BECKER'S
ASC REVIEW

A game-changer for patients and ASCs: 3 surgeons discuss sacroiliac joint fusion

Sacroiliac joint fusion has historically been an overlooked opportunity for ASCs. That's where SI-BONE's **iFuse Implant System®** comes into play. Designed to permanently stabilize the sacroiliac (SI) joint through both bony adherence to implants and intraarticular joint fusion, iFuse has been used in over 38,000 minimally invasive procedures since its commercial launch in 2009.

Along with evidence from more than 70 peer-reviewed publications, surgeon users of iFuse attest to its positive outcomes. *Becker's* recently spoke with three surgeons about SI joint pain and why incorporating iFuse procedures was a turning point for their practices and patients.

The participating surgeons were:

- Gary Dix, MD, Riva Road Surgery Center (Annapolis, Md.)
- Troy Lowell, MD, Marion Surgery Center (Ocala, Fla.)
- David Baker, MD, Cascade Outpatient Surgery Center (Bellingham, Wash.)

Dr. Dix is a paid consultant to SI-BONE, Inc.

Note: These responses have been edited for length and clarity.

Question: Can you tell us about SI joint pain and dysfunction and why you incorporated minimally invasive SI joint fusion into your practice?

Dr. Gary Dix: For a long time, a distinct subset of patients I was seeing, who had been through a variety of conservative and/or surgical treatment modalities, seemed to come back with ongoing pain. They were then sent for further conservative management when there was no obvious spine pathology present. None of them seemed happy with that, either. It started to dawn on me that these patients didn't actually have spine problems, but rather had junctional disease below their previous fusions or adjacent to minor radiographic changes in their spine.

Dr. Troy Lowell: So many patients have back pain that's not central, and then they come back with a negative MRI. Until a number of years ago, the medical community was stumped about what to do with them. As it turns out, a lot of these patients had SI problems. When I was a resident and a fellow, it wasn't even mentioned as a disease. Now that I see how common it is, it's really astonishing how little attention was paid to it in the past. [For] surgeons who do keep an awareness of this, it opens up a whole new area of the body to treat and makes them stand out.

Q: Why is the iFuse Implant System your product of choice for this procedure, and what differentiates SI-BONE from other companies out there?

Dr. David Baker: The iFuse is very consistent in where you can place the implants and generally, in my experience, results in very few complications. That's why we can do the SIJ fusion as an outpatient procedure. I would say the complication rate in my practice is less than 2 percent. iFuse is a system that has good peer review and can actually be reproduced in the private setting.

GD: It works. From the very first patient I operated on using this product, the feedback I had was overwhelmingly positive. I realized that to be called somewhat of an expert in this area, I needed to look at competing systems, none of which used the triangular dowel SI-BONE has patented. I performed two or three cases with another system and did not find it to be as useful or beneficial; for example, one of the patients ended up having a nonunion. I've never seen a nonunion in almost 200 SI-BONE cases.

Q: How have the awareness-building efforts and resources provided by SI-BONE helped you to incorporate iFuse into your practice and the facility's caseload?

TL: SI-BONE has been excellent in trying to get the word out about SI problems. They've given me opportunities to educate the medical community and patients that this exists and there's a treatment for it. The company has also gone through some design changes with the implant. They've changed it so that it's 3D-printed with a lot of nooks and crannies and holes. I believe that the bone's ability to grow into these spaces provides further strength. They haven't just put out an implant and then stopped doing research; they've tweaked it and made it even better.

GD: They've created a team of professionals that helps patients with trying to get authorization for the operation from various third-party insurance companies, as part of a comprehensive effort by SI-BONE to gain uniform coverage for the procedure. I became involved in discussions with medical directors of big insurance companies to try and help them understand this wasn't a fly-by-night gimmick, but something that actually benefited patients. We're finally starting to see them coming around as they begin to appreciate the value to their customers.

Q: Why do you think iFuse complements the other procedures already offered in your ASC?

DB: Patients love that the procedure is minimally invasive and that most patients can go home soon afterward. The cost for the procedure in the ASC is much less than at the hospital, resulting in savings for both the payers and the patients. At our ASC, postoperative pain is very well-controlled with Exparel®, which has negated the need for postoperative opioids. In fact, most patients say they've had very little pain for two days postoperatively. In the two years I've been doing this in the ASC, I've had five patients that were taking narcotic pain medications preoperatively for over two years – none of the five required opioids after their procedure.

TL: The iFuse Procedure only requires about a 1-inch incision or less, the blood loss is usually less than 100 cubic centimeters, it usually only takes about 45 minutes, and based upon my experience, the complication rate is low. CMS reimbursement is sufficient for my practice. From my experience, it can be a valuable addition to the set of services offered by the surgery center.

Q: What processes and criteria did you establish for appropriate patient selection?

DB: The most important thing is to be highly selective of the patients. They have to be medically fit; if they don't meet the health criteria, they're not an appropriate candidate. In fact, I've done an 80-year-old patient in the ASC because she was very healthy and had very good support at home. So, her age was really not a factor; it's how healthy the patients are.

GD: For me, the key is confirming the diagnosis. Once you start to recognize the primary complaints and the nuances of how they present, it's easier to separate these patients out from those with lumbar spine or hip pathology, with whom they're often confused. I like to know that they have a very compelling history. I also look for patients who've had previous lumbar fusions, because sacroiliitis can present from junctional breakdown, once the lumbosacral segment has been fused. The gold standard for confirming the diagnosis is two separate fluoroscopically-guided injections into the SI joint with local anesthetic and steroid. If these provide significant short-term relief on each occasion, that clinches it.

Q: What are some key preparatory steps and best practices for integrating this procedure?

TL: The most important thing would be that the pain location is exactly where the SI joint is. No. 2 would be that they have been ruled out for any lumbar complaints, because lumbar problems can cause very similar symptoms. No. 3 would be that they respond in a physical exam more appropriately to an SI problem than a lumbar problem.

DB: Using a long-acting local anesthetic and preparing the patient preoperatively are best practices. My staff goes through how the procedure is going to be done, what they can expect postoperatively and when they're going to follow up.

Q: How has integrating iFuse impacted your facility, patients and practice?

GD: SI joint fusion has helped strengthen my practice, given the generally positive outcomes that result from the surgery. People who have had a successful result will tell their friends and family, who will then seek me out for their SI joint and low back problems. The other thing that has been eye-opening is the amount of pain relief my patients have experienced after surgery. One of the earliest patients I operated on was a woman who had fallen off her horse, landed on her tailbone and been in debilitating pain for 5 years. Being one of the first folks to have a SI joint fusion, she paid out of pocket. She did very well, and about three months later, gave me a phone call. She said, 'I'm talking to you on the back of my horse. I haven't been able to ride him for five years, and I'm up in the saddle again right now.' That was very rewarding for me. It speaks to the fact that this is an amazing operation when done on the right people. Based on my experience, it has the potential to change lives dramatically.

Over 100 health plans, including all Medicare Administrative Contractors, Tricare, UnitedHealthcare, 30-plus BCBS plans, and other large commercial health plans cover SI joint fusion, many exclusively with the triangular iFuse Implant System. The procedure is performed in all three sites of service, depending on the condition and health of the patient.

SI-BONE estimates that over 30 million American adults have chronic lower back pain. Studies have shown that 15% to 30% of patients with chronic lower back pain have pain stemming from a dysfunctional SI joint. SI-BONE's experience in both clinical trials and commercial settings indicates that iFuse could be beneficial for at least 30 percent of patients who are properly diagnosed and screened for surgery by trained healthcare providers.

This article was sponsored by SI-BONE, Inc. The views expressed by the surgeons interviewed for this article are theirs alone. The iFuse Implant System® is intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months. The iFuse Implant System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit: www.si-bone.com/risks. ■