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PERCUTANEOUS ARTHRODESIS OF SACRO-ILIAC JOINT: A PILOT STUDY

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Percutaneous arthrodesis of sacro-iliac joint: a pilot study

P. GAETANI [1], D. MIOTTI [2], A. RISSO [1], R. BETTAGLIO [2], D. BONGETTA [1], V. CUSTODI [1], V. SILVANI [1]

***Aim*. Between 15-30% of patients presenting with low back pain have some SI joint involvement. The diagnosis of SI joint involvement in low back pain is quite difficult and depends on a detailed combination of clinical manoeuvres and injection tests. In 5% of patients with SI joint pain, the joint is physically unstable (termed disruption) resulting in ineffective medical and conservative therapeutic options. In this study we present the results of the first 12 cases of SI joint disruption treated using a minimally invasive SI joint arthrodesis system in order to evaluate the safety and the efficacy of this system.**

***Methods*. Medical charts at a single center were reviewed for demographics, perioperative metrics, patient reported outcomes for pain, function and quality of life (NRS, ODI and RDQ respectively), as well as satisfaction with surgery (yes/no) and results of postoperative CT scan.**

***Results*. Mean age was 53 years (range 36-71) and all patients were female. Patient reported outcomes at follow up (range 8-18 months) improved clinically as well as statistically as evidenced by a mean improvement in pain on NRS of 4 points, back related function on ODI by 19.4 points, and in quality of life measured using RDQ of 13.6 points (all P=0.01). Local hematoma requiring drainage was apparent in 2 patients. Patient satisfaction was 100%. All 3 month CT scans showed initial fusion.**

***Conclusion*. The results of this study confirm that MIS SI joint fusion using the iFuse Implant System is safe and effective method of treating patients with SI joint disruption.**

KEY WORDS: Sacroiliac joint - Surgical procedures, minimally invasive - Arthrodesis.

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Low back pain is one of the primary causes of loss of productivity and medical expenses in modern society, involving nearly 90% of adults at least one time.[1, 2] The treatment of low back pain requires the identification the pain triggers and this may represent a significant challenge for the clinician due to the multifactorial picture of low back pain. Conditions such as disc herniation, lumbar stenosis, facet arthropathy or disc degeneration are easily diagnosed, while the role of SI joint as low back pain generator has only recently been considered.[3] The SI joint is approximately 6-fold more resistant to lateral forces than the lumbar tract, but has 1/12 of the resistance to axial direction and 1/2 of the resistance to rotation forces than the lumbar spine.[4] The rotation movement of the SI joint is about 4 degrees with a translation capacity of 1.6 mm.[5] Such movement of the SI joint plays an important role in distributing the forces and is influenced by the movement of the lumbar tract.[5] Recent studies have shown the SI joint to be the primary cause of low back pain in almost 15% of cases [6] and that, moreover up to 75% of patients treated with lumbar instrumented arthrodesis develop significant SI joint degeneration within 5 years.[7, 8]

This large number of subjects affected by SI joint problems requires an answer in terms of efficacy of treatment. Conservative therapeutic approaches in the majority of cases is limited to non operative care

with intensive physical therapy and local SI joint injection, radiofrequency ablation, and/or rhizotomy. In cases of demonstrated SI joint instability (approximately 5%), surgical options are indicated. Open arthrodesis of the SI joint requires large skin incisions, bone harvesting, relatively long length of hospital stay, and patients are typically kept non-weight bearing for few months.[9-11]

In order to minimize these issues, a minimally invasive arthrodesis device has been developed (i-Fuse implant System, SI-BONE Inc., San Jose, CA). The aim is to achieve arthrodesis through the placement of a series of triangular, porous plasma spray coated titanium implants (Figure 1) across the SI joint: this facilitates bone ingrowth and permanent stabilization of the joint.[12] In the present pilot study we report the results of the first 12 cases treated at our institution.

Figure 1.—iFuse implants.

Materials and methods

Study design

From May 2012 and March 2013, 10 consecutive patients with diagnosis of SI joint instability (disruption) were admitted at the Neurosurgical Unit of the Fondazione IRCCS Policlinico San Matteo, Pavia, Italy. The diagnosis of SI joint disease was performed using a combination of clinical symptom description and positive diagnostic block tests. All patients presented with low back pain and SI joint pain and were previously treated for at least 4 months with intensive physical therapy. Clinical examination at admission reported the results of provocative SI joint pain manoeuvres and patients were asked to fill out the Roland Morris Disability Questionnaire (RDQ), the Oswestry Disability Index (ODI) and a 10 point Visual Analog (VAS) pain score scale.

Radiographic assessment

MRI of the lumbar spine was performed in all cases in order to assess the presence of any concomitant pathology of the lumbar tract. At admission CT scan of SI joint was performed before surgery in order to exclude specific diseases, such as bone tumors or rheumatoid arthritis. According to Ha K-Y et al.,[7] the diagnosis of SI joint disruption and instability was based on the presence of one or more of the following CT items: sclerosis, erosion, osteophyte, joint narrowing, intra-articular bone fragment and subchondral cyst.

Block tests

When clinical, physical and radiological examinations were concordant with suspected diagnosis, patients underwent confirmatory image-guided diagnostic local injection of the SI joint with local anaesthetic agent (lidocaine) and steroid. This block test allows confirmation of two specific items: (a) a 75% reduction of pain, immediately after local injection allows to confirm the SI joint as the pain trig-

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ger;[8] (b) a significant reduction of pain lasting few hours until one or 2 days allows to consider the SI joint as instable.

Surgical technique

Minimally invasive SI joint fusion with the iFuse Implant System (SI-BONE Inc., San Jose,CA) was performed in all cases by two neurosurgeons (PG and VS). The patient is placed under general anaesthesia in the prone position on a radiolucent table. A 3 cm skin incision is made with radiographic coordinates in order to gain access to the outer table of ilium. A Steinmann pin is inserted through the SI joint, lateral to the S1 neural foramen. A drill is used in order to create the pathway and decorticate the bone through the ilium and the sacrum. After the drill is removed, a broach is malleted across the joint and finally the first of three implants is tapped into place. The second implant is located above the S1 foramen and the third between S1 and S2 foramen. Patients are required to use a walker for 3 weeks after which time they begin physical therapy for at least one month before the return to normal life activities.

Outcomes

Patients returned to the clinic for follow up at one month, 3 months, 6 and 12 months. At each visit patients were asked to fill the quality of life questionnaires and the VAS scale. All patients underwent CT scan at the 3 month visit to assess implant placement, status and progression of fusion.

Statistical analysis

The data were analyzed using the SPSS software (version 10.0, SPSS, Chicago, Ill, USA). The P values were based on the Student's t test for independent variables and statistical significance was accepted for $P<0.05$. The dichotomous variables were compared using the Fisher exact test.

Results

All patients were female. Mean age was 53.2 years. (range 36-71). One patient was previously treated for lumbar instability. All patients presented at admission with positive results on at least 3 out of 5 provocative clinical tests. A unilateral approach was performed in 9 cases, while in 1 case a bilateral approach was required. Average (±SD) operation time was 65±16 minutes. Blood loss was minimal in all cases (<45 cc). Postoperatively, 2 patients presented with painful local hematoma, which required local drainage and healed in two days. One patient presented at 1 month follow-up with intense low back pain and which was successfully treated with facet joint injections.

Mean follow up was 10 months (range 6-18). A clinically and statistically significant (all values $P<0.001$) improvement in all patient reported measures (VAS, RDQ and ODI) was observed (Figure 2). Back related disability improved on average by 19.4 points, exceeding the reported minimal clinically important difference (MCID) of 12.8.[13] Mean (±SD) ODI scores were 31.4 (±6.3) preoperatively and 12 (±3.5) postoperatively (Figure 2). Quality of life also showed great improvement with scores decreasing on average by 14.6 points from a baseline mean of 17.6 (±1) to 3 (±4.1) at follow up (Figure 3). Mean pre operative VAS score was 7.7 (±1.3) and at follow up these scores had improved by an average of 4.7 points for a mean follow up score of 3 (±1.2), far exceeding MCID of >2 points (Figure 4). Patients declared in all cases their satisfaction. Figure 5 shows

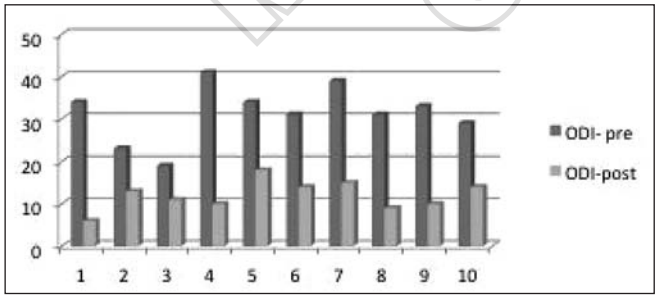

Figure 2.—Results – Oswestry Disability Index.

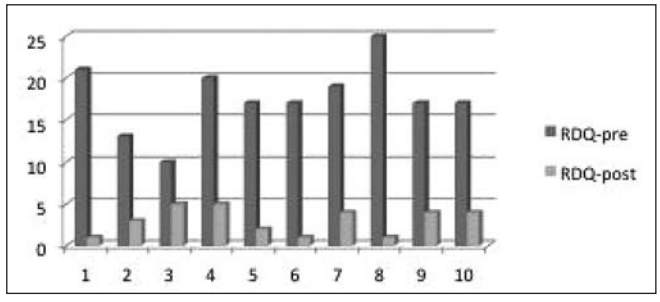

Figure 3.—Results – Roland Morris Disability Questionnaire.

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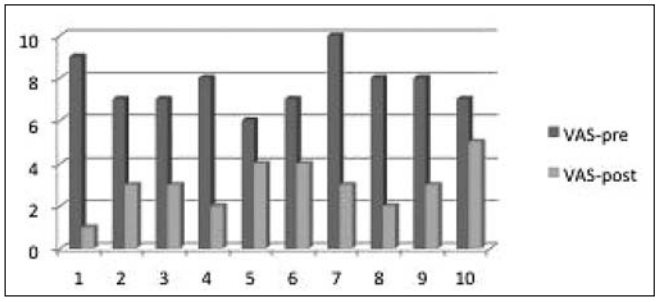

Figure 4.—Results – Visual Analog Scale.

an example of the post operative Rx scan examination at 3 months follow-up.

Discussion

The results of our preliminary experience show that a minimally invasive surgical approach to SI joint fusion for SI joint disruption is a safe and effective method leading to significant clinical improvement in patients with pain caused by SI joint disruption. The importance of a careful pre operative clinical and physical examination (provocative manoeuvres) together with the results of SI image guided block was previously demonstrated by other authors.[14, 15] In our experience the 75% of pain relief and the positivity to at least three of provocative manoeuvres was reported in all 10 cases.

The clinical results with a minimally invasive approach using the i-Fuse Implant System (Figures 1-3) suggest that the improvement is not only related to pain reduction but also in quality of life standards as measured with RDQ and ODI. The reduction of VAS scores deserves some comments. If the target of surgical approach is the arthrodesis of SI joint in cases of instability, one might evaluate as disappointing the persistence of lumbar pain after surgery. This is not entirely unexpected however as it is well known that SI joint instability is often associated with facet arthropathy and trocanteric bursitis, both as a result of the abnormal and asymmetrical distribution of postural load.

The results of the present series suggest that SI joint arthrodesis may generate a significant improvement of postural load leading to good clinical results, but that the other conditions might be subsequently considered for specific treatment in cases of persistent lumbar pain (as in 3 cases in our series).

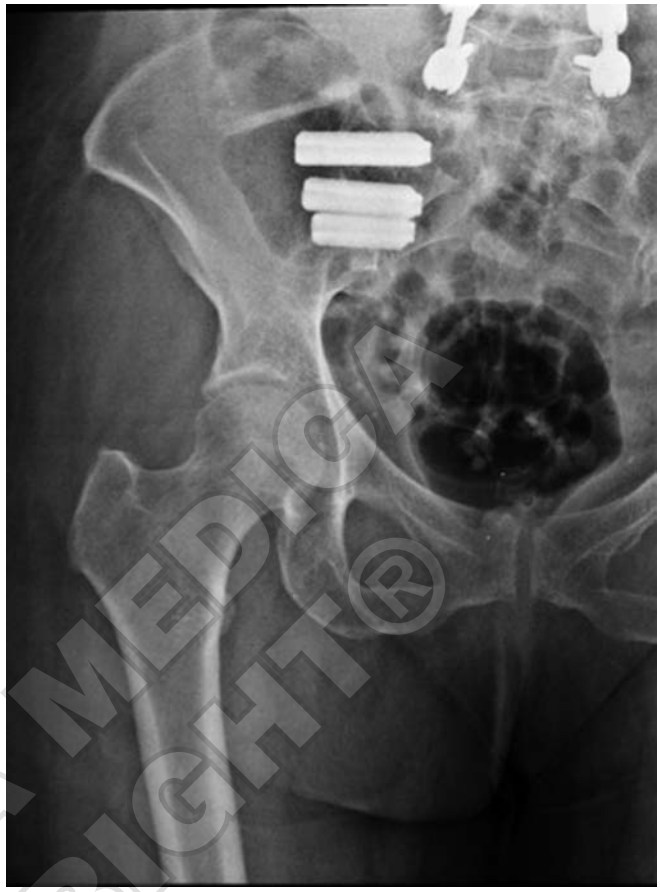
Figure 5.—Rx scan showing implant placement at 3 months post-operative.

The technical advantages of the technique reported herein include a small surgical incision, relatively short operative time, minimal blood loss, bone and ligament preservation and the relatively short period of immobilization. Other studies have recently reported about small series with single hollow modular anchorage (HMA) screw packed with bone graft [16] or with demineralised bone matrix,[17] or using 11x25 mm threaded fusion cages packed with rhBMP-2. In all these series good outcomes in short follow-up are reported but these devices are more expensive than the triangular shaped titanium implants and do not address common complications observed with screws such as loosening or breakage.[18] The triangular shape of i-Fuse implant was designed in order to minimize microrotation and micromotion encountered with classical screws. To date we have not observed any case of mechanical complication.

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Conclusions

In conclusion the results of this preliminary experience lead to the necessity to plan a randomized larger study comparing the minimally invasive surgical approach to SI vs. a conservative intensive treatment.

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