Minimally invasive sacroiliac joint fusion vs. conservative management for chronic sacroiliac joint pain

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Dengler et al. have reported the 12-month results of a randomized controlled trial comparing minimally invasive sacroiliac joint fusion to conservative measures (1). This study is the second RCT (randomized control trial) of MIS SI (minimally invasive sacroiliac joint) fusion versus CM (conservative management) and it has findings consistent in direction and magnitude of effect as the first RCT (2). Why is this study important?

Low back pain (LBP) is the number one cause of disability in the world. 15–30% of LBP comes from the SI joint, probably higher in those who have had a prior spinal fusion to the sacrum (3-7). Patients with SIJ pain have a very decreased quality of life, similarly disabled as those needing a total hip, total knee, surgery for spinal stenosis or degenerative spondylolisthesis (8).

The SI joint moves a little bit (9-12). It is innervated with pain sensing nerve fibers (13,14). Specific physical exam maneuvers that stress the SI joint can reliably determine that the SI joint is the source of pain (15). Intra-articular local anesthetic injections into the joint can confirm the diagnosis by pain relief of >50% (16).

Non-operative treatment is the first line of treatment. There are guidelines for this (17) but the level of evidence supporting their efficacy is limited. The risk is also low. It does however have recurring costs that could perhaps be offset with a surgical intervention (18).

How did this study improve upon the previous study? Here the randomization was 1:1 instead of 2:1. It incorporated 2 new outcome measures—the active straight leg raise test and walking distance. It also used generic patient reported outcomes tools as well as disease targeted tools.

This study had strict inclusion and exclusion criteria and high-quality follow-up. There has been some criticism about allowing cross over at 6 months, but given that this device and procedure were commercially available this was a considered approach to allow enrollment and adequate treatment of those failing to respond to CM.

So, what were the findings? There was statistically and clinically significant improvement in the VAS LBP (41.6 SIJF vs. 14.0 CM). The same was true for Oswestry Disability Index (25.0 SIJF vs. 8.7 CM). Once patients crossed over they had similar rates of improvement. These changes very closely parallel the findings of INSITE and SIFI.

What were the study limitations? There was no blinding of the outcomes assessments. These were patient reported outcomes, so it is unclear how much effect the lack of blinding has on these. Also, the 2 functional tests were objective (ASLR and walking distance).

What are the takeaways? These patients averaged 4 years of pain prior to entering the clinical trial. For
patients who meet the trial inclusion criteria (positive Fortin finger test, 3/5 positive physical exam maneuvers and a positive response to image guided intra-articular local anesthetic injections) there is a high likelihood that they will experience a 50% reduction in their VAS back and leg pain, ODI and a significant improvement in their health-related quality of life. The risks are low. Other studies now indicate that the procedure is durable (19-22). In the United States this procedure is commonly done as an outpatient basis.

This data should not be extrapolated to those who have a negative physical exam and a positive response to injection. Similarly, as in this trial other sources such as the hip and spine should be ruled out. In my clinical practice I have many patients referred for SIJF who have had spinal fusion and are in positive sagittal balance. This results in erector spinae over pull on the posterior pelvis. Fixing the SIJ does not solve this malalignment problem.

This study has now completed and published their 2-year results as well (1). The benefits seen at 1 year persist through 2 years.

In summary, for patients with SIJ pain meeting these inclusion criteria can expect to have a 50% pain reduction with this intervention.

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None.

Footnote
Conflicts of Interest: Dr Polly is a consultant to SI Bone. To date has received no money from them.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References