http://dx.doi.org/10.2106/JBJS.18.00022

Appendix

Details on Study Design

Participants

Adults who were 21 to 70 years of age were recruited if they had the following: diagnosed sacroiliac joint pain for >6 months (or, if related to pregnancy, >18 months), an Oswestry Disability Index (ODI) at baseline of ≥30%, and a low back pain visual analog scale (VAS) score at baseline of at least 50 points (0 to 100-point scale). Sacroiliac joint pain was diagnosed using the following criteria: pain in the vicinity of the posterior superior iliac spine in which the patient points with a single finger to a location within 1 cm inferomedial to the posterior superior iliac spine (Fortin Finger Test), at least 3 of 5 positive findings in provocative physical examination maneuvers focused on the sacroiliac joint, and a reduction in pain of at least 50% after fluoroscopically guided injection of a local anesthetic into the sacroiliac joint. The most relevant exclusion criteria were other causes of severe low back pain, autoimmune sacroiliitis, a spine surgical procedure in the last 12 months, recent pelvic trauma, osteoporosis, or allergy to titanium. Written consent was acquired from all patients. Patients signed a written study-specific informed consent form.

Randomization and Blinding

After baseline assessments, a web-based 1:1 randomization to sacroiliac joint arthrodesis or conservative management was conducted, stratified by site and pregnancy-relatedness of sacroiliac joint pain, using random block sizes of 4 or 6. Neither subjects nor investigators were blinded to treatment assignment.

Interventions and Follow-up

Consistent with European guidelines[32] and to promote uniform application across study sites, conservative management consisted of optimization of medical therapy, individualized physical therapy twice per week for at least 8 weeks, and multifactorial treatment including sufficient information and reassurance. Physical therapy recommendations included mobilization and stabilization exercises for control and stability. Sacroiliac joint corticosteroid injections and radiofrequency ablation procedures were not considered to be part of conservative management, as there was little evidence for long-term effectiveness at the time of the study design.

Minimally invasive sacroiliac joint arthrodesis was performed using triangular titanium implants (iFuse Implant System; SI-BONE), placed through a lateral transarticular route[12]. Of the 9 participating study centers, sacroiliac joint arthrodesis was performed by a single surgeon at each of 8 centers, and 2 physicians performed sacroiliac joint arthrodesis at the remaining center. Subjects requiring bilateral sacroiliac joint treatment had the option of undergoing staged procedures. Subjects were kept at partial weight-bearing to half body weight for 3 weeks, with ensuing complete ambulation depending on individual tolerance. Figure 7-A shows a typical post-implantation configuration of implants in the sacroiliac joint.

Follow-up visits occurred at 1, 3, 6, 12, 18, and 24 months. If the contralateral sacroiliac joint was treated as part of the study, the visit clock was reset after the second procedure. Subjects assigned to conservative management could cross over to sacroiliac joint arthrodesis after 6 months, with postoperative visits at months 1, 3, 6, and 12.

http://dx.doi.org/10.2106/JBJS.18.00022

Outcomes

The primary end point was the change in low back VAS pain scores at 6 months after sacroiliac joint arthrodesis or conservative management. Secondary end points included the change from baseline in low back VAS pain and leg VAS pain scores over time, changes in active straight leg raise for the affected side[20], ODI[21], EQ-5D quality-of-life measures[22], Zung Depression Scale[23], walking distance, and a global comparison with baseline. Also, any adverse events (defined per International Organization for Standardization [ISO] 14155:2011 as any negative change in health) were documented. Additional analyses compared the proportion of subjects showing an improvement in low back VAS pain score by at least 20 points and an improvement in the ODI by at least 15 points (values consistent with minimal clinically important changes[33,34]), including an analysis of those achieving such improvements according to the assigned treatment only. Responses from subjects in the group who underwent conservative management and then crossed over to sacroiliac joint arthrodesis after 6 months were also compared with responses from the group originally assigned to sacroiliac joint arthrodesis.

Subjects who underwent sacroiliac joint arthrodesis also underwent a computed tomographic scan postoperatively and at month 12. All 12-month scans were read by an independent radiologist unaware of clinical outcomes. Analysis end points included evidence of breakage or migration, evidence and degree of breach of the sacrum, evidence of radiolucency as potentially indicating implant loosening, and implant engagement, measured on the axial view as the distance from the distal implant end anteriorly and posteriorly to the lateral sacral cortex and on the coronal view as the distances superiorly and inferiorly to the sacral cortex.