

*SI Fusion should NOT be performed routinely*

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 Northwestern University Feinberg School of Medicine

2/21/2018 Park City, UT

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Entity	Consulting	Advisory Board	Speaker's Bureau	Research Grant
Medtronic	X			
Stryker	X			
Allosource	X			
Wright Medical			X	
Nuvasive		X		
Xtant		X		
Bioventus		X		
Mirus		X		
Graftys	X			
LSRS		X		
CSRS				X
OREF				X

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Disclosures

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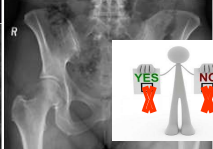


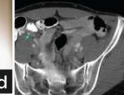


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- 34 yo F
- Active marathoner
- Mother of 3
- Pediatrician
- Debilitating Right sided Buttocks pain
- Conservative care for over two years
- 50% relief with SI jt injx for 24 hr
- NO red flags

Tric/ Psychosocial  
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 ese  
 rmyalgia  
 Non-litigation

- Yes or No?

Burden of proof is on Yes...

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Issue	Concede
Sacroiliac joint exists	✓
Patients can have pain localized over the SIJ	✓
RCT show improvements with SI fusion over nonop tx	✓
A candidate subpopulation may exist	✓

Issue	Debatable
Can the SIJ cause pain?	
If it can cause pain, how do I know I have it?	
If I really have it, how do I know if SIJ fusion is the answer?	
If SIJ fusion is the answer, is it cost-effective?	



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## Hsu Scale of New Technology

Technology	Quality of Diagnosis	Prevalence of Dx	Quality of Alternatives	Evidence	Total
IS Spacers	5	5	1	2	<u>13</u>
Lumbar TDA	2	5	4	2	<u>13</u>
Cervical TDA	5	5	3	4	<u>17</u>
SI Fusion					<u>2</u>

Scale: 1 to 5  
 < 10 – non-adoptable  
 10-15 – worth consideration  
 > 15 – has role in spine care

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## Albee, JAMA 1909

**A STUDY OF THE ANATOMY AND THE CLINICAL IMPORTANCE OF THE SACROILIAC JOINTS**

FRED H. ALBEE, M.D.  
Instructor in Orthopedic Surgery, College of Physicians and Surgeons and


Some of the findings of the study are as follows: 1. The sacroiliac articulation is a true joint, and some of its features are as follows: 1. The sacroiliac articulation is a true joint, and some of its features are as follows:

ing the presence of persistent pain in the distribution of the nerve, i. e., sciatica.

The articulation is easily opened by incising the anterior part of the capsule and forcing the pelvic bones apart in front, the symphysis pubis having already been separated. The sacrum and the ilium swing on the posterior and intersosseous ligaments, as a door on its hinges. Hence the infrequent interference with locomotion.

**CONCLUSIONS**

1. The sacroiliac articulation has all the elements of a joint and therefore has a similar pathology.
2. It has motion and plays an important rôle in labor.
3. Its variation, according to individual, age or sex, is very slight.
4. Its anatomy is such that drainage into the pelvis is very apt to occur, and, therefore, in the event of infection, early posterior drainage is often indicated.
5. Its affections are, undoubtedly, the cause of many obscure and unexplained backaches and persistent sciaticas.



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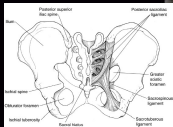

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## Sacroiliac Joint Pain

- Largest axial joint in human body
  - Synovial joint (75% of surface is not synovial)
  - Fibrous capsule surrounds SIJ
  - Posterior border is tough interosseous ligament
  - Synovial cleft narrows to 1-2 mm in 50-70 yo, 0-1 mm in > 70 yo
- Surrounded by muscles
  - Gluteus maximus/medius
  - Erector Spinae
  - Latissimus dorsi
  - Psoas
  - Piriformis
  - Abdominus M

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## Sacroiliitis



- Unilateral left SI jt involvement
- Pseudo-widening of articular space
- Subchondral sclerosis
- Small bony bridges
- Multi-colored SI X-ray picture
- AP radiograph 70 and 80% sensitive and specific

- Bilateral multicolored X-ray picture
- Sequestration seen



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## Sacroiliac Joint Dysfunction

- Is this a real condition?
  - Difficult to distinguish between discogenic causes or others
  - No reliable radiographic evidence
  - No reliable clinical tests
  - No reliable treatment



– “My back pain is better, but I have this new pain...”

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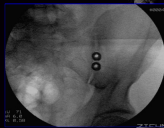
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## Sacroiliac Joint Pain

- Is there motion?
  - Has not been formally quantitated
  - Rotation <math><4^\circ</math> of rotation and 1.6 mm of translation<sup>1</sup>
  - Increased SIJ motion only after interosseous lig severed
  - No difference in jt motion between Asx and Sx joints!



<sup>1</sup>Stuesson et al Spine 1989...

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Overview  
Dr. Anthony B. the area, including...  
Dr. Antho...  
Phone Num...  
Years in P...  
Gender

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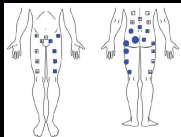
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## Differential

- After ruling out surgical diagnoses, spondy, stenosis, HNP, sacroiliitis/AS, Reiter's syndrome, Psoriatic arthritis
- Lumbar DDD
- Piriformis syndrome
- Gluteal insertional pain
- SIJ sprain
- Hip pathology
- Posterior iliac crest pain



No neurologic deficits
No dorsal tension signs
No laboratory, imaging, or clinical evidence of medical causes of sacroiliac joint pain
Maximal pain below L5
No evidence of lumbar pain generators (if indicated, maximally assessed with negative angiography and diskography)
At least 50% relief with controlled, dual fluoroscopically guided, contrast-enhanced intra-articular sacroiliac joint injections

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## Candidates for surgery?

**Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes**

- + 3 clinical tests
- Positive response from injection
- F**ocieties.<sup>47-51</sup> Although this diagnostic strategy represents the current best practice, it should be noted that it does not completely rule out other possible pain generators such as pathology in the hip or spine,<sup>52</sup> which may frequently coexist. This diagnostic strategy

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Clinical Study

**Posterior iliac crest pain after posterolateral fusion with or without iliac crest graft harvest**

Jennifer M. Howard, MPH<sup>1</sup>, Steven D. Glassman, MD<sup>2\*</sup>, Leah Y. Carreon, MD, MSc<sup>3,4\*</sup>

<sup>1</sup>Department of Learning Health Systems, University of Michigan, 1010 S. University, #1-4001, 48106  
<sup>2</sup>Department of Orthopedic Spine, University of Michigan, 210 East Chapel St., Room 400, Ann Arbor, MI 48106, USA  
<sup>3</sup>Department of Orthopedic Surgery, University of Michigan School of Medicine, 200 East Chapel St., Room 4000, Ann Arbor, MI 48106, USA  
 Received 22 February 2018; revised 4 August 2018; accepted 2 September 2018

- 112 pt with posterior lumbar fusion
- Independent investigator – examined pt for TTP over surgical site, L/R iliac crest
- Incidence of pain over iliac crest similar whether ICBG was harvested or not
- Patients not accurate in identifying which side ICBG was harvested

**False-Positive Findings on Lumbar Discography**  
 Reliability of Subjective Concordance Assessment During Provocative Disc Injection

Eugene J. Carragee, MD, Cary M. Tansler, MD, Benjamin Yang, BS, Jorge L. Brito, MA, and Thao Truong, BS

- 8 patients with no h/o LBP with discography, but had ICBG done for non-spine
- 9 of 14 patients experienced "concordant painful sensation" on lumbar discography with usual gluteal area pain from ICBG harvest

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**FLUOROSCOPICALLY-GUIDED DIAGNOSTIC AND THERAPEUTIC SACROILIAC INTERVENTIONS**

Kennedy DJ, Engel AJ, Kreiner DS, Nampiaparampil D, Duszynski B, MacVicar J.  
 Fluoroscopically guided diagnostic and therapeutic sacroiliac joint injections: a systematic review. *Pain Med* 2015; 16: 1500-1518.

- Systematic review – 45 publications on diagnostic validity
  - Diagnostic data for SIJ pain
  - Therapeutic effectiveness
- Overall quality of evidence is MODERATE for effectiveness of SIJ injx
- Unclear whether image-guided SIJ can predict positive responses to therapeutic agents

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### Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study

Bradley S. Duhon<sup>1</sup> Daniel J. Cher<sup>2</sup> Kathryn D. Wine<sup>2</sup> Don A. Kovatsky<sup>3</sup> Harry Lockstadt<sup>4</sup> on behalf of the SIFI Study Group

- SIFI group
- Prospective, single-arm clinical trial
- 172 patients with SIJ, 2012-14
- Same diagnostic criteria
- 12-month fu
- "SI Joint pain", ODI, SF-36 improved significantly
  - ODI improved to 31.4

Medical Devices Evidence and Research | DOR | ORIGINAL RESEARCH

Durable intermediate- to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants

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### Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating From the Sacroiliac Joint

A Pooled Analysis

Julius Dengler, MD,<sup>1</sup> Bradley Duhon, MD,<sup>1</sup> Peter Whang, MD,<sup>1</sup> Clay Frank, MD,<sup>2</sup> John Glaser, MD,<sup>3</sup> Bengt Stansson, MD, PhD,<sup>1</sup> Steven Garin, MD,<sup>1\*</sup> Daniel Cher, MD,<sup>1\*</sup> Aaron Rendahl, PhD,<sup>1†</sup> and David Polly, MD<sup>1§</sup>, On behalf of the INSITE, iMIA, SIFI study groups

- Pooled data from 423 patients
  - 326 SIJ
  - 97 non surgical management
- SIJ fusion led to ↓ in SIJ pain and ↑ in ODI
- Reduced improvement in outcome
  - Smokers, opioid use, lower patient age, lower duration of pain

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### Designing the appropriate trial



Accounting for the placebo effect...

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**Use of placebo controls in the evaluation of surgery: systematic review**  
OPEN ACCESS

Karolina Wartolowska NDORMS research fellow<sup>1,2</sup>, Andrew Judge university research lecturer<sup>1,2</sup>, Sally Hopewell senior research fellow<sup>3</sup>, Gary S Collins NDORMS senior research fellow<sup>4</sup>, Benjamin J F Dear OPIHS student<sup>5</sup>, Ives Rombach statistician<sup>1</sup>, David Binstley OPIHS student<sup>6</sup>, Julian Savulescu Uehiro chair in practical ethics<sup>7</sup>, David J Beard professor of musculoskeletal sciences<sup>1,2</sup>, Andrew J Carr professor of orthopaedic surgery<sup>1,2</sup>

- Systematic review to November 2013
  - RCT comparing surgical intervention with placebo
  - Placebo – surgical placebo, sham surgery, imitation procedure
- 53 trials met inclusion criteria
  - 39 had improvement in placebo arm (74%)
  - 27 had no difference b/w placebo and surgery (51%)
- Well-designed placebo controlled trials necessary for scientific investigation

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**Placebo Effect**

- Well-designed RCT for DDD
  - Conservative care trials
  - Stem cell injections
  - Steroid injections
  - Procedure
- Perfect storm
  - Controversial diagnosis
  - Chronic pain
  - Failure of previous treatments
  - Desire to improve
  - Invested patient
  - Educated on "cutting-edge technology"

Effect = **50%**

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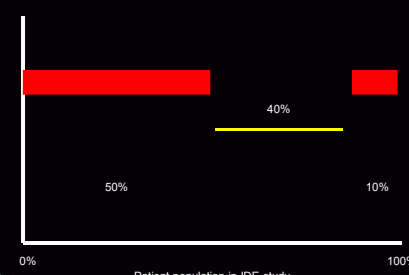
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**Why you won't see a true RCT...**



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Clinical Study

Postoperative complications in patients undergoing minimally invasive sacroiliac fusion

Kyle Schoell, BA, Zorica Buser, PhD<sup>1\*</sup>, Andre Jakoi, MD<sup>2</sup>, Martin Pham, MD<sup>3</sup>,  
Neil N. Patel, MD<sup>4</sup>, Patrick C. Hsieh, MD<sup>5</sup>, John C. Liu, MD<sup>6</sup>, Jeffrey C. Wang, MD<sup>7</sup>

- Retrospective Humana database study
- MIS SIJ fusion 2007-14
- Complications – chronic pain, radiculitis, wound, etc
- 469 underwent SIJ
  - 13.2% complication rate at 90 days postop
  - 16.4% at 6 months
  - Postoperative infx rate: 4.1%
- Most common age group 70-74 (n=85)
- Novel lumbar pathology 3.6% at 90 days, 5.3% at 6 months

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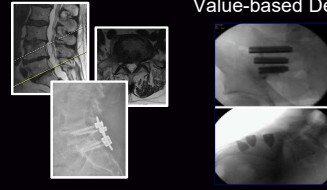

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Value-based Decision Making

	TLIF	SIJ Fusion
Parts	4 screws, 2 rods	3 tri implants
Costs	\$2250	\$10,000
QALY	\$33,000	?

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Hsu Scale of New Technology

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Lumbar TDA	2	5	4	2	13
Cervical TDA	5	5	3	4	17
SI Fusion	1	1	3	2	7

Scale: 1 to 5

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- 34 yo F
- Active marathoner
- Mother of 3
- Pediatrician
- Debilitating Right sided Buttocks pain
- Conservative care for over two years
- 50% relief with SI jt injx for 24 hr
- NO red flags
  - Psychiatric/Psychosocial
  - Non-smoker
  - Non-WC
  - Non-narcotics
  - Non-obese
  - Non-fibromyalgia
  - Non-litigation
- Yes or No?

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**FAILURE**  
When you can't own the face of pure disappointment.

**SUCCESS**  
Success is how you can own the face of pure disappointment.

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<http://www.nwspine.org>

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