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Research Article

Minimally invasive sacroiliac joint fusion using a novel hydroxyapatite-coated screw system improves functional outcomes in patients with sacroiliitis at two year follow-up

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ABSTRACT

Purpose: The aim of the present study is to understand the clinical outcomes of a novel hydroxyapatite-coated (HA-coated) titanium screw for surgical treatment of SI joint dysfunction.
Background: The mainstay of therapy for disorders of the sacroiliac (SI) joint has been non-operative treatment including activity modification, non-steroidal anti-inflammatory drugs, and physical therapy. SI joint injections provide diagnostic information and occasional durable therapeutic benefit. When these modalities fail, sacroiliac joint fusion may be recommended.
Objective: The objective of this study is to describe the clinical outcomes of a novel HA-coated titanium screw for surgical treatment of SI joint dysfunction.
Methods: This study is a retrospective Institutional Review Board-exempt chart review of 45 consecutive patients who underwent minimally invasive SI joint fusion with a novel HA-coated screw system. Patients were diagnosed based on North American Spine Society guidelines and evidence-based criteria. Clinical assessments were collected, evaluated, and compared preoperatively and at 3, 6, 12, and 24 months postoperatively.
Results: Mean patient age was 68.8 ± 9.4 years, and 61.7% of patients were female. Of the 44 patients, nine underwent bilateral SI joint fusion, while the remaining were unilateral. Screw size ranged from 10 × 35 mm to 10 × 50 mm. Mean preoperative visual analog scale (VAS) SI pain scores decreased significantly by a mean of 6.1 points at 12 months postoperatively ($P < 0.001$). Mean Oswestry Disability Index (ODI) scores significantly improved from 52.3% at baseline to 11.3% at 3-month follow-up, 11.5% at 6 months, 10.9% at 12 months, and 9.5% at 24 months, leading to improvements of 41.0, 40.8, 41.4, and 42.8 points, respectively.
Conclusion: The clinical outcomes of SI joint fusion using an HA-coated screw system to treat sacroiliitis demonstrated significant decreases in VAS SI and ODI scores at 3, 6, 12, and 24 months.

1. Introduction

The SI joint has been reported to be a source of pain in 15% of patients suffering from low back pain [1]. This diagnosis is based on provocative physical examination maneuvers [2] and diagnostic intra-articular fluoroscopy-guided anesthetic injection with 50–75% pain relief [3]. The first line of treatment, conservative therapy, can range from anti-inflammatory medication to intra-articular steroid injections and in some cases, radiofrequency ablation. When conservative treatment fails, SI joint fusion has been shown to be effective at alleviating low back pain [4,5].

To date, there has been an increase in SI joint arthrodesis procedures with a variety of implants [4–6]. Clinical outcome studies are needed to determine the effectiveness of these procedures. The objective of this study is to determine the clinical and functional outcomes of patients who underwent minimally invasive (MIS) SI joint fusion using HA-coated SI joint screws (SI-LOK®, Globus Medical, Inc., Audubon, PA, USA) (Fig. 1).

2. Materials and methods

This is a retrospective chart review of patients who were diagnosed

Abbreviations: HA-coated, Hydroxyapatite-coated; SI, Sacroiliac; VAS, Visual Analog Scale; ODI, Oswestry Disability Index; MIS, Minimally invasive; MCID, Minimal clinically important difference

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Fig. 1. Side view of the 10 × 60 mm slotted HA-coated SI joint screw.

with sacroiliitis or SI joint dysfunction, have failed conservative treatment, and underwent SI joint fusion using HA-coated screws. The diagnosis was based on North American Spine Society guidelines for the diagnosis of SI joint dysfunction, which include three out of five positive provocative physical exam maneuvers [2] and 50–75% pain relief after anesthetic intra-articular SI joint injection [3].

Patient demographics, VAS SI pain, and ODI scores were collected at 3, 6, 12, and 24 months postoperatively. Frequencies and measures of central tendencies were used for descriptive statistics. A paired *t*-test was used to determine the significant differences between pre- and post-operative scores with $P < 0.05$ being significant. The statistical analysis was performed using IBM® SPSS® Version 25 (IBM® Corp., Armonk, NY, USA).

3. Results

A total of 47 consecutive patients underwent MIS SI joint fusion from November 2013 to December 2017; however, only 44 patients had at least 12-month follow-up and were included in this study. The patients were 61.7% (29/47) female and 38.3% (18/47) male with an average age of 68.8 ± 9.4 years (range: 44–84 years). The average BMI was 31.1 ± 6.9 kg/m^2 (range: 18–55 kg/m^2). Sixty-six percent of patients were either former or current smokers. The average pre-surgical pain relief duration from SI injections lasted only 6.5 ± 7.5 days (range: 0.17–30 days). Forty-one patients underwent at least one previous lumbar fusion surgery (87.2%) (Table 1). Of the 44 patients included in this study, 35 underwent unilateral and 9 underwent bilateral SI joint fusion. Nearly all implants were 10 mm in diameter (99.15%) and either two or three implants were used in 79.6% of cases (Table 2). All patients had three or more positive provocative SI joint physical examination maneuvers.

Mean ODI scores significantly improved from 52.3% at baseline to 11.3% at 3 month follow-up, 11.5% at 6 months, 10.9% at 12 months, and 9.5% at 24 months, leading to improvements of 41.0, 40.8, 41.4, and 42.8 points, respectively, which are at least twice the minimal clinically important difference (MCID) of 20 points for ODI scores ($P < 0.001$, Fig. 2) [7–11]. Mean VAS SI pain scores significantly improved from 7.8 points at baseline to 2.8 at 3 months, 1.7 at 6 months, 1.7 at 12 months, and 1.0 at 24 months, corresponding to improvements of 5.0, 6.1, 6.1, and 6.8 points, respectively, which are three times the MCID for VAS SI pain scores ($P < 0.001$, Fig. 3, Table 3) [7–11]. All patients were surgically treated as outpatients and were discharged home. There were 3 mortalities due to cardiopulmonary issues at least 1 year after the index procedure within the 24-month post-operative period. One patient had a post-operative gluteal hematoma that manifested approximately 10 days after the index procedure due to inadvertent ingestion of anticoagulation medication prior to surgery. The hematoma resolved with no permanent sequelae. Two patients experienced sacral side lucency on CT at 18 months postoperatively but were asymptomatic.

Table 1
Baseline Characteristics.

Parameter	Overall
Number of Patients	47
Sex	
Female, n (%)	29 (62%)
Male, n (%)	18 (38%)
Age, mean (SD, range)	69 (9) (44–84)
BMI, mean (SD, range)	31 (7) (18–55)
Smoker, n (%)	
Current	2 (4.3%)
Former	29 (61.7%)
Never	16 (34.0%)
Marital Status, n (%)	
Married	34 (72.3%)
Divorced	7 (14.9%)
Widowed	4 (8.5%)
Single	2 (4.3%)
Pre-surgical Pain Relief Duration, days	
SI Joint Injections, mean (SD, range)	7 (8) (0.2–30)
Previous Lumbar Fusion Surgery, n (%)	41 (87.2%)

Table 2
MIS SI Fusion Procedure Characteristics.

Parameter	Overall
Type of Surgery, n (%)	
Unilateral	35 (79.5%)
Bilateral	9 (20.5%)
Number of Implants Used, n (%)	
2	23 (52.3%)
3	12 (27.3%)
4	9 (20.4%)
Implant Size, n (%)	
10 × 30 mm	10 (8.5%)
10 × 35 mm	24 (20.3%)
10 × 40 mm	44 (37.3%)
10 × 45 mm	26 (22.0%)
10 × 50 mm	12 (10.2%)
10 × 55 mm	1 (0.85%)
12 × 45 mm	1 (0.85%)

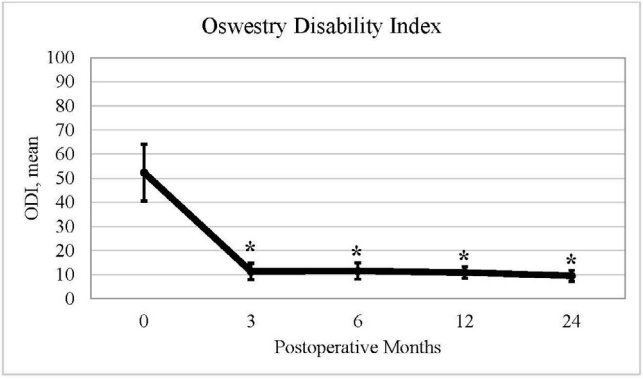

Fig. 2. Mean ODI is shown. The results show a decrease in ODI scores from baseline and sustain at 3, 6, 12 and 24 months. *$P < 0.001$ compared to baseline.

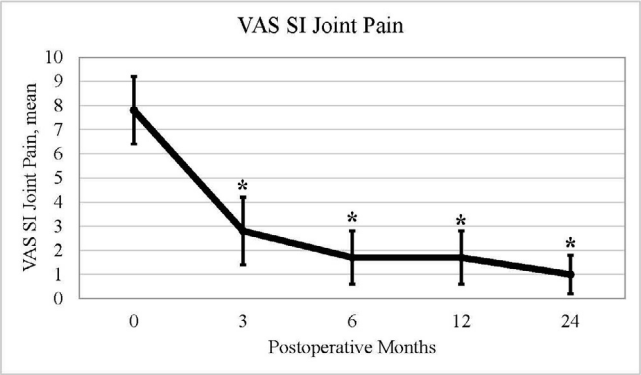

Fig. 3. Mean VAS SI joint pain is shown. The results show a decrease in VAS SI joint pain from baseline and sustain at 3, 6, 12 and 24 months. *P < 0.001 compared to baseline.

Table 3
VAS SI Pain and ODI Scores.

Parameter	Baseline	3 Months	6 Months	12 Months	24 Months
VAS SI	7.8 (1.4)	2.8 (1.4)*	1.7 (1.1)*	1.7 (1.1)*	1.0 (0.8)*
ODI	52.3 (11.8)	11.3 (3.4)*	11.5 (3.4)*	10.9 (2.4)*	9.5 (2.3)*

P < 0.001 compared to baseline.

4. Discussion

Long-term outcomes are essential to provide evidence on the use of SI screws as an effective fixation for SI joint fusion. Clinical outcomes of this study showed that SI joint fusion using HA-coated screws is effective at improving the average change in VAS SI pain and ODI scores by two or three times the MCID at 1 year, and these results were sustained through 2 year follow-up.

The North American Spine Society evidence-based guidelines for the diagnosis of SI joint dysfunction were followed in this study [2]. In a prospective, multicenter, parallel-group, open-label randomized controlled clinical trial by Polly et al. [4,5], SI joint fusion improved ODI scores at 6, 12, and 24-month follow-up by 27.4, 28.9, and 28.4 points, respectively. In the current study, the mean ODI improved by 41.0, 40.8, 41.4, and 42.8 points at 3-, 6-, 12-, and 24-month follow-up, respectively, suggesting short- and long-term improved clinical function.

Similar results are also found in retrospective studies [12–15], providing strong evidence that SI joint fusion using HA-coated SI screws is safe and effective at improving clinical and functional outcomes. In a cohort of 18 patients, Kube and Muir [12] describe a significant 20.5-point improvement in ODI at 12 months compared to baseline. In a multi-center retrospective cohort study with a prospective evaluation, Sachs et al. [13] demonstrated a mean ODI of 28.2 ± 21.3 at follow-up, which ranged from 3.0 to 4.7 years. In the current study, the mean ODI was lower at 11.3 ± 3.4, 11.5 ± 3.4, 10.9 ± 2.4, and 9.5 ± 2.3 at 3, 6, 12, and 24-month follow-up, respectively. All patients achieved significant clinical benefit [7–11], with 100% of patients achieving at least a 20-point ODI improvement by only 3 months (ODI range: 20–62) and 95.5% of patients sustaining this improvement through 12 months (ODI range: 18–62).

Although this is a single-surgeon single-site retrospective study with a small patient population, the results are consistent with findings from the literature. Another limitation of this study is that the follow-up rates were 93.6% (44/47) at 1 year and 70.2% (33/47) at 2 years.

5. Conclusion

This study provides clinical evidence that the use of HA-coated screws in MIS SI joint fusion is safe and effective at improving functional and clinical outcomes in selected patients suffering from SI joint dysfunction or sacroiliitis. These average improvements were evident at 3-month follow-up and sustained up to 12- and 24-month follow-up.

6. Ethics approval and consent to participate

As the research conducted for this manuscript was a retrospective study on patient data, compliance with the ethical standards of the responsible committee on human experimentation (institutional and national) and the Helsinki Declaration of 1975 was not required.

CRediT authorship contribution statement

Alex Mohit: Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing. **Torrey Shirk:** Formal analysis, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Funding for this project was provided by the Musculoskeletal Education and Research Center (MERC), a Division of Globus Medical, Inc (GMI). The HA-coated SI joint screws (SI-LOK®) are manufactured by GMI. AM is a consultant for, receives royalties, and receives research support from Globus Medical, Inc. AM is also a consultant for K2M Spine. TS is a salaried employee of Globus Medical, Inc.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.inat.2020.100834.

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