# Analysis of Complications in Sacroiliac Joint Fusions Using FDA 510(k) Cleared Devices

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**Study Design:** This was a level III—retrospective cohort study.

**Objective:** The objective of this study was to present an unbiased report of the current rate of severe complications for Federal Drug Administration (FDA) 510(k) cleared sacroiliac joint (SIJ) fusions and investigate the underlying cause of these complications.

**Summary of Background Data:** The number of yearly SIJ fusions is on an upward trend. Currently, the most utilized implants to fuse the SIJ have been FDA 510(k) cleared devices. Studies reporting on complications following SIJ fusions are mostly industry-sponsored.

**Materials and Methods:** The Manufacturer and User Facility Device Experience (MAUDE) database was searched for all reported FDA 510(k) cleared SIJ fusion device complications. Several data points were obtained from each report and recorded. The Hospital Inpatient National Statistics and the Center for Medicare and Medicaid Services (CMS) was also searched for the number of SIJ fusions performed each year.

**Results:** A search of the MAUDE database returned 1115 reports, with the first report on June 30, 2011, and the last report on July 28, 2020. Patient injury was the most common type of event reported at 97.5% (1080/1107). Death was reported in 3 patients (0.3%). Malposition was the most common device problem at 49.5% (548/1107). The root cause of these events was primarily user error at 58.2% (644/1107). Revision surgery or reoperation occurred in 92.8% (1028/1107) of reports. Data for SIJ fusions through CMS showed an overall trend of increasing yearly SIJ fusions.

**Conclusions:** The majority of complications reported to MAUDE for FDA 510(k) cleared SIJ fusion devices are user error due to improper placement of implants. These complications are likely underreported, and there is currently no formal tracking system of total SIJ fusions performed to calculate accurate complication and revision rates. Patient injury and health care costs can potentially be reduced with improved education, training, and oversight, which is currently lacking.

**Key Words:** sacroiliac joint, fusion, complications

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The prevalence of low back pain originating from the sacroiliac joint (SIJ) is thought to range anywhere from 2% to 30%.[1–4] The SIJs are mobile in all 3 anatomic planes[5–8] and have been shown to have intra-articular pain generators along with closely associated extra-articular pain generators.[9,10] When conservative treatment for SIJ pain fails, arthrodesis becomes a viable option to reduce or eliminate pain from this joint.

The number of SIJ fusions continues to be on an annually accelerating upward trend.[11,12] There are many techniques and hardware options for fusing the SIJ, with minimally invasive, Federal Drug Administration (FDA) 510(k) cleared implants being the most utilized. The complication rate for minimally invasive SIJ arthrodesis has been reported to be between 0% and 18%[11–14] with revision rates ranging from 0% to 6.3%.[11,13–17] The majority of these studies are industry-sponsored and risk varying degrees of bias.

The purpose of this study was to present an unbiased report of the current rate of severe complications for FDA 510(k) cleared SIJ fusion implants and to investigate the reported underlying cause of these complications. Our hypothesis was that most of the reported complications are technical errors, which if true, could potentially be decreased with improved training, education, and oversight in coordination with the major spine research and teaching societies and government institutions.

## MATERIALS AND METHODS

The Manufacturer and User Facility Device Experience (MAUDE) database is a passive surveillance system that records medical device reports submitted by mandatory and voluntary reporters of suspected device-associated deaths, serious injuries, and malfunctions. This includes complications reported in patients undergoing SIJ fusions using FDA 510(k) cleared devices. The MAUDE database was searched in September 2020 using "Sacroiliac Joint Fixation" as the Product Class search criteria. A single reviewer (M.D.R.) manually screened all of the medical device reports returned from the search. Several data points, including manufacturer, brand name, date report was received, event date, event type, device problem, root cause, initial procedure, number of implants per side, time to correction, patient symptoms, complication, corrective action, and outcome, were obtained from each report and recorded.

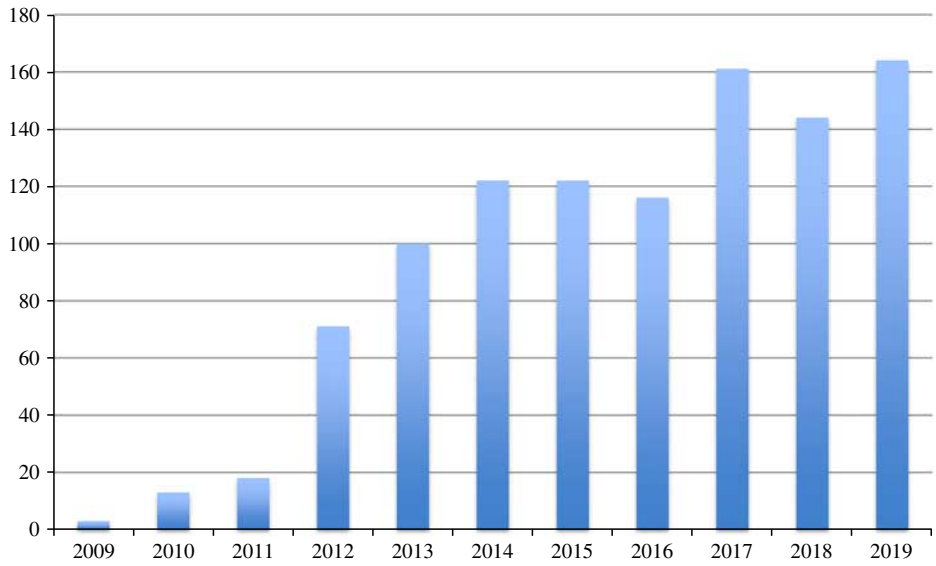


**FIGURE 1.** Number of adverse sacroiliac joint fusion events reported per year.

The Hospital Inpatient National Statistics were searched through the Agency for Healthcare Research and Quality (AHRQ). Fusion of the SIJ by total discharges was searched from 2011 to 2017. The number of all fusions, including open, percutaneous, and endoscopic, were obtained and recorded.

The Center for Medicare and Medicaid Services (CMS) was also searched through the Medicare Provider Utilization and Payment Data: Physician and Other Supplier system. Physician and Other Supplier data from CY2012 to CY2017 was collected. A search for sacroiliac fusion was performed, and information related to MD and DO surgeons was filtered out. *International Classification of Disease* (ICD-9 and ICD-10) codes 27280 and 27279 were used. Total providers and the number of fusions (open and minimally invasive) were obtained and recorded by year.

## RESULTS

The MAUDE database was searched from the first report on June 30, 2011, through the last report on July 28, 2020. A total of 1115 reports were identified. Duplicate reports and complications not involving the SIJ were removed, leaving 1107 medical device reports. The number of reports per year steadily increased from 3 in 2009 to 120 in 2014. Reports then increased again in 2017, plateauing around 150 reports until present (Fig. 1). Surgeon and patient demographics were not available in these reports.

Eight device manufacturers were included in the medical device reports (Table 1). Patient injury was the most common type of event reported at 97.5% (1080/1107). Death was reported in 3 patients (0.3%). Malposition was the most common device problem at 49.5% (548/1107). All common device problems are listed in Table 2. The root cause of these events was primarily user error at 58.2% (644/1107). The other root causes are listed in Table 3.

Unilateral SIJ fusion was the initial procedure in 91.3% (1011/1107) of the medical device reports. Bilateral SIJ fusions, including staged fusions, made up 6.6% (73/1107) of reports. Three implants per side were used in 911 procedures. This was followed by 2 implants per side in 101 procedures.

The most common symptom reported by patients was radicular pain (38%, 421/1107). This was followed by unspecified pain (25.7%, 284/1107) and SIJ pain (17.2%, 190/1107). Time to reoperation occurred mostly between 1 week and 11 months (38.9%, 431/1107) (Table 4).

There were 1495 contributing complications reported in 1107 medical device reports. Complications were most often the result of an implant breeching the neuroforamen or sacral cortex with or without nerve impingement (34%, 508/1495). The most common implant involved was the most cranial implant (61.2%, 311/508). All complications are listed in Table 5. Revision surgery or reoperation occurred in 92.8% (1028/1107) of reports.

Ultimate patient outcome was unknown in 58.9% (653/1107) of reports. Resolved pain, improved pain, and continued pain were the next most common outcomes at 20.3% (225/1107), 15% (167/1107), and 2.3% (25/1107), respectively.

**TABLE 1.** Manufacturer (Brand Name) of Federal Drug Administration (FDA) 510(k) Cleared Devices Included in Complication Reports to Manufacturer and User Facility Device Experience (MAUDE)

| Manufacturer (Brand Name) | n (%) |
|---|---|
| SI-Bone (iFuse) | 1047 (94.5) |
| Zyga (Simmetry) | 39 (3.5) |
| X-Spine Systems (Silex) | 10 (0.9) |
| Warsaw Orthopedics/Medtronic (Rialto) | 5 (0.5) |
| Unknown | 2 |
| DePuy Synthes | 1 |
| Medacta | 1 |
| Spine Frontier (Sacrofuse) | 1 |
| Tenon (Catamaran) | 1 |
| Total | 1107 |

**TABLE 2.** Device Problem

| Device Problem | n (%) |
|---|---|
| Malposition of device | 548 (49.5) |
| Adverse event without identified device or use problem | 236 (21.3) |
| Insufficient information | 67 (6) |
| Loss of osseointegration | 41 (3.7) |
| Inadequacy of device shape and/or size | 33 |
| Device operates differently than expected | 27 |
| Failure to osseointegrate | 25 |
| Device slipped | 19 |
| Appropriate term/code not available | 15 |
| Migration or expulsion of device | 13 |
| Improper or incorrect procedure or method | 12 |
| Break | 11 |
| Unknown | 10 |
| Difficult to remove | 8 |
| Device dislodged or dislocated | 6 |
| Device handling problem | 6 |
| Loose or intermittent connection | 6 |
| Patient-device incompatibility | 4 |
| Contamination | 3 |
| Entrapment of device | 3 |
| Fitting problem | 3 |
| Fracture | 3 |
| Equipment failure | 2 |
| Unstable | 2 |
| Device damaged by another device | 1 |
| Extrusion | 1 |
| Human device interface problem | 1 |
| Unexpected therapeutic results | 1 |
| Total | 1107 |

Data for SIJ fusions through the Hospital Inpatient National Statistics (AHRQ) was only available for 2016 and 2017. There were a total of 3220 and 3035 SIJ fusions, including open, endoscopic, and percutaneous, for 2016 and 2017, respectively. Data on SIJ fusions, including open and minimally invasive procedures, from the CMS Medicare Provider Utilization and Payment Data system was obtained from 2012 to 2017. The total number of fusions performed by M.D. and D.O. surgeons for 2012, 2013, and 2014 were 583, 778, and 668, respectively. The total number of fusions for 2015, 2016, and 2017 were 771, 1082, and

**TABLE 3.** Root Cause of Complications Determined by Manufacturer and User Facility Device Experience (MAUDE)

| Root Cause | n (%) |
|---|---|
| User error | 644 (58.2) |
| Unknown | 207 (18.7) |
| Loosening | 91 (8.2) |
| Patient request | 37 (3.3) |
| Procedural | 27 (2.4) |
| Late recurrence of symptoms | 18 |
| Pseudoarthrosis | 16 |
| Fall | 16 |
| Infection | 12 |
| Poor patient selection | 6 |
| Hematoma | 6 |
| Precaution | 4 |
| Postoperative infection | 4 |
| Patient noncompliance | 3 |
| Other pain generators then sacroiliac joint | 3 |
| Fracture | 3 |
| Surgeon's decision | 2 |
| Equipment failure | 2 |
| Allergy | 2 |
| Motor vehicle accident | 1 |
| Deep venous thrombosis | 1 |
| Chronic pain | 1 |
| Bleeding | 1 |
| Total | 1107 |

**TABLE 4.** Time to Reoperation Following Complication

| Time to Reoperation | n |
|---|---|
| Intraoperative | 35 |
| < 1 wk | 105 |
| 1 wk–1 mo | 431 |
| 1–3 y | 377 |
| 4+ y | 69 |
| Unknown | 90 |
| Total | 1107 |

**TABLE 5.** Description of Complication

| Complication | n |
|---|---|
| Superior implant | |
| Into neuroforamen/breeched cortex/impinging on nerve | 311 |
| Too short | 3 |
| Too proud | 8 |
| Malpositioned | 10 |
| Loose | 28 |
| Middle implant | |
| Into neuroforamen/breeched cortex/impinging on nerve | 77 |
| Too short | 19 |
| Too proud | 10 |
| Malpositioned | 8 |
| Loose | 23 |
| Inferior implant | |
| Into neuroforamen/breeched cortex/impinging on nerve | 47 |
| Too short | 29 |
| Too proud | 16 |
| Malpositioned | 333 |
| Loose | 31 |
| Implant not specified | |
| Into neuroforamen/breeched cortex/impinging on nerve | 73 |
| Too short | 11 |
| Too proud | 15 |
| Malpositioned | 43 |
| Loose | 105 |
| Neuromusculoskeletal | |
| Pseudoarthrosis/nonunion | 33 |
| Fracture | 14 |
| Scar tissue with nerve compression | 2 |
| Nerve damage | 2 |
| Medical | |
| Infection | 23 |
| Pulmonary embolism | 4 |
| Cardiac | 4 |
| Allergy | 2 |
| Equipment | |
| Guide pin/tool broken or malpositioned | 11 |
| Hematologic | |
| Hematoma | 15 |
| Pseudoaneurysm/vascular injury/bleeding | 13 |
| Deep venous thrombosis | 3 |
| Other | |
| Unknown | 107 |
| Patient request | 61 |
| Nonsterile implant | 1 |
| Total | 1495 |

1165, respectively. Neither database provided information on the indication for surgery or the type of device used.

## DISCUSSION

The MAUDE database tracks global complications to include FDA 510(k) cleared SIJ fusion devices marketed in the United States. There were 1107 complications reported to MAUDE over an 11-year period that were considered severe, with most causing patient injury. Of these complications, 92.8% required reoperation. The current literature reports an overall low complication rate following minimally invasive SIJ arthrodesis. This number ranges anywhere from 0% to 18%.[11–14] Revision and reoperation rates reported range anywhere from 0% to 6.3% based on total SIJ fusions.[11,13–17] Complications reported to MAUDE are conducted as passive surveillance. While the manufacturers of these devices are required to report all complications, the number of complications is likely underreported by up to 35%.[18] This is because reporting is voluntary for health care professionals, patients, and consumers. An active surveillance system would offer a more accurate representation of true complication numbers and reoperation rates.

Exacting an accurate number for the complication rate when using these FDA 510(k) cleared devices for SIJ fusions is difficult because there is a complete lack of formal tracking for the number of SIJ fusions performed. Currently, there is no database that tracks all SIJ fusions performed in the United States. CMS does track SIJ fusions under their Provider Utilization and Payment Data system. From 2012 to 2017, their numbers show SIJ fusions increasing from 582 in 2012 to 1165 in 2017. A study by Schoell et al[12] used the Humana database and found that from 2007 to 2014, the number of SIJ fusions increased from 14 in 2007 to 142 in 2014. Two SI-Bone sponsored studies showed that their product was implanted 31 times in 2009, and this steadily increased to 3611 in 2012, while the overall number of fusions between 2009 and 2014 was 11,820.[11,19] The SI-Bone Web site reports over 45,000 SIJ fusions since 2009 using their product.[20] If ~80% of SIJ fusions use SI-Bone's iFuse system, a conservative estimate, it could be estimated that ~60,000 SIJ fusions may have been performed over the time period in question. This would put the complication rate at about 2%. Due to likely underreporting to the MAUDE database, the true percentage is most likely much higher. The AHRQ also has the Hospital Inpatient National Statistics that report fusion of the SIJ by total hospital discharges. They reported 3220 discharges in 2016, followed by 3035 discharges in 2017. If these numbers were to be hypothetically extrapolated out to include the 10 years this study covers, the overall number of SIJ fusions would be far more, making the likely percentage of complications much higher. The American Spine Registry does not currently track SIJ fusions, making it impossible for the major orthopedic, neurosurgery, and spine academies and societies to follow this data accurately. While there is similarly no formal tracking of all of the SIJ fusions performed in the United States yearly, it can be seen that with the available data, the number of SIJ fusions performed each year continues to increase.

Given that an accurate number of SIJ fusions using FDA 510(k) cleared devices in the United States each year cannot be generated, the severe complications that have been reported are meaningful because they are occurring with an increasing trend. They are altering patients' lives and do result in death, morbidity, and many return trips to the operating room. Therefore, these MAUDE reports are worth reviewing by those either directly impacted by them or in a position to make potential positive changes.

The root cause of the complications reported to MAUDE was user error at 58.2% (644/1107). The root cause was further broken down into specific complications. Malposition of the implant(s) was the most common device problem reported at 49.5% (548/1107). This rate is slightly higher than the symptomatic malposition rate reported by Cher et al[19] at 38.4%. Complications were most often the result of an implant breeching the neuroforamen or sacral cortex with or without nerve impingement (34%, 508/1495). The most common implant involved was the most cranial implant (61.2%, 311/508). More than 50% of the complications reported to MAUDE were due to surgeon error. Therefore, a significant number of these complications were potentially avoidable. The available data currently lacks specific surgeon demographics, so further categorization is not possible.

Returning to the operating room for additional procedures due to complications increases the cost to the health system. Overall, 92.8% of the complications reported to MAUDE needed to return to the operating room for an additional procedure. Of these, 9.5% required reoperation within 1 week, and 38.9% returned to the operating room between 1 week and 1 year. Childers and Maggard-Gibbons,[21] recently showed that the cost of an inpatient operating room was $37.45 per minute. If a separate trip is needed to return to the operating room, then costs associated with this surgical procedure increase drastically.

Formal education regarding SIJ fusions is currently lacking, as there is no standard central institution within spine surgery or the government that provides surgical education for the dysfunctional SIJ. Currently, the industry and its surgeon surrogates deliver most of the training. Informal training from partners and other more experienced surgeons is also common, with the understanding that they too have not been formally trained via a standard educational protocol that is not proprietary. With the increasing number of SIJ fusions each year and with most of the complications reported being surgeon error, an argument can be made that there needs to be formal training. Cher et al[19] reported that revision rates dropped as the number of SIJ fusion cases performed increased (6.0% down to 0.7%). In their study, 2.6% of surgeons were responsible for 34% of revisions. While more experience leads to fewer complications is a truism for any surgery, formal training in SIJ fusions during residency and fellowship is lacking and making this learning curve steeper. With more education, training, and

experience, the number of complications and the need for reoperation should decrease. This lack of education and training is also reflected in the orthopedic and neurosurgery board examinations. Currently, there is nothing mentioned regarding the SIJ or SIJ fusion surgery in the American Board of Neurological Surgery board preparation Content Categories. The American Board of Orthopedic Surgery examination preparation Blueprint mentions that at least 1 question will address sacroiliac dysfunction but is not necessarily specific to fusions.

While the numbers of complications reported to MAUDE are most likely less than the true value, this is the first analysis of all the available data on the 510(k) cleared devices being utilized for this purpose over a consecutive 10-year period. An industry-sponsored study was published in 2015 that looked specifically at their own device and MAUDE-reported complications.[19] More studies are needed to further evaluate the underlying causes and true complication and revision rates following SIJ fusions. With the implementation of formal training and more transparent tracking systems, the number of complications should decrease, making this surgery much safer for patients.

This study has several limitations. This is a retrospective database analysis. While temporal trends, risk-stratification, and cost-analysis are possible, there are few studies available to validate these database findings and their inherent limitations.[22] Data obtained for this study regarding SIJ fusion complications is from a passive surveillance system. Therefore, we believe complications from this procedure are significantly underreported. There is currently no standardized tracking system of total annual SIJ fusions performed. Therefore, accurate complication and reoperation rates are impossible to calculate. The best available data was obtained, extrapolated, and analyzed for overall trends. More specific information regarding surgeon and patient demographics was not available to further analyze possible contributing factors to these complications. Finally, user error is a broad term. While more specific information was not available, it was determined that the root cause of these complications was due to the person placing the implant, not the device itself. SIJ fusions can be difficult, and the implants are not perfect.

In conclusion, the majority of complications reported to MAUDE for FDA 510(k) cleared SIJ fusion devices are from user error due to improper placement of implants. Many of these reported complications required a return to the operating room for correction, which did not always resolve the symptoms resulting from those complications. The complications reported and examined here are likely underreported, and there is currently no formal tracking system of total SIJ fusions performed to calculate accurate complication and revision rates. Patient injury and health care costs associated with these fusions can likely be reduced with improved education, training, and oversight.

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