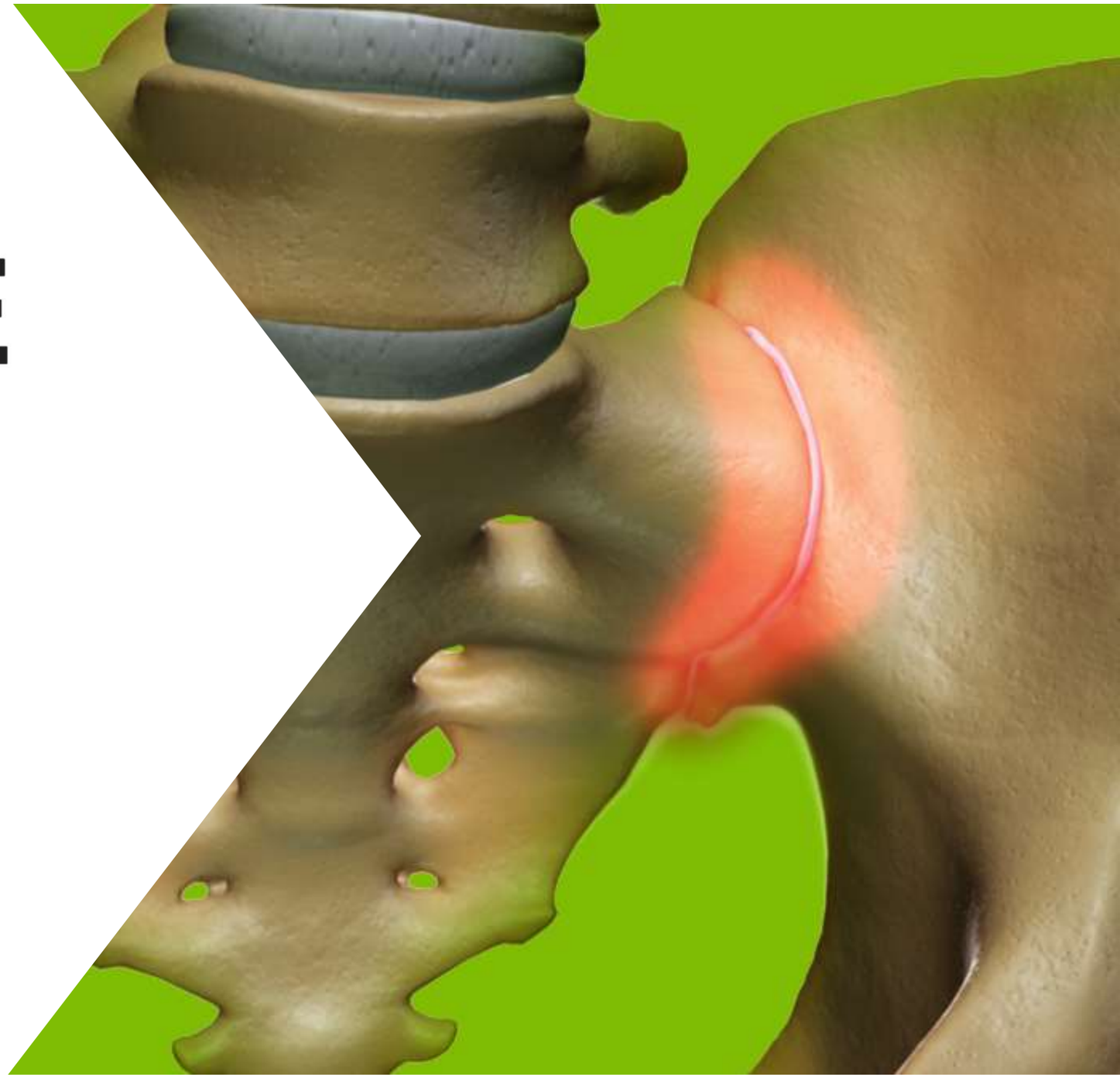
SI-BONE

North American Spine Society

Analyst Surgeon Panel

7:00 – 8:00AM PT

October 8, 2020



Safe Harbor Statement

This presentation contains “forward-looking statements,” which are statements related to future events, expectations, results, activities, events or developments that SI-BONE expects, believes or anticipates will or may occur in the future. Forward-looking often contain words such as “intends,” “estimates,” “anticipates,” “hopes,” “projects,” “plans,” “expects,” “seek,” “believes,” "see," “should,” “will,” “would,” “target,” and similar expressions and the negative versions thereof. Such statements are based on SI-BONE’s experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances, and speak only as of the date made. Forward-looking statements are inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, please review our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, especially the information contained in the section captioned “Risk Factors”. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise unless required by law.

Surgeon Introductions

~200 iFuse Cases Performed

Peter Whang, MD
Yale School of Medicine

William Tobler, MD
Mayfield Clinic

Bharat Desai, MD
Panorama

Robert Eastlack, MD
Scripps Health

SI-BONE®

Executives Attending

Proven track records

Jeffrey Dunn

Chairman, President, CEO & Founder

7 time CEO

INBONE TECHNOLOGIES · TOPEZ, Inc. · REILEY ORTHOPEDICS

Tony Recupero

Chief Commercial Officer

USSC · KYPHON AHEAD OF THE CURVE™ · BAXANO

W. Carlton Reckling, MD

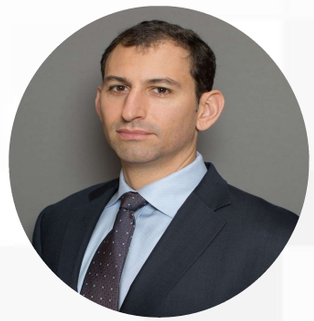
Chief Medical Officer

Private practice for 20 years

Laura Francis

Chief Financial Officer & Chief Operating Officer

BRUKER · pwc · McKinsey&Company



Mike Pisetsky

General Counsel & Chief Compliance Officer

New Wave Surgical · Cooley

Nikolas Kerr

VP, Global Product Management & Business Development

BAXANO · Medtronic

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NASS - Analyst Surgeon Panel

Peter Whang, MD, FACS

- **Medical Education:** Duke University, 1999
- **Residency:** Orthopaedic Surgery, University of California, Los Angeles
- **Fellowship:** The Rothman Institute at Thomas Jefferson University, Philadelphia, PA
- **Board Certifications:** AB of Orthopaedic Surgery, Orthopaedic Surgery, 2009, recertified 2020

Yale University
School of Medicine

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Dr. Whang's Background

- Associate Professor, Yale Department of Orthopaedics and Rehabilitation
- Specializes in treating diseases of the cervical, thoracic, and lumbar regions of the spine
- Topic: Prevalence, Education and Treatment of SI Dysfunction

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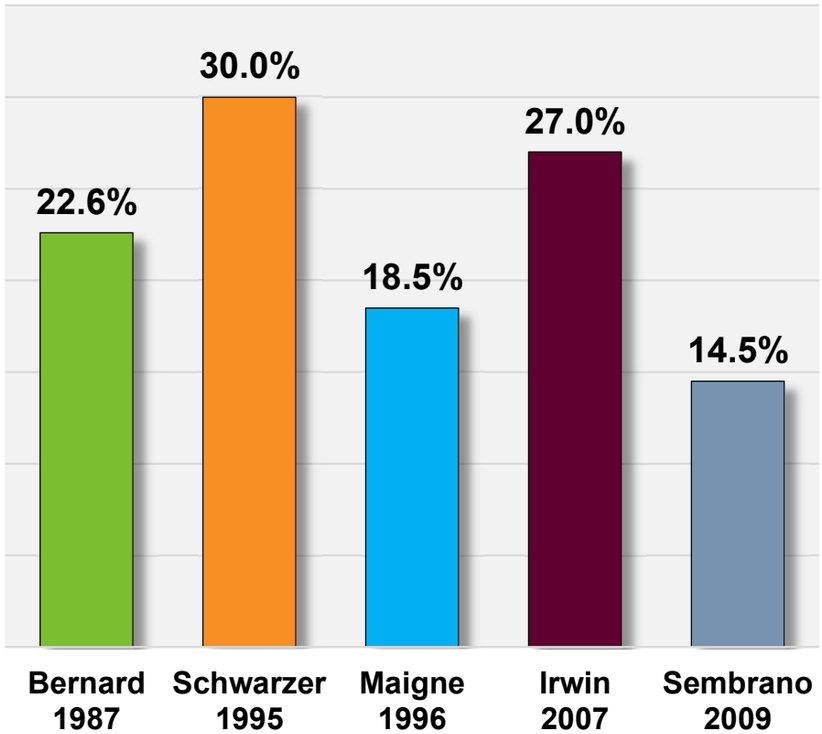
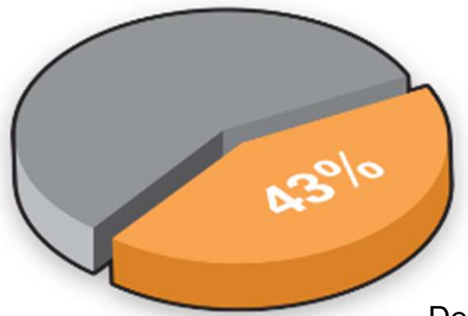
15-30%

Component of chronic LBP



32-43%

Symptomatic Post-Lumbar Fusion



DePalma – *Pain Med* 2011

32% Katz 2003
35% Maigne 2005
43% DePalma 2011
40% Liliang 2011

Burden of Disease: Utility Values

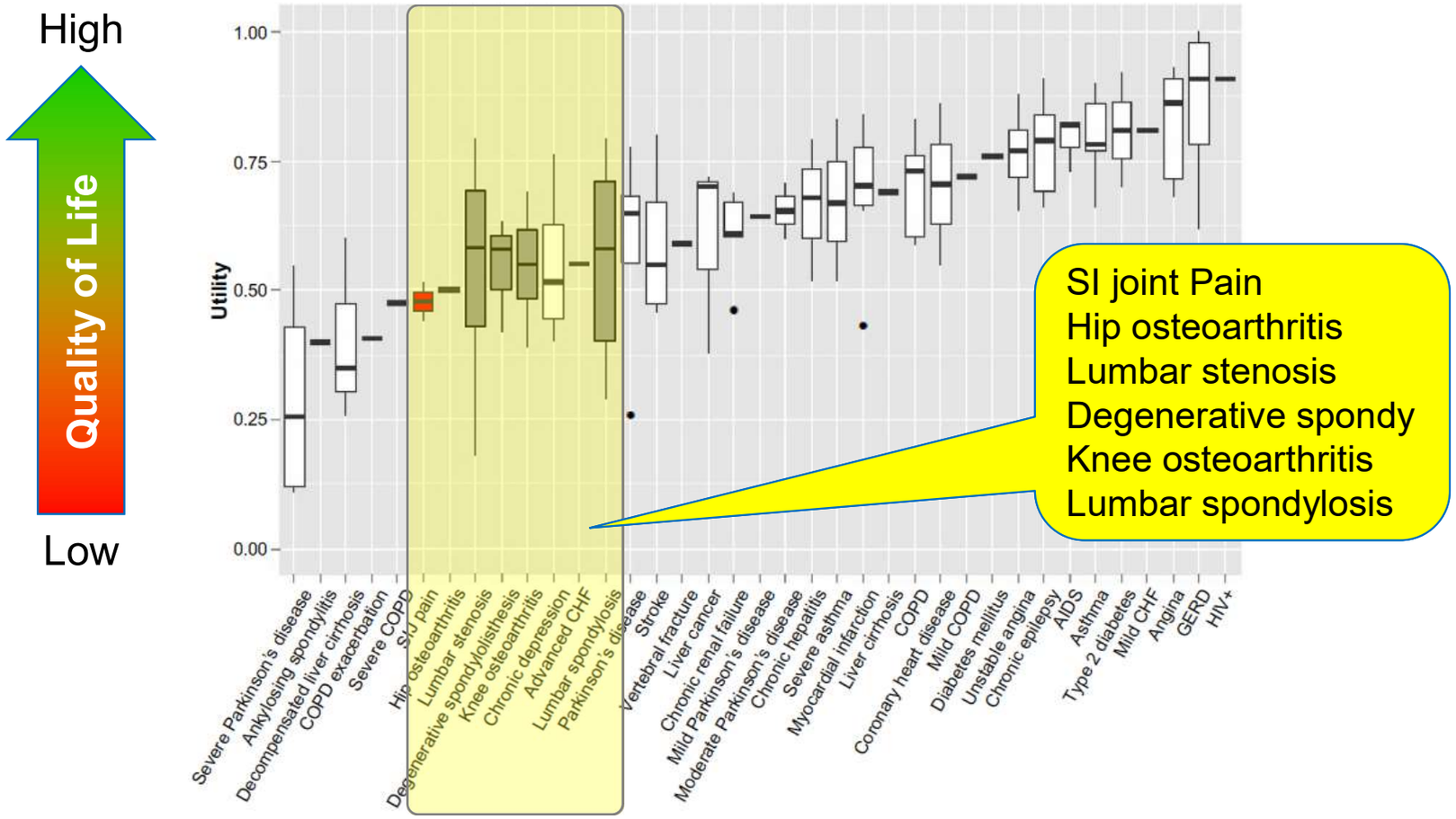


Figure 3 Comparison of utility of SIJ pain with utility values for major diseases, ordered by impact on quality of life.
Abbreviations: COPD, chronic obstructive pulmonary disease; SIJ, sacroiliac joint; CHF, congestive heart failure; AIDS, acquired immunodeficiency syndrome; GERD, gastroesophageal reflux disease; HIV+, human immunodeficiency virus positive.

Cher – *Med Devices Evid Res* 2014

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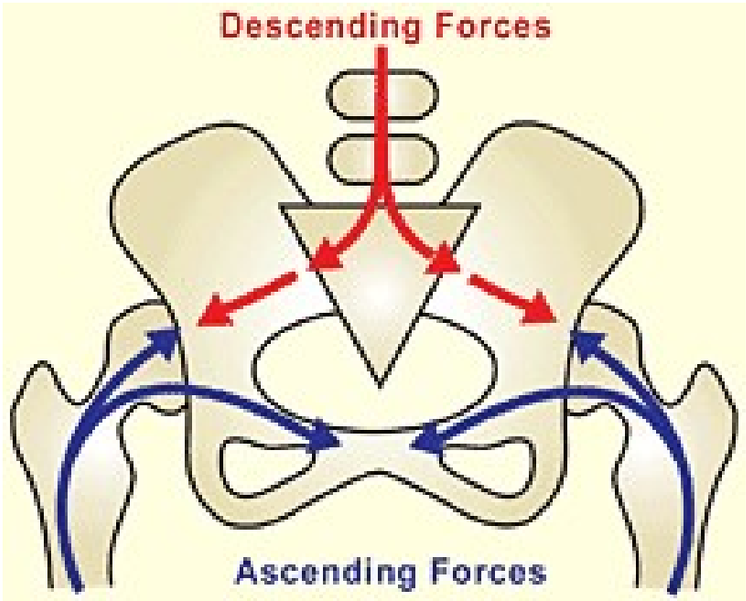
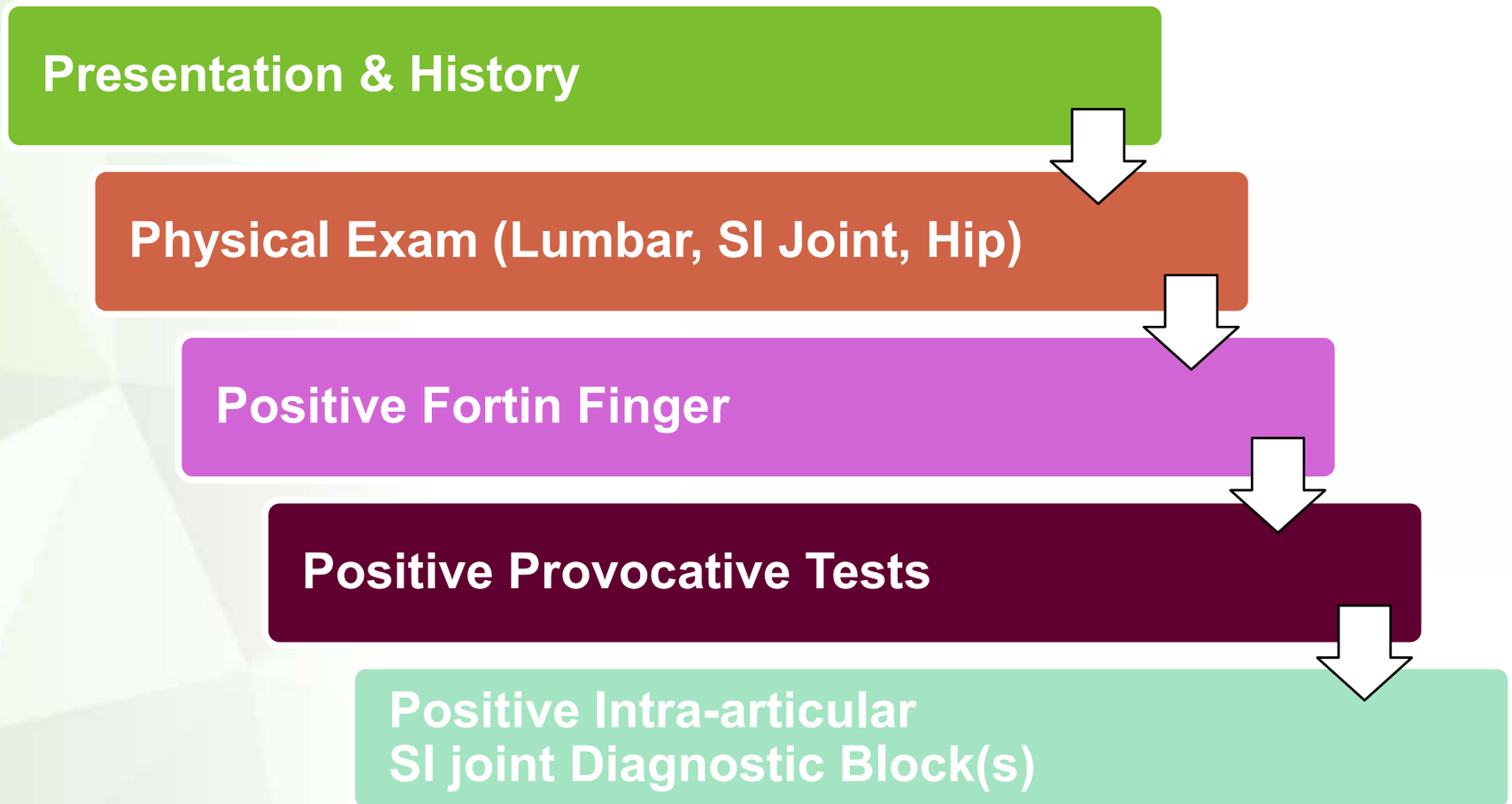
- **SI joint symptoms are similar to those of other lumbar spine and hip conditions**
- **Imaging studies often inconclusive**
- **Referral pain patterns from the three structures overlap**
  (Lumbar Spine – SI – Hip)

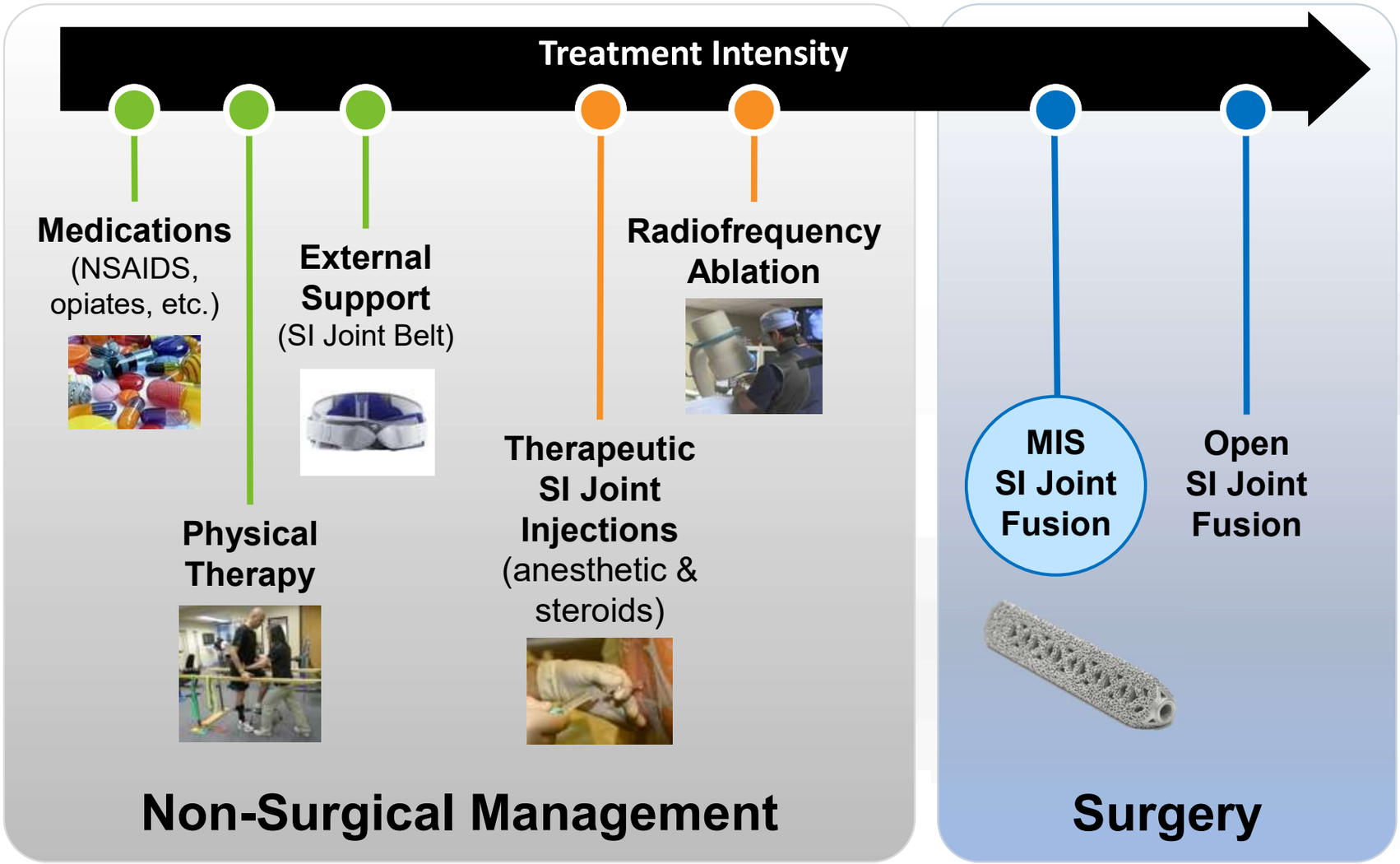
Lumbar Spine – SI – Hip



Diagnostic Algorithm



SI Joint Treatment Continuum



iFuse Implant System®

Unique Patented Design

- Triangular shape (minimizes rotation)
- Interference press fit (immediate fixation)
- Porous titanium surface
  (allows for bony ongrowth/ingrowth for long-term fusion)*

Specifications

3X stronger than screw

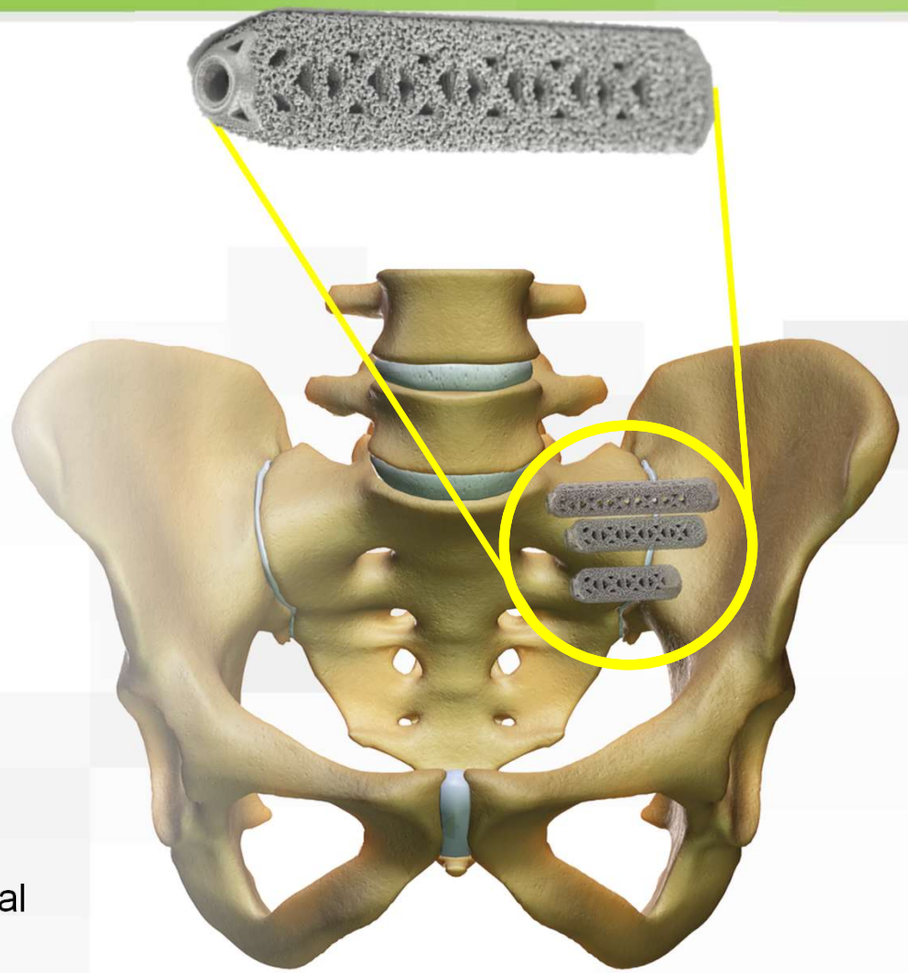
(iFuse vs. 8.0mm cannulated screw, Mauldin 2009, SI-BONE)

6X greater rotational resistance than screw

(Test Report. SI-BONE 300610-TS Revision A, vs. Rialto)

Clinical Evidence

- **ONLY** SI joint fusion product with multiple prospective clinical safety and effectiveness publications including 2 RCTs
- More than **80+** peer-reviewed publications (www.si-bone.com/results)



* MacBarb – *Int J Spine Surg* 2017 (Part 2)

SI-BONE®

iFuse – 3D™

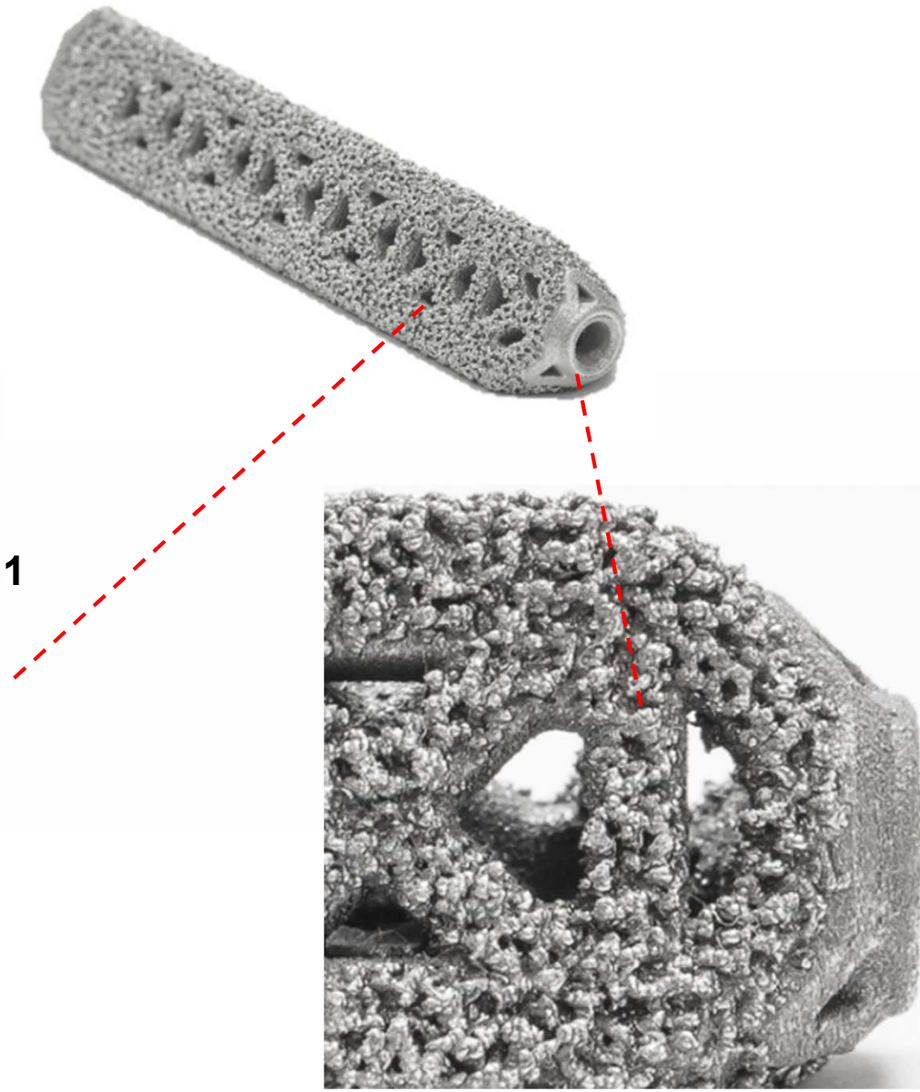
Proven triangular shape

1st 3D-printed implant for the SI joint

Demonstrates Substantial

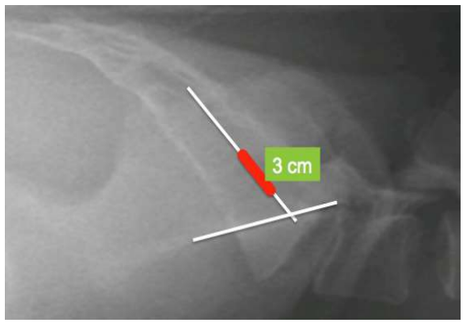
Bone Ingrowth, Ongrowth, and Through Growth[1]

- Porous surface mimics cancellous bone
- Self-harvesting technology
- Ability to apply graft material



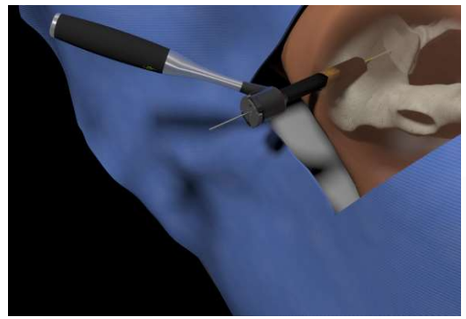
1. MacBarb G, et al. *Int J Spine Surg*. 2017:11;116-28.

iFuse Procedure Overview

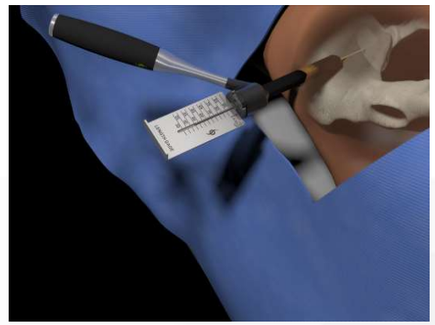


Incision
(~3 cm)

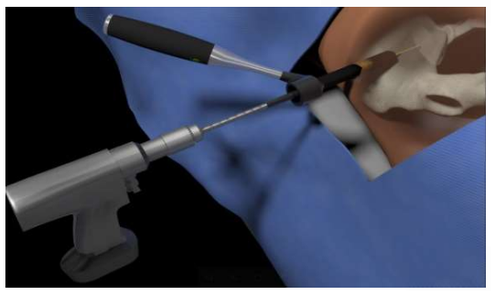
Pin



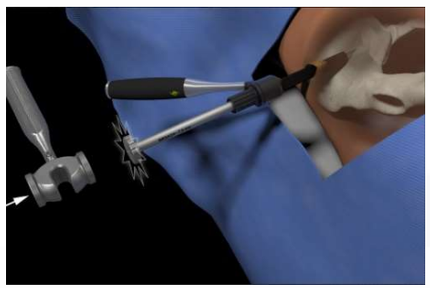
Soft Tissue Protector



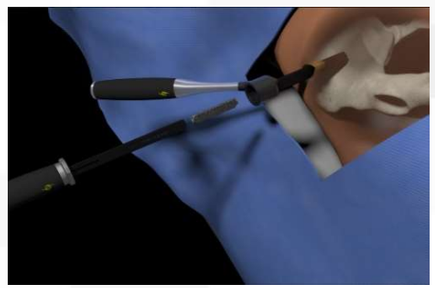
Measure



Drill
(*optional with sharp-tip broach)*



Broach



Insert Implant

Repeat
(2 more times)

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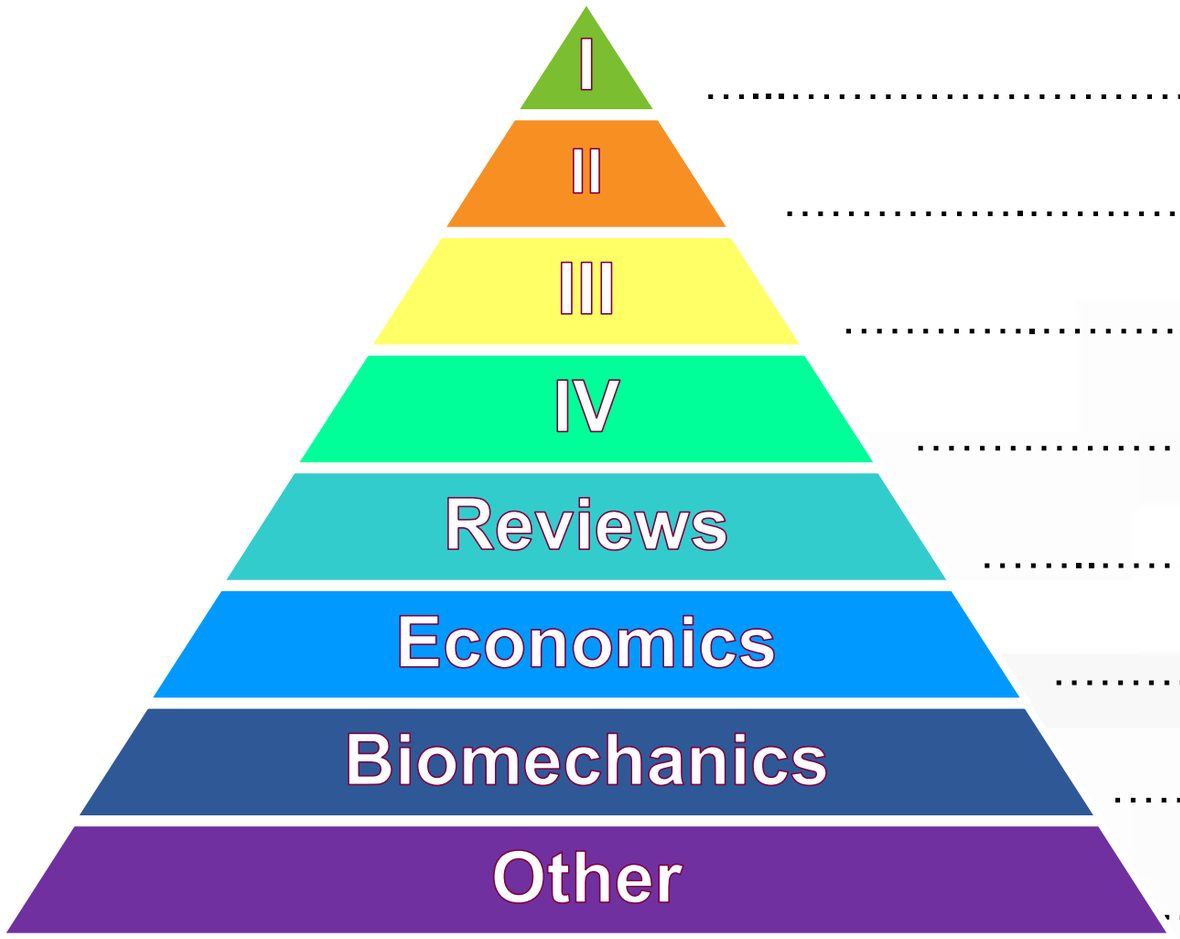
iFuse Implant System® Publications



I	10	RCT (INSITE, iMIA)
II	9	Prospective, Multicenter
III	7	Comparative
IV	19	Retrospective Case Series
Reviews	8	Systematic Review, Meta-analysis
Economics	7	Cost-effectiveness, Productivity, etc.
Biomechanics	10	Stability, Implant Placement, etc.
Other	13	Complications, Survivorship, etc.

80+
February 2020

SI-BONE®

Prospective Clinical Studies

RCTs

INSITE
NCT01681004

Completed

Investigation of **S**acro**i**liac Fusion **T**reatm**e**nt

Multicenter,
Prospective, RCT (USA)
2-year follow-up
148 patients enrolled
(102 iFuse, 46 NSM)
19 sites

Publications
6mo
1yr
2yr

iMIA
NCT01741025

Completed

iFuse Implant System®
Minimally **I**nvasive
Arthrodesis

Multicenter,
Prospective, RCT (EU)
2-year follow-up
103 patients enrolled
(52 iFuse, 51 CM)
9 sites, 4 countries

Publications
6mo
1yr
2yr

SIFI
NCT01640353

Completed

Sacro**i**liac Joint **F**usion with **i**Fuse Implant System

Multicenter, Prospective,
Single-arm
2-year follow-up
172 iFuse patients
26 sites

Publications
6mo interim
1yr
2yr

LOIS
NCT02270203

Completed

Long-Term Follow-up in **I**NSITE/**S**IFI

Extended follow-up for
INSITE & SIFI
5-year follow-up
Safety & Effectiveness
103 iFuse patients from
select SIFI & INSITE
sites (12)

Publications
3yr
4yr
5yr

SALLY
NCT03122899

Study of Bone Growth in the Sa**c**roi**l**iac Joint After Minima**l**ly Invasive Surger**y** with Titanium Implants

SI joint fusion with the
iFuse-3D implant
5-year follow-up
(outcomes & CT scans)
51 Patients
11 sites

Publications
6mo interim

(follow-up continues)

Deformity - RCT

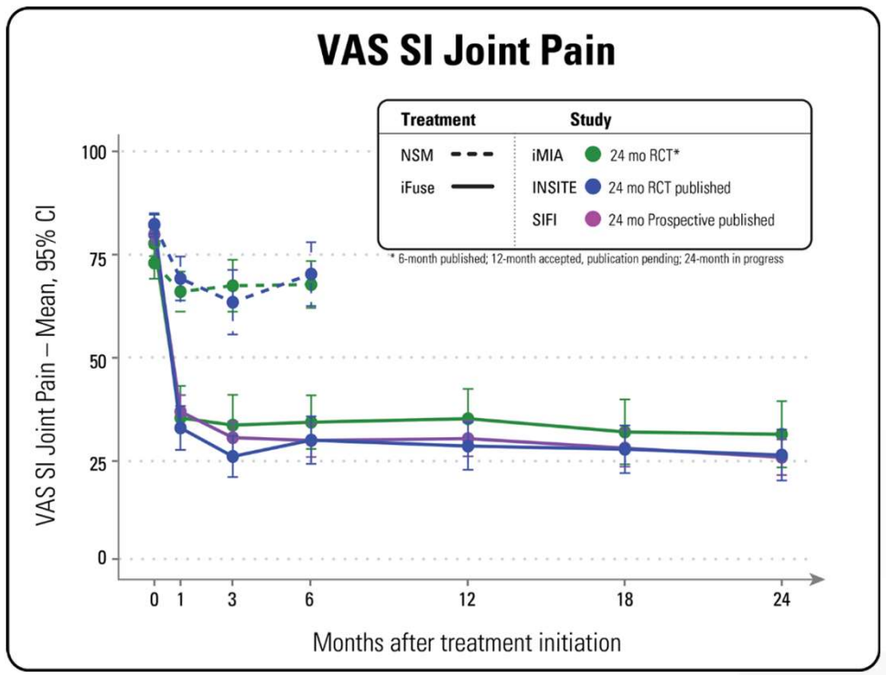
SILVIA
NCT04062630

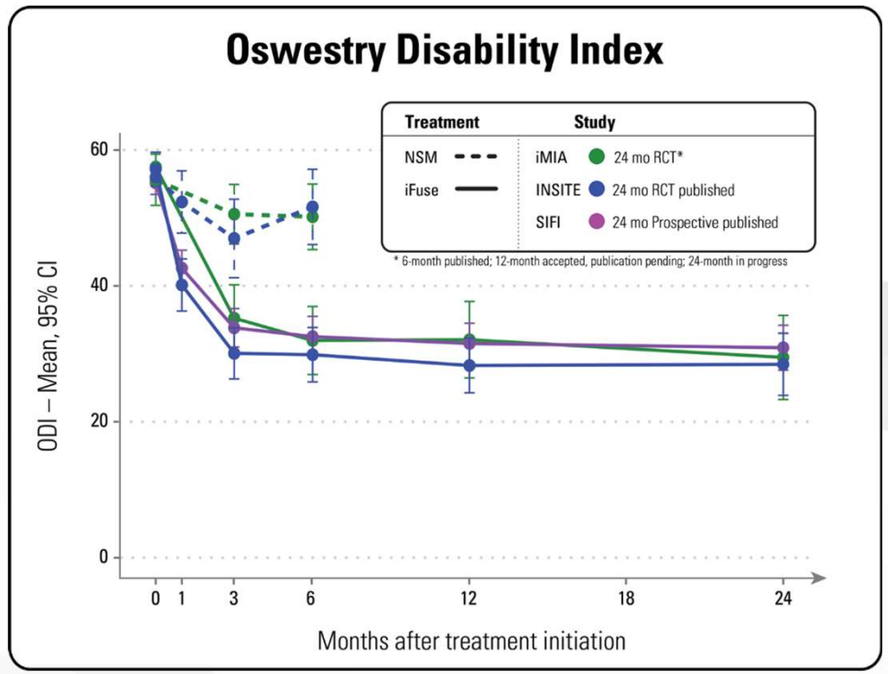
SIJ Stabilization in **L**ong Fusion to the Pel**vi**s: Prospective Cohort **A**nalysis

Multicenter,
Prospective, RCT (USA)
2-year follow-up
- Standard multilevel fusion with fixation to pelvis using S2AI screws
- Same + use of iFuse-3D in the "bedrock" trajectory

Site enrollment in progress

Consistent Prospective Study Results (INSITE, iMIA, SIFI)





Graphs using data from:

iMIA 24mo data as of August 17, 2017
(publication in progress)

Polly – *Int J Spine Surg* 2016 (INSITE 2yr)

Duhon – *Int J Spine Surg* 2016 (SIFI 2yr)

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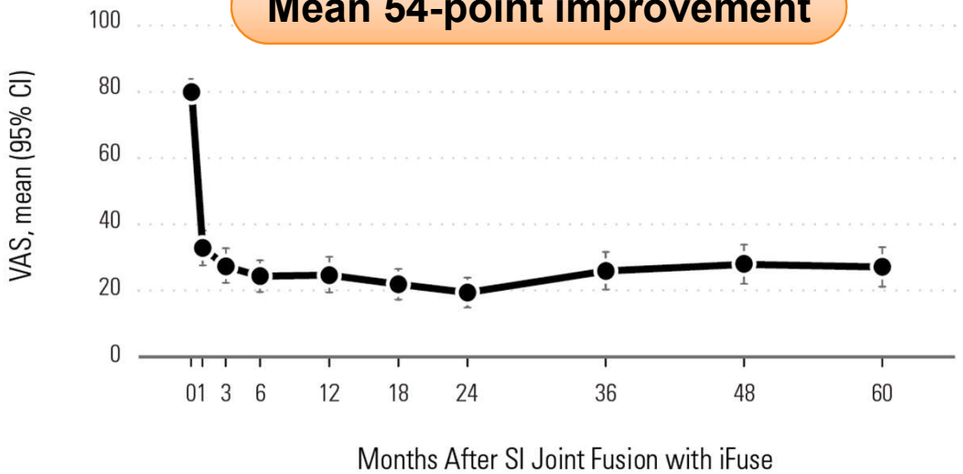
SI Joint Pain

Mean 54-point improvement

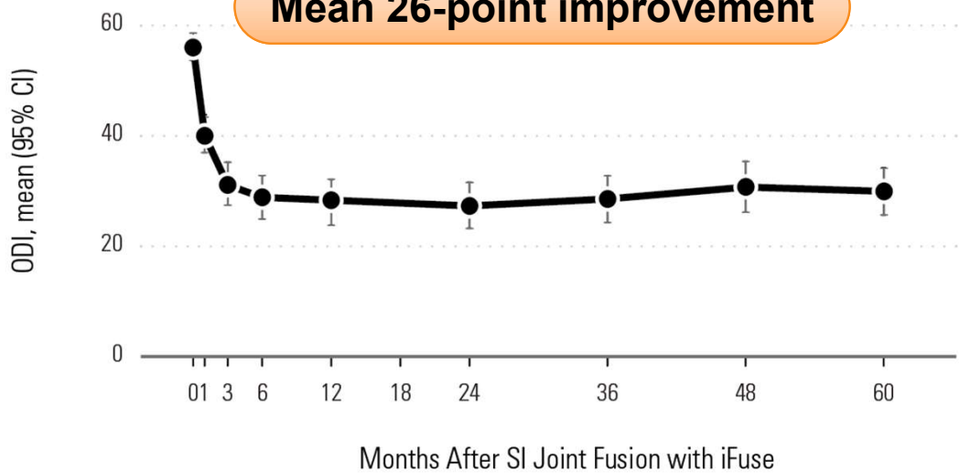


	Clinically Meaningful Improvement
VAS	20 points

Source: Childs – *Spine 2005;30:1331.*

Oswestry Disability Index

Mean 26-point improvement



	Clinically Meaningful Improvement
ODI	15 points

Source: Copay – *Spine J* 2008

Whang – *Med Devices Evid Res* 2019 (LOIS 5yr)

iFuse Implant System Clinical Evidence

Consistent Positive Clinical Outcomes

- Rapid pain relief (~50-point improvement)
- Improvement in back function (~30-point ODI improvement)
- High patient satisfaction (>90%)
- Superior outcomes compared to non-surgical management
- Durable outcomes (out to 5 years)
- Low revision rate (< 5%)
- Better outcomes *vs*. open fusion
- Solid biomechanical analysis
- Cost-effective

Only SI Joint Fusion Device Cleared by the FDA with multiple RCTs and prospective clinical publications

February 2020

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Bharat Desai, MD

- **Medical Education:** Temple University School of Medicine
- **Residency:** Geisinger Medical Center
- **Rotating Internship / Residency:** Geisinger Medical Center, Orthopedic Surgery
- **Orthopedic Trauma Fellowship:** Harborview Medical Center/UW School of Medicine

PANORAMA
Orthopedics & Spine Center

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Dr. Desai's Background

- Clinical Practice: Orthopedic Trauma & Foot/Ankle Panoramaorthopedic & Spine Center, Golden CO
- Orthopedic Pelvis/ Acetabular Surgeon:
- Chief Medical Officer (CMO) OrthoColorado Hospital
- Topic: Sacroiliac Joint Fusion in Trauma and the Role of Telehealth

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Non-Traumatic Fractures Are Often Occult

- Few are identified with plain X-ray
- CT and MRI are more sensitive
- 70% of patients with pubic rami fx also have sacral fx

1. Lyders EM *et al. Amer J Neurorad* 2010;31(2): 201-210.
2. Sahota O, *et al. FFN Meeting.* 2019; Abstract 249.

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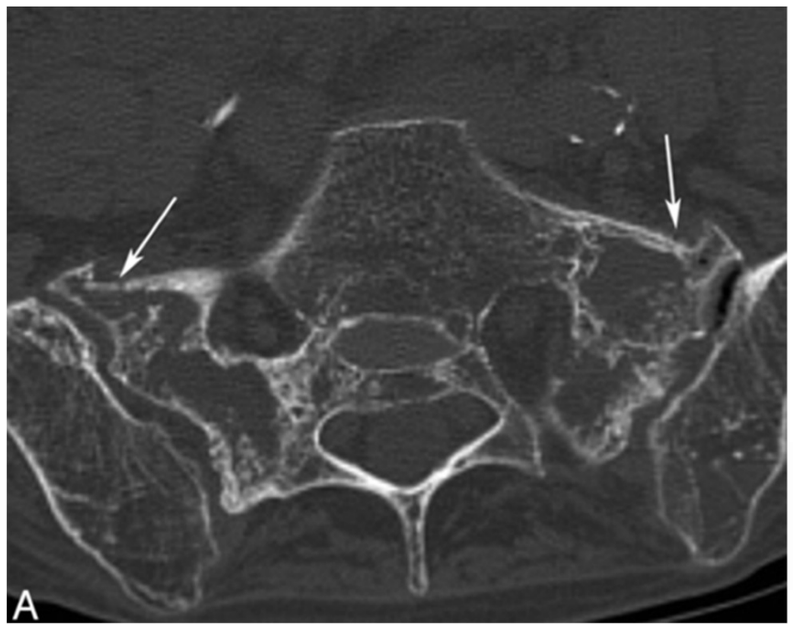
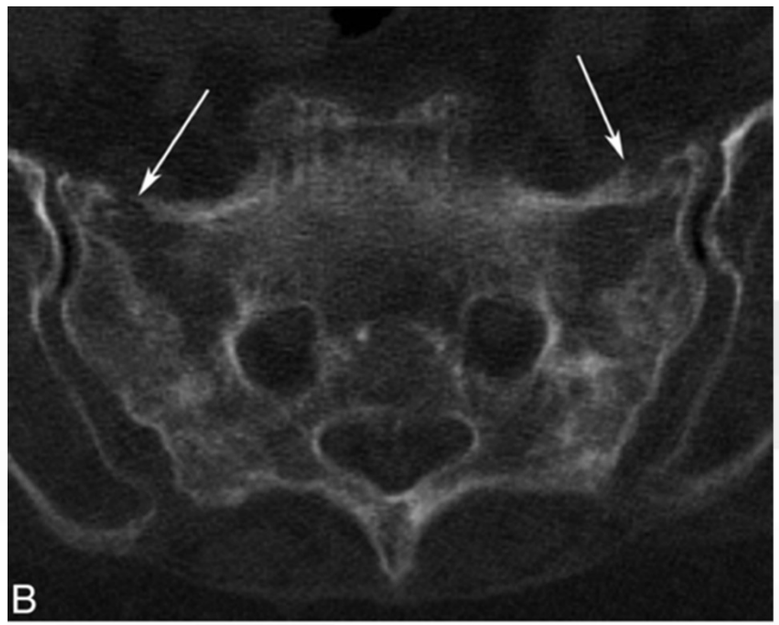
CTs are 75% Sensitive





Axial CT scans of the pelvis in 2 different patients demonstrate bilateral non-traumatic sacral fractures (*white arrows*) with mottled sclerosis/lucency and cortical breaks.

Lyders EM *et al. Amer J Neurorad* 2010;31(2): 201-210.

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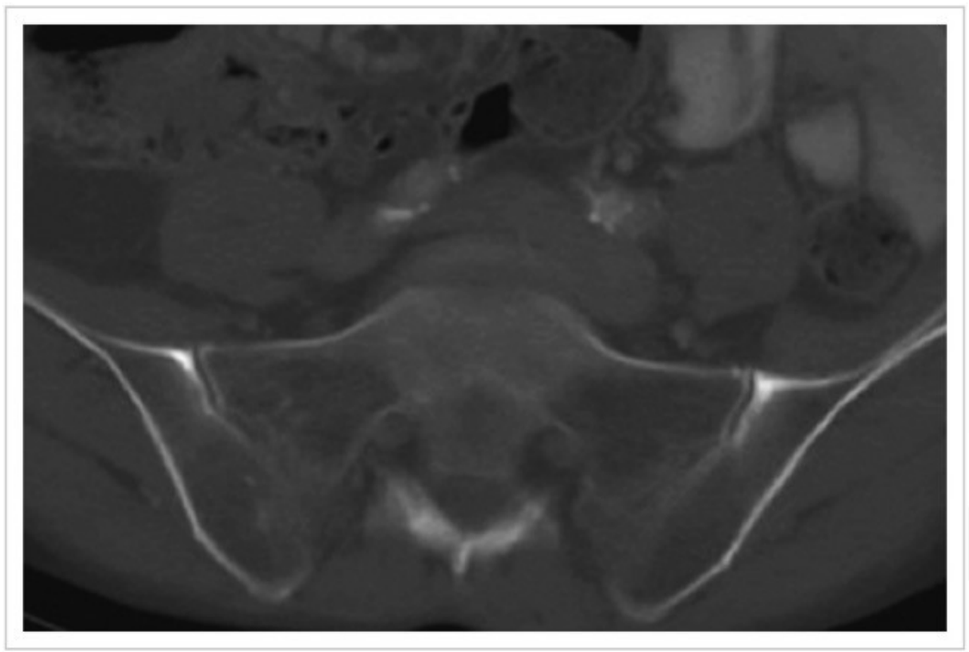
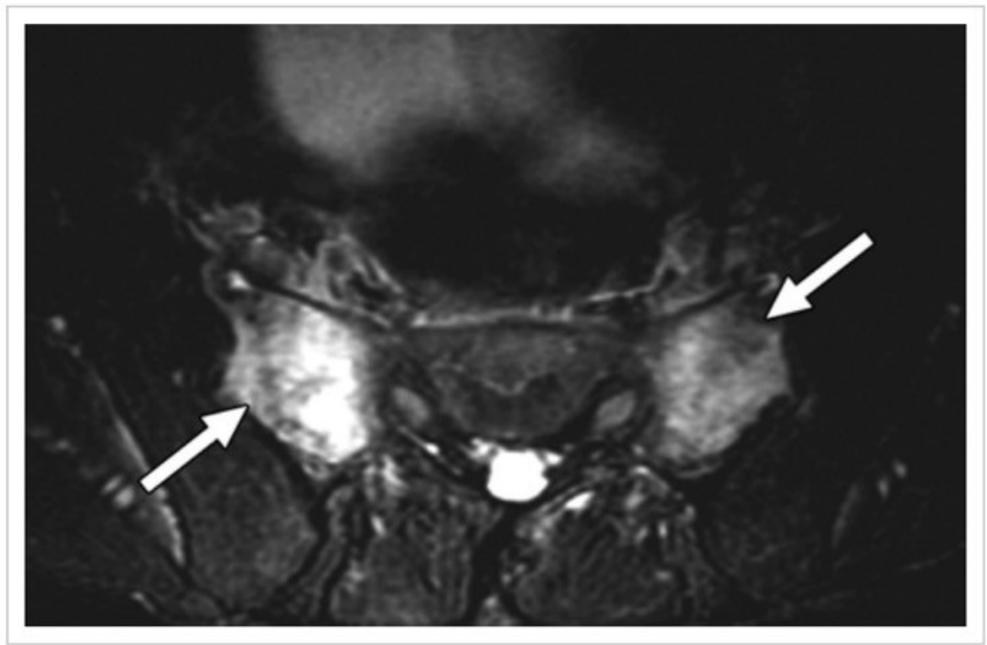
MRI vs. CT

- MRI was substantially better than CT in detecting non-traumatic fractures
- In addition, two or more non-traumatic fractures were frequently present





Cabarrus MC, *et al. American Journal of Roentgenology.* 2008;191: 995-1001.

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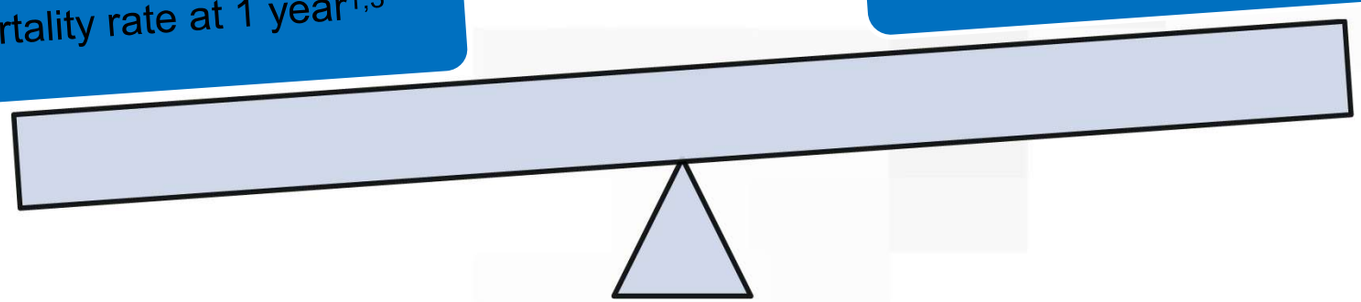
Nonsurgical VS Surgical

Nonsurgical management:

- 14-45 day avg. hospital stay[1-3]
- 29-61% risk of thromboembolic disorder [4,5]
- 14-27% mortality rate at 1 year[1,3]

Surgical management:

- 20% risk of iliosacral screw backout[6]
- 32% risk of extravasation in sacroplasty procedures[7]



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Non-surgical treatment: High Mortality (up to 27%)

Postgrad Med J 2000;**76**:646–650

Closed pelvic fractures: characteristics and outcomes in older patients admitted to medical and geriatric wards

Robert O Morris, Adeniyi Sonibare, Desmond J Green, Tahir Masud

148 patients (126 women) were studied:

- 83% (n=123) of patients suffered a pelvic fracture in low energy trauma
- Mean (SD) length of hospital stay was 21.3 (17.6) days
- Inpatient mortality was 7.6% and at one year was 27%
- There was a marked adverse effect on the mobility of survivors with all patients using at least a walking stick at discharge and 51.1% (n=70) needing assistance for mobility
- Rates of institutionalization rose from 20.9% (n=31) at admission to 35.8% (49/137) of survivors at discharge

Morris R, *et al. Postgrad Med J.* 2000;76 (900):646.

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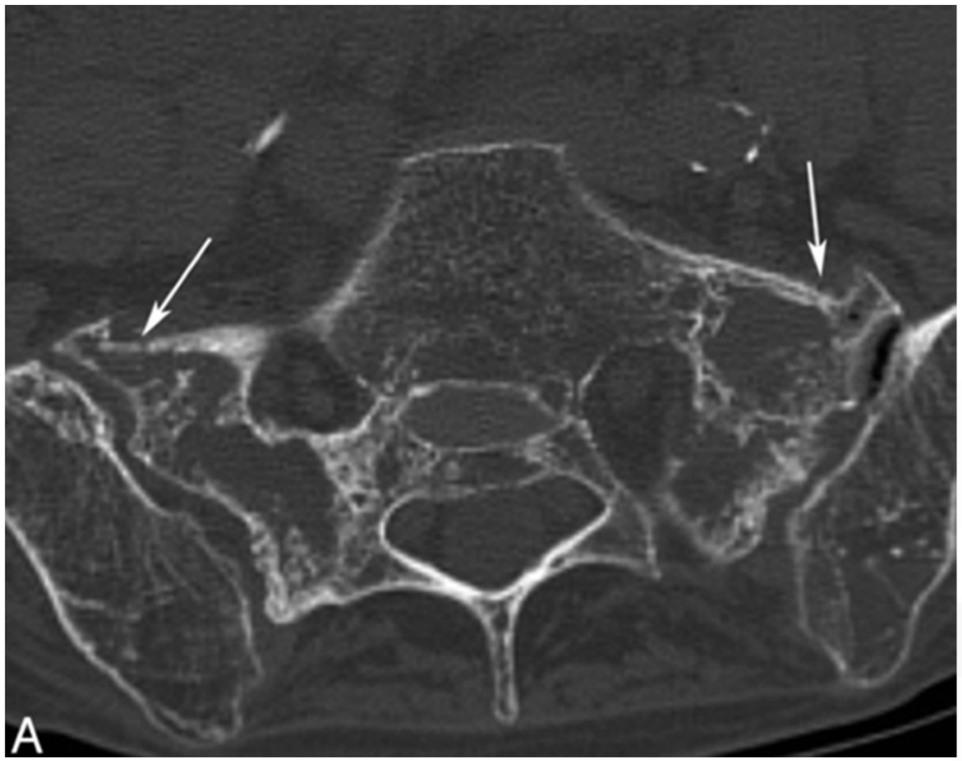
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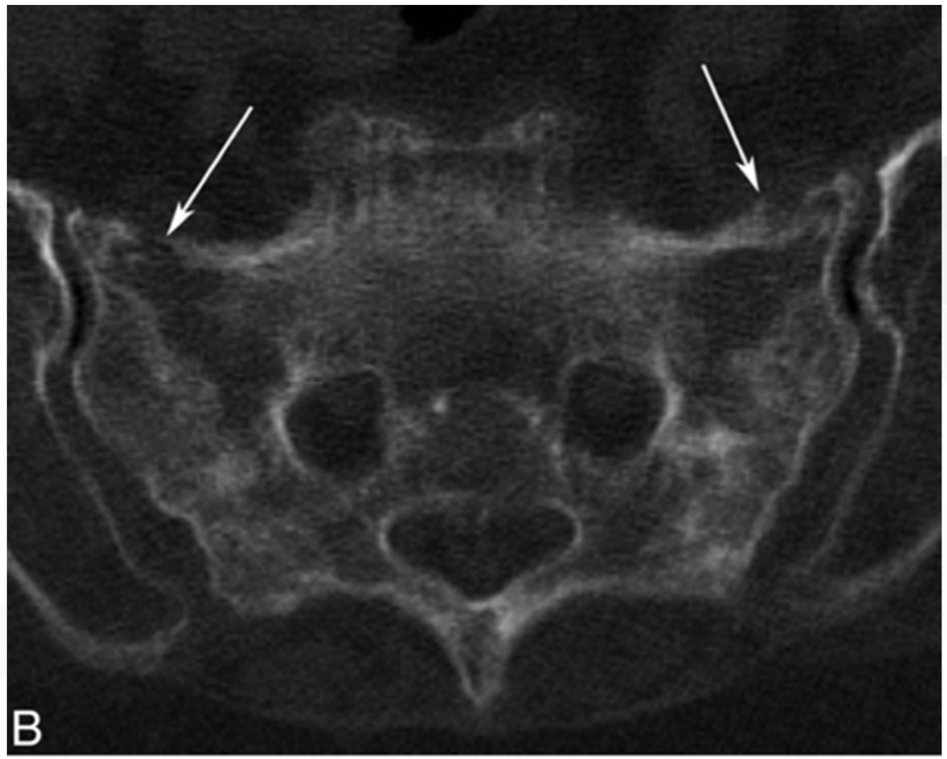
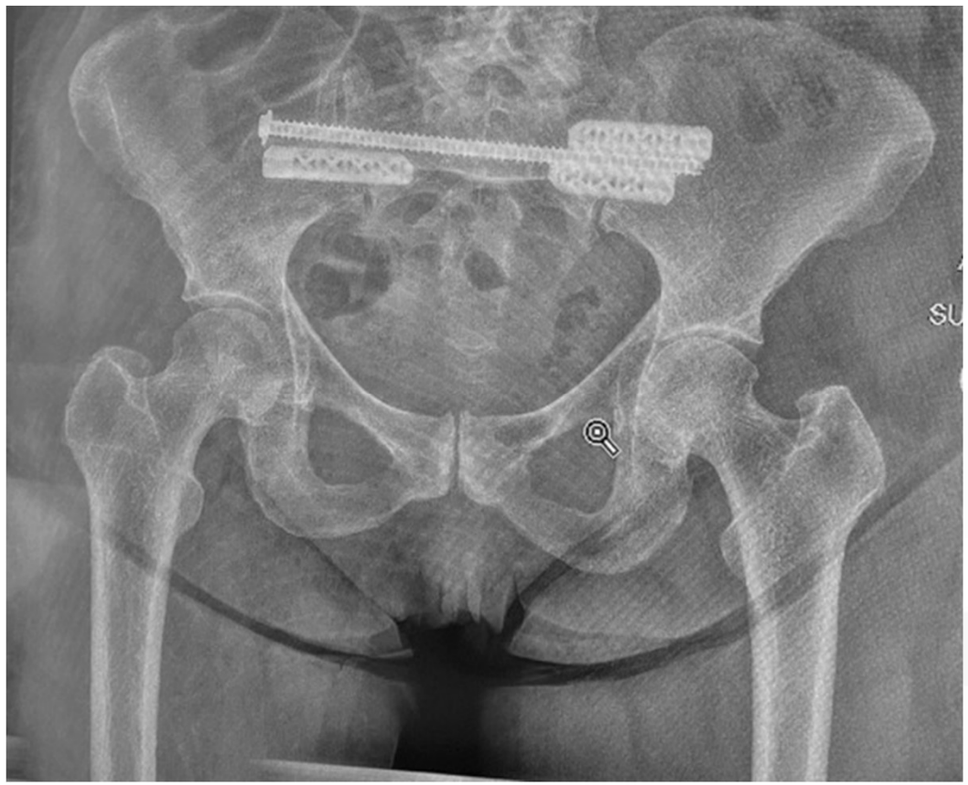

B



Case courtesy of Bharat Desai, MD, Panorama, Golden, CO
*Results may vary

William Tobler, MD

- **Undergraduate:** University of Notre Dame, 1974; University of Innsbruck, Austria, 1971-1972
- **Medical Education:** University of Cincinnati College of Medicine, 1978
- **Internships:** Internal Medicine, 1978-1979, and General Surgery, 1979-1980, Good Samaritan Hospital, Cincinnati
- **Residency:** Neurosurgery, UC Medical Center & Mayfield Clinic, 1980-1985

MAYFIELD
Brain & Spine

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Dr. Tobler's Background

- Clinical Practice
- Sacro Pelvic, Trauma or Adult Deformity Experience
- Topic: The shift in spino-pelvic procedures to the ASC setting and why are sacroiliac fusions with iFuse a good fit.

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Robert Eastlack, MD

- **Medical Education:** Baylor College of Medicine, MD, 1999
- **Residencies:** University of California, San Diego, Orthopaedic Surgery, 2005
- **Fellowships:** Mayo Clinic, Orthopaedic Surgery, Spine, 2006
- **Board Certifications:** American Board of Orthopaedic Surgery, Orthopaedic Surgery, 2008

Scripps

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Dr. Eastlack's Background

- MIS degenerative and open/MIS deformity practice
- ISSG member and SRS Adult Spinal Deformity Committee Chairman
- Division Head, Spine Surgery at Scripps Clinic
- Topic: Biomechanical and clinical evidence for long constructs including the ISSG study and SILVIA

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JNS SPINE

CLINICAL ARTICLE

J Neurosurg Spine 23:67–76, 2015

Unplanned reoperation after lumbopelvic fixation with S-2 alar-iliac screws or iliac bolts

Marcus D. Mazur, MD,[1] Vijay M. Ravindra, MD,[1] Meic H. Schmidt, MD, MBA,[1] Darrel S. Brodke, MD,[2] Brandon D. Lawrence, MD,[2] Jay Riva-Cambrin, MD, MSc,[1] and Andrew T. Dailey, MD[1]

Retrospective, 60 patients (37 IS; 23 S2AI)

6 reop for IS vs. 1 reop for S2AI (OR 8.1)

- **5 reop in IS**
- **Reoperation higher for iliac bolts**

Failure rate at 2 years 26.5%

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ASIAN SPINE JOURNAL
Clinical Study
Asian Spine J 2020;14(2):177-184 • https://doi.org/10.31616/asj.2019.0127

The Prevalence and Risk Factors for S2 Alar-Iliac Screw Loosening with a Minimum 2-Year Follow-up

Hiroaki Nakashima[1], Tokumi Kanemura[1], Kotaro Satake[1], Kenyu Ito[1], Yoshimoto Ishikawa[1], Jun Ouchida[1], Naoki Segi[2], Hidetoshi Yamaguchi[2], Shiro Imagama[2]

[1]*Department of Orthopedic Surgery, Konan Kosei Hospital, Konan, Japan*
[2]*Department of Orthopedic Surgery, Nagoya University Graduate School of Medicine, Nagoya, Japan*

Evaluated 35 patients with S2AI screw fixation, PLIF/TLIF at L5-S1

CT analysis with > 2yr f/u

Concluded

- **50% loosening by 2yrs**
- **Loosening correlated with lower fusion at L5-S1**

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Clinical Challenges with Iliac & S2AI Screws

Review

Long Construct Complications	ILIAC SCREWS (IS)	S2 ALAR-ILIAC SCREWS (S2AI)
2015 – 2019, 8 studies with 729 Patients		
RE-OPERATION	21.1%	19.0%
2015 – 2019, 5 studies with 575 Patients		
PAINFUL PROMINENCE	5.8%	1.7%
2013 – 2019, 6 studies with 610 Patients		
SCREW LOOSENING	6.6%	10.2%

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Iliac Screws vs. S2AI Screws

Author	Date	Follow-up	Construct	# Patients	Construct Failure	Infection	Screw Prominence	Halo / Loosening	SI Joint Pain / Pathology	Pseudarthrosis
Mazur	2015	2 to 41 mo	Iliac Screw	37	1	1	3	N/A	N/A	7
			S2AI	23	0	1	2	N/A	N/A	2
Guler	2015	6 to 24 mo	Iliac Screw	25	3	N/A	1	2	N/A	N/A
			S2AI	20	7	N/A	0	0	N/A	N/A
Ilyas	2015	Avg 29 mo	Iliac Screw	43	3	15	13	8	N/A	N/A
			S2AI	22	1	1	2	0	N/A	N/A
Ishida	2016	Min 12 mo	Iliac Screw	32	0	4	8	9	3	N/A
			S2AI	68	0	1	2	7	6	N/A
Elder	2017	Min 12 mo	Iliac Screw	25	5	11	3	3	3	2
			S2AI	68	6	1	0	2	6	4
Total			**Iliac Screw**	**162**	**12/162 (7.4%)**	**31/137 (22.6%)**	**28/162 (17.3%)**	**22/125 (17.6%)**	**6/57 (10.5%)**	**9/62 (14.5%)**
			S2AI	**201**	**14/201 (7.0%)**	**4/181 (2.2%)**	**6/201 (3.0%)**	**9/178 (5.1%)**	**12/136 (8.8%)**	**6/91 (6.6%)**

Mazur *et al*. JNS Spine 2015;23:67-76
Guler *et al*. Eur Spine J 2015;24:1085-1091
Ilyas *et al*. J Spinal Dis Tech 2015;28:E199-E205
Ishida *et al*. Global Spine J 2017;7:672-680
Elder *et al*. Spine 2017;42:E142-E149

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Rates of Loosening, Failure, and Revision of Iliac Fixation in Adult Deformity Surgery

Eastlack RK, Sorceneau A, Mundis GM, Daniels A, Smith JS, Line B, Passias P, Nunley P, Okonkwo DO, Than K, Uribe J, Mummaneni P, Chou D, Kebaish K, Shaffrey C, Bess S, ISSG

ISSG PON-database Inclusion

- ASD (coronal Cobb≥20°, SVA≥5cm, pelvic tilt ≥25° and/or thoracic kyphosis >60°)
- ≥ 18 years old
- 2yr f/u
- >5 level fusion with pelvic fixation

Multicenter with 410 patients with available at radiographs

Endpoints

- Loosening = lucency around the screw on radiographs
- Failure = breakage
- Rod fracture below L4
- Revision surgery

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Results

Overall Rates (iliac and S2AI combined)	
Loosening	13.41%
Fracture screw	2.37%
S1 screw loosening	2.92%
Lower rod fracture (below L4)	14.08%
Revision (any)	22.77%

HRQL improvements <u>WORSE with pelvic fixation failures</u>:

PCS 7.69/10.46	p=0.028
SRS 0.83/1.03	p=0.019
ODI 12.91/19.77	p=0.0016

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Conclusion

Substantial rate (29.4%) of pelvic fixation failure following ASD correction with IS/S2AI screws

<u>Poorer outcomes as a result</u>

Compared to IS, S2AI screws had:

- Higher rate of loosening
- Lower rate of rod fracture

Implications:

- Sacropelvic fixation with long constructs have high failure rates
- Probable differential failure mechanism between iliac and S2AI fixation
- Less optimal/durable clinical improvements with failures

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Pelvic Fixation and the SI joint in Deformity

Does continued motion at the SI joints cyclically stress the lumbopelvic fixation to failure?

Effect of Long-Construct Fusion on the SI Joint: *Biomechanical Study,* J Uribe, et al., 2019

How does additional sacroiliac joint stabilization affect:

- L5-S1 Range of Motion
- Sacroiliac Joint Range of Motion
- L5 Screw Stress
- S1 Screw Stress
- S2AI Screw Stress

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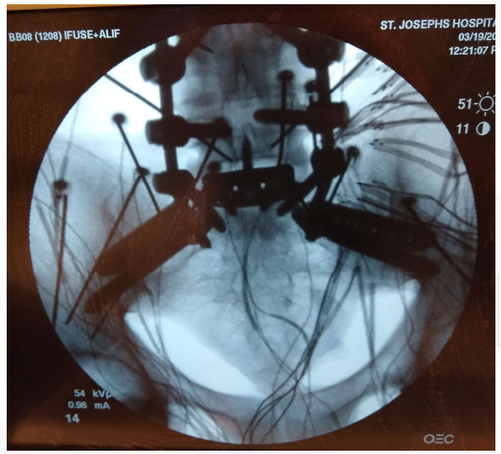
Methods

Cadaveric Model

- 7 specimens (5F/2M, 44-66yrs); L1 - Pelvis

Loading

- 7.5 N-m Moments
  - Flexion/Extension
  - Lateral Bending
  - Axial Rotation

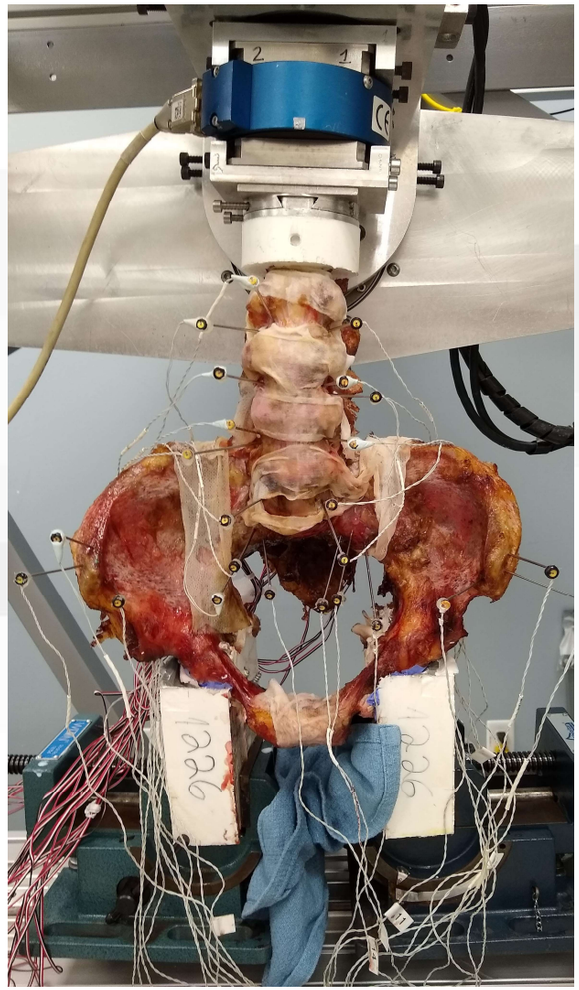


Treatment Groups

- Intact
- L2 – S1 pedicle screws + ALIF
- L2 – S2AI + ALIF
- L2 – S2AI + ALIF + SAI (iFuse-3D)

Metrics

- Range of Motion: L5-S1 and SI Joint
- Screw Moments: S1 and S2AI



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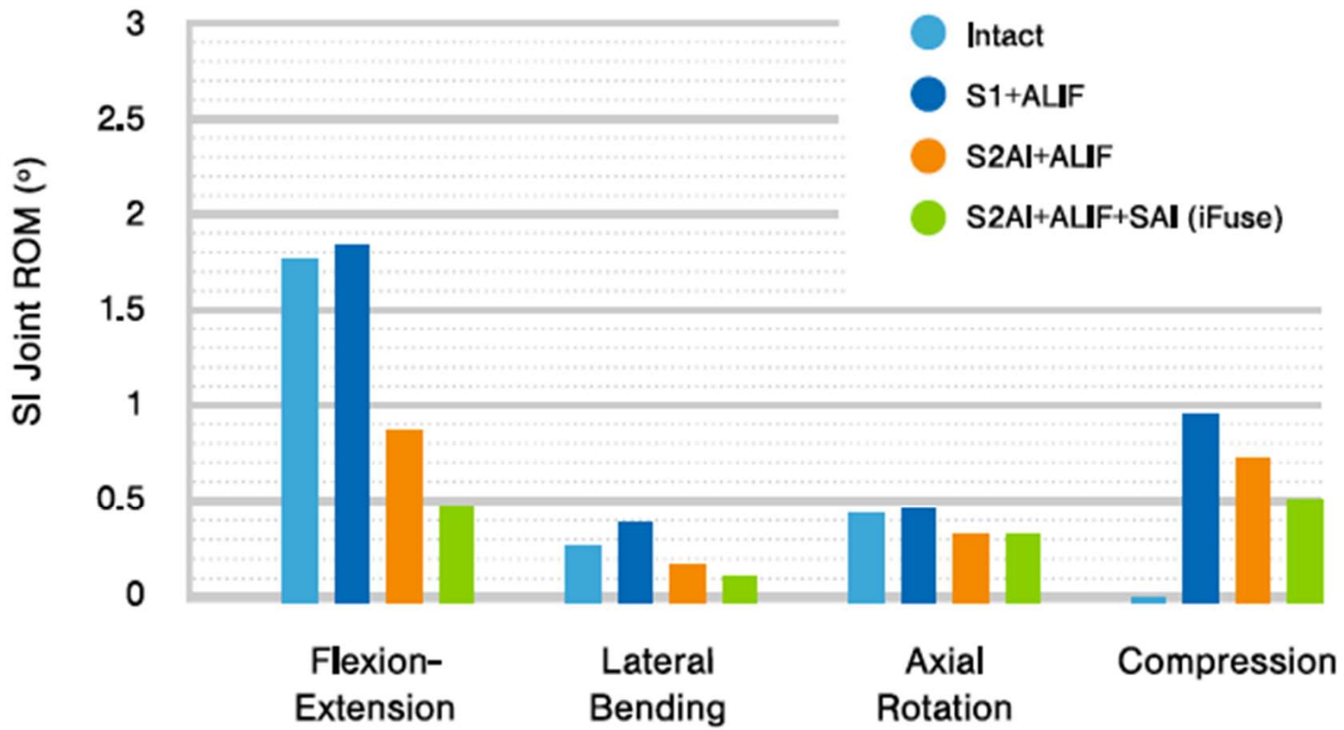
BEDROCK: Reduction in SIJ Range of Motion

Barrows Neurological Institute: iFuse Bedrock Biomechanical Study Fact Sheet

SI Joint Range of Motion (ROM)



RESULTS

iFuse Bedrock reduced SI Joint ROM in:

- Flexion – Extension 33%
- Lateral Bending 33%
- Compression 29%

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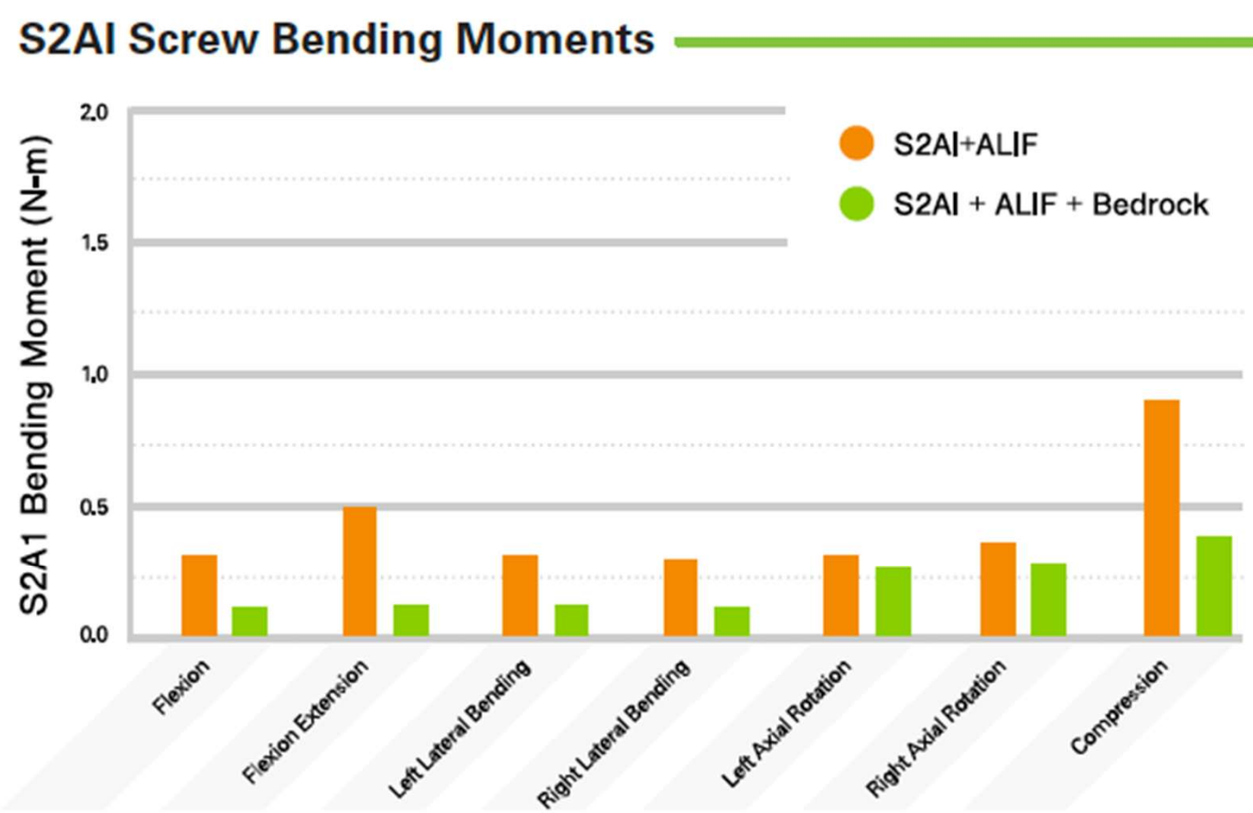
S2AI Screw Bending Moment



RESULTS

Bending Moments reduced in all vectors.

KEY TERMS

N-m or Newton meter is a unit of torque (also called moment). One Newton metre is equal to the torque resulting from a force of one newton applied perpendicularly to the end of a moment arm that is one metre long.

Bending moment is the reaction induced in a structural element (i.e., screw or rod) when an external force or moment is applied to the element causing the element to bend.

Bedrock/SI joint stabilization reduced S2AI screw bending moments in all loading directions.

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Conclusions

- Bedrock stabilizes the SI joint
- Bedrock protects the S2AI screw
- May facilitate SI joint fusion

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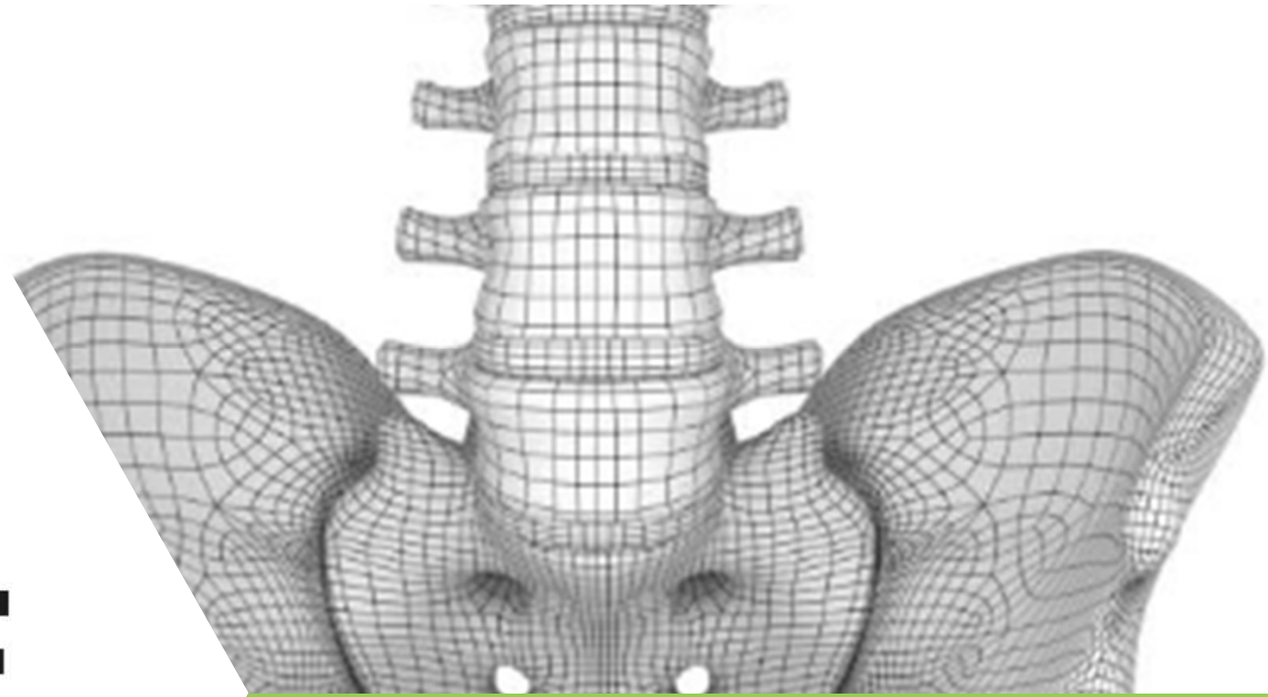

Thank you for joining us today

Disclosure

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

The iFuse Implant System is also indicated for sacroiliac fusion to augment stabilization and immobilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. Risk information available upon request**.**

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