

Quality of life in preoperative patients with sacroiliac joint dysfunction is at least as depressed as in other lumbar spinal conditions

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Background: Pain from the sacroiliac joint (SIJ) is an under-recognized cause of low back pain. The degree to which SIJ pain decreases quality of life has not been directly compared to other more familiar conditions of the lumbar spine.

Methods: Multivariate regression analysis of individual patient data from two prospective multicenter clinical trials of SIJ fusion and three prospective multicenter clinical trials of surgical treatments for degenerative lumbar spine conditions.

Results: Controlling for baseline demographic parameters as well as a validated disability score, quality of life scores (EuroQOL 5-D and SF-36) were, in most cases, lower in the SIJ cohorts compared to the three other spine surgery cohorts.

Conclusion: Patients with SIJ dysfunction considering surgery have decrements in quality of life as or more severe compared to patients with degenerative spondylolisthesis, spinal stenosis, and intervertebral disc herniation.

Keywords: spine surgery, disability, low back pain, sacroiliac joint pain, lumbar stenosis, intervertebral disc herniation, degenerative spondylolisthesis, sacroiliac joint fusion

Background

Chronic back pain is an exceedingly common and important worldwide health problem. Back pain rates are higher than cancer and chronic obstructive pulmonary disease as a cause of poor health, and lower back pain is the sixth most common cause of loss of global disability-adjusted life years.¹

Degenerative conditions of the lumbar spine, including intervertebral disc herniation (IDH), spinal stenosis (SPS), and degenerative spondylolisthesis (DS), are accepted as common causes of lower back pain that often require definitive surgical treatment. The rate of lumbar fusion has risen 2.4-fold in the decade between 1998 and 2008, and the cost-per case has more than tripled during this period.² Despite this increase in use, success rates from lumbar fusion, especially in patients with isolated degenerative disc disease, continue to be unacceptably low.³

One explanation for low success rates is the inability to accurately diagnose the source of lower back pain. Pain emanating from the sacroiliac joint (SIJ) is an under-recognized cause of chronic lower back pain. SIJ dysfunction can cause back and pelvic pain with radiation into the groin, legs, or hips,⁴ and can be mistaken for other causes of pain. Nonetheless, SIJ pain may be very common. In patients presenting for evaluation of low back pain, the SIJ was determined to be the source of lower back pain in 14%–22% of patients presenting for back pain evaluation.^{5,6} The SIJ is even more commonly (up to 40%^{7,8}) suspected as a source of lower back pain in patients who have undergone prior lumbar fusion.

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Currently available treatment options for SIJ dysfunction include physical therapy,⁹ SIJ steroid injections,^{10,11} Radiofrequency ablation of the neural structures posterior to the SIJ,^{12,13} and open¹⁴ or minimally invasive^{15–19} SIJ fusion. A recently published surgery vs non-surgery randomized trial of SIJ fusion using triangular titanium implants substantiates the use of this technology.²⁰

Many surgeons do not consider SIJ dysfunction in their diagnostic workup of low back pain. This could be because of inadequate recognition of the importance of SIJ dysfunction as a contributor to poor health quality, disability, and pain. Although multiple studies have been published regarding SIJ pain, direct comparisons with other sources of back pain have not been published. In earlier work, we demonstrated that preoperative quality of life scores in patients with SIJ pain are low, indicating a substantial burden of disease.²¹ In this report, we used primary data sets to compare disability and quality of life scores in patients participating in two sets of clinical trials, one enrolling patients with SIJ pain and the other enrolling patients with three common spinal conditions (IDH, SPS, and DS) often treated surgically. The goal was to directly compare decreased quality of life across disease categories.

Methods

Data sources

Data for this study were taken from multicenter prospective clinical trials performed in the USA in two settings: two trials of minimally invasive SIJ fusion for SIJ dysfunction and three trials of commonly accepted surgical treatments for IDH, SPS, and DS. Four of the trials directly compared pain, disability, and quality of life scores in patients randomized to either surgical treatment or non-surgical care. The fifth trial was a single-arm SIJ study only but was included because enrollment criteria were identical to the randomized trial. All trials used similar assessments, as detailed in the later text. Only baseline (preoperative) scores were compared. Trial eligibility criteria are described in Table S1.

SIJ trials

Baseline scores were taken from two ongoing prospective multicenter clinical trials of SIJ fusion. Sacroiliac Joint Fusion With iFuse Implant System[®] ([SIFI], NCT01640353, N=172 subjects) is a prospective multicenter single-arm study of minimally invasive SIJ fusion using titanium triangular implants (iFuse Implant System[®]; SI-BONE, San Jose, CA, USA) with enrollment at 19 US centers. Investigation of Sacroiliac Fusion Treatment ([INSITE], NCT01681004) is a prospective multicenter randomized controlled trial of the same surgical treatment vs best-available non-surgical management, which

included pain medications, physical therapy, SIJ steroid injections, and radiofrequency ablation of the lateral branches of the sacral nerve roots. INSITE (N=148 subjects) enrolled subjects at 19 US sites. Eligibility criteria were identical between INSITE and SIFI. The primary endpoints for these studies were success/failure endpoints based on SIJ pain responses. Twelve month results from INSITE²⁰ and SIFI²² have been published.

Lumbar spine trials

Data for lumbar spinal conditions were taken from the Spine Patient Outcomes Research Trial (SPORT). SPORT is a set of National Institutes of Arthritis and Musculoskeletal and Skin Diseases-funded (U01-AR45444) prospective multicenter randomized controlled trials of surgical vs non-surgical treatment for three conditions: IDH (NCT00000410), SPS (NCT00000409), and DS (NCT00000411). SPORT was performed in collaboration with the Trustees of Dartmouth College. In each case, subjects were randomized at baseline to receive either immediate surgical treatment or non-surgical care. The primary endpoint of these studies was improvements in SF-36 physical function scores. SPORT data were provided by SPORT authors (Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth, NH, USA) for this analysis.

Assessments

Both SIJ trials and SPORT performed similar assessments at baseline and follow-up. SIJ trials included Oswestry Disability Index (ODI), while SPORT included the “MODEMS” version of ODI, which is very similar in structure and content. ODI is a validated, ten-question survey that measures disability due to back pain, with higher scores representing increased disability.²² Both trials included EuroQOL-5D (EQ-5D),²³ a six-question general health survey. The first five questions (three responses each) result in $3^5=243$ unique responses that can be mapped to time-trade off (TTO) health state utility.²⁴ In both studies, US norms of TTO were used for this mapping. The TTO value extends from -0.3 (indicating very poor health) to 1.0 (indicating perfect health).

Both studies included SF-36, a 36-question general health survey that has been used in thousands of studies.²⁵ As confirmed by SPORT authors, SPORT utilized version 1 of SF-36 and the SIJ trials utilized version 2. Both versions assess quality of life in eight subdomains and produce two summary scores (physical component summary [PCS] and mental component summary [MCS]). SF-36 subdomain assessments are identical across versions for four of the eight subdomains; for the other four domains, the survey questions and response categories were modified between versions.²⁶ However, both survey versions report norm-based scores, with values based on popu-

Table 1 Demographic characteristics

	SIJ		SPORT		
	INSITE N=148	SIFI N=171	DS N=607	IDH N=1,244	SPS N=654
Female, Number (%)	103 (69.6%)	119 (69.6%)	418 (68.9%)	522 (42.0%)	254 (38.8%)
Age (years), mean (SD)	51.3 (11.2)	50.8 (11.3)	66.1 (10.3)	41.7 (11.4)	64.6 (11.7)
Body mass index, mean (SD)	30.4 (6.5)	29.3 (6.6)	29.1 (6.2)	28.0 (5.5)	29.4 (5.6)

Abbreviations: DS, degenerative spondylolisthesis; IDH, intervertebral disc herniation; INSITE, Investigation of Sacroiliac Fusion Treatment; SIFI, Sacroiliac Joint Fusion with iFuse Implant System®; SIJ, sacroiliac joint; SPORT, Spine Patient Outcomes Research Trial; SPS, spinal stenosis.

lation means of 50 with standard deviations of 10. With the help of Optum (Lincoln, RI, USA), who owns and administers SF-36, individual values from the SIJ trials utilized version 2 (SIJ) trials were converted to norm-based scores using the same 1998 norms as used by SPORT. These adjustments allowed direct comparison of both summary scales (PCS and MCS) and individual norm-based subdomains.

Statistical methods

After combining data sets, statistical analysis consisted of tabular and graphical summaries. In addition, general linear models were used to compare EQ-5D TTO and SF-36 scores across studies controlling for age, sex, body mass index, and ODI (or MODEMS) scores. Both linear and squared terms

were included in all models. Interaction terms did not add to the model fit and were therefore not used further. For each linear model, the IDH group was chosen as the reference level, since these patients had the highest scores and were youngest. The primary goal of the analysis was to determine the relative differences in quality of life scores among the four diagnoses while controlling for potential baseline covariates. All statistical analysis was done in R.²⁷ Graphical analysis with smoothing was performed using the ggplot2 library.²⁸

Results

Demographic characteristics of trial participants are shown in Table 1. Due to large sample sizes, all baseline demographic characteristics show statistically significant differences

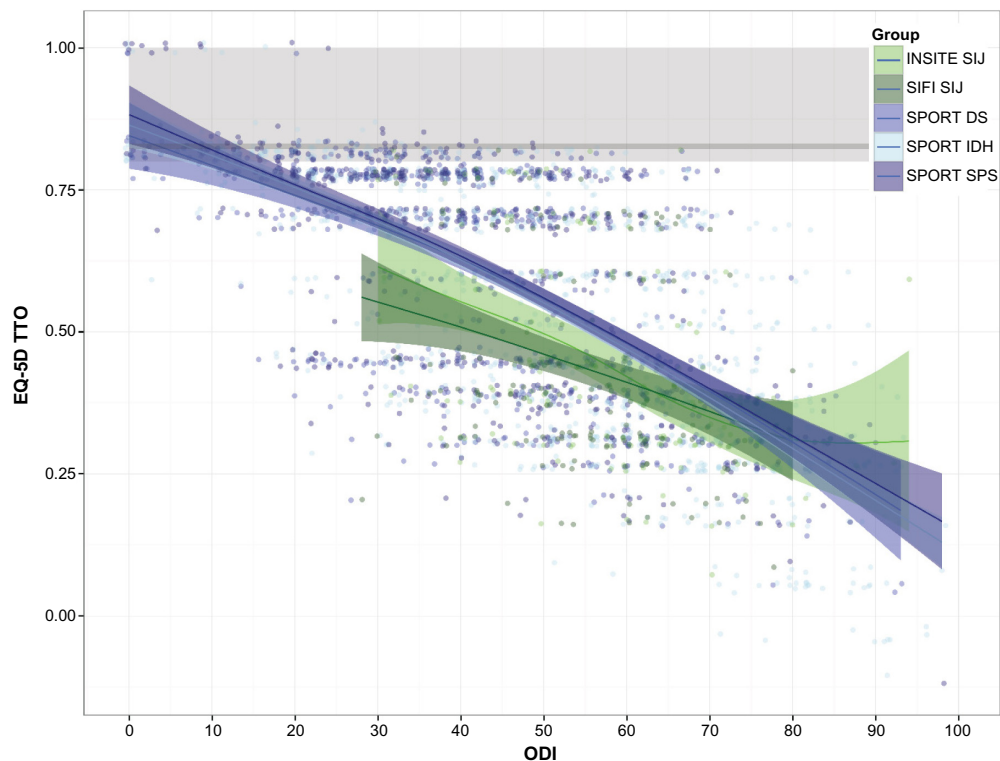


Figure 1 Baseline EQ-5D as a function of baseline ODI scores by trial.

Notes: SIJ trials are shown in green; SPORT trials are shown in blue. Individual patient scores are plotted as points and jittered slightly. Ribbons show family-wise 95% confidence limits (using geom_smooth from ggplot2). Gray line and bars show normal population median (82) and interquartile ranges (80–100).

Abbreviations: DS, degenerative spondylolisthesis; IDH, intervertebral disc herniation; INSITE, Investigation of Sacroiliac Fusion Treatment; ODI, Oswestry Disability Index; SIFI, Sacroiliac Joint Fusion with iFuse Implant System®; SPORT, Spine Patient Outcomes Research Trial; SIJ, sacroiliac joint; SPS, spinal stenosis; TTO, time-trade off.

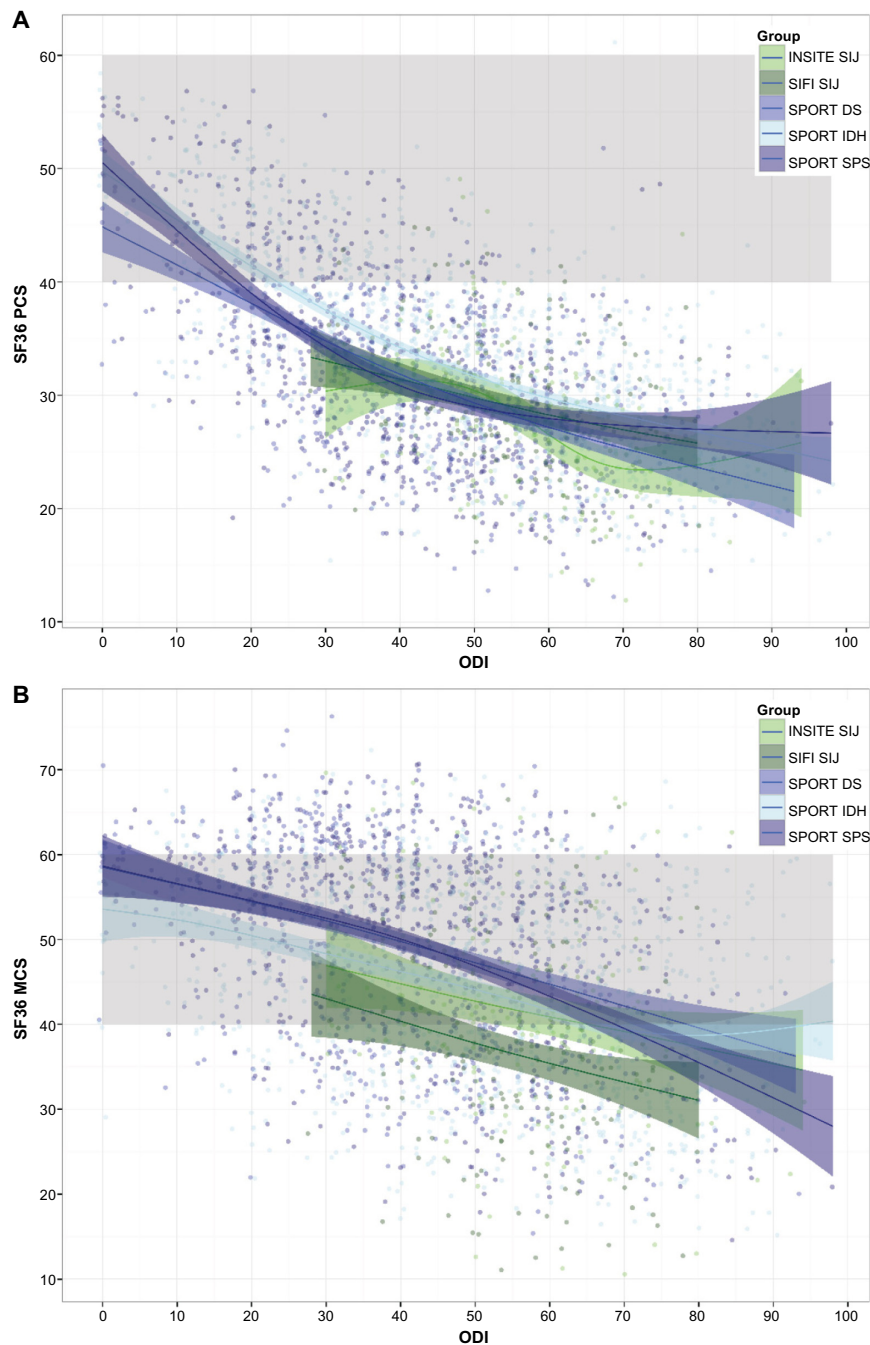


Figure 2 Baseline SF-36 PCS (A) and MCS (B) as a function of baseline ODI scores by trial.

Notes: SIJ trials are shown in green; SPORT trials are shown in blue. Individual patient scores are plotted as points and jittered slightly. Ribbons show family-wise 95% confidence limits (using `geom_smooth` from `ggplot2`). Gray band shows expected range for normal population (50 ± 10) whereby data are presented as mean \pm standard deviation.

Abbreviations: ODI, Oswestry Disability Index; INSITE, Investigation of Sacroiliac Fusion Treatment; SIFI, Sacroiliac Joint Fusion with iFuse Implant System®; SPORT, Spine Patient Outcomes Research Trial; MCS, mental component summary; SIJ, sacroiliac joint; DS, degenerative spondylolisthesis; IDH, intervertebral disc herniation; SPS, spinal stenosis; PCS, physical component summary.

across studies. Across the studies, IDH participants were younger, DS and SPS patients were older, and IDH and SPS participants were less likely to be female.

EQ-5D TTO had a modest but statistically significant ($P < 0.0001$ each) linear relationship to age (increase of 0.002 points per year) and sex (0.05 points higher for men

vs women). Not surprisingly, EQ-5D TTO strongly correlated with ODI (Pearson $r = -0.687$, $P < 0.0001$, Figure 1), with increasing disability (higher ODI) showing decreased quality of life (lower EQ-5D TTO index). At any ODI level, EQ-5D TTO scores were lower for the SIJ trial subjects compared to SPORT subjects. To compare mean EQ-5D

Table 2 SF-36 norm-based subdomain scores, raw mean (SD)

	SIJ		SPORT		
	INSITE	SIFI	DS	IDH	SPS
PF	25.5 (8.0)	24.6 (6.7)	29.5 (9.4)	31.1 (10.7)	29.7 (9.8)
BP	28.4 (4.8)	28.5 (5.2)	34.2 (8.2)	31.5 (8.6)	34.3 (8.5)
GH	43.3 (10.0)	44.5 (9.7)	48.8 (9.1)	50.4 (8.8)	48.1 (9.1)
RP	26.4 (8.2)	26.3 (7.5)	33.1 (8.6)	31.7 (7.7)	33.3 (9.0)
RE	33.3 (14.4)	29.1 (14.7)	42.5 (13.7)	40.5 (14.0)	42.1 (14.2)
VT	39.0 (9.8)	34.6 (8.7)	43.5 (10.5)	41.3 (9.6)	43.1 (10.4)
SF	29.9 (10.1)	28.1 (9.5)	39.1 (12.2)	33.2 (12.2)	38.3 (12.1)
MH	41.8 (11.6)	38.3 (12.1)	47.1 (10.7)	43.1 (11.4)	46.8 (11.4)

Abbreviations: BP, bodily pain; DS, degenerative spondylolisthesis; GH, general health; IDH, intervertebral disc herniation; INSITE, Investigation of Sacroiliac Fusion Treatment; MH, mental health; PF, physical function; RE, role emotional; RP, role physical; SF, social functioning; SIFI, Sacroiliac Joint Fusion with iFuse Implant System®; SIJ, sacroiliac joint; SPORT, Spine Patient Outcomes Research Trial; SPS, spinal stenosis; VT, vitality.

TTO values across trials, multivariate linear regression was performed controlling for age (including a term for age²), sex, body mass index, and ODI score (including ODI²). Compared to the IDH group, mean EQ-5D TTO scores were depressed by 0.023 and 0.01 points in the DS and SPS groups ($P=0.0276$ and 0.1461) respectively, and 0.057 and 0.084 points in the two SIJ groups ($P<0.0001$ each). In all populations, EQ-5D scores were substantially lower than population norms.²⁹

Similar to EQ-5D, SF-36 PCS and MCS showed the modest correlations with age (Pearson r of -0.63 , $P=0.0008$ and r of -0.156 , $P<0.0001$, respectively) and sex (2.5 points higher each for men vs women, $P<0.0001$) and strong associations with ODI scores (Pearson r -0.596 and -0.405 , respectively, Figure 2). At any level of ODI, PCS scores were similar between the SIJ and SPORT populations, but MCS scores were lower in the SIJ trials. In similar multivariate regressions, compared to IDH, mean PCS scores were lower by 0.786 and 0.667 points in the DS and SPS groups ($P=0.0523$ and 0.0829 , respectively), and mean PCS scores were 2.07 and 1.02 points lower in the two SIJ groups ($P=0.0002$ and 0.0512 , respectively). Compared to IDH, mean MCS scores were higher by 2.0 and 1.17 points in the DS and SPS groups ($P=0.0067$ and 0.0932) and 1.17 and 6.43 points lower in the two SIJ groups ($P=0.2476$ and <0.0001).

Norm-based SF-36 subdomain scores were low for all groups (Table 2). Figure 3 shows multivariate regression coefficients for the difference in means for each subdomain from the IDH reference group by study controlling for the same factors as in other regressions. Adjusting for differences in demographic characteristics and ODI, most subdomains showed lower scores in the SIJ cohorts compared to both IDH (reference group) and the other non-SIJ cohorts.

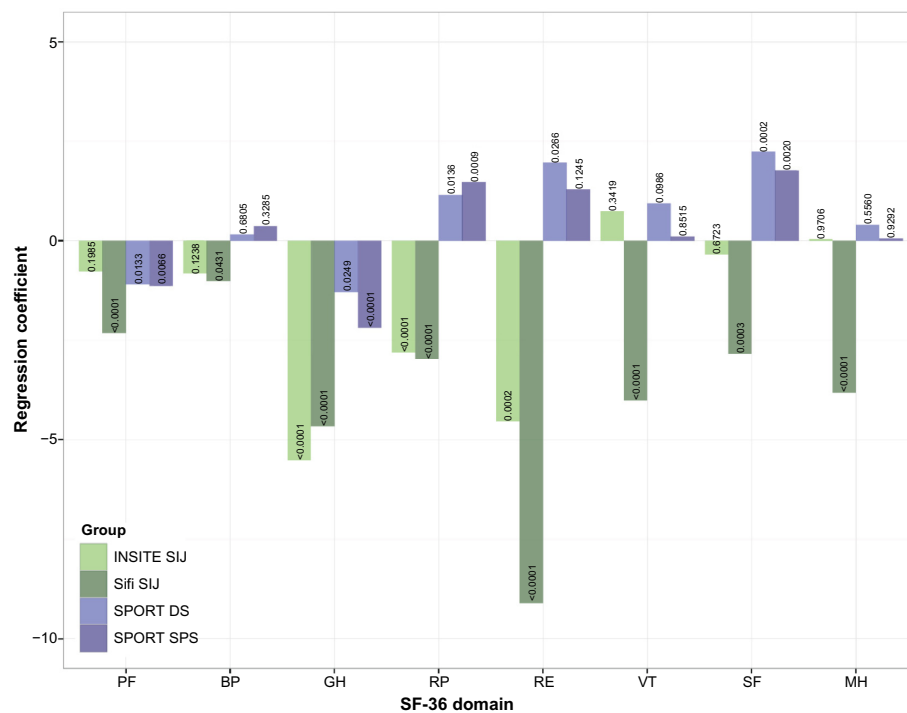


Figure 3 Multivariate regression coefficients for SF-36 subdomains by domain and study (IDH as reference group).

Notes: All regressions controlled for age, age², sex, BMI, ODI, and ODI². Small numbers in bars indicate P -value for regression coefficient.

Abbreviations: BMI, body mass index; BP, bodily pain; DS, degenerative spondylolisthesis; IDH, intervertebral disc herniation; GH, general health; INSITE, Investigation of Sacroiliac Fusion Treatment; MH, mental health; ODI, Oswestry Disability Index; PF, physical function; RE, role emotional; RP, role physical; SPORT, Spine Patient Outcomes Research Trial; SPS, spinal stenosis; SIFI, Sacroiliac Joint Fusion with iFuse Implant System®; SIJ, sacroiliac joint; SF, social functioning; VT, vitality.

Discussion

Chronic low back pain is a costly and complex illness that markedly impairs quality of life and is unquestionably associated with high annual health care expenditures. Pathology of the SIJ, resulting in SIJ dysfunction, is a common cause of low back pain. Unfortunately, due to a historical lack of effective surgical treatments for SIJ dysfunction, the condition has, until recently, been largely ignored by the surgical community. With the availability and increasing popularity³⁰ of minimally invasive surgical techniques to treat the SIJ, interest in the impact of SIJ dysfunction has increased.

In a previous report based on the SIJ trials examined herein,²¹ we compared health utility values in the same SIJ cohorts to both a normal cohort as well as reported health state utilities available through a national clearinghouse of utilities used in published cost-effectiveness analyses. The decrement in health quality associated with SIJ dysfunction was marked and consistent with major diseases, such as liver cirrhosis and chronic obstructive pulmonary diseases, and slightly more burdensome than lumbar stenosis and DS. Moreover, observed values for the SIJ population were similar to those reported in other prominent spinal and other orthopedic (eg, hip and knee osteoarthritis) conditions for which surgery is commonly provided.

In the current study, we extend these findings by directly comparing individual patient health quality of life scores across two sets of prospective clinical trials involving patients with either SIJ dysfunction or three common spine conditions (DS, SPS, and IDH). This analysis showed that the decrement in health state utility for SIJ dysfunction was at least as severe as those seen in DS, SPS, and IDH. In most cases, the decrement was larger. This analysis confirms prior work and suggests that SIJ dysfunction is a cause of prominent decrements in quality of life at least as severe as those in other spinal conditions for which surgery is commonly provided. As SIJ dysfunction may be misdiagnosed as a degenerative spine condition, it is important that surgeons carefully examine and distinguish the cause of chronic lower back pain so as to provide treatments directed at the correct underlying disease.

Not surprisingly, quality of life measurements (EQ-5D and SF-36 scores) were strongly inversely correlated with ODI disability scores. Although ODI scores varied between trials, our analyses comparing baseline quality of life values in these trials controlled for individual ODI scores. In multivariate analyses that also accounted for baseline demographic factors, quality of life scores were as depressed in all cases and more depressed in most cases in the SIJ cohorts compared to the other cohorts.

Advantages of our study are as follows. The primary input data for the analysis consist of two carefully performed sets of large, multicenter prospective trials, including four randomized controlled trials and one single-arm study. Both study sets had large sample sizes, represent multicenter experience, and employed similar assessment tools. Both study sets focused on diseases of the lower back for which surgical treatments are commonly provided.

Limitations of our findings include the following. Studies were performed in different time periods (the SIJ studies enrolled subjects in the 2012–2015 time frame, whereas SPORT studies enrolled subjects in the early 2000s). The two study sets used slightly different versions of ODI and SF-36 surveys. However, the version differences were accounted for by using norm-based scores (for SF-36) and adjusting to the same normal population (1998 norms).

Conclusion

Based on individual data from multicenter clinical trials, the decrement in quality of life in patients with SIJ dysfunction is as or more marked compared to patients with DS, SPS, and IDH.

Acknowledgments

This paper was not prepared in collaboration with investigators of SPORT and does not necessarily reflect the opinions or conclusions of SPORT investigators.

Disclosure

DJC and WCR are SI-BONE employees. The authors report no other conflicts of interest in this work.

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Table SI Eligibility criteria for SIJ and SPORT studies**SIJ studies****SIFI: NCT01640353****INSITE: NCT01681004****Inclusion criteria**

1. Age 21–70 years at time of screening
2. Patient has lower back pain for >6 months inadequately responsive to conservative care
3. Diagnosis of sacroiliac joint disruption or degenerative sacroiliitis based on ALL of the following:
 - a) Patient has pain at or close to the posterior superior iliac spine with possible radiation into buttocks, posterior thigh or groin and can point with a single finger to the location of pain (Fortin Finger Test)
 - b) Patient has at least three of five physical examination maneuvers specific for the SIJ
 - c) Patient has improvement in lower back pain numeric rating scale of at least 50% after injection of local anesthetic into affected SIJ(s)
 - d) One or more of the following:
 - i. SIJ disruption: Asymmetric SIJ widening on X-ray or CT scan or leakage of contrast on diagnostic arthrography
 - ii. Degenerative sacroiliitis: Radiographic evidence of SIJ degeneration, including sclerosis, osteophytes, subchondral cysts, or vacuum phenomenon on CT or plain film, or due to prior lumbosacral spine fusion
4. Baseline Oswestry Disability Index score of at least 30%
5. Baseline SIJ pain score of at least 50 on 0–100 mm visual analog scale
6. Patient has signed study-specific informed consent form
7. Patient has the necessary mental capacity to participate and is physically able to comply with study protocol requirements

Exclusion criteria

1. Severe back pain due to other causes, such as lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, and lumbar vertebral body fracture
2. Other known sacroiliac pathology such as
 - a) Sacral dysplasia
 - b) Inflammatory sacroiliitis (eg, ankylosing spondylitis or other HLA-associated spondyloarthropathy)
 - c) Tumor
 - d) Infection
 - e) Acute fracture
 - f) Crystal arthropathy
3. History of recent (<1 year) major trauma to pelvis
4. Previously diagnosed osteoporosis (defined as prior T-score <−2.5 or history of osteoporotic fracture)
5. Osteomalacia or other metabolic bone disease
6. Chronic rheumatologic condition (eg, rheumatoid arthritis)
7. Any condition or anatomy that makes treatment with the iFuse Implant System® infeasible
8. Chondropathy
9. Known allergy to titanium or titanium alloys
10. Use of medications known to have detrimental effects on bone quality and soft-tissue healing
11. Prominent neurologic condition that would interfere with physical therapy
12. Current local or systemic infection that raises the risk of surgery
13. Patient currently receiving or seeking worker's compensation, disability remuneration, and/or involved in injury litigation
14. Currently pregnant or planning pregnancy in the next 2 years
15. Patient is a prisoner or a ward of the state
16. Known or suspected drug or alcohol abuse
17. Diagnosed psychiatric disease (eg, schizophrenia, major depression, personality disorders) that could interfere with study participation
18. Patient is participating in an investigational study or has been involved in an investigational study within 3 months prior to evaluation for participation

SPORT, Intervertebral Disc Herniation: NCT00000410**Inclusion criteria**

1. Duration of symptoms: 6 or more weeks
2. Treatments tried: Non-steroidal anti-inflammatory medical therapy and physical therapy
3. Surgical screening: Persistent radicular pain provoked by moderate exercise, sitting, increased abdominal pressure, decreased mobility, list (scoliosis), straight leg raising
4. Tests: MRI to confirm diagnosis and level(s)

Exclusion criteria

1. Previous lumbar spine surgery
2. Not a surgical candidate for any of these reasons: Overall health which makes spinal surgery too life-threatening to be an appropriate alternative, dramatic improvement with conservative care, or inability (for any reason) to undergo surgery within 6 months
3. Possible pregnancy
4. Active malignancy: A patient with a history of any invasive malignancy (except non-melanoma skin cancer) is ineligible unless he or she has been treated with a curative intent AND there has been no clinical signs or symptoms of the malignancy for at least 5 years

(Continued)

Table S1 (Continued)

5. Current fracture, infection, and/or deformity (greater than 15° of lumbar scoliosis, using Cobb measure technique) of the spine
6. Age less than 18 years
7. Cauda Equina syndrome or progressive neurological deficit (usually requiring urgent surgery)
8. Unavailability for follow-up (planning to move, no telephone, etc) or inability to complete data surveys
9. Symptoms less than 6 weeks
10. Patient currently enrolled in any experimental “spine-related” study

SPORT, Degenerative Spondylolisthesis: NCT00000409**Inclusion criteria**

1. Duration of symptoms: 12 or more weeks
2. Treatments tried: Nonsteroidal anti-inflammatory medical therapy and physical therapy
3. Surgical screening: Pain in low back, buttocks, or lower extremity that becomes worse with lumbar extension. Must be confirmed by evidence of central or central-lateral compression of the cauda equina by a degenerative lesion of the facet joint, disc, or ligamentum flavum on MRI, computed tomography scans, or myelograms
4. Tests: MRI to confirm diagnosis and level(s)

Exclusion criteria

1. Previous lumbar spine surgery
2. Not a surgical candidate for any of these reasons: Overall health that makes spinal surgery too life-threatening to be an appropriate alternative, patient has improved dramatically with conservative care, or the patient is unable (for any reason) to undergo surgery within 6 months
3. Possible pregnancy
4. Active malignancy: Patients with a history of any invasive malignancy (except non-melanoma skin cancer) are ineligible unless they have been treated with curative intent AND have not had any clinical signs or symptoms of the malignancy for at least 5 years
5. Current fracture, infection, and/or deformity (greater than 15° of lumbar scoliosis, using Cobb measure technique) of the spine
6. Age less than 18 years
7. Cauda Equina syndrome or progressive neurologic deficit (usually requiring urgent surgery)
8. Unavailability for follow-up (planning to move, no telephone, etc) or inability to complete data surveys
9. Symptoms less than 12 weeks
10. Patient currently enrolled in any experimental “spine-related” study

SPORT, Spinal Stenosis: NCT00000411**Inclusion criteria**

1. Duration of symptoms: 12 or more weeks
2. Treatments tried: Nonsteroidal anti-inflammatory medical therapy and physical therapy
3. Surgical screening: Pain in low back, buttocks, or lower extremity that becomes worse with lumbar extension. Must be confirmed by evidence of central or central-lateral compression of the cauda equina by a degenerative lesion of the facet joint, disc, or ligamentum flavum on MRI, computed tomography scans, or myelograms
4. Tests: MRI to confirm diagnosis and level(s)

Exclusion criteria

1. Previous lumbar spine surgery
2. Not a surgical candidate for any of these reasons: Overall health that makes spinal surgery too life-threatening to be an appropriate alternative, patient has improved dramatically with conservative care, or the patient is unable (for any reason) to undergo surgery within 6 months
3. Possible pregnancy
4. Active malignancy: Patients with a history of any invasive malignancy (except non-melanoma skin cancer) are ineligible unless they have been treated with curative intent AND have not had any clinical signs or symptoms of the malignancy for at least 5 years
5. Current fracture, infection, and/or deformity (greater than 15° of lumbar scoliosis, using Cobb measure technique) of the spine
6. Age less than 18 years
7. Cauda Equina syndrome or progressive neurologic deficit (usually requiring urgent surgery)
8. Unavailability for follow-up (planning to move, no telephone, etc) or inability to complete data surveys
9. Symptoms less than 12 weeks
10. Patient currently enrolled in any experimental “spine-related” study

Abbreviations: CT, computed tomography; HLA, human leukocyte antigen; INSITE, Investigation of Sacroiliac Fusion Treatment; MRI, magnetic resonance imaging; SIFI, Sacroiliac Joint Fusion with iFuse Implant System®; SJJ, sacroiliac joint; SPORT, Spine Patient Outcomes Research Trial.

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