Silex®

Sacroiliac Joint Fusion System

XTANT MEDICAL

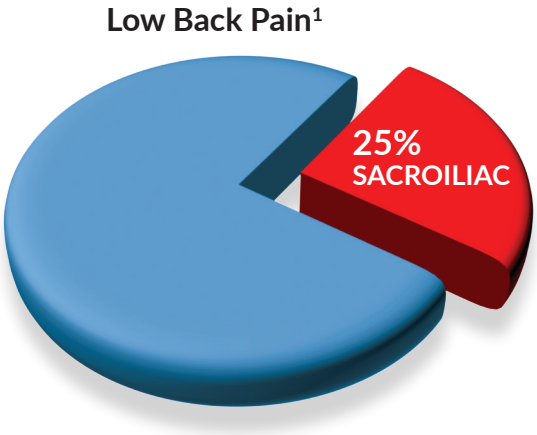
Sacroiliac compression and stability for rapid and solid joint fusion

Often Hidden Diagnosis

The Sacroiliac (SI) Joint is a significant pain generator in nearly 25% of lower back pain patients.[1] SI joint pain and dysfunction may be caused by many factors, and is often misdiagnosed as discogenic pain.[2]

While conservative treatment of SI joint dysfunction is essential, it often targets pain alleviation without addressing the root cause.

Fusion of the SI joint may be the right solution for patients who continue to be symptomatic despite conservative treatment. SI joint fusion has been shown to result in rapid and sustained relief of pain which is significantly improved over conservative treatment.[3]



Patient Candidate

As symptoms are often similar to those for lumbar disorders, a simple diagnostic algorithm may be applied to determine if the pain is sacroiliac in origin.

During physical examination, there are several orthopedic provocative tests which may reproduce symptoms associated with sacroiliac joint dysfunction.

Radiology can help rule out other potential sources of pain, but is unable to discern SI joint dysfunction.

Analgesic injections into the joint can isolate the source of the pain directly, and may temporarily improve symptoms. However, since analgesics fail to address the cause of the pain, symptoms may recur and fusion may be the best treatment option.

Common Causes

- Degenerative arthritis
- Pregnancy
- Trauma
- Previous lumbar fusion
- Leg length discrepancy
- Ankylosing spondylitis or other inflammatory disease

Common Symptoms

- Low back pain (below L5)
- Pelvis/buttock, hip/groin pain
- Lower extremity pain (numbness, tingling, weakness)
- Worsens with increased physical activity or prolonged inactivity
- Insomnia

SI Fusion Patient Selection

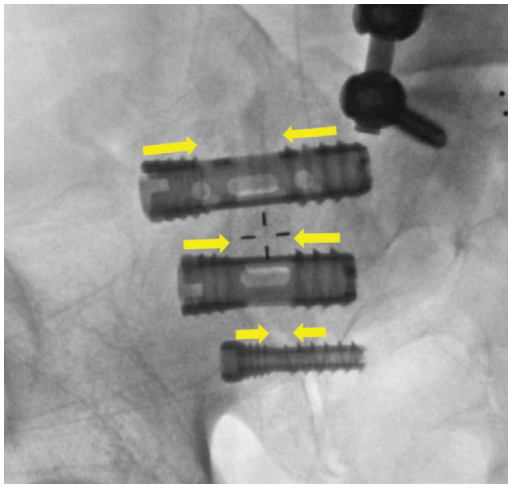
- Chronic acute pain
- Failed conservative treatment
- Failed diagnostic exams including provocative testing and SI joint injection
- Motivated and capable of post-surgical rehabilitation

Reliable Fusion

For patients diagnosed with sacroiliac joint dysfunction, the Silex system provides controlled compression and stability encouraging rapid and solid fusion.

Controlled Compression

The Silex® implants have a compression thread pattern providing 0.9mm of joint compression with every turn of the Anchor Implant once the locking threads are engaged.



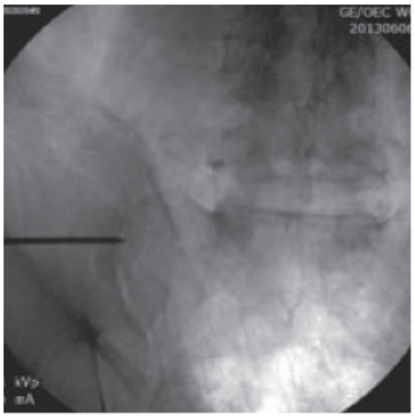
Enhancing Fusion

Early bone apposition is encouraged by the titanium plasma-spray coating on the surface of the implant. This coating further enhances the stability of the large threaded implant, and provides an osteoconductive surface for bony ongrowth.[4]

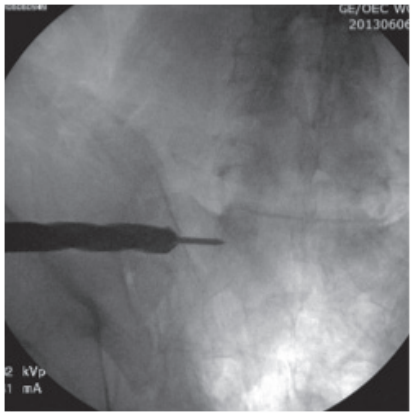
Fusion across the joint space is encouraged by the addition of bone graft material which can be filled into the lumen of the implant and exuded through the fenestrations.

Routine Procedure

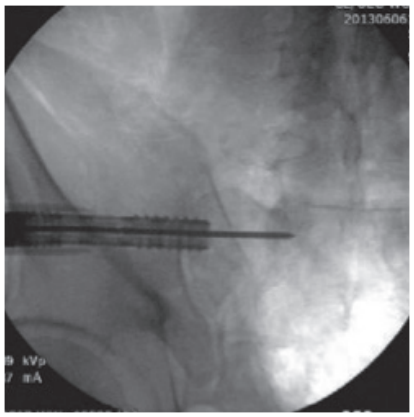
Whether performed open, mini-open or MIS, the Silex® procedure mirrors the technique for a traditional cannulated bone screw.



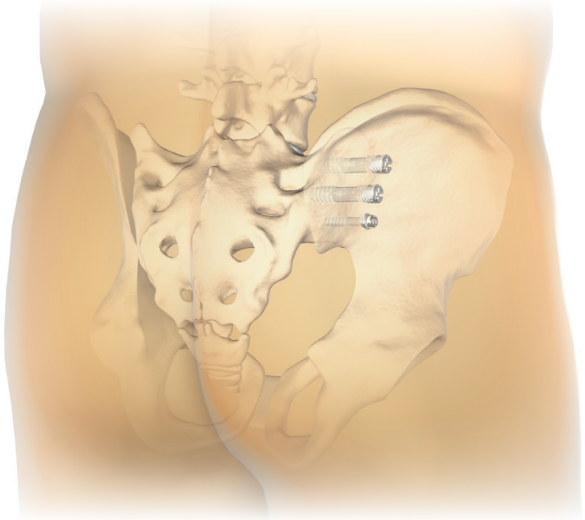
Each implant is targeted using a Steinmann pin under fluoroscopy, with or without direct visualization.



The bone is prepared by advancing a cannulated drill and tap over the Steinmann pin.



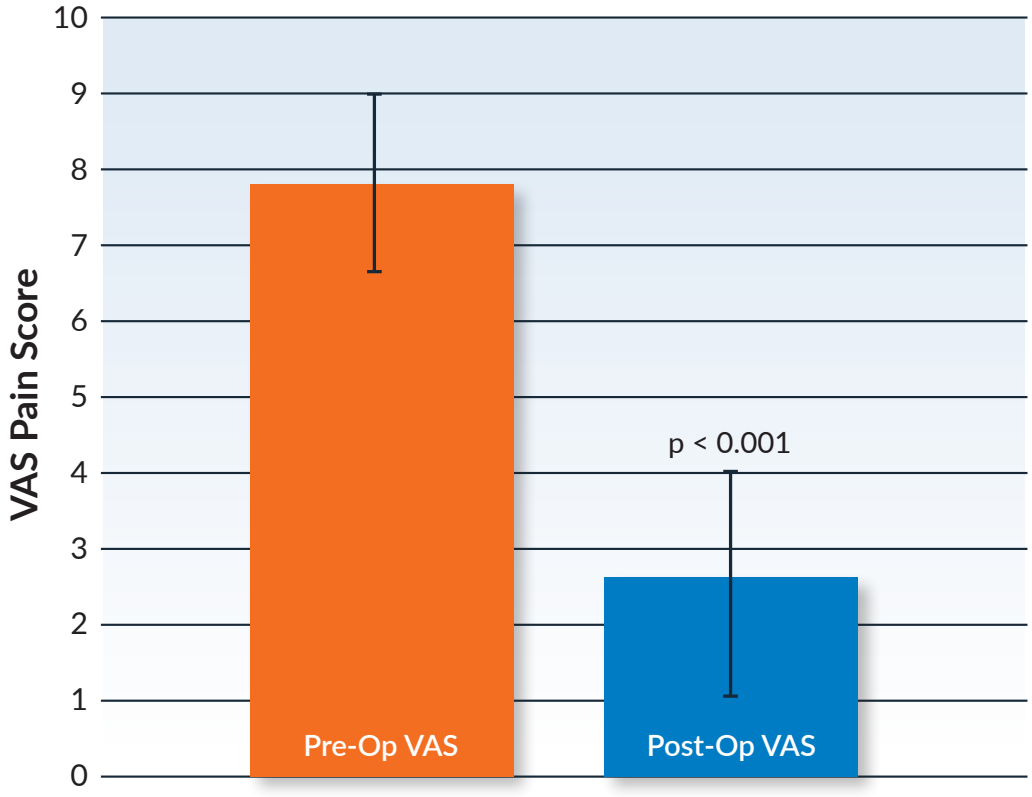
The implant is driven into place by threading over the Steinmann pin and is advanced until the second set of threads have fully engaged and compressed the joint space.



This procedure is repeated until all implants are implanted.

Clinical Outcomes

A 2016 study followed 45 patients with degenerative sacroiliitis following joint fusion with the Silex system.[5] Pain was measured pre-operatively and at 10 weeks post-operatively (range 6-12 weeks) using a visual analog scale (VAS). All patients reported a reduction in pain with an average reduction of 69%, and 84% of these patients reported postoperative pain scores of less than half of their pre-operative pain level. Based on the results of this study, the use of Silex® Sacroiliac Joint Fusion System is effective at significantly reducing pain in patients with degenerative sacroiliitis.



Graph 1. *Mean VAS pain scores pre-operative and 10 weeks post-operative Silex sacroiliac joint fustion.*

Case Report

Patient Demographics

Age: 44 BMI: 21.9
Sex: M Other: Smoker

Clinical History

The patient presented with a nine year history of non-radiating left sacroiliac pain with recent exacerbation over the previous six months. A work injury had occurred and was felt to be contributing to the patient's diagnosis. The patient had undergone a prior L4 to S1 fusion, with continued low back and sacroiliac symptomology.

Physical Examination and Diagnosis

On office evaluation the patient had a positive response to the Fortin Finger test and provocative testing with the following maneuvers: FABER test, compression test, and thigh thrust. The patient exhausted conservative treatment. Courses of physical therapy, acupuncture and interventional pain management were attempted without improvement. A diagnosis of refractory sacroiliac dysfunction was made.

Treatment

In November 2014, the patient underwent a left sacroiliac fusion and fixation using three Silex® (Xtant Medical) implants through the left SI joint. All three implants were 12.5mm in diameter and ranged in length from 40-50mm. The sacroiliac joint was visualized and curetted. Each implant was packed with local autograft, BMA, and OsteoSponge® Strip (Xtant Medical). Operative time was one hour and seven minutes, with 2.2 minutes of fluoroscopy time and 150mL of blood loss.

Post Operation Protocol

The patient was discharged on postoperative day one. His postoperative course was unremarkable, consisting of six weeks of partial weight bearing, followed by six weeks of normal ambulation and physical therapy at three months. Radiographic follow-up was performed at one day postoperatively, six weeks, three months, and a CT scan at six months (shown below). Pre-operative VAS score was a 7/10 and three month post-operative VAS score was a 3/10.

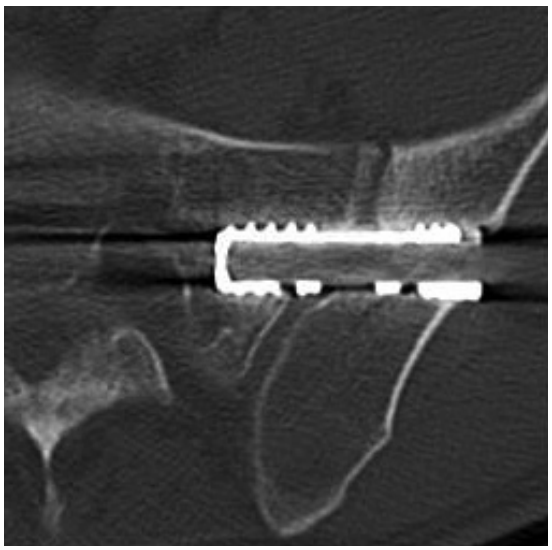


Fig. 1. *A/P view of sacroiliac joint 6 weeks post-operative*

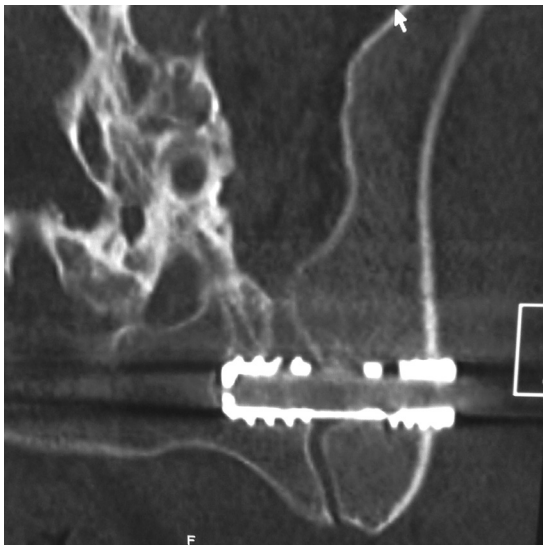


Fig. 2. *Axial view of sacroiliac joint 6 weeks post-operative*

NOTES

References

1. Sembrano J, Polly D: How Often is Low Back Pain Not Coming From the Back? SPINE. 2008; 34: 27-32.
2. Sembrano J, et al: Diagnosis and treatment of sacroiliac joint pain. CURRENT ORTHOPAEDIC PRACTICE. 2011.
3. Polly D, et al: Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants Vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. NEUROSURGERY. 2015; 77: 674-691.
4. Novaes, et al.: Influence of Implant Surfaces on Osseointegration. Braz Dent J (2010) 21(6): 471-481.
5. Scott B, Graven T: Clinical Outcomes of the Silex Sacroiliac Joint Fusion System: A Multi-Center Retrospective Review. XTANT MEDICAL WHITEPAPER. 2016; F-1060.4.

XTANT MEDICAL

888.886.9354

CS@xtantmedical.com

xtantmedical.com

FM-C-MRK-80 Rev C 11/21