

## A consideration for the utility of the post-operative Oswestry Disability Index for measuring outcomes after sacroiliac joint fusion

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### Abstract

Sacroiliac joint (SIJ) dysfunction and its surgical treatment remain a controversial topic in spine surgery. Determining success after SIJ fusion may be difficult due to pre-existing back pain, lumbar fusion (LF), and functional disability. We examine the utility of Oswestry Disability Index (ODI) as a measure of clinical outcomes after minimally invasive SIJ fusion. A retrospective review of 24 patients with at least 12-months follow-up. Patients were divided into two groups based on presence of previous LF. Their post-operative ODI was compared with overall satisfaction, pain reduction, and return to work status. No difference in demographics was found in patients with and without prior LF with 92% of patients reporting lower post-operative pain and 96% being satisfied. Presence of LF did not show any statistically significant differences in pain or satisfaction. However, patient with prior LF reported lower ODI than those without LF at 1-year post-operatively ( $P=0.015$ ). Postoperative ODI may give a falsely pessimistic impression of outcomes in SIJ fusion patients with prior LF, and its use and limitations should be carefully considered in future studies.

### Introduction

The sacroiliac (SI) joint can be a site of pathologic motion, presenting as low back, sacral, pelvic, gluteal, or general hip pain.<sup>1,2</sup> Patients with SI joint pain can undergo many conservative treatment options, including medication optimization, physical therapy, therapeutic injection, and radiofrequency ablation.<sup>1,3-6</sup> When these measures

fail to provide adequate relief, fusion of the joint is often recommended, most recently with a minimally invasive surgical technique.<sup>7</sup>

In order to assess the success of these different treatment modalities, researchers have turned to various instruments of patient reported outcomes. One of the most commonly used has been the Oswestry disability index (ODI).<sup>8-12</sup> Since its introduction in 1980, the ODI has been cited more than 200 times, translated to multiple languages and undergone multiple revisions.<sup>13</sup> However, though the ODI has been extensively validated in the lower back pain population, research validating its use in the SI joint population has been sparse.

In spite of a lack of validation, ODI has played a large role in the post-operative evaluation of SI Fusion.<sup>8-10,12</sup> Smaller analyses, such as those done by Al-Khayer *et al.*, or Cummings and Capobianco, used the ODI as a key measure of their patient's post-operative disability.<sup>9,14</sup> Others, such as Rudolf *et al.*, develop their own study instruments to analyze outcomes, but based it closely on the ODI.<sup>10</sup> The ODI was also utilized in larger studies as a secondary endpoint, such as the prospective cohort study run by the SIFI group (Sacroiliac Joint Fusion with iFuse Implant System) or the randomized control trial by INSITE (Investigation of Sacroiliac Fusion Treatment).<sup>8,12,15-17</sup>

However, despite ODI's extensive validation in lower back pain literature and frequent use in SI Fusion studies, its application in the SI Fusion population may not be straightforward. First, the SI fusion population is different from other low back pain (LBP) groups. In particular, a large portion of this group has had previous lumbar fusion procedures prior to the development of SI pain, in part because lumbar fusion is a known risk factor for its development.<sup>1</sup> In fact, studies investigating the SI fusion procedures have reported that anywhere from 39% to 61% of their study groups have had previous lumbar fusion.<sup>14-16</sup> Second, though both ODI and pain measures improve significantly in the studies mentioned above, the ODI improvement is often shown to be little above the Minimum Clinically Important Difference (MCID), whereas pain improves by multiples of the MCID. This discrepancy between measures suggests that the ODI may not translate cleanly to the SI fusion population.

The application of the ODI to the SI fusion population may provide misleading results, in part due to the large portion of patients with previous lumbar fusions. In the current study, patient charts were analyzed beginning with the pre-operative clinical

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ical history through follow-up at 12 months. The outcome measures included ODI, overall satisfaction, and Numerical Rating Scale (NRS) for pain. Adverse events and return to work rates are also reported. In order to assess the utility of the ODI in evaluating SI fusion outcomes, 1 year outcomes after minimally invasive SI fusion are compared in patients with and without previous lumbar fusion.

### Materials and Methods

This study consists of a retrospective review of 24 patients who underwent minimally invasive SI fusion by a single surgeon between May 09, 2012 and March 18, 2014. Institutional IRB approval was acquired prior to initiation of any study related procedures.

Patients were evaluated for the study with a clinical assessment included five maneuvers: distraction, compression, FABER test (Patrick's test), thigh thrust and Gaenslen's test. All patients had improvement from 50 to 100 % of SI symptoms after fluoroscopically guided intra-articular injection. Further, all patients had localized SI joint pain indicated by a positive Fortin finger test, or specific localized pain over the posterior superior iliac spine, and all patients ultimately had a strong clinical diagnosis of sacroiliitis based on the aforementioned criteria and physician discretion. Patients included in the study had failed at least 6-8 weeks of conservative management.

No exclusion criteria were considered, and all available patients with at least 12 months post-operative were included.

Patients were stratified into 2 groups; those without prior lumbar fusion (NLF; n=11), and those with prior lumbar fusion (LF; n=13). The iFuse Implant System was used in all patients. Post-operative clinic notes for fusion progress, and adverse events such as wound healing issues and condition related adverse events were recorded. Thereafter, outcomes were evaluated using the ODI, overall patient satisfaction, medication usage, return to work (if working prior to surgery), and a numerical rating scale (NRS) for pain at 12 months after the surgery.

Patients were given a questionnaire that includes all outcome instruments; this questionnaire was given to nearly half of patients in the clinic on their 12 months follow-up. For the others the questionnaire was sent by mail while 2 patients filled the questionnaire by a phone call. For those with a bilateral SI fusion, a questionnaire was filled 12 months after the second surgery.

Statistical analysis was completed to evaluate for differences in both baseline background characteristics, as well as categorical post-operative outcome variables,

between the 2 comparison groups. The Student's T-test was used to assess for differences in age between groups while the Pearson's Chi-squared test was used to assess differences in gender between the groups. The Mann-Whitney-Wilcoxon test was used to assess ordinal outcome variables such as surgery satisfaction and numerical rating scale. Finally, post-operative ODI score comparison between the two groups was calculated via an unpaired 2-sample Student's T-test with assumption of unequal variance. Significance was set at  $P \leq 0.05$ .

## Results

Demographics can be seen in Table 1. The overall mean age at the time of diagnosis was 57.3 (SD = 11.7; range 35-80 years), and no difference in age was detected between groups ( $P=0.571$ ). Of the 24 patients, there was a clear majority of females to males in both the LF and NLF groups but no difference in the male-female ratio between the 2 groups. ( $P=1$ ). In addition, males who had prior LF compared to NLF was not significant ( $P=0.50$ ), and the same was observed for females ( $P=0.50$ ).

History of pre-existing trauma on the low back and pelvis region was recorded in 2 cases from the LF Group. The trauma happened 3 years before the time of the diagnosis for one of these patients and 1 year prior to diagnosis for the other. All

cases had relief from pain after the fluoroscopically guided intra-articular injection with pain relief varying from 50% to 100 %.

One of the 2 patients who developed opposite side pain needed a contralateral SI fusion procedure at 12 months. Another subject underwent a contralateral SI fusion; however, the case was not included in post-operative events as the bilateral fusion was planned from the baseline due to bilateral pain (Table 2).

Initially considered to be a failed fusion and an open revision procedure proposed. Later, the patient showed a gradual improvement without need of further intervention, and had reported a return to work and satisfaction with the procedure.

### NRS of pain at 12 months

12 patients (92.3%) of LF group had NRS of pain from 0 to 4; the same score was seen in 10 patients (90.9%) of NLF group (Table 3). Only 2 patients had higher scores, with an NRS of 5 (LF group) and 7 (NLF group). There was no significant difference in pain scores between the LF and NLF patients (LF mean = 2.5, NLF mean = 1.9,  $P=0.166$ ) as tested by the Mann-Whitney-Wilcoxon test.

### 12 months satisfaction rate

The satisfaction rate was divided into 5 categories ranging from dissatisfied to extremely satisfied. 100% of LF group cases were satisfied with varied degrees shown in Figure 1, while 1 patient from NLF group was Somewhat Dissatisfied. No

**Table 1. Demographics.**

	N	Mean age (years)	Sex	
			Male	Female
Lumbar fusion	13	58.6	3	10
No prior lumbar fusion	11	55.8	2	9
Overall	24	57.3	5	19

**Table 2. Post-operative events.**

	Lucency	Same side pain	Contralateral side pain	LBP +/- LEP	Hip pain	Trauma	Wound heal-ing issues
Lumbar fusion group	1	-	2	3	3	1	3
No prior lumbar fusion group	1	1	-	1	-	-	-

**Table 3. NRS score of pain at 12 months follow-up.**

	0	1	2	3	4	5-10
Lumbar fusion	2	1	2	5	2	1*
No prior lumbar fusion	2	4	3	0	1	1 <sup>z</sup>
Overall	91.7%	91.7%	91.7%	91.7%	91.7%	8.3%

\*NRS of pain = 5; <sup>z</sup>NRS of pain = 7.

patient was Dissatisfied. Overall 95.83% of patients were some degree of satisfied. There was no significant difference between patients without prior fusion compared to patients with prior lumbar fusion ( $P=0.736$ ).

### Post-operative Oswestry Disability Index

At 1 year post-op, 15% of cases of LF group reported minimal disability (ODI 0-20) versus 64% from the no prior LF group (Figure 2). On the other hand, 85% of the LF reported moderate, severe, or crippling pain disability (ODI 20-80) versus only 36% of patients without prior fusion. This difference groups in functional outcomes between the patient groups reached statistical significance with  $P=0.015$  by an unpaired 2-sample Student's T-test (LF ODI mean = 39.5, NLF ODI mean = 18.5)

### Return to work

Prior to surgery, 5 patients were retired, 6 were disabled or not working because of back pain, 4 were not working for a reason not related to back pain and 9 were working. After surgery, all of working patients were able to return to work within 3 weeks to 8 months (mean = 9.9 weeks,  $SD \pm 9.84$ ).

## Discussion

The SI fusion population is unique among other low back pain groups in that it contains many patients with previous lumbar fusion.<sup>14,16</sup> In our study, more than half of the patients had a history of prior lumbar fusion. Additionally these patients had a high preexisting disease burden, with about a third of the group being disabled preoperatively, and more than half developing sep-

arate degenerative pathology. It is not unreasonable to expect this higher disease burden to influence the patient reported outcome measures between LF and NLF patient groups. In the current study, these two patient groups had a clear inconsistency between their outcomes as measured by post-operative satisfaction and pain metrics versus the ODI. For both the pain scale and the satisfaction measurements at 12 months after surgery, there were very clearly no significant difference due to a preexisting lumbar fusion. On the other hand, when the same patients completed the ODI, the analysis produced a significant difference in the outcomes of the two groups. Though overall 37.5% of patients had minimal disability (0-20%) on ODI, this broke down to 63.6% of NLF patients with good outcomes versus only 15.4% of the patients with previous LF. This data suggests that, as an instrument, the post-operative ODI is more sensitive to the heterogeneous population presented by SI fusion patients, and therefore any data point that combines LF and NLF patients will result in a lower ODI with relatively stable pain and satisfaction metrics. Though most studies do not report their results broken down between LF and NLF groups, a preliminary analysis of the size of clinical improvements can be obtained when comparing their Minimum Clinically Important Difference (MCID). Certain values of the MCID are commonly accepted for the metrics in question: a change of 15 points on the ODI is considered clinically significant, as is a change of 2 points or 20mm on either the Visual Analogue scale (VAS) or NRS for pain.<sup>15,18,19</sup> With this background, it is clear that other studies report much larger clinical effect from SI fusion surgery with pain and satisfaction

metrics, rather than the ODI. For example, the SIFI study group reported that at 2 years, 72% of their patients reported a VAS improvement of 40mm, or twice the MCID threshold while only 46.3% of their patients reached a similar threshold by ODI.<sup>15</sup> In the INSITE study group reported a VAS improvement of 54 mm at 12 months, three times the MCID threshold, while their patients' ODI scores improved by less than twice the MCID threshold.<sup>16</sup> Cummings et al., likewise reported a VAS improvement of more than three times the MCID threshold (6.56 points) while their patients' ODI scores improved by about twice the threshold.<sup>14</sup> This analysis demonstrates that the large clinical improvement from the patients' reported pain relief and satisfaction is not reflected in their ODI scores.

The discrepancy noted both in this data and the data published elsewhere on SI fusion outcomes may be due to the scope of the different outcome measures. On one hand, the pain metrics and patient satisfaction questions are targeted to the procedure; that is, the patient is asked to specifically think of his or her pain and satisfaction as it related to the procedure and initial complaint. On the other hand, the ODI is a more global instrument looking at the patient's disability overall. It is understandable then, that though patients may be very satisfied with the SI fusion procedure, patients with an existing disease burden such as that from a preexisting lumbar fusion, may continue to report higher than usual disability levels. In other words, the SI fusion procedure relieved the patients' SI pain but their abilities are still highly affected by the other degenerative pathologies. Furthermore, though this challenge in the application of the ODI is applicable in other populations

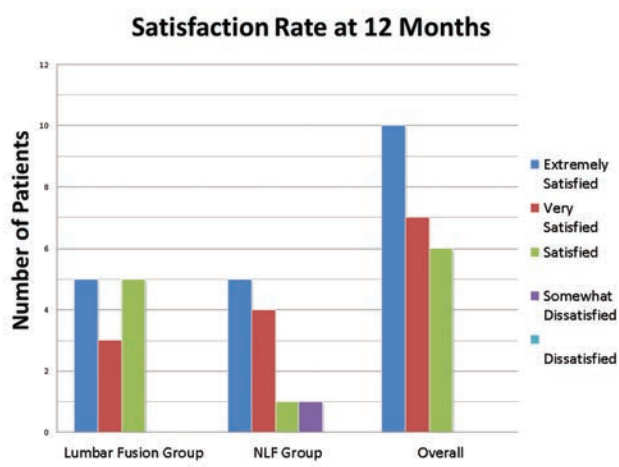


Figure 1. Overall patient satisfaction with their surgery at 12 months after sacroiliac joint fusion.

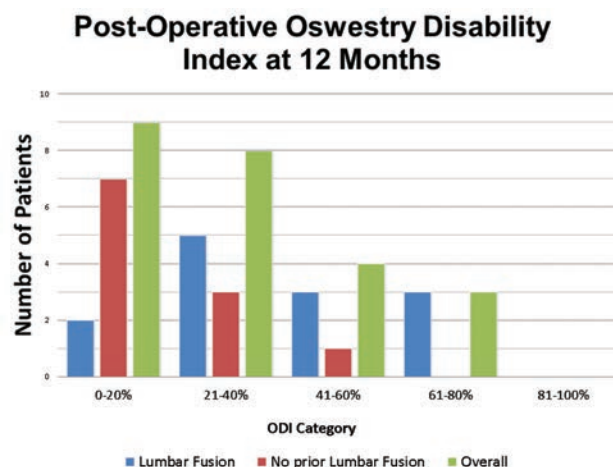


Figure 2. Self-reported Oswestry Disability Index at 12 months after sacroiliac joint fusion.

with lower back pain, the uniquely high percentage of patients with SI pain with previous lumbar fusion procedures makes this a particularly important consideration in future studies around SI pain.

One recent study has attempted to validate the ODI in the SI pain population.<sup>20</sup> In this study, there was no difference in outcomes between their patients with previous lumbar fusions and those without in the ODI. However, though their study was larger, they admitted to having very strict inclusion and exclusion criteria, excluding patients with other sources of significant back pain. As a result, their preoperative ODI scores were the same whether or not patients had a previous LF. These selection criteria may be too narrow, since the patients in this study's LF group often had serious degenerative spinal disease before or after their procedure. Therefore, it is possible that through the strict inclusion criteria, the study excluded patients with more severe limitations secondary to a previous lumbar fusion, the very patients that make the SI population unique. Further study is merited. The major limitation of this study, besides the limited sample size, is the lack of preoperative ODI data that is available in prospective trials. Because pre-operative ODI data is absent, a direct analysis of any differences in ODI change between the LF and NLF groups cannot be completed. While this study suggests caution when interpreting postoperative ODI values in isolation without baseline values, several controlled trials have already shown that the change (response rate) in ODI following surgery remains robust regardless of prior lumbar fusion history. The RCT INSITE study has noted no differences in LF vs NLF groups for both surgical and non-surgical groups based on a composite success measure of VAS improve >20 pts and no neurological or instrumentation complications.<sup>17</sup> The INSITE study also noted no effect on ODI change for the surgical group between LF and NLF group, but did not report preoperative or postoperative ODI values for each group. Similarly, while the prospective SIFI study noted no difference in effect between LF and NLF groups for VAS and ODI response after surgery at 24 months, baseline and postoperative ODI characteristics between the 2 groups are published.<sup>15</sup>

## Conclusions

The postoperative ODI was not consistent in this series with other outcome measures of MIS SIJ Fusion. Comparing patients with and without previous lumbar fusions,

there were no differences in outcomes as measured by the NRS for pain or the patient's overall satisfaction with the procedure at 12 months. On the other hand, the ODI measured an overall quality of life clearly worse in patients of preexisting lumbar fusion. This difference is likely due to the fact that the NRS and patient satisfaction were targeted questionnaires framed in terms of the SIJ fusion, while the ODI is a broader instrument that captures a patient's whole disability and quality of life. Therefore, the ODI resulted in lower scores by capturing patient disability secondary to the previous lumbar fusions, as well as unrelated pelvic degenerative pathology, and non-SIJ joint pain in the back or lower extremities. Though the post-operative ODI is a useful instrument and adjuvant to retrospective study of procedures for low back pain, it nonetheless may lead to misleading conclusions if investigators are not able to simultaneously assess baseline ODI value and ODI response rates especially when patients with previous disability are included without proper subset analysis.

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