or EZ Fit (patent pending) for internal massage.

these devices is because the medical-grade glass can be warmed or cooled for comfort.

- **Biofeedback.** When patients can't make the neuromuscular connections she'll send them home with a biofeedback device to help so that, by the time they return in two weeks, they've already had 14 treatments.

- **Electrical Stimulation.** When muscles just aren't working properly, she'll have patients use electrical stimulation or interferential therapy at home, especially Empi's IF3WAVE.

- **Exercise.** Freedman recommends aerobic exercise, stretching, and core stabilization.

- **Paradoxical relaxation.** Patients also use her tapes for "paradoxical relaxation" similar to the Wise approach, and after they have learned to relax muscles, they can do core and pelvic floor strengthening.



Empi's IF3WAVE interferential stimulator, which has a program specifically for IC pain.

Interferential Therapy—A Stimulating Experience

Interferential therapy, a kind of electrical stimulation therapy, has been available for some time. But recently, Empi released a device with programming specifically designed for management of IC pain. Daniel

Brookoff, MD, PhD, worked with the company to develop the IC program that has just been integrated into the IF3WAVE stimulator. Dr. Brookoff is an ICA Medical Advisory Board member and Medical Director of the Center for Pain Management at Presbyterian/St. Luke's Medical Center in Denver, Colorado.

The therapy is "interferential" because, instead of delivering electrical stimulation from one source, impulses are actually sent from different areas to "interfere" with each other where they cross at the point of pain in deep tissues. The frequency of the stimulation is much higher than with a transcutaneous

“ The people who we help become responsible for their own therapy—those are the ones who really get better. ”

Marilynn Freedman, PT

electrical nerve stimulator (TENS) unit or other electrical stimulation devices—another reason the stimulation reaches deep into tissues instead of staying near the skin surface, explained Jim Pomonis, Director of Clinical Programs at Empi in Shoreview, Minnesota.

Whereas the sensation that comes from TENS units is tingling at the surface, the sensation from the interferential stimulator feels like a massage coming from inside the body that replaces and relieves the painful sensations of pelvic floor spasm, said Dr. Brookoff. He also noted that, for the first few weeks, patients feel pain relief during stimulation, but after that, they should also start feeling relief after the stimulator is turned off.

In the IC-specific treatment, four electrode pads are placed in an "X" pattern, two on the lower abdomen at the pubic hair line and two directly opposite them on the lower back where the sacrum meets the pelvic bone, to allow the currents to cross in the pelvic muscle. The wires from the electrodes are connected to the current generator, which can be worn on a belt clip. Penetrating deep into tissues, the currents then cancel each other except for producing a separate electrical wave deep in the pelvic floor. The IC treatment program runs for 40 minutes, which Dr. Brookoff often has his patients use two or three times a day.

The device can also help ease pain in the vaginal and urethral areas. Employing a different program, a pair of electrode pads is placed on the lower abdomen and a second pair is placed either at the lower end of the pubic triangle or on the topmost areas of the left and right inner thighs. Whether this therapy stimulates nerves in the topmost areas as well as muscle is still not well understood, but it is likely both.

Like Freedman, Dr. Brookoff is enthusiastic about the results his patients get with new pain control techniques. In fact, he shared that, over the past two years, using the device with this programming has obviated the need for an implanted neurostimulator in 80 percent of his patients who were candidates for one.

To use this therapy, patients need a doctor's prescription, which can either be a direct prescription or an order for evaluation and treatment by a physical therapist who uses and carries the device. Although the device has FDA approval, not all insurance carriers as yet may cover the device. Patients should check with their insurer. At a retail cost of \$2,395, the device is more expensive than TENS units, but the cost is much lower than the \$30,000 to \$50,000 total (non-Medicare) cost of implanting the most popular internal neurostimulator and, of course, doesn't require surgery.

Botox Breaks Muscle Spasm

Botulinum toxin A (Botox) injections into the bladder itself have been researched recently as IC treatments, but some clinicians are also trying injections of Botox into the pelvic floor to break muscle spasm. Urologist Robert Moldwin, MD, and urogynecologist Stuart Hart, MD, both use these therapies in patients. A member of the ICA's Medical Advisory Board, Dr. Moldwin is Director of the Interstitial Cystitis Center at Long Island Jewish Medical Center in New Hyde Park, New York, and Dr. Hart is an Assistant Professor of Obstetrics and Gynecology in the Division of Urogynecology and Pelvic Reconstructive Surgery at the University of South Florida in Tampa.

When PFD doesn't respond to more traditional therapies aimed at the pelvic floor, Dr. Moldwin tries anesthetic blocks in the region first before considering Botox injections. But when even blocks don't work, he said, "We have been having some nice successes [with Botox] in carefully selected patients."

Similarly, Dr. Hart uses the therapy when other therapy fails, including physical therapy. Sometimes, he will offer the injections as first-line therapy for patients who have such terrible pelvic floor pain that they can't even be examined, let alone undergo physical therapy.

Botox is thought to work by paralyzing muscle tissue, in other words, not allowing it to contract. The injections don't paralyze the whole pelvic floor, he explained. "The thinking is, if you can paralyze enough that it helps break up the spasm, then maybe pelvic floor physical therapy will work better."

Typically, with the patient under anesthesia, he uses 100 U diluted to 10 mL or 200 U diluted to 20 mL and makes some 20 injections on each side, injecting into the major pelvic floor muscle groups—the puborectalis, iliococcygeus/pubococcygeus, and the obturator internus muscles—but concentrating more on the trigger point areas that he identified during his initial physical examination. He will also perform modified pelvic floor physical therapy during the procedure, while the patient is under anesthesia, to further relax the pelvic muscles. He makes sure patients have pain control for postoperative soreness if they need it. The goal of this therapy is not only to provide immediate relief for the patient but also to pave the way for physical therapy "because I really believe that physical therapy is essential for long-term relief of their pelvic floor pain."

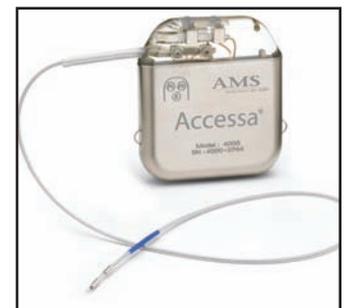
"This therapy is probably in the early infancy of our understanding," Dr. Hart noted. The techniques and dosages aren't yet standardized, but the research he is doing should help. He is identifying which muscle groups are affected and is working on grading the pain, so that we will know, not only what percentage of IC patients have PFD, but also what proportion have severe versus mild or moderate dysfunction.

Implant Stimulates Pelvic Muscles

There's a new twist on implantable pulse generators, and that's stimulation of the pelvic floor muscles, not a specific nerve. Studies on the MiniaturO device, which does that, were presented at European meetings in 2007.

MiniaturO has approval for marketing in the European Union, but is not being actively marketed there yet since European studies on efficacy are continuing, said Elizabeth Groover, Director of Marketing for the Female Incontinence Group at American Medical Systems, Inc. (AMS), Minnetonka, Minnesota, which has acquired the device and has rebranded it as Accessa.

The device's lead, which goes to pelvic floor muscle, is implanted through an incision beside the urethra and



Accessa pelvic floor stimulator from American Medical Systems, Inc.

runs under the skin to a pulse generator, similar in size to InterStim. The pulse generator is implanted just above the pubic bone in the lower abdominal wall under a small “Caesarean scar,” as Bruce Farnsworth, MD, described it to the *ICA Update*. Dr. Farnsworth, who helped research the device, is Director of the Centre for Pelvic at Sydney Adventist Hospital, Wahroonga, Australia.

The procedure is minimally invasive and easier to do than surgery for sacral nerve or spinal cord stimulators. The lead is not placed into the spinal cord or nerve roots, no fluoroscopy (x-ray guidance) is needed to place it, and there is minimal surgical tunneling, noted Groover.

In the study on IC patients, results were better for pain (reported to drop from 7 to 4 on a 10-point scale) than for urgency and frequency. That may be another indication that pelvic floor-directed therapy is key for reducing IC patients’ pain.

On the other hand, Dr. Farnsworth noted that the device may have been more helpful with pain because only severe cases of IC were admitted to the study, and all patients had small bladder volumes.

The cost of the device and implantation is not yet known, but Dr. Farnsworth anticipates that it will be similar to that for sacral neuromodulation.

The Accessa is evidence of another trend that should benefit IC patients in the future, and that’s toward less invasive treatments with devices that may be able to be implanted in the office, which is a future goal for AMS’s device development, said Groover.

Easing Your Pain

Although the cause of pain in IC is not entirely clear, therapies aimed at the pelvic floor muscles seem to be easing IC patients’ pain when other therapies don’t go the distance. Creative clinicians and researchers are exploring this territory and have come up with innovative therapies that you can try now. Certainly, we can look forward to even more. 

For More Information

Marilyn Freedman, PT
Essential Physical Therapy
8 Bond Street, Suite 202
Great Neck, NY 11021 / <http://essentialphysicaltherapy.com/>

Thera Cane
Thera Cane Company
P.O. Box 9220
Denver, CO 80209 / www.theracane.com

EZ Magic and EZ Fit
IC Relief, LLC
PO Box 47806
Tampa, FL 33647 / <http://icrelief.com>

IF3WAVE
Empi
599 Cardigan Road
St. Paul, MN 55126 / www.empi.com

Stuart Hart, MD
Division of Urogynecology and Pelvic Reconstructive Surgery
University of South Florida
<http://health.usf.edu/medicine/obgyn/facstaf/shart.htm>

Bruce Farnsworth, MD
Centre for Pelvic and Reconstructive Surgery
Sydney, Australia / www.drbruce.com.au/access.htm

Call to Action

Are You a Woman who Suffers from Painful Intercourse?

Clinical Study Under Way for Treatment of Vaginal Pain

If you suffer from vaginal pain you may qualify to participate in a clinical research study. The study is looking for participants who have unexplained vulvar pain, sexual dysfunction, burning, irritation, or rawness and are willing to participate in a clinical research study of an investigational medication to reduce the symptoms associated with vulvar vestibulitis.

This study is currently taking place only in the United States and participation will last approximately 18 weeks and will require approximately 8 visits to the doctor’s office.

Visit the February 2008 issue of Café ICA (section 3.5) at www.ichelp.org to learn more about how you can participate!