

Sacroiliac joint fusion

Draft key questions: public comment and response

July 16, 2018

Health Technology Assessment Program (HTA)

Washington State Health Care Authority

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Public Comments Submitted

The State of Washington’s Health Technology Assessment Program posted for public comment the draft key questions and proposed scope for a health technology assessment (HTA) on the topic of “Sacroiliac Joint Fusion” between June 20, 2018 and July 5, 2018. **Table 1** lists the comments received and submitting individual/organization.

Table 1. Number of Comments Received on Draft Key Questions on Sacroiliac Joint Fusion HTA

Comment Number	Name and Title	Organization	Location
1	Daniel Cher, MD Vice President of Clinical Affairs	SI-BONE, Inc	San Jose, California
2	Catherine Jeakle Hill Senior Manager Regulatory Affairs	On behalf of: <ul style="list-style-type: none"> • American Association of Neurological Surgeons • Congress of Neurological Surgeons • Washington State Association of Neurological Surgeons 	Various

Summary of Comments and Response

Most comments provided did not suggest any changes to the key questions or scope of the review. The comments are summarized in **Table 2**.

Table 2. Summary of Comments Received on Sacroiliac Joint Fusion Draft Key Questions

Comment Number	Name and Title	Summary of comment	Response
1	Daniel Cher, MD Vice President of Clinical Affairs	This commenter provided a 16-page document summarizing the evidence for use of the iFUSE Implant System for each of the draft key questions. No changes or revisions to the draft key questions were suggested by the commenter.	Thank you for the information.
2	Catherine Jeakle Hill Senior Manager Regulatory Affairs	This commenter provided a 3-page letter in response to the draft key questions. The commenter suggests that post-operative referral to an acute or sub-acute rehabilitation facility may be a better measure than length of stay. No other suggestions for changes to the key questions or scope were offered.	We have added “referral to acute or sub-acute rehabilitation facility” as an efficacy outcome for EQ1a.

Comment Number	Name and Title	Summary of comment	Response
		The commenter also expressed a general concern about the 14-day comment period being too short, particularly when the comment period falls over a holiday.	We will refer this comment to the state's HTA Program Office.

From: [Daniel Cher](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: comments on sacroiliac joint fusion questions document
Date: Friday, June 29, 2018 4:30:41 PM
Attachments: [Comments Sacroiliac Joint Fusion DJCher.pdf](#)

Dear sir/madam:

I am vice president of clinical affairs at SI-BONE, Inc., in Santa Clara, CA. SI-BONE manufactures implants for sacroiliac joint (SIJ) fusion.

I am writing in response to Washington State's call for public comments on sacroiliac joint (SIJ) fusion as published at the link below. I hope my comments are helpful.

<https://www.hca.wa.gov/about-hca/health-technology-assessment/sacroiliac-joint-fusion>

Efficacy question 1 (EQ 1). What is the effectiveness and comparative effectiveness of sacroiliac joint fusion surgery on health outcomes?

Effectiveness of SIJ fusion surgery using triangular titanium implants (iFuse Implant System) on health outcomes has been documented in a large number of clinical trials, including:

- Two prospective, multicenter randomized controlled trials against non-surgical treatment
- One large prospective multicenter single-arm clinical trial
- An individual patient-level pooled analysis of the above two sets of evidence
- Several comparative case series
- Several single center and multicenter retrospective case series

A small number of publications (but no randomized trials) have suggested that devices other than triangular titanium implants may also be effective. Please note that most commercial health plans cover only SIJ fusion using triangular titanium implants because of the high level of clinical evidence and the lack of effectiveness, safety, revision and economic data on other products.

I have summarized each clinical study using triangular titanium implants briefly in a section below called "Summary of Studies". Taken together, these data allow the following conclusions:

- SIJ fusion produces marked, immediate and sustained improvement in SIJ pain vs. very little change in the same parameter for non-surgical treatment
- SIJ fusion produces marked, immediate and sustained improvement in disability as measured by Oswestry Disability Index vs. very little change in the same parameter for non-surgical treatment
- SIJ fusion produces marked, immediate and sustained improvement in quality of life as measured by both SF-36 and EuroQOL-5D vs. very little change in the same parameters for non-surgical treatment
- SIJ fusion reduces opioid usage
- SIJ fusion may improve worker productivity
- Ignoring the SIJ in the diagnosis of low back pain is likely to result in poorer health outcomes and increased expenditures (~\$3,100 per chronic low back pain patient over 2 years)
- Findings from clinical trials were replicated in real-world comparisons of SIJ fusion vs. non-surgical treatment
- Increasing evidence to support long-term efficacy

Justification for Trial Design

When discussing clinical trial design with study investigators in 2012, SI-BONE decided not to do a sham-controlled randomized trial in either the US or Europe for the following reasons:

- The device (iFuse Implant System) was already commercially available in both geographies.
- Physicians believed that a trial that included a sham surgery arm was unethical and would not have passed review by an institutional review board.
- Patients in their clinics would be very unlikely to participate in a study with a sham arm. Any patient indicating a desire to participate in such a study would likely have been far different from the typical patient, greatly limiting generalizability.

We therefore decided to include as control groups the following:

- In the US, maximal non-surgical therapy, consisting of medication optimization, physical therapy, SIJ steroid injections and RF ablation of the SIJ
- In Europe, conservative treatment, consisting of prolonged physical therapy and medication optimization with optional cognitive behavioral therapy

I note that:

- No high-quality evidence supports the use of SIJ steroid injections.
- No high-quality evidence supports long-term efficacy of RF ablation (2 of 4 blinded randomized trials show short-term benefits of RF ablation for SIJ pain)
- In the two randomized trials of SIJ fusion vs. non-surgical treatment, we observed minimal responses in the non-surgical groups.

Efficacy question 1a (EQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

By intermediate efficacy outcomes, I assume Washington State means pain and/or disability relief and improvement in quality of life. Radiographic endpoints (specifically, radiographic fusion) in spine surgery may not be predictive of long-term health outcomes.

A few case series have compared outcomes of open SIJ fusion surgery and minimally invasive SIJ fusion surgery with iFuse Implant System. These show that:

- Minimally invasive SIJ fusion surgery with triangular titanium implants produces better healthcare outcomes
- Minimally invasive SIJ fusion surgery with triangular titanium implants results in far shorter hospital lengths of stay

Please note that no study has directly or indirectly compared open SIJ fusion surgery against non-surgical treatment. Studies supporting open SIJ fusion are scattered, of small sample sizes, and use a large variety of techniques. Most surgeons no longer perform SIJ fusion surgery because recovery times are very long and satisfaction rates highly variable.

Safety question 1 (SQ 1). What is the safety of sacroiliac joint fusion surgery?

Prospective randomized controlled trials have shown that SIJ fusion surgery using triangular titanium implants (iFuse Implant System) carries a low risk of device-related adverse events. Overall event rates between the surgery and non-surgery groups were not statistically different.

The most common device-related adverse event is inadequate final implant placement.

- Implants placed too deeply into the sacrum can irritate local nerves, causing new onset radicular pain. This pain typically resolved when implants are pulled back. This event occurs at a rate of ~1%. Use of cross-sectional imaging may reduce this rate.
- Implants placed insufficiently into the sacrum may cause inadequate pain relief due to lack of complete stabilization.

Implant failures (breakage) and device migration have not been seen to date.

Procedure-related adverse events were uncommon and easily treated.

Safety question 1a (SQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

SIJ fusion can now be performed with numerous FDA-cleared devices. However:

- No studies directly comparing safety outcomes have been published or, to my knowledge, are in process.
- Other than triangular titanium implants (iFuse) no study has directly compared results of its technology or technique against either other techniques or non-surgical treatment.

In general SIJ fusion surgeries are brief and have good safety profiles.

Cost question 1 (CQ 1). What is the cost and cost-effectiveness of sacroiliac joint fusion surgery? In addition, we will address the following contextual questions:

The cost-effectiveness of SIJ fusion surgery using iFuse Implant System was addressed as part of a US multicenter prospective randomized controlled trial.¹ Based on Medicare cost estimates and health utilities derived from this randomized trial, the direct healthcare cost per QALY gained as \$13,313. This is in the same range as hip and knee replacement surgery.

The cost-effectiveness of other devices has not been demonstrated or, to my knowledge, investigated.

Contextual questions:

1. What are the recommended ways to diagnose SI joint pain or disruption, and what is the accuracy of various diagnostic tests?

SIJ pain is typically diagnosed via a combination of history, physical examination and diagnostic SIJ block, combined with imaging to rule out other causes. This was covered in the Washington State document. Briefly:

- **History:** Patients typically report off-center low back pain with radiation into the buttocks, groin or legs. Pain is often worse with sitting on the affected side, driving over bumps and rolling over in bed.
- **Physical examination.** Physicians typically perform a series of 5 or more physical examination maneuvers that stress the SIJ and reproduce typical SIJ pain. The predictive accuracy of 3 or more positive tests is high, as per a meta-analysis,² with a sensitivity of 85%, specificity of 76% and diagnostic odds ratio of 17. Another meta-analysis stated that clinical examination maneuvers for SIJ pain are amongst the most accurate clinical tests for low back pain diagnosis.³
- **Diagnostic SIJ block.** As described by the Washington State document, diagnostic block with injection of local anesthetic into the affected joint causing a marked acute reduction in typical pain is universally used. In contrast to comments in the Washington State document, this test is not expensive or invasive. Diagnostic blocks are commonly used and commonly available.
- **Radiographic imaging.** Imaging is performed typically to rule out other causes of low back pain. The accuracy of radiographic imaging for lumbar spine conditions is notoriously poor,^{4,5} so the degree to which imaging rules out other causes of low back pain is unclear.

2. What is known about the frequency of various diagnostic approaches to SI joint pain or disruption in usual clinical practice?

In my interactions with physicians providing SIJ fusion, nearly all use the diagnostic algorithm described above.

Please see the “Summary of Studies” section below. Please do not hesitate to contact me with questions.

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Summary of Studies

1 Randomized Trials

Two randomized trials of SIJ fusion with triangular titanium implants (iFuse Implant System) vs. non-surgical treatment have been published to date.

1.1 INSITE Study

INSITE is a prospective randomized controlled trial at 19 centers across the United States. Eligible patients were randomly assigned to either non-surgical management of SI joint fusion using iFuse Implant System. 2-year follow-up was published in 2016.⁶ The study showed marked, immediate and sustained improvement in low back pain (SI joint pain), back function as measured by Oswestry Disability Index (Figure 1) and quality of life with two measures. These are cardinal measures of SI joint pain. All measures were statistically superior in the surgery group compared to non-surgical treatment. Improvements in the non-surgical group were minimal, meaning that non-surgical treatment was both expensive and of no value.

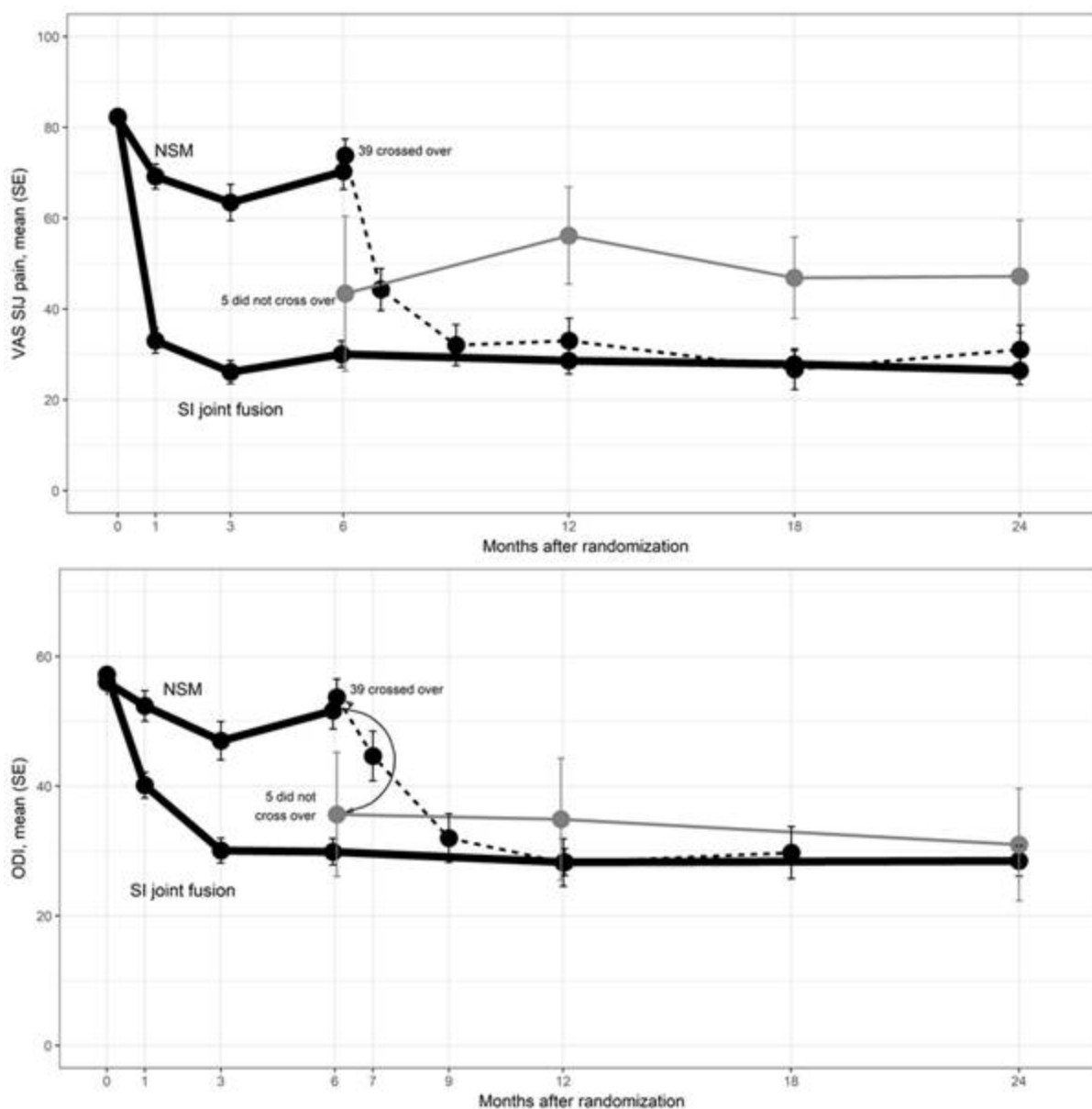


Figure 1. Improvements in SI joint pain (top) and disability (bottom) in INSITE subjects undergoing either non-surgical management (NSM) or SI joint fusion with iFuse Implant System.

In summary, compared to non-surgical management:

- SI joint fusion subjects had **larger improvement in back pain**
- SI joint fusion subjects had **larger improvements in disability related to back pain**
- SI joint fusion subjects had **larger improvements in quality of life**
- SI joint fusion subjects had higher satisfaction rates and would more likely undergo the assigned treatment
- SI joint fusion subjects were more likely to cease opioid use

1.2 iMIA Study

iMIA is a prospective multicenter randomized trial conducted at 9 centers in Europe. Eligible patients with SI joint pain were randomly assigned to SI joint fusion or conservative management (CM, consisting primarily of physical therapy). 24-month follow-up shows marked superiority of SI joint fusion over CM in pain relief (Figure 2) and functional tests (Figure 3). A number of other items (global comparisons,

walking distance, satisfaction) were also superior in the SI joint fusion group compared to conservative treatment (Figure 4). The proportion of patients using opioids decreased 40% in the surgical group but not the non-surgical group (Figure 5).

A 12-month manuscript was recently published⁷ and a 24-month manuscript is under review. In summary, compared to conservative management:

- SI joint fusion subjects had larger improvement in back and leg pain.
- SI joint fusion subjects had larger improvements in disability related to back pain
- SI joint fusion subjects had **larger improvements in quality of life**
- SI joint fusion subjects had **decreases in depression scores**
- SI joint fusion subjects had **better pelvis function (active straight leg raise test)**
- SI joint fusion **subjects could walk further**
- SI joint fusion subjects were **less likely to take opioids**
- SI joint fusion subjects were less likely to be not working due to back pain
- SI joint fusion subjects reported more overall improvement
- SI joint fusion subjects had higher satisfaction rates and would more likely to undergo the assigned treatment

In each parameter, improvements after SI joint fusion were sustained at 2 years.

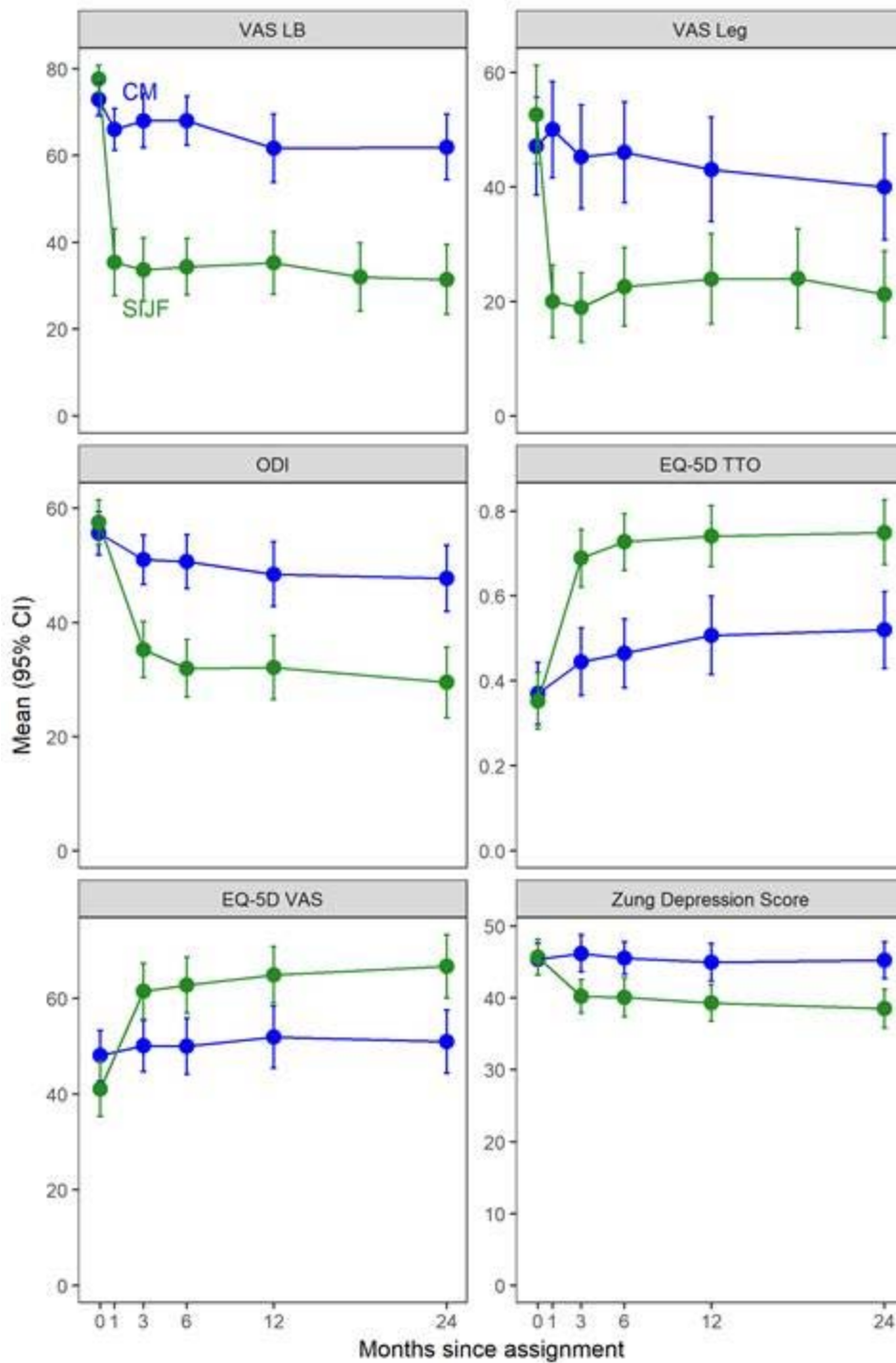


Figure 2. iMIA study: Change in visual analog scale (VAS) low back (LB) pain, leg pain, Oswestry Disability Index, EuroQOL-5D time trade-off (TTO) and VAS, and Zung Depression Scale scores. Blue = CM, green = SI joni fusion.

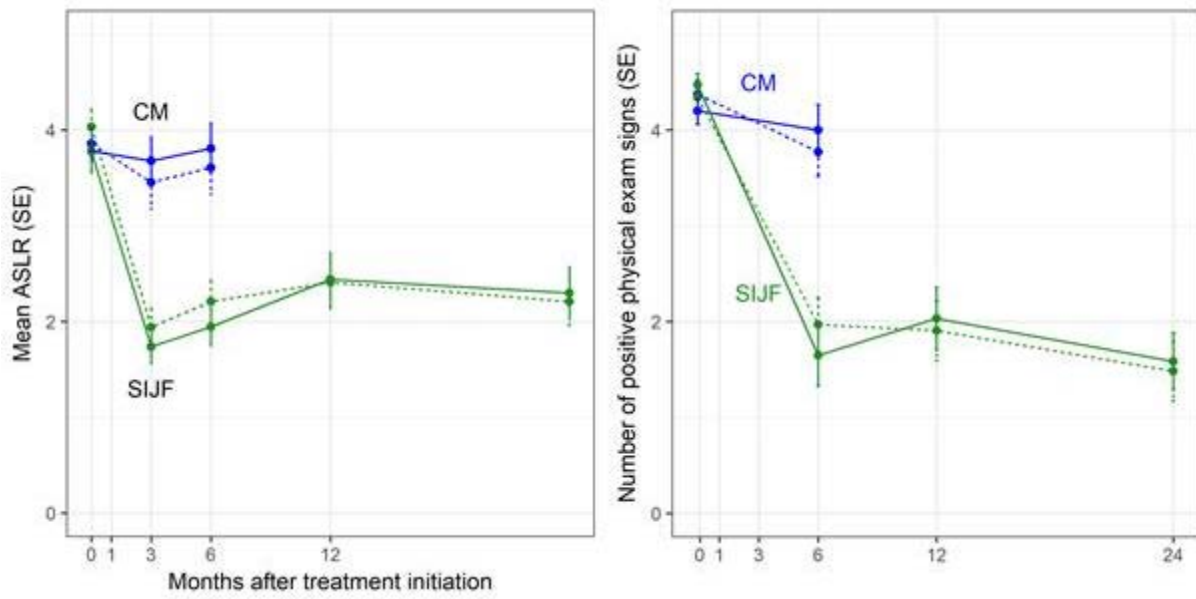


Figure 3. iMIA study: Improvement in functional test (active straight leg raise test) by treatment and time (left) and number of positive physical examination signs (right).

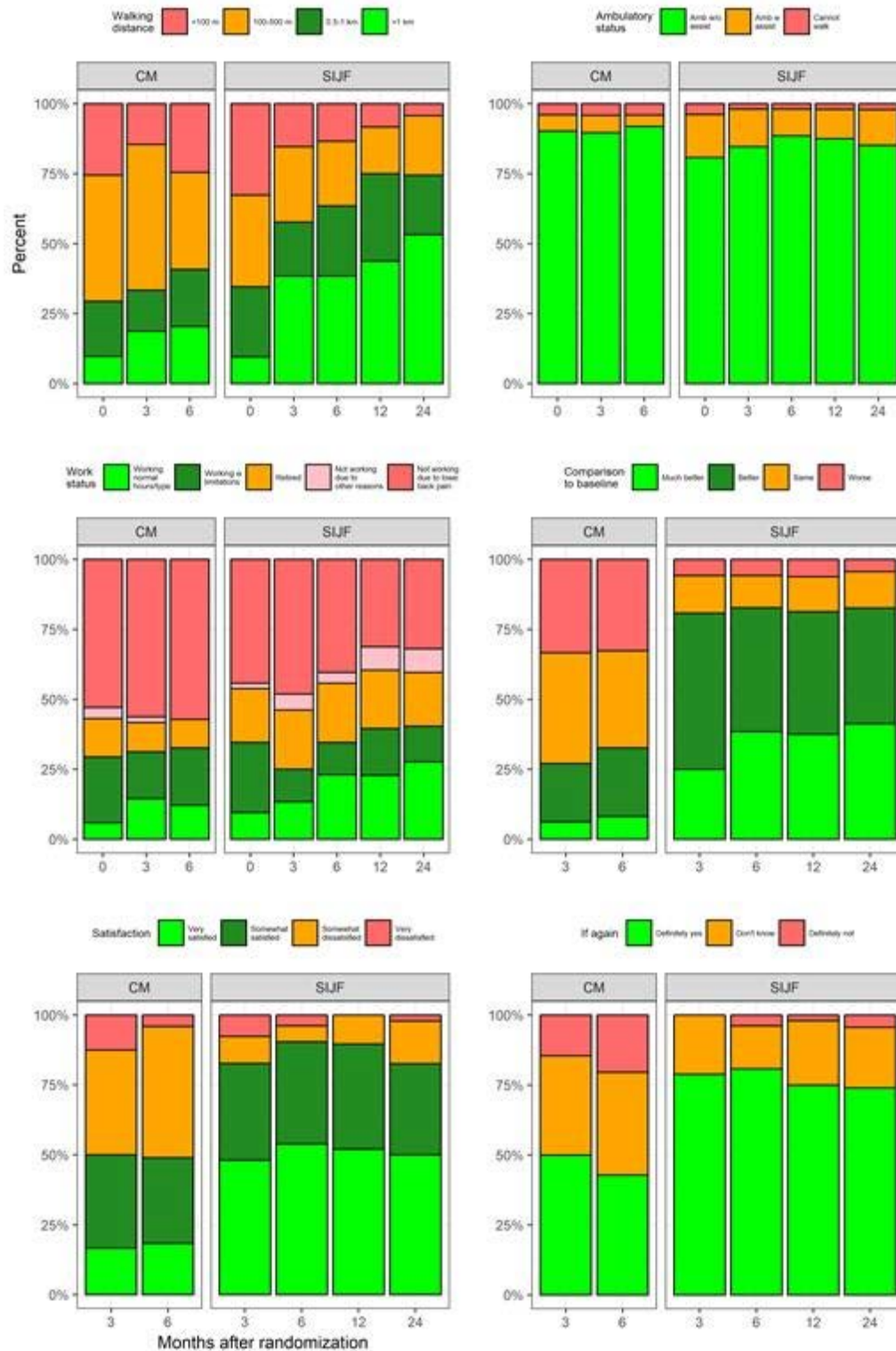


Figure 4. iMIA study: Improvement in walking distance, ambulatory status, work status, comparison to baseline, satisfaction and desirability of having surgery again by treatment and follow-up visit.

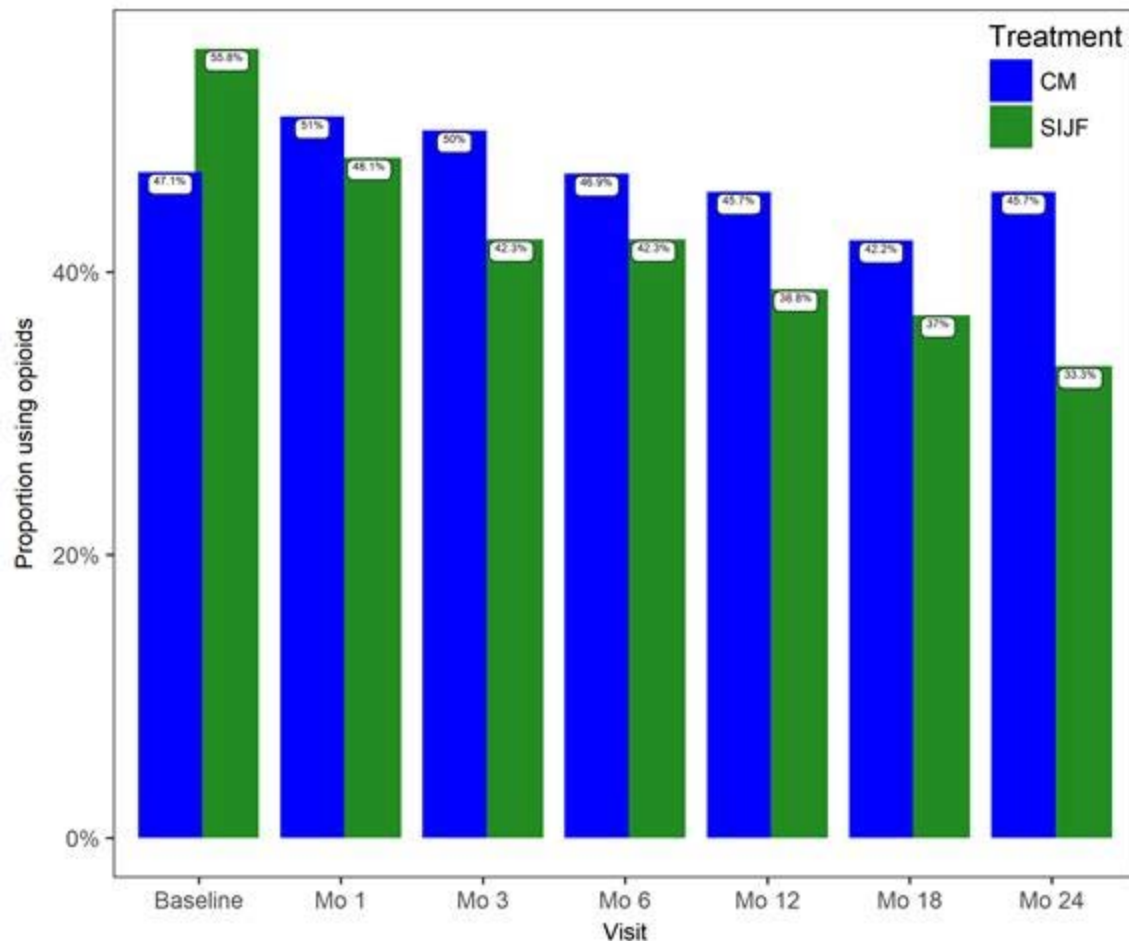


Figure 5. Proportion of iMIA subjects using opioids at each study visit by treatment. The proportion decreased significantly in the surgical group (green) but not in the conservative management group (blue).

2 Prospective Trials

2.1 SIFI Study

SIFI is a prospective multicenter single-arm study of SI joint fusion for patients with SI joint pain.⁸ Enrollment criteria were similar to INSITE. This study also showed improvement in back pain, disability and quality of life.

A subgroup analysis from this study showed that women whose SIJ pain began in the postpartum period had excellent responses to treatment.⁹ These patients are younger on average than the overall SIFI cohort.

3 Pooled Analysis

A pooled analysis of the 3 prospective trials listed above was recently published in the prestigious journal *Spine*.¹⁰ This analysis included 326 trial subjects who underwent SI joint fusion and 97 who underwent non-surgical treatment. A pooled analysis plot is shown in Figure 6. This plot was the basis of the *Spine* manuscript. The data show:

- Marked consistency across studies
- Large improvements in the SI joint fusion group
- Small changes in the non-surgical groups

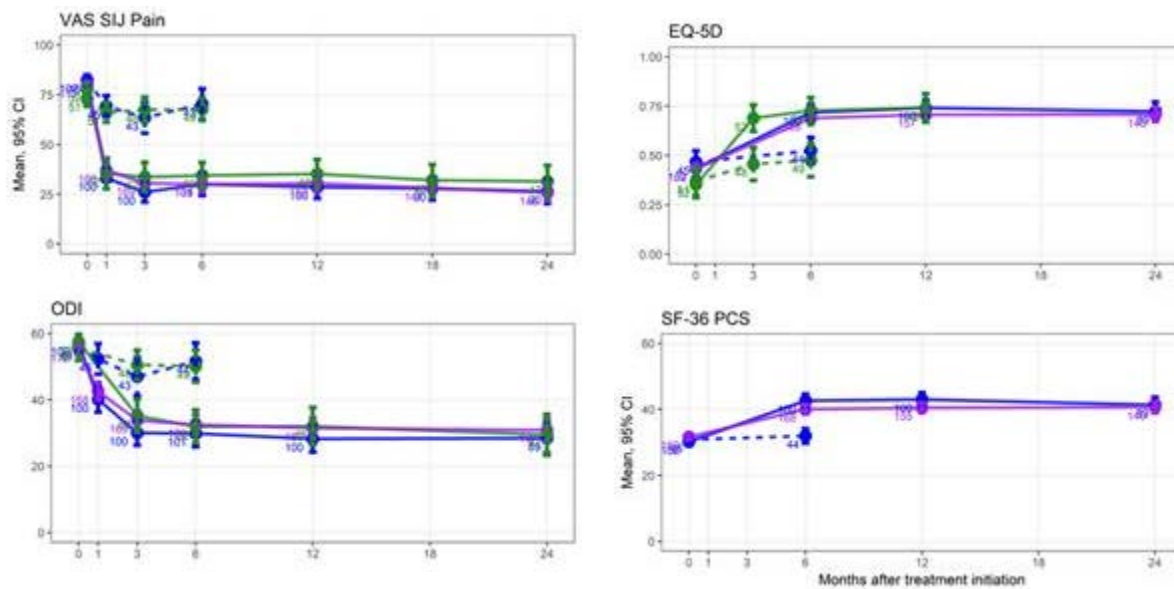


Figure 1. Improvement in pain (upper left), disability (lower left), and quality of life (right) in 2 real-world randomized trials of SIJF vs. non-surgical treatment and a multicenter trial of SIJF. Solid lines = SIJ fusion; dotted lines = non-surgical treatment. Blue = INSITE (US randomized clinical trial); green = iMIA (European randomized clinical trial); purple = prospective single-arm study. Small numbers represent sample sizes at each time point.

4 Long-Term Prospective Follow-Up

LOIS is a follow-up study of subjects who participated in the two US studies summarized above (INSITE and SIFI). 3-year follow-up after SI joint fusion from these subjects shows sustained pain relief and disability improvement (**Figure 7**).¹¹

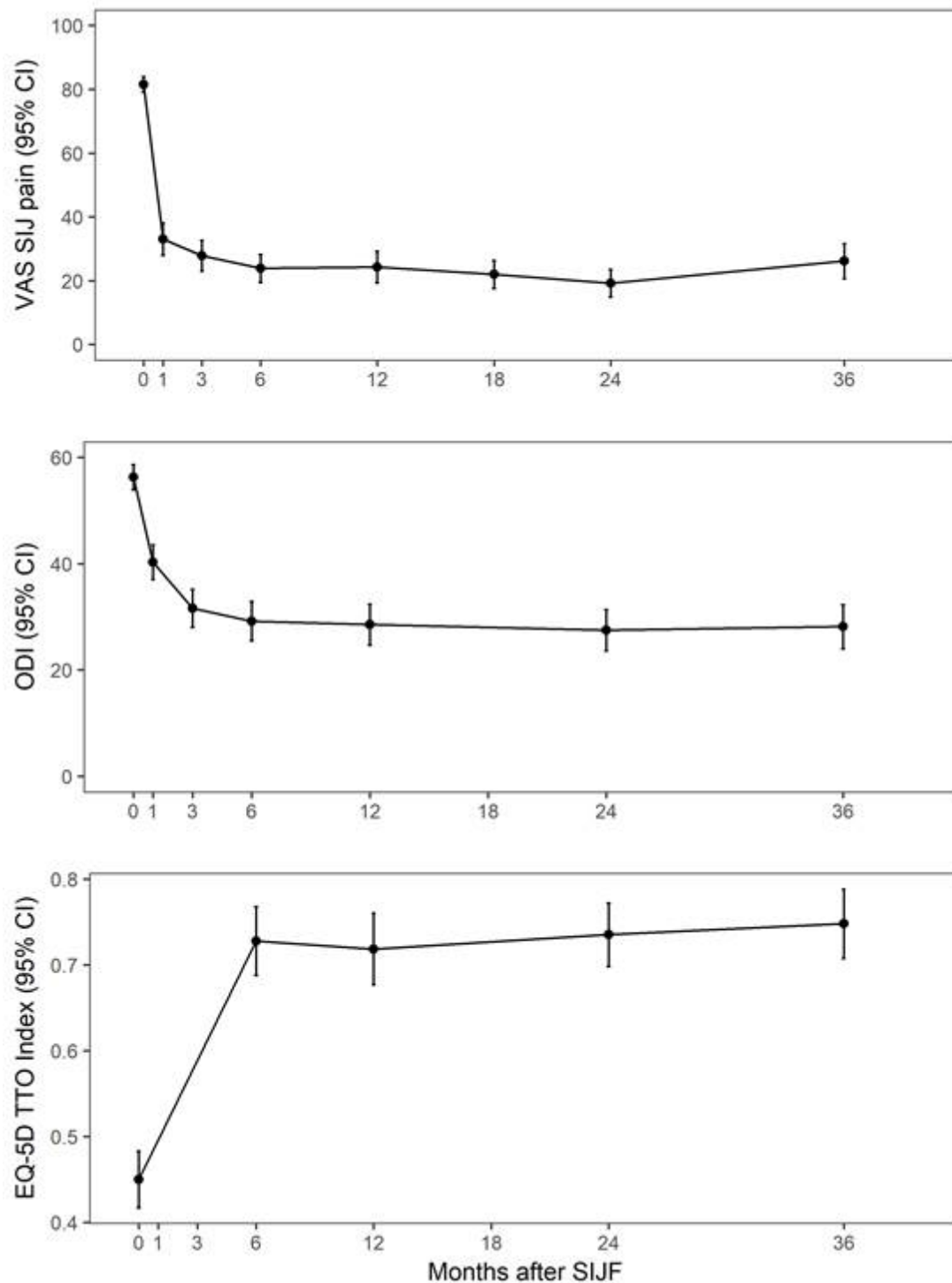


Figure 7. LOIS study: 3-year follow-up.

5 Comparative Case Series

5.1 Vanaclocha et al

Vanaclocha (neurosurgeon from Spain) published an important long-term retrospective cohort study.¹² In this study, patients whose insurance companies did not cover SI joint fusion or radiofrequency ablation of the SI joint had to undergo continued conservative management.

As shown in Figure 8, conservative management patients had worsened pain and disability throughout follow-up. In contrast, patients who were able to undergo SI joint fusion had marked, immediate and

sustained improvement in pain and disability. Moreover, patients undergoing conservative treatment had increased opioid use and worsened work status at last follow-up, whereas patients undergoing SI joint fusion had decreased opioid use and improved work status (Table 1).

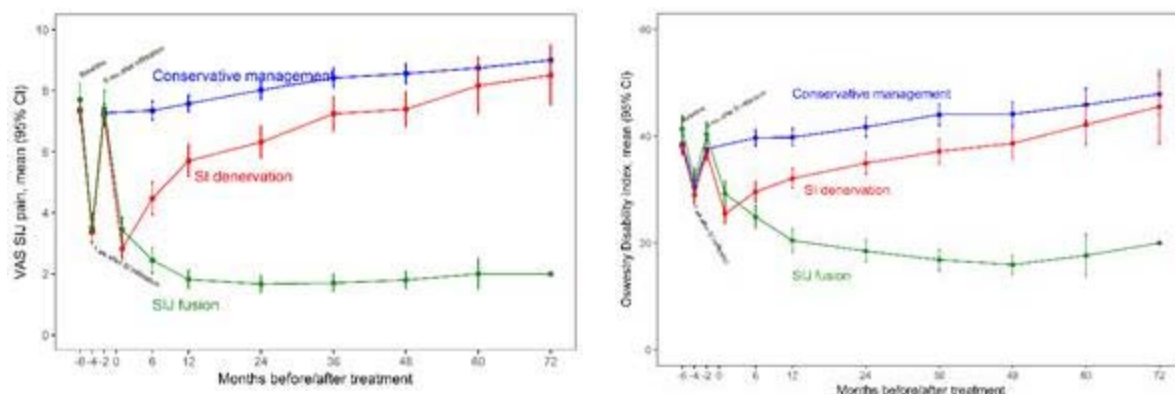


Figure 8. Patients whose surgeries were covered by the payer and who underwent SI joint fusion had marked improvement in pain and disability. Patients who were forced to undergo conservative management had no improvement or worsening.

Table 1. Patients whose surgeries were covered by the payer and who underwent SI joint fusion were much less likely to be opioid users at last follow-up. Patients forced to undergo conservative management had marked increases in opioid use.

	Conservative management	SI Joint Fusion
Taking opioids		
Baseline	49%	63%
Last follow-up	84%	7%
Working full or part time		
Baseline	49%	52%
Last follow-up	19%	70%

5.2 Comparison vs. Open SIJ Fusion

Graham-Smith published a multicenter comparative cohort study of open vs. minimally invasive SIJ fusion.¹³ Patients who received minimally invasive SIJ fusion had a shorter hospital length of stay and better pain relief compared to open SIJ fusion.

Ledonio published two comparisons from University of Minnesota of open and minimally invasive SIJ fusion.^{14,15} Both showed better responses after minimally invasive SIJ fusion.

6 Multicenter Retrospective Case Series

A large retrospective case series showed excellent 3-year responses to SIJ fusion.¹⁶ Another multicenter series showed consistent relief 1 year after SIJ fusion.¹⁷

7 Single-Center Case Series

Several single-center case series have shown consistent responses to SIJ fusion surgery with triangular titanium implants:

- Bornemann¹⁸
- Gaetani¹⁹

- Schroeder

8 Additional Articles

- Using data from INSITE and SIFI, an analysis performed by an independent group showed the potential for increased productivity in workers with SIJ pain who undergo minimally invasive SIJ fusion²¹

9 Non-iFuse Cohorts

Single center case series of devices that are not triangular titanium implants have been published: Kancherla,²² Rappoport,²³ and Kube.²⁴

10 Economic Studies

Cost-effectiveness of SIJ fusion vs. non-surgical treatment was reported in Polly et al.¹

Two-year healthcare costs were modeled for patients with severe low back pain refractory to conservative management.²⁵ Costs associated with an approach that ignores the contribution of SIJ pain were \$3100 higher than if SIJ pain is diagnosed and treated using SIJ fusion.

Citations

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Washington State Healthcare Authority
Washington Health Technology Assessment Program

June 29, 2018

I am vice president of clinical affairs at SI-BONE, Inc., in Santa Clara, CA. SI-BONE manufactures implants for sacroiliac joint (SIJ) fusion.

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- Physicians believed that a trial that included a sham surgery arm was unethical and would not have passed review by an institutional review board.
- Patients in their clinics would be very unlikely to participate in a study with a sham arm. Any patient indicating a desire to participate in such a study would likely have been far different from the typical patient, greatly limiting generalizability.

We therefore decided to include as control groups the following:

- In the US, maximal non-surgical therapy, consisting of medication optimization, physical therapy, SIJ steroid injections and RF ablation of the SIJ
- In Europe, conservative treatment, consisting of prolonged physical therapy and medication optimization with optional cognitive behavioral therapy

I note that:

- No high-quality evidence supports the use of SIJ steroid injections.
- No high-quality evidence supports long-term efficacy of RF ablation (2 of 4 blinded randomized trials show short-term benefits of RF ablation for SIJ pain)
- In the two randomized trials of SIJ fusion vs. non-surgical treatment, we observed minimal responses in the non-surgical groups.

Efficacy question 1a (EQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

By intermediate efficacy outcomes, I assume Washington State means pain and/or disability relief and improvement in quality of life. Radiographic endpoints (specifically, radiographic fusion) in spine surgery may not be predictive of long-term health outcomes.

A few case series have compared outcomes of open SIJ fusion surgery and minimally invasive SIJ fusion surgery with iFuse Implant System. These show that:

- Minimally invasive SIJ fusion surgery with triangular titanium implants produces better healthcare outcomes
- Minimally invasive SIJ fusion surgery with triangular titanium implants results in far shorter hospital lengths of stay

Please note that no study has directly or indirectly compared open SIJ fusion surgery against non-surgical treatment. Studies supporting open SIJ fusion are scattered, of small sample sizes, and use a large variety of techniques. Most surgeons no longer perform SIJ fusion surgery because recovery times are very long and satisfaction rates highly variable.

Safety question 1 (SQ 1). What is the safety of sacroiliac joint fusion surgery?

Prospective randomized controlled trials have shown that SIJ fusion surgery using triangular titanium implants (iFuse Implant System) carries a low risk of device-related adverse events. Overall event rates between the surgery and non-surgery groups were not statistically different.

The most common device-related adverse event is inadequate final implant placement.

- Implants placed too deeply into the sacrum can irritate local nerves, causing new onset radicular pain. This pain typically resolved when implants are pulled back. This event occurs at a rate of ~1%. Use of cross-sectional imaging may reduce this rate.
- Implants placed insufficiently into the sacrum may cause inadequate pain relief due to lack of complete stabilization.

Implant failures (breakage) and device migration have not been seen to date.

Procedure-related adverse events were uncommon and easily treated.

Safety question 1a (SQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

SIJ fusion can now be performed with numerous FDA-cleared devices. However:

- No studies directly comparing safety outcomes have been published or, to my knowledge, are in process.
- Other than triangular titanium implants (iFuse) no study has directly compared results of its technology or technique against either other techniques or non-surgical treatment.

In general SIJ fusion surgeries are brief and have good safety profiles.

Cost question 1 (CQ 1). What is the cost and cost-effectiveness of sacroiliac joint fusion surgery? In addition, we will address the following contextual questions:

The cost-effectiveness of SIJ fusion surgery using iFuse Implant System was addressed as part of a US multicenter prospective randomized controlled trial.¹ Based on Medicare cost estimates and health utilities derived from this randomized trial, the direct healthcare cost per QALY gained as \$13,313. This is in the same range as hip and knee replacement surgery.

The cost-effectiveness of other devices has not been demonstrated or, to my knowledge, investigated.

Contextual questions:

1. What are the recommended ways to diagnose SI joint pain or disruption, and what is the accuracy of various diagnostic tests?

SIJ pain is typically diagnosed via a combination of history, physical examination and diagnostic SIJ block, combined with imaging to rule out other causes. This was covered in the Washington State document. Briefly:

- **History:** Patients typically report off-center low back pain with radiation into the buttocks, groin or legs. Pain is often worse with sitting on the affected side, driving over bumps and rolling over in bed.
- **Physical examination.** Physicians typically perform a series of 5 or more physical examination maneuvers that stress the SIJ and reproduce typical SIJ pain. The predictive accuracy of 3 or more positive tests is high, as per a meta-analysis,² with a sensitivity of 85%, specificity of 76% and diagnostic odds ratio of 17. Another meta-analysis stated that clinical examination maneuvers for SIJ pain are amongst the most accurate clinical tests for low back pain diagnosis.³
- **Diagnostic SIJ block.** As described by the Washington State document, diagnostic block with injection of local anesthetic into the affected joint causing a marked acute reduction in typical pain is universally used. In contrast to comments in the Washington State document,

this test is not expensive or invasive. Diagnostic blocks are commonly used and commonly available.

- **Radiographic imaging.** Imaging is performed typically to rule out other causes of low back pain. The accuracy of radiographic imaging for lumbar spine conditions is notoriously poor,^{4,5} so the degree to which imaging rules out other causes of low back pain is unclear.

2. *What is known about the frequency of various diagnostic approaches to SI joint pain or disruption in usual clinical practice?*

In my interactions with physicians providing SIJ fusion, nearly all use the diagnostic algorithm described above.

Please see the “Summary of Studies” section below. Please do not hesitate to contact me with questions.

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Summary of Studies

1 Randomized Trials

Two randomized trials of SIJ fusion with triangular titanium implants (iFuse Implant System) vs. non-surgical treatment have been published to date.

1.1 INSITE Study

INSITE is a prospective randomized controlled trial at 19 centers across the United States. Eligible patients were randomly assigned to either non-surgical management of SI joint fusion using iFuse Implant System. 2-year follow-up was published in 2016.⁶ The study showed marked, immediate and sustained improvement in low back pain (SI joint pain), back function as measured by Oswestry Disability Index (Figure 1) and quality of life with two measures. These are cardinal measures of SI joint pain. All measures were statistically superior in the surgery group compared to non-surgical treatment. Improvements in the non-surgical group were minimal, meaning that non-surgical treatment was both expensive and of no value.

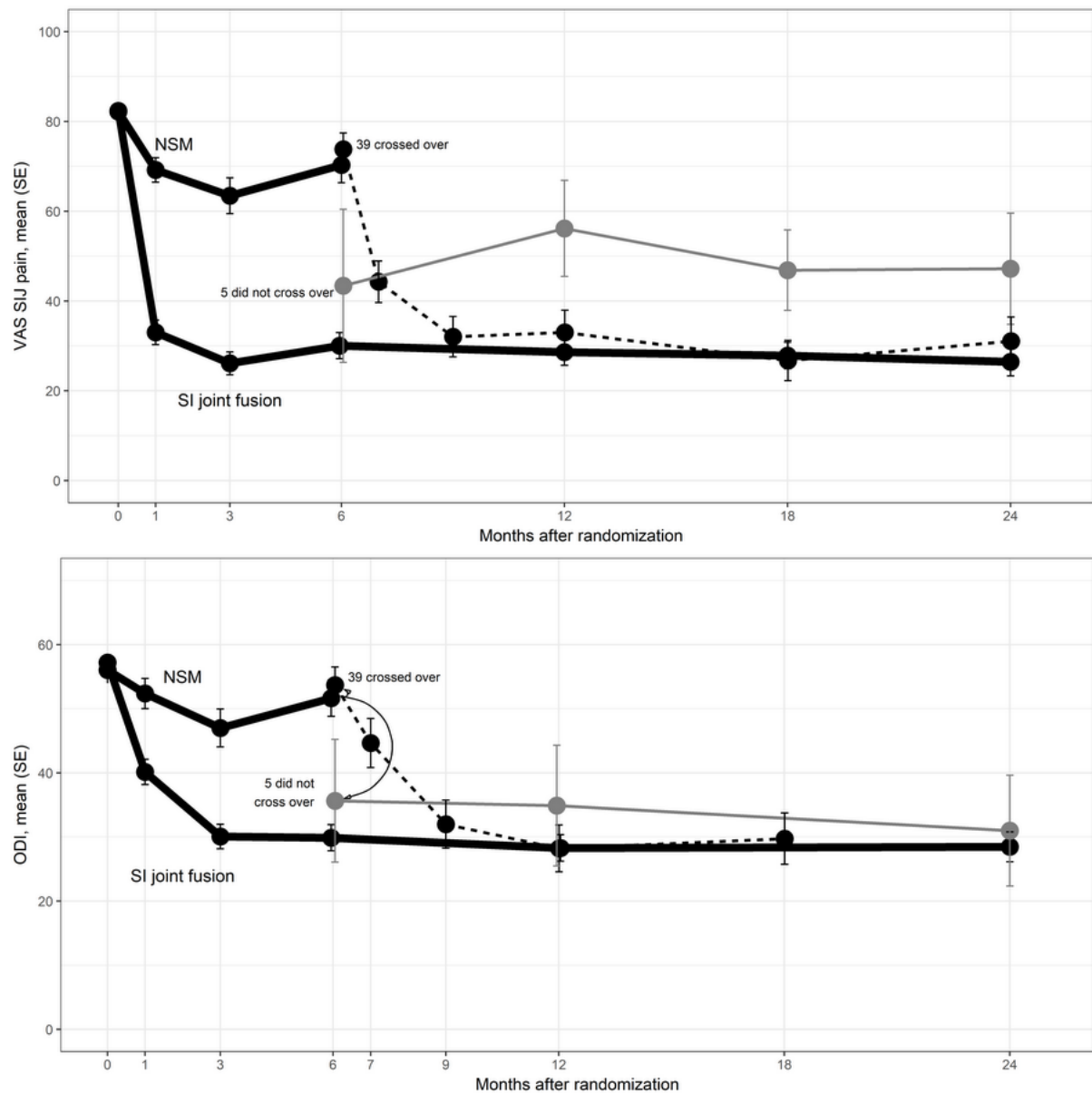


Figure 1. Improvements in SI joint pain (top) and disability (bottom) in INSITE subjects undergoing either non-surgical management (NSM) or SI joint fusion with iFuse Implant System.

In summary, compared to non-surgical management:

- SI joint fusion subjects had **larger improvement in back pain**
- SI joint fusion subjects had **larger improvements in disability related to back pain**
- SI joint fusion subjects had **larger improvements in quality of life**
- SI joint fusion subjects had higher satisfaction rates and would more likely undergo the assigned treatment
- SI joint fusion subjects were more likely to cease opioid use

1.2 iMIA Study

iMIA is a prospective multicenter randomized trial conducted at 9 centers in Europe. Eligible patients with SI joint pain were randomly assigned to SI joint fusion or conservative management (CM, consisting primarily of physical therapy). 24-month follow-up shows marked superiority of SI joint fusion over CM in pain relief (Figure 2) and functional tests (Figure 3). A number of other items (global comparisons, walking distance, satisfaction) were also superior in the SI joint fusion group compared to conservative treatment (Figure 4). The proportion of patients using opioids decreased 40% in the surgical group but not the non-surgical group (Figure 5).

A 12-month manuscript was recently published⁷ and a 24-month manuscript is under review. In summary, compared to conservative management:

- SI joint fusion subjects had larger improvement in back and leg pain.
- SI joint fusion subjects had larger improvements in disability related to back pain
- SI joint fusion subjects had **larger improvements in quality of life**
- SI joint fusion subjects had **decreases in depression scores**
- SI joint fusion subjects had **better pelvis function (active straight leg raise test)**
- SI joint fusion **subjects could walk further**
- SI joint fusion subjects were **less likely to take opioids**
- SI joint fusion subjects were less likely to be not working due to back pain
- SI joint fusion subjects reported more overall improvement
- SI joint fusion subjects had higher satisfaction rates and would more likely to undergo the assigned treatment

In each parameter, improvements after SI joint fusion were sustained at 2 years.

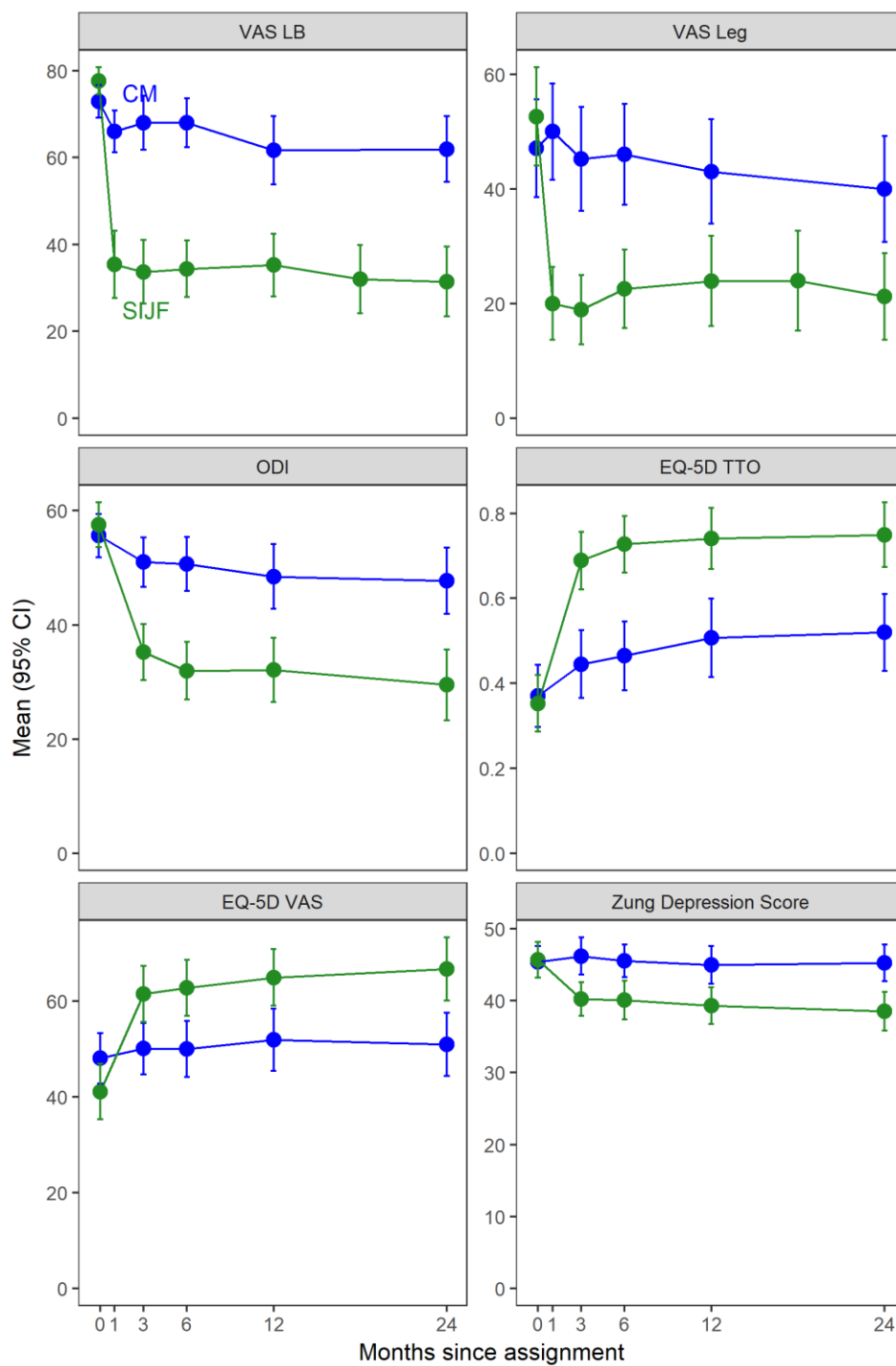


Figure 2. iMIA study: Change in visual analog scale (VAS) low back (LB) pain, leg pain, Oswestry Disability Index, EuroQOL-5D time trade-off (TTO) and VAS, and Zung Depression Scale scores. Blue = CM, green = SI joni fusion.

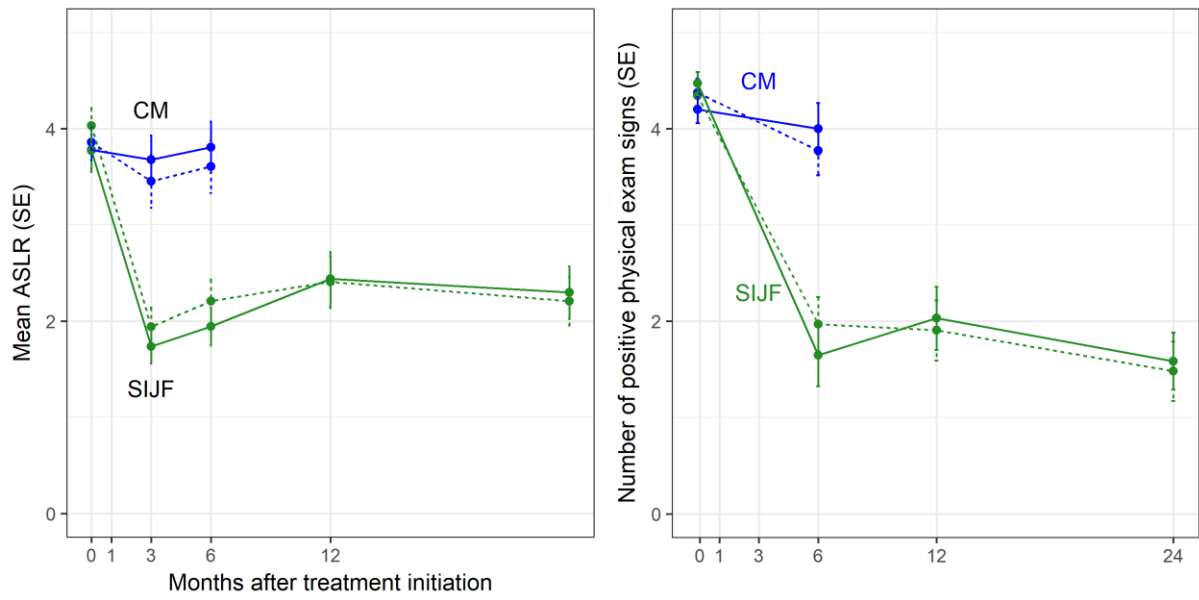


Figure 3. iMIA study: Improvement in functional test (active straight leg raise test) by treatment and time (left) and number of positive physical examination signs (right).

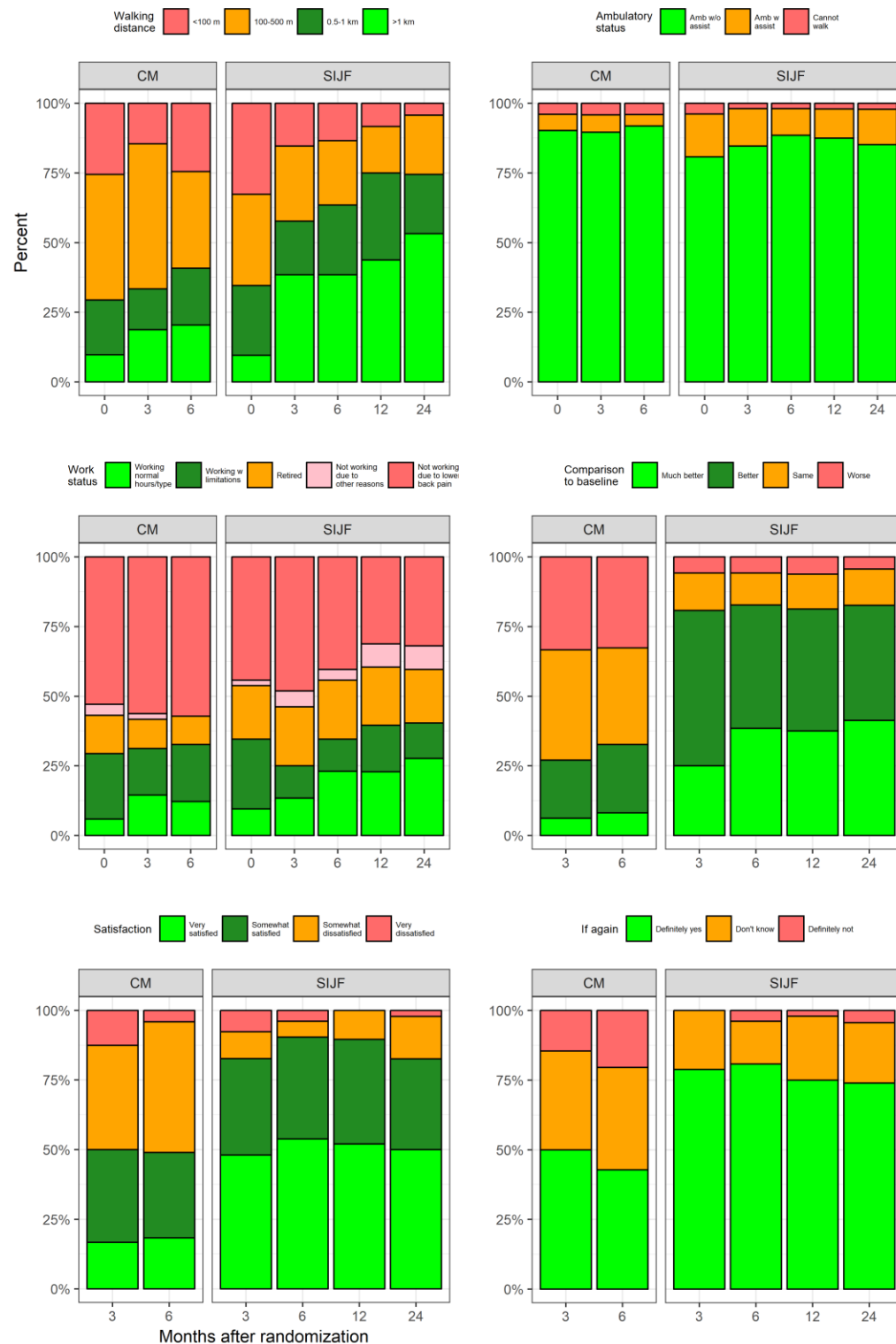


Figure 4. iMIA study: Improvement in walking distance, ambulatory status, work status, comparison to baseline, satisfaction and desirability of having surgery again by treatment and follow-up visit.

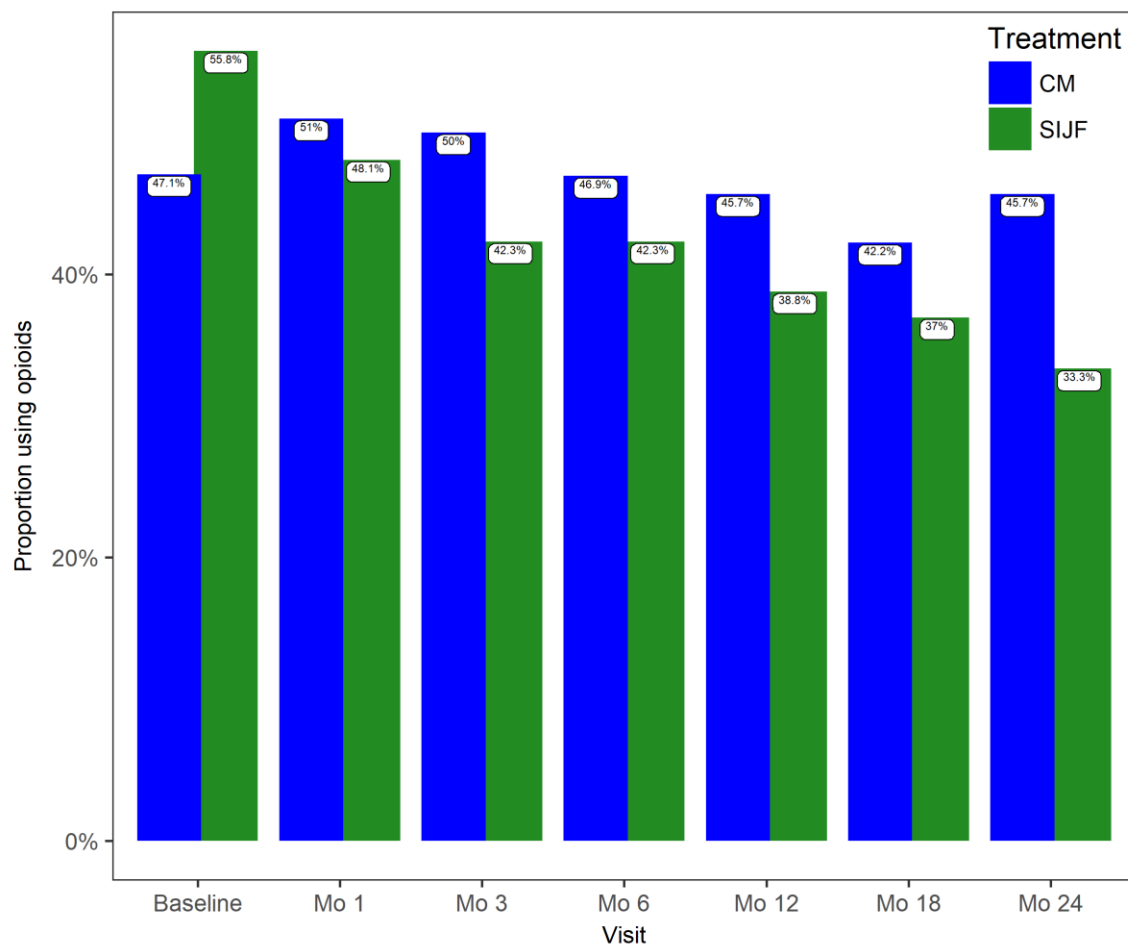


Figure 5. Proportion of iMIA subjects using opioids at each study visit by treatment. The proportion decreased significantly in the surgical group (green) but not in the conservative management group (blue).

2 Prospective Trials

2.1 SIFI Study

SIFI is a prospective multicenter single-arm study of SI joint fusion for patients with SI joint pain.⁸ Enrollment criteria were similar to INSITE. This study also showed improvement in back pain, disability and quality of life.

A subgroup analysis from this study showed that women whose SIJ pain began in the postpartum period had excellent responses to treatment.⁹ These patients are younger on average than the overall SIFI cohort.

3 Pooled Analysis

A pooled analysis of the 3 prospective trials listed above was recently published in the prestigious journal *Spine*.¹⁰ This analysis included 326 trial subjects who underwent SI joint fusion and 97 who underwent non-surgical treatment. A pooled analysis plot is shown in **Error! Reference source not found.** This plot was the basis of the *Spine* manuscript. The data show:

- Marked consistency across studies
- Large improvements in the SI joint fusion group
- Small changes in the non-surgical groups

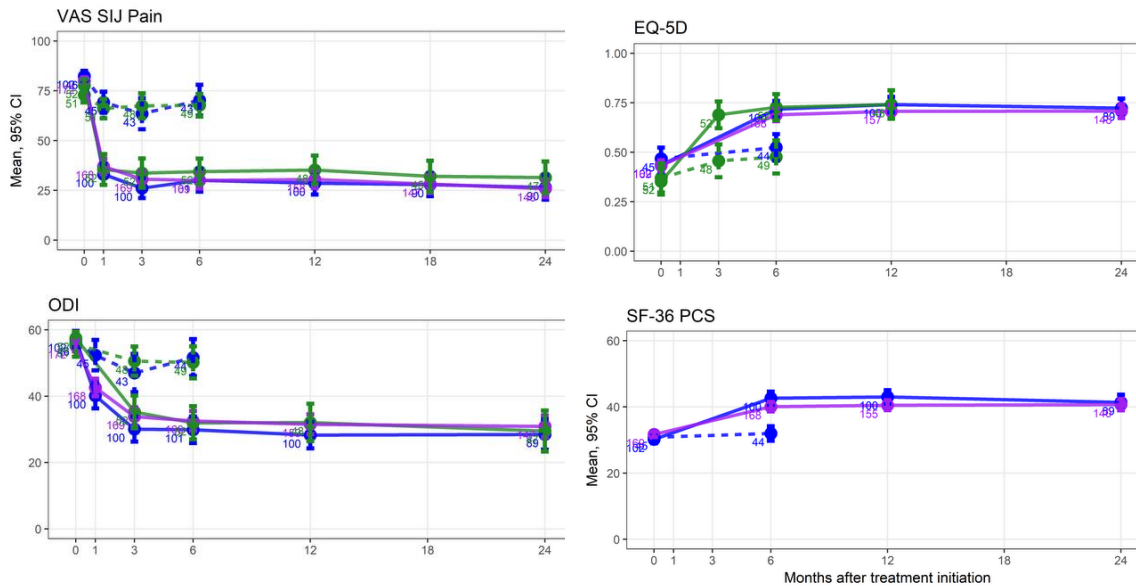


Figure 6. Improvement in pain (upper left), disability (lower left), and quality of life (right) in 2 real-world randomized trials of SIJF vs. non-surgical treatment and a multicenter trial of SIJF. Solid lines = SIJ fusion; dotted lines = non-surgical treatment. Blue = INSITE (US randomized clinical trial); green = iMIA (European randomized clinical trial); purple = prospective single-arm study. Small numbers represent sample sizes at each time point.

4 Long-Term Prospective Follow-Up

LOIS is a follow-up study of subjects who participated in the two US studies summarized above (INSITE and SIFI). 3-year follow-up after SI joint fusion from these subjects shows sustained pain relief and disability improvement (**Figure 7**).¹¹

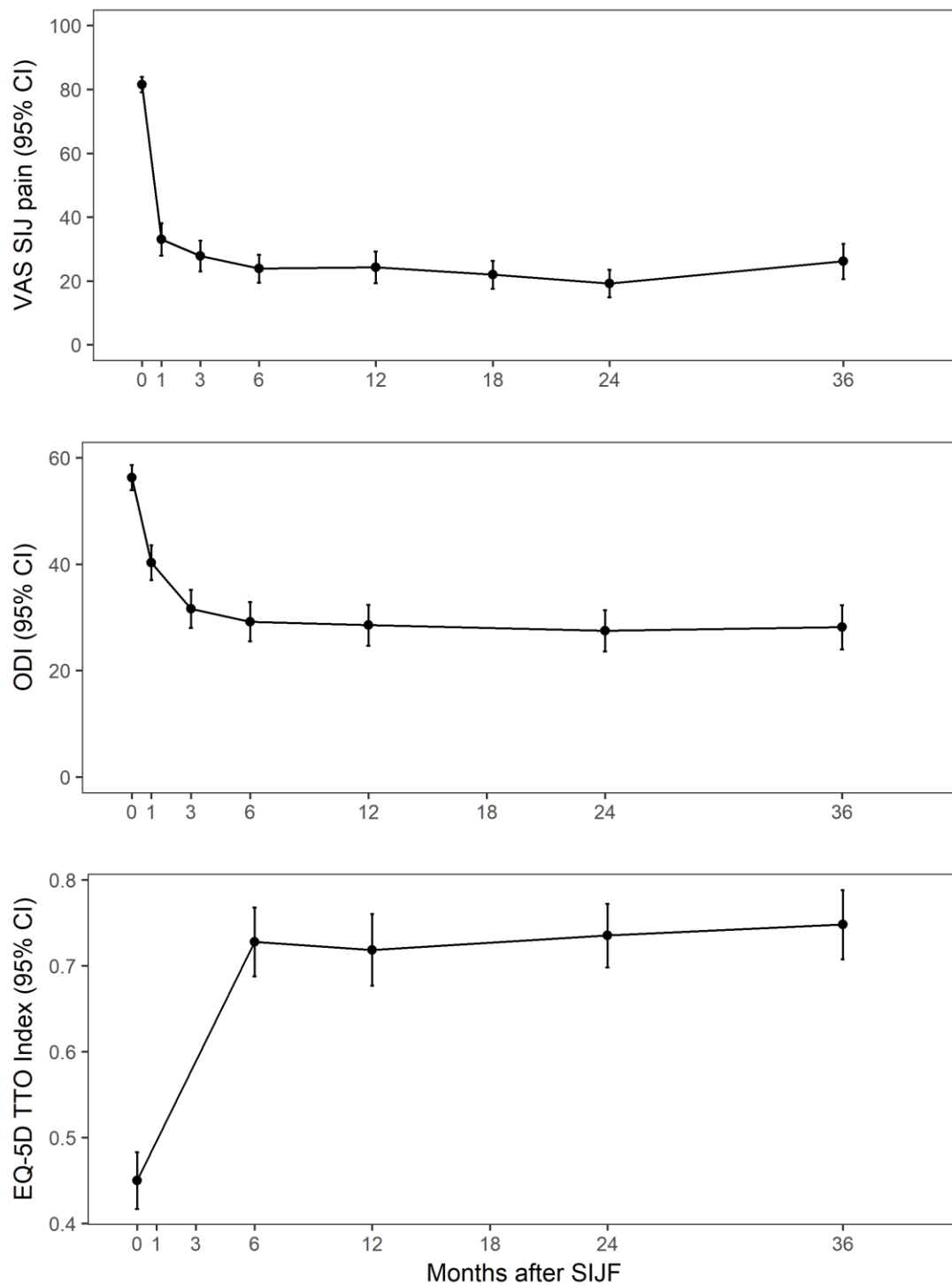


Figure 7. LOIS study: 3-year follow-up.

5 Comparative Case Series

5.1 Vanaclocha et al

Vanaclocha (neurosurgeon from Spain) published an important long-term retrospective cohort study.¹² In this study, patients whose insurance companies did not cover SI joint fusion or radiofrequency ablation of the SI joint had to undergo continued conservative management.

As shown in Figure 8, conservative management patients had worsened pain and disability throughout follow-up. In contrast, patients who were able to undergo SI joint fusion had marked, immediate and sustained improvement in pain and disability. Moreover, patients undergoing conservative treatment had increased opioid use and worsened work status at last follow-up, whereas patients undergoing SI joint fusion had decreased opioid use and improved work status (Table 1).

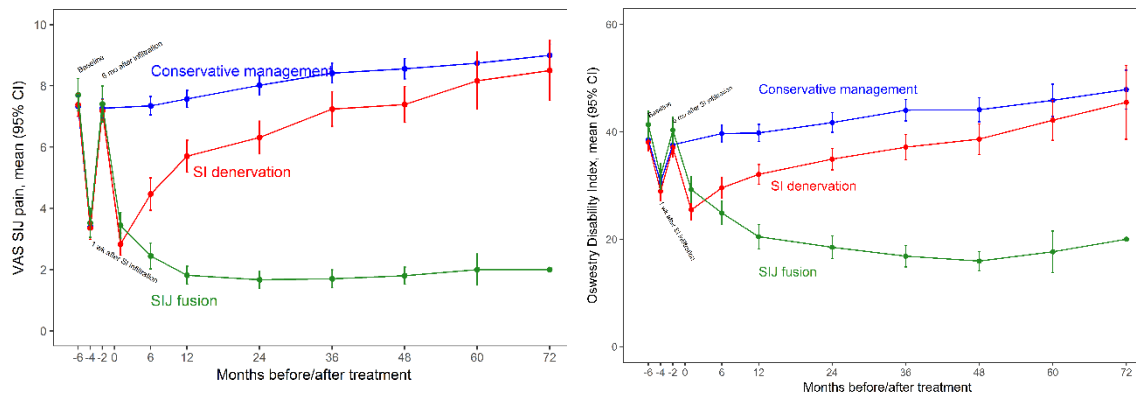


Figure 8. Patients whose surgeries were covered by the payer and who underwent SI joint fusion had marked improvement in pain and disability. Patients who were forced to undergo conservative management had no improvement or worsening.

Table 1. Patients whose surgeries were covered by the payer and who underwent SI joint fusion were much less likely to be opioid users at last follow-up. Patients forced to undergo conservative management had marked increases in opioid use.

	Conservative management	SI Joint Fusion
Taking opioids		
Baseline	49%	63%
Last follow-up	84%	7%
Working full or part time		
Baseline	49%	52%
Last follow-up	19%	70%

5.2 Comparison vs. Open SIJ Fusion

Graham-Smith published a multicenter comparative cohort study of open vs. minimally invasive SIJ fusion.¹³ Patients who received minimally invasive SIJ fusion had a shorter hospital length of stay and better pain relief compared to open SIJ fusion.

Ledonio published two comparisons from University of Minnesota of open and minimally invasive SIJ fusion.^{14,15} Both showed better responses after minimally invasive SIJ fusion.

6 Multicenter Retrospective Case Series

A large retrospective case series showed excellent 3-year responses to SIJ fusion.¹⁶ Another multicenter series showed consistent relief 1 year after SIJ fusion.¹⁷

7 Single-Center Case Series

Several single-center case series have shown consistent responses to SIJ fusion surgery with triangular titanium implants:

- Bornemann¹⁸
- Gaetani¹⁹
- Schroeder²⁰

8 Additional Articles

- Using data from INSITE and SIFI, an analysis performed by an independent group showed the potential for increased productivity in workers with SIJ pain who undergo minimally invasive SIJ fusion²¹

9 Non-iFuse Cohorts

Single center case series of devices that are not triangular titanium implants have been published: Kancherla,²² Rappoport,²³ and Kube.²⁴

10 Economic Studies

Cost-effectiveness of SIJ fusion vs. non-surgical treatment was reported in Polly et al.¹

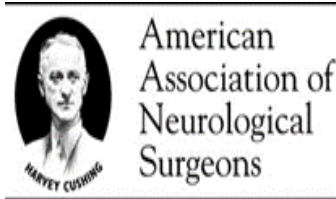
Two-year healthcare costs were modeled for patients with severe low back pain refractory to conservative management.²⁵ Costs associated with an approach that ignores the contribution of SIJ pain were \$3100 higher than if SIJ pain is diagnosed and treated using SIJ fusion.

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July 5, 2018

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**Subject: Draft Key Questions for Health Technology Assessment (HTA) Program
Review of Sacroiliac Joint Fusion**

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of Spine and Peripheral Nerves (DSPN) and Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to provide feedback on the draft key questions for evidence review for sacroiliac (SI) joint fusion. In our estimation, the draft questions are generally reasonable and appropriate for the evaluation of efficacy, safety and cost of SI joint fusion procedures. However, we offer the comments below regarding some of the specifics proposed to assess the procedure.

Efficacy Questions

Efficacy question 1 (EQ 1). What is the effectiveness and comparative effectiveness of sacroiliac joint fusion surgery on health outcomes?

Question EQ 1 refers to effectiveness of SI joint fusion on health outcomes. Outcomes include pain, function, quality of life (QOL), patient satisfaction, opioid use and return to work. These outcome measures are all used in the available randomized controlled trials (RCTs) for SI joint fusion and represent readily quantifiable outcome measures. We feel these are appropriate.

Efficacy question 1a (EQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

Question EQ 1a asks about comparative effectiveness for intermediate outcomes. Proposed outcomes include length of stay and non-union. Fusion rate may be a good intermediate outcome measure to investigate for SI joint fusion. Fusion status at a certain time point could correlate with the long-term

outcomes and is worth investigating. Length of stay seems problematic as an intermediate outcome measure, as there are many variables outside of surgery and patient function that can contribute to a longer hospital stay without necessarily compromising the long-term effectiveness of surgery, including comorbidities and minor complications. Length of stay may be more relevant as a safety measure to assess the general morbidity of the surgery, but seems inappropriate as an efficacy measure. A better measure may be post-operative referral to an acute or subacute rehabilitation facility. A patient who meets discharge criteria for home is more functional than a patient who requires post-operative rehabilitation and, therefore has an increased likelihood for a better long-term outcome.

Safety Questions

Safety question 1 (SQ 1). What is the safety of sacroiliac joint fusion surgery?

SQ 1 concerns the safety of SI joint fusion. Safety measures include rates of infection, serious adverse events and surgical morbidity. These rates of complications all seem reasonable as basic measures of safety.

Safety question 1a (SQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

SQ 1a asks about comparative effectiveness on intermediate safety outcomes including intraoperative blood loss and duration of surgery. These also seem reasonable as assessments of the relative morbidity of a procedure and possibly correlate with rates of adverse events.

Cost Questions

Cost question 1 (CQ 1). What is the cost and cost-effectiveness of sacroiliac joint fusion surgery?

CQ 1 seems fairly straight forward with assessment of cost and cost per QOL-adjusted life years gained. These costs must be put in perspective in comparison to the costs of continued non-surgical interventions as well as the opportunity cost of lost productivity in those patients with disability recalcitrant to non-surgical therapy.

Contextual Questions

Contextual Question 1. What are the recommended ways to diagnose SI joint pain or disruption, and what is the accuracy of various diagnostic tests?

We understand that the contextual questions will not be part of the systematic review for SI joint fusion. Nevertheless, an examination of the tests used to diagnose and appropriately select patients is vital to consider for any treatment. The first question regarding recommended ways to diagnose SI joint pain and relative accuracy of diagnostic tests is important to study to further enhance the reliability of establishing a diagnosis of SI joint dysfunction.

Contextual Question 2. What is known about the frequency of various diagnostic approaches to SI joint pain or disruption in usual clinical practice?

The second contextual question seems less important in determining the utility of the procedure itself but could be helpful in determining how frequently an average clinician will initiate a diagnostic process for SI joint symptoms and give an idea of prevalence of these symptoms.

Process Concerns

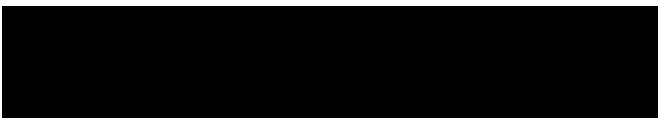
We are concerned that a 14 day comment period for draft key questions is not long enough. Although in the particular case of SI joint fusion, we believe the draft key questions are generally appropriate, this is not always the case and limiting the comment period to two weeks, particularly over a major national holiday, does not permit adequate time for a thorough vetting. Organized neurosurgery has been active in reviewing, commenting upon and attending meetings regarding procedures under consideration by the HTA program for over a decade. We urge the Washington State Health Care Authority to allow more time for stakeholders to review and respond to draft documents posted for coverage policy considerations. We also ask for consideration of national holidays when setting a deadline for a response.

Conclusion


We appreciate the opportunity to review and comment upon the draft key question that will be used in the development of the evidence review for SI Joint Fusion. The key questions are generally reasonable and we look forward to the opportunity to comment on the draft evidence report in October.

Thank you for considering our comments.


Sincerely,




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American Association of Neurological Surgeons



Ashwini D. Sharan, MD, President
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