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Spinopelvic Fixation Using an Osseointegrative Implant: Analysis of Postmarket Surveillance to Determine the Failure Rate

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ABSTRACT

Background: Adult spinal deformities, affecting up to 60% of individuals older than 60 years, often require long segment fusions. Constructs spanning the lumbosacral junction commonly include pelvic fixation. Despite robust pelvic fixation, distal junctional failure, such as pseudoarthrosis, bone fracture, and instrumentation failure, occurs in 24%–34% of these cases. A novel implant designed for both durable pelvic fixation and sacroiliac joint fusion was recently cleared by the US Food and Drug Administration. This implant is engineered to address some of the pelvic fixation failure mechanisms by reducing motion at the lumbosacral junction and sacroiliac joint while decreasing stress on S1 pedicle screws and S2AI implants.

Objective: To determine the failure rate of a novel osseointegrative implant for spinopelvic fixation/fusion.

Study Design: Analysis of manufacturer postmarket surveillance database.

Methods: A postmarket surveillance database was analyzed to determine the type and rate of complaints and revisions of a novel osseointegrative implant. These were then compared with the published literature.

Results: A total of 15,628 implants were identified in 6907 patients. The postmarket surveillance of the novel screw fusion device revealed a low complaint rate of 0.75% and no postoperative implant breakage. Revision procedures were mostly due to set screw dissociation (0.4%) and implant loosening (0.15%), which was primarily linked to pre-existing conditions or infection. The mean (SD) time from index procedure to the complaint was 7.1 (5.4) months.

Conclusions: Compared with published literature, this novel osseointegrative implant demonstrates a significantly lower incidence of set screw dissociation than traditional pelvic screws with no incidence of breakage or back out, underscoring its durable integration with bone, with low rates of revisions and mechanical failures.

Clinical Relevance: A novel osseointegrative implant offers reduced rates of mechanical failures and revisions, helping to reduce complications in pelvic fixation procedures.

Level of Evidence: 4.

Complications

Keywords: pelvic fixation, sacroiliac joint, adult spinal deformity, spinal fusion

INTRODUCTION

Adult spinal deformities are complex conditions with varied clinical and radiological presentations, affecting up to 60% of those older than 60 years.[1,2] Surgical correction of spinal deformity often involves multilevel spinal fusion, involving the thoracic, lumbar, and sacral spine. In most cases, the rigid fixation of multiple spinal segments, necessary to maintain deformity correction, results in large, levered forces above the base of the construct. In these procedures, pelvic fixation is commonly used to provide a solid base for the construct, decreasing motion across L5 to S1 and therefore reducing lumbosacral junctional failure by improving the fusion success.[3,4]

Pelvic fixation requires fixation past the L5 to S1 pivot point, as originally documented by McCord et al.[5] This can be accomplished using several well-established techniques, with the most common historically involving the placement of a screw into the ilium. The traditional iliac screw technique involves placing the screw into the iliac wing from the posterior superior iliac spine, anchoring into the ilium without crossing the sacroiliac (SI) joint. More recent techniques have developed and involve the placement of the screw through the sacrum into the ilium in a sacro-alar-iliac trajectory or a modified medial start point of the traditional iliac screw. These approaches have been utilized to reduce issues such as implant prominence and wound complications,

potentially reducing rates of revision surgery.[6] The modified iliac screw technique has allowed for a reduction in prominence issues, but the implant remains solely engaged within the ilium and thus bypasses the SI joint. In contrast, the sacro-alar-iliac (commonly at the level of S2 and S2AI) screw technique involves inserting the screw dorsally between the neural foramina of S1 and S2, traversing the SI joint, and anchoring into the ilium.[7] The deeper insertion point for this trajectory reduces the risk of implant prominence.[8] However, the S2AI screw crosses the SI joint without fusing it, creating a single linear pivot point in the axis of SI joint mobility.[9] In all techniques, this residual mobility, along with the transfer of stress from the instrumented lumbar spine, may lead to SI joint dysfunction and postoperative SI joint pain.[10,11]

In patients with adult spinal deformity, lumbopelvic fixation using iliac and S2AI screws has been associated with a fixation failure rate of 24% to 34% within 2 to 5 years after the operation, including loosening of fixation to the pelvis, loosening of S1 screws, and rod fractures below L4.[3,12,13] Recently, a novel osseointegrative implant designed for both pelvic fixation and simultaneous SI joint fusion (iFuse Bedrock Granite, SI-BONE, Inc.; Santa Clara, CA) was cleared by the US Food and Drug Administration (FDA). This implant was engineered with multiple features to address the mechanical pelvic fixation failure mechanisms, allow permanent biological integration with the host bone, and potentially mitigate new onset SI joint pain following spinal fusion to the pelvis. Key features of this implant include a larger diameter of 10.5 mm, a 6.35-mm neck, and a stronger connection of the implant to the rod by way of a T30 hexalobe set plug with a locking torque of 115 in-lbs and a negative rake thread on the tulip. The implant has a composite construction with a machined inner shank for strength and an outer fusion sleeve for biological integration. The fusion sleeve is additively manufactured with self-harvesting fenestrations along the fusion sleeve to promote bone growth onto and into the implant. Additionally, the tulip head allows for up to 40° of favored angulation, aiding in construct alignment and rod capture.

The FDA requires medical device manufacturers to perform postmarket surveillance (PMS) to ensure that the use of their products in the commercial setting continues to be safe and effective. The law is codified in Title 21 Part 803 of the US Code of Federal Regulations. This regulation contains mandatory requirements for device manufacturers, importers, and device user facilities (eg, hospitals, surgical facilities, and other health care sites of service) to report device-related adverse events and product problems ("complaints") to the FDA.[14,15] Event reporting can help identify unforeseen risks and confirm the safe use of commercialized devices.[16] Furthermore, device manufacturers are required to catalog and investigate any complaints as to the performance or safety of their devices.

In the present article, we present the postmarket experience of a novel osseointegrative screw using PMS data from the time of product commercialization in May 2022 through May 2024. Additionally, we compare these rates with those reported in the published literature.

METHODS

The iFuse Bedrock Granite Implant System received Breakthrough Device Designation in November 2021 and 510(k) marketing clearance in April 2022 with restricted spinal system compatibility and broad compatibility with 5.5 or 6.0 rods in December 2022.

Device usage and complaint reporting are cataloged by the manufacturer. Complaints, defined as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution,"[17] are gathered from multiple sources, including company employees, physician and hospital users, social media, patient contact, clinical trials, and published literature. As part of the standard PMS process, the company logs and investigates all complaints associated with the device, regardless of their origin or how they were communicated. Each complaint is assessed for reportability in accordance with the US FDA's Medical Device Reporting requirements.[14]

Essential data related to the use of the manufacturer's implants are systematically documented in an inventory database. This database includes details such as a unique identifier, procedure date, medical facility, surgeon performing the operation, the implant's catalog and lot number, and the patient's sex and age. Each reported complaint was systematically investigated by a multidisciplinary team. This process included a comprehensive review of patient history, detailed case specifics, and pre- and posttreatment imaging to identify the root cause of the complaint. All reported complaints undergo manual review to ascertain whether they constituted surgical revisions. If further details are necessary, the treating physician is contacted.

We analyzed the PMS database for all implant-related complaints and subsequent revisions. A revision

Table 2. Listing of implant-related complaints.

Complaint	Count	Days to Event, Mean (SD)	Procedural Complaint Rate, % (*N* = 6907)
Set screw disassociation	23	133.0 (102.2)	0.33
Implant loosening	10	375.6 (103.1)	0.15
Infection (unrelated to implant)	8	215.4 (107.7)	0.12
Implant sleeve separation	5	116.8 (163.4)	0.07
Lucency/halos	4	414.0 (222.7)	0.06
Malpositioned implant	2	178.5 (212.8)	0.03

is defined as any modification of the implant, including removal with or without replacing the implant. Each complaint that resulted in a revision surgery was matched to its corresponding initial surgery to determine the time to revision and evaluate any inconsistencies in the initial case. Institutional review board approval was not necessary for this study because it involved an analysis of internal company data routinely gathered during PMS. No protected health information was reviewed at any time in this analysis.

Statistical Analysis

Continuous variables are summarized as means and SDs. Binary outcomes are summarized as percentages. Procedural percentages are calculated by dividing individual event counts by total number of surgeries. For patients with revision surgery, "days to event" was defined as days from index surgery date to revision surgery.

RESULTS

From May 2022 to May 2024, 6907 cases were performed using 15,628 implants. Of these, 22 were used in trauma cases. Of the nontrauma cases, 64% used 1 implant per side, 16% used 2 novel implants per side, and 20% used 1 novel implant and an additional fusion implant per side (Table 1).

A total of 52 implant-related complaints were reported, corresponding to a rate of 0.75%. The most common complaints were set screw disassociation and implant loosening, occurring at the rate of 0.32% and 0.15%, respectively (Table 2). All other complaints resulting in revision surgery occurred at very low rates or not at all, including implant breakage, rod displacement, and rod fracture (Table 2). The mean (SD) time from index procedure to the complaint was 7.1 (5.4) months.

Table 1. Breakdown of pelvic fixation configurations of the osseointegrative implant.

Pelvic Fixation Configuration	Count	Reported Complaints, *n* (%)
Single osseointegrative implant	4381	1 (0.02)
2+ osseointegrative implants	1110	38 (3.40)
Osseointegrative implant + additional fusion device	1394	13 (1.35)
Trauma fixation	22	-

Of the 52 implant-related complaints, 41 (0.59%) resulted in revision surgery and 11 did not (Table 2). Those complaints requiring revisional surgery were further classified as early (≤90 days postoperative) or late (>90 days postoperative) revisions. Early revisions accounted for 23.8% of cases and were performed due to set screw disassociation (n = 8), asymptomatic implant malposition (n = 1), and precautionary measures for infection unrelated to the implant (n = 1; Table 3). Notably, no early revisions were reported due to rod displacement, rod breakage, implant loosening, or implant breakage.

Late revisions accounted for 75.6% of reported revisions, the majority of which were performed for set screw disassociation (n = 11) and implant loosening (n = 10). Indications for late revisions also included asymptomatic implant malposition (n = 1), possible lucency or haloing (n = 3), and as a precautionary measure for an infection unrelated to the implant (n = 6; Table 3). There were no reports of late revisions due to rod fracture or implant breakage.

An additional analysis was conducted to examine the relation between fusion construct length, the number of implants used for pelvic fixation, and implant complaints. For this, complaints were categorized based on construct length: long constructs, defined as those with an upper instrumented level (UIV) at L1 or higher, and short constructs, with an UIV at L2 or lower. Our findings revealed that long construct fusions experienced set screw disassociation at a rate of 0.33%. In 65% of these cases, pelvic fixation involved 2 osseointegrative implants placed on each side, while 22% utilized 1 osseointegrative implant placed in combination with an additional fusion device not connected to the construct on either side. Implant loosening was observed in 0.06% of procedures involving long constructs, 75% of which used 2 osseointegrative implants at S1AI and S2AI bilaterally. In procedures involving short constructs, implant loosening occurred at a rate of 0.09%, with the majority using a single osseointegrative implant in combination with an additional fusion device not connected to the construct, bilaterally.

Table 3. Indications for early and late surgical revisions.

	Early Revisions		Late Revisions	
Indication	**Count**	**Days to Event, Mean (SD)**	**Count**	**Days to Event, Mean (SD)**
Lucency/haloing	0	-	3	487.7 (163.4)
Set screw dissociation	8	47.9 (14.3)	11	199.3 (103.1)
Implant loosening	0	-	10	375.6 (103.1)
Malpositioned (asymptomatic)	1	28.0 (0.0)	1	329.0 (0.0)
Infection (unrelated to implant)	1	90.0 (0.0)	6	375.6 (103.1)
Total	**10**	**50.1 (19.9)**	**31**	**299.5 (140.9)**

DISCUSSION

In this analysis of a novel method of pelvic fixation combined with SI joint fusion, failures and revisions were notably very low when compared with the available literature comparators. Martin et al reported early failure rates of pelvic fixation at more than 5% within 6 months of surgery in a large multicenter cohort.[13] Eastlack et al reported pelvic fixation loosening and/or fracture rates of approximately 15% with follow-up longer than 2 years and an 8.5% pelvic fixation revision rate.[3] In comparison, the novel osseointegrative implant studied for the present analysis yielded complaints in less than 1% of cases (0.75%), and a smaller percentage ultimately underwent revision (0.59%).

Additionally, the angulation required to connect S2AI screw heads to the supporting rods increases mechanical strain on the screws.[18] This added strain may contribute to mechanical failures. In a multicenter retrospective study, Martin et al reported a 5% incidence of acute S2AI failure, which included set screw or rod disassociation from the S2AI tulip head and rod displacement. These failures typically occurred within the first 6 weeks postoperatively. Of note, no failures were reported in cases that included 2 or more points of fixation, including rods, per side.[10]

Biomechanical and finite element analysis studies suggest that using multiple fixation points across the SI joint can provide significant benefits, including reduced rod strain, decreased bending or breakage of S2AI and iliac screws, and improved stabilization of the SI joint.[18–20] For example, 1 study found that combining S2AI screws with an SI joint fusion device in a cadaveric model reduced SI joint motion by 30% compared with using S2AI screws alone.[19] Furthermore, Panico et al recently reported that incorporating either a single fixation/fusion device at the S2AI trajectory or 2 stacked fixation/fusion devices can reduce the screw stresses associated with acute mechanical failures at S2AI by up to 50% and 66%, respectively.[18]

Notably, nearly half of the implant-related complaints resulted from an appearance of lucency postoperatively. Although this phenomenon occurred significantly less frequently with this osseointegrative screw compared with traditional pelvic fixation methods, the haloing (or lucency) seen around these newer implants has a different significance than that observed around standard fixation screws. Standard buttress screws have an outward compressing function and thus can impart a negative necrosing effect on the surrounding bone, which may be further influenced through stress from the construct.[21] Alternatively, the bioactive nature of the osseointegrative implant encourages bony apposition and ingrowth. Such behavior may have unique imaging characteristics, like fracture healing, in which case lucency may not confer loosening. Rather, it may simply represent a more vascular and healing bone physiology adjacent to the surface of this novel device. Given this, loosening of the osseointegrative implant was confirmed during the revision procedure in 71% of reported complaints of lucency or haloing.

In total, only 41 revisions of this implant have been required out of nearly 7000 cases. Additionally, nearly 25% of these revisions were unrelated to the device's mechanical behavior, as they were performed in the setting of broader infections or due to malposition. Revision rates in other studies have generally been much higher, regardless of cause, with reported rates ranging between 5% and 26% in adults with spinal deformity.[8,12,13,22,23]

This novel implant has yielded a strikingly lower failure rate when compared with alternative fixation devices studied in the literature, and it also has the potential to reduce longer-term clinical failures both radiographically and clinically. The clinical and radiographic deterioration of the SI joint subsequent to long lumbar fusions has been well documented.[24,25] SI joint pain of disabling nature develops in up to 40% of patients following long fusions,[26,27] and degenerative changes advance in approximately 75% of these patients based on computed tomography analysis.[11,28] In addition to markedly reducing radiographic failures of pelvic fixation, this osseointegrative implant, along

with stable durable fixation across the SI joint, has the potential to limit SI deterioration and pain syndrome subsequent to deformity reconstruction.

The implant manufacturer is currently conducting a multicenter study (PAULA, NCT05640908) to collect continued evidence of implant safety and effectiveness under real-world conditions. This more scrutinized assessment of implant and fixation durability will shed further light on the overall benefits of employing this device. Similarly, the clinical pain syndrome related to SI joint deterioration and stress after surgery is the subject of a randomized controlled trial (SILVIA, NCT 04062630). This trial evaluates construct failure and SI joint pain after long construct (4+ levels) fusion to the pelvis using either a single S2AI screw or a screw plus a fusion implant not fixed to the spinal instrumentation (iFuse 3D, SI-BONE, Inc, Santa Clara, CA).

This analysis has several limitations. First, it focuses exclusively on failures of the novel osseointegrative implant, which represents a single component of a larger construct. Failures of other components, such as rod fractures, pedicle screw failures at cephalad locations (including the sacrum), and pseudarthroses, could not be reasonably captured using the methodology employed. Failures in components not manufactured by the same source are outside the scope of this dataset and are therefore not represented, limiting direct comparisons to studies evaluating entire constructs or components from other manufacturers.

Despite these limitations, a very large number of implants were included in this analysis, providing a robust dataset for evaluating the osseointegrative implant. The fidelity of revision surgery reporting is particularly high in this case, as removal of this specific implant requires specialized tools and expertise unique to the manufacturer's products. This inherent specificity ensures accurate identification and documentation of revision procedures.

While the use of complaint data to identify failures may result in some cases being missed (ie, false negatives), the reported revision rates are unlikely to deviate significantly from actual rates. The novel design and implementation of this osseointegrative implant necessitate the involvement of company representatives and the use of specialized equipment during revision surgeries. This close involvement triggers mandatory reporting mechanisms, thereby enhancing the reliability and completeness of the data presented.

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