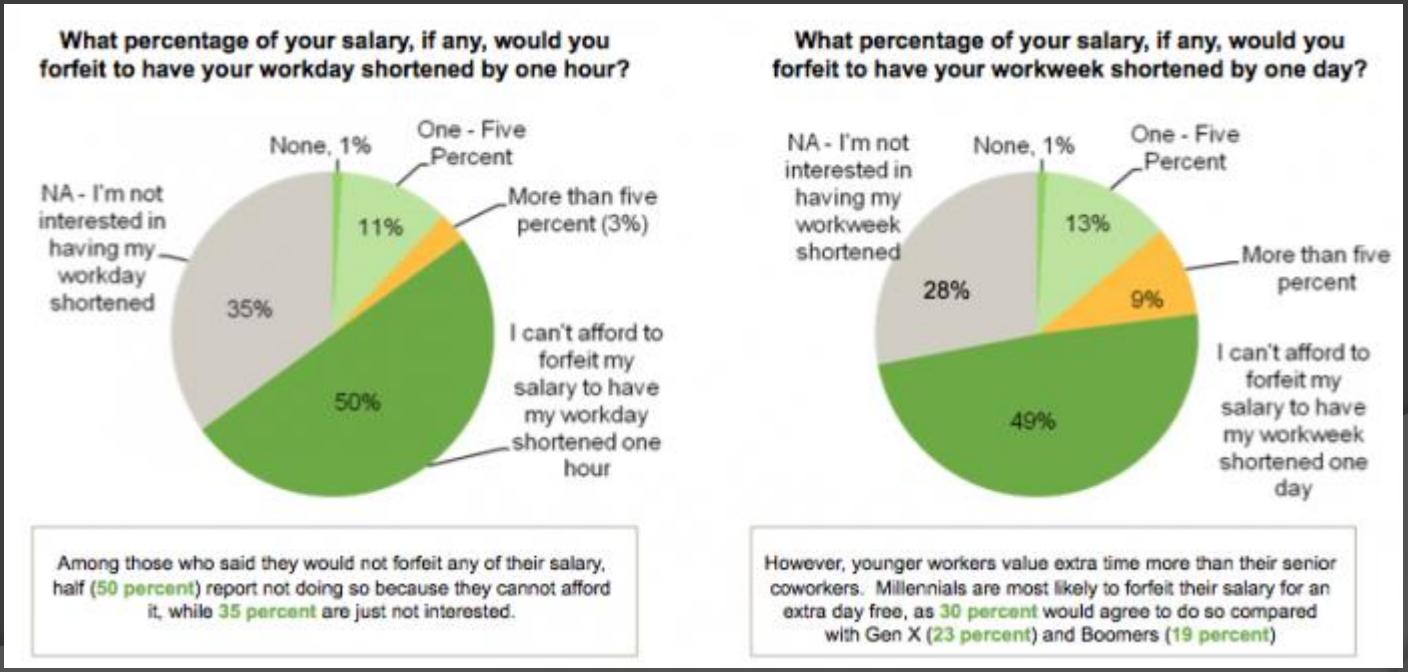
SPINE INNOVATIONS

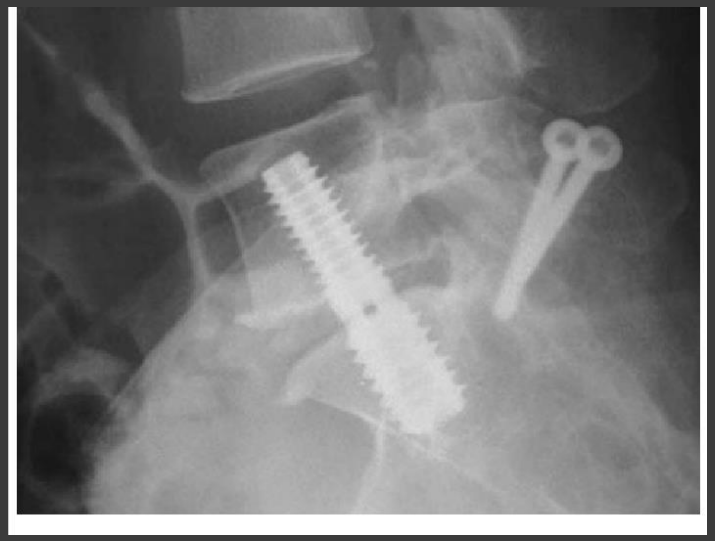
Fred Mo, MD
Associate Professor of Orthopaedics
Georgetown University

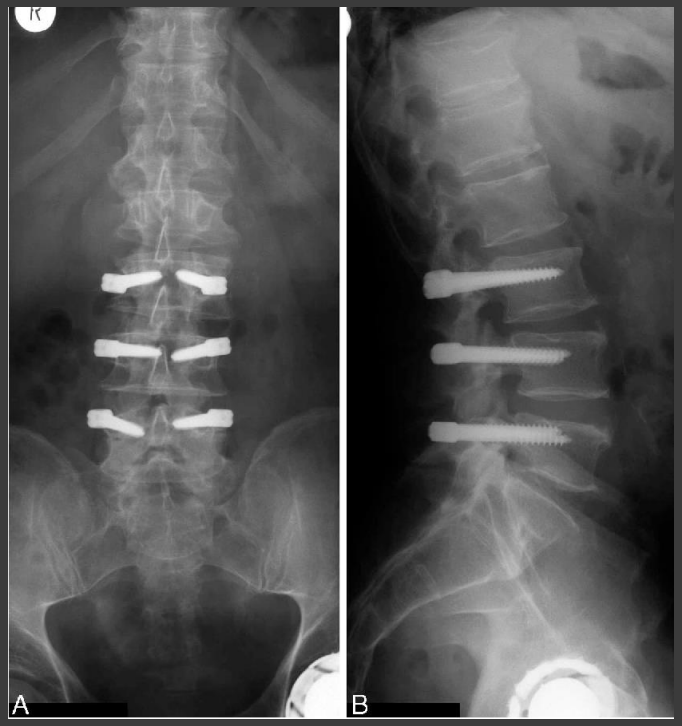
What is valuable

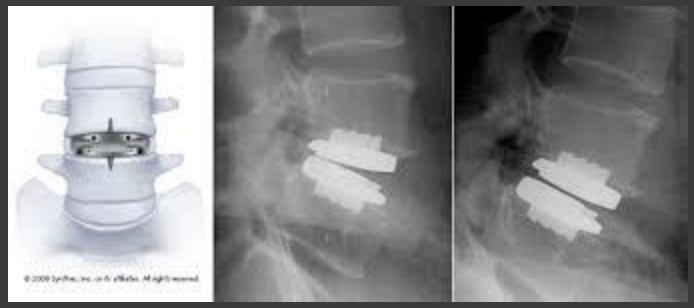
- Time
- Money
- New technology
- Staying power?



New products every year

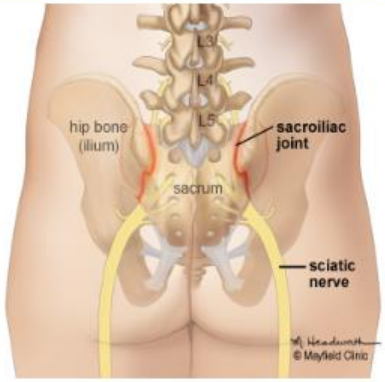






Mayfield neurosurgeon performs first RIALTO™ sacroiliac joint fusion at outpatient center using the O-arm™ Imaging System and StealthStation™ Navigation System

William Tobler, MD, of Mayfield Brain & Spine recently became the first surgeon in the United States to perform a sacroiliac joint (SI) fusion at an outpatient spine surgery center using the RIALTO™ system with O-arm™ and StealthStation™ technology for 3-D navigation. The patient went home to recuperate a few hours after the one-hour procedure was completed.

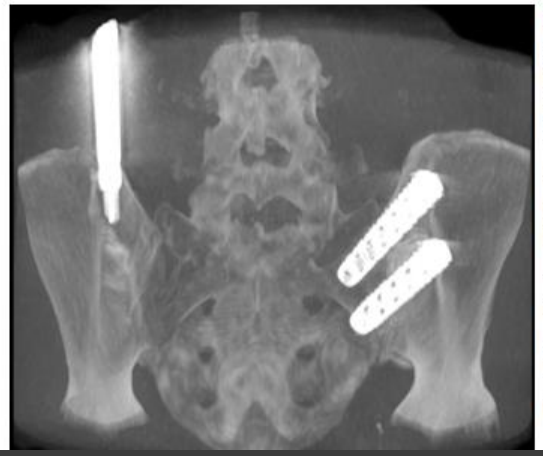


The O-arm is a technology that provides high-resolution images of the spine and surgical site before, during and immediately after surgery. It is marketed by Medtronic.

The RIALTO fusion system, a set of specialized fixation screws for sacroiliac (SI) joint fusion, is also marketed by Medtronic.

"The O-arm imaging device, when used with navigation technology, enabled me to do a sacroiliac fusion at Mayfield's Spine Surgery Center," Dr. Tobler says. "We have used the O-arm at the Spine Surgery Center before, but never for an SI fusion. This was a fantastic way to do this particular procedure."

The benefits of using the O-arm during an SI fusion, Dr. Tobler says, include real-time images of the anatomy. The procedure involves the placement of titanium implants and bone graft material to stabilize the joint and promote bone growth.



The SI joints, which connect the spine to the hips, provide support and stability. They also absorb impact when an individual walks or lifts an object. Sacroiliac pain can occur when bones become arthritic and ligaments stiffen during the aging process.

Typically, SI joint fusion has been performed in a hospital setting, with patients staying overnight and going home the next day.

"Performing the SI fusion at the Spine Surgery Center is significant, because it demonstrates our ability to perform more and more sophisticated surgeries at an ambulatory center," Dr. Tobler says.

Mayfield acquired the O-arm system in 2016.

O-arm

November 15, 2016
FOR IMMEDIATE RELEASE

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Buyer beware

NEUROSURGICAL FOCUS

Neurosurg Focus 40 (1):E2, 2016

Complications associated with the Dynesys dynamic stabilization system: a comprehensive review of the literature

Martin H. Pham, MD,[1] Vivek A. Mehta, MD,[1] Neil N. Patel, MD,[2] Andre M. Jakoi, MD,[2] Patrick C. Hsieh, MD,[1] John C. Liu, MD,[1] Jeffrey C. Wang, MD,[2] and Frank L. Acosta, MD[1]

Departments of [1]Neurosurgery and [2]Orthopedic Surgery, Keck School of Medicine, University of Southern California, Los Angeles, California

The Dynesys dynamic stabilization system is an alternative to rigid instrumentation and fusion for the treatment of lumbar degenerative disease. Although many outcomes studies have shown good results, currently lacking is a comprehensive report on complications associated with this system, especially in terms of how it compares with reported complication rates of fusion. For the present study, the authors reviewed the literature to find all studies involving the Dynesys dynamic stabilization system that reported complications or adverse events. Twenty-one studies were included for a total of 1166 patients with a mean age of 55.5 years (range 39–71 years) and a mean follow-up period of 33.7 months (range 12.0–81.6 months). Analysis of these studies demonstrated a surgical-site infection rate of 4.3%, pedicle screw loosening rate of 11.7%, pedicle screw fracture rate of 1.6%, and adjacent-segment disease (ASD) rate of 7.0%. Of studies reporting revision surgeries, 11.3% of patients underwent a reoperation. Of patients who developed ASD, 40.6% underwent a reoperation for treatment. The Dynesys dynamic stabilization system appears to have a fairly similar complication-rate profile compared with published literature on lumbar fusion, and is associated with a slightly lower incidence of ASD.

http://thejns.org/doi/abs/10.3171/2015.10.FOCUS15432

KEY WORDS complications; infection; screw loosening; screw fracture; adjacent-segment disease; reoperation; Dynesys

Department of Justice

U.S. Attorney's Office

District of Maryland

FOR IMMEDIATE RELEASE — Wednesday, July 3, 2013

Trans1, Inc. To Pay U.s. $6 Million To Settle False Claims Act Allegations

Baltimore, Maryland – Medical device manufacturer TranS1, Inc., now known as Baxano Surgical, Inc., has agreed to pay the United States $6 million to resolve allegations under the civil False Claims Act that the company caused health care providers to submit false claims to Medicare and other federal health care programs for minimally-invasive spine surgeries.

The settlement was announced today by United States Attorney for the District of Maryland Rod J. Rosenstein; Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division; Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services; Special Agent in Charge Robert Craig of the Defense Criminal Investigative Service - Mid-Atlantic Field Office; and Special Agent in Charge Drew Grimm, Office of Personnel Management, Office of Inspector General.

This settlement resolves allegations that TranS1 knowingly caused health care providers to submit claims with incorrect diagnosis or procedure codes for certain minimally-invasive spine fusion surgeries in which physicians used TranS1's AxiaLIF System™, a device developed as an alternative to invasive spine fusion surgeries. The United States further alleges that TranS1 improperly counseled physicians and hospitals to bill for the AxiaLIF System™ by using incorrect and inaccurate codes intended for more invasive spine fusion surgeries. As a result, the United States contends that health care providers received greater reimbursement than they were entitled to for performing the minimally-invasive AxiaLIF procedures.

"A medical device manufacturer violates the law when it advises physicians and hospitals to report the wrong codes to federal health insurance programs in order to increase reimbursement rates," said Rod J. Rosenstein, United States Attorney for the District of Maryland. "Health care providers are required to bill federal health care programs truthfully for the work they perform."

"The Justice Department is committed to ensuring that medical device manufacturers follow the law when providing devices to beneficiaries of federal health care programs," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "It is critical that health care providers bill federal health care programs accurately and honestly for the work they perform, and it is imperative that they base their selection of medical devices on the best interests of their patients, not on whether a device manufacturer is paying them for promotional speaking or consulting."

High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis

Olaf J. Verhoof, Johannes L. Bron, Frits H. Wapstra, and Barend J. van Royen✉

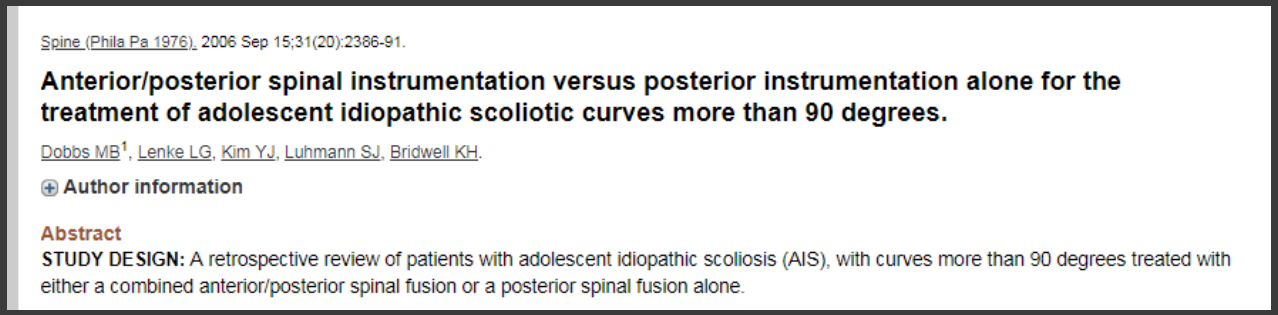
Abstract

Go to:

The X-Stop interspinous distraction device has shown to be an attractive alternative to conventional surgical procedures in the treatment of symptomatic degenerative lumbar spinal stenosis. However, the effectiveness of the X-Stop in symptomatic degenerative lumbar spinal stenosis caused by degenerative spondylolisthesis is not known. A cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis were treated with the X-Stop interspinous distraction device. All patients had low back pain, neurogenic claudication and radiculopathy. Pre-operative radiographs revealed an average slip of 19.6%. MRI of the lumbosacral spine showed a severe stenosis. In ten patients, the X-Stop was placed at the L4–5 level, whereas two patients were treated at both, L3–4 and L4–5 level. The mean follow-up was 30.3 months. In eight patients a complete relief of symptoms was observed post-operatively, whereas the remaining 4 patients experienced no relief of symptoms. Recurrence of pain, neurogenic claudication, and worsening of neurological symptoms was observed in three patients within 24 months. Post-operative radiographs and MRI did not show any changes in the percentage of slip or spinal dimensions. Finally, secondary surgical treatment by decompression with posterolateral fusion was performed in seven patients (58%) within 24 months. In conclusion, the X-Stop interspinous distraction device showed an extremely high failure rate, defined as surgical re-intervention, after short term follow-up in patients with spinal stenosis caused by degenerative spondylolisthesis. We do not recommend the X-Stop for the treatment of spinal stenosis complicating degenerative spondylolisthesis.

Keywords: Lumbar spinal stenosis, X-Stop, Degenerative spondylolisthesis

Lateral Interbody Fusion



Spine (Phila Pa 1976). 2006 Sep 15;31(20):2386-91.

Anterior/posterior spinal instrumentation versus posterior instrumentation alone for the treatment of adolescent idiopathic scoliotic curves more than 90 degrees.

Dobbs MB[1], Lenke LG, Kim YJ, Luhmann SJ, Bridwell KH.

Author information

Abstract

STUDY DESIGN: A retrospective review of patients with adolescent idiopathic scoliosis (AIS), with curves more than 90 degrees treated with either a combined anterior/posterior spinal fusion or a posterior spinal fusion alone.

JNS JOURNAL OF NEUROSURGERY

OFFICIAL JOURNALS OF THE AANS SINCE 1944

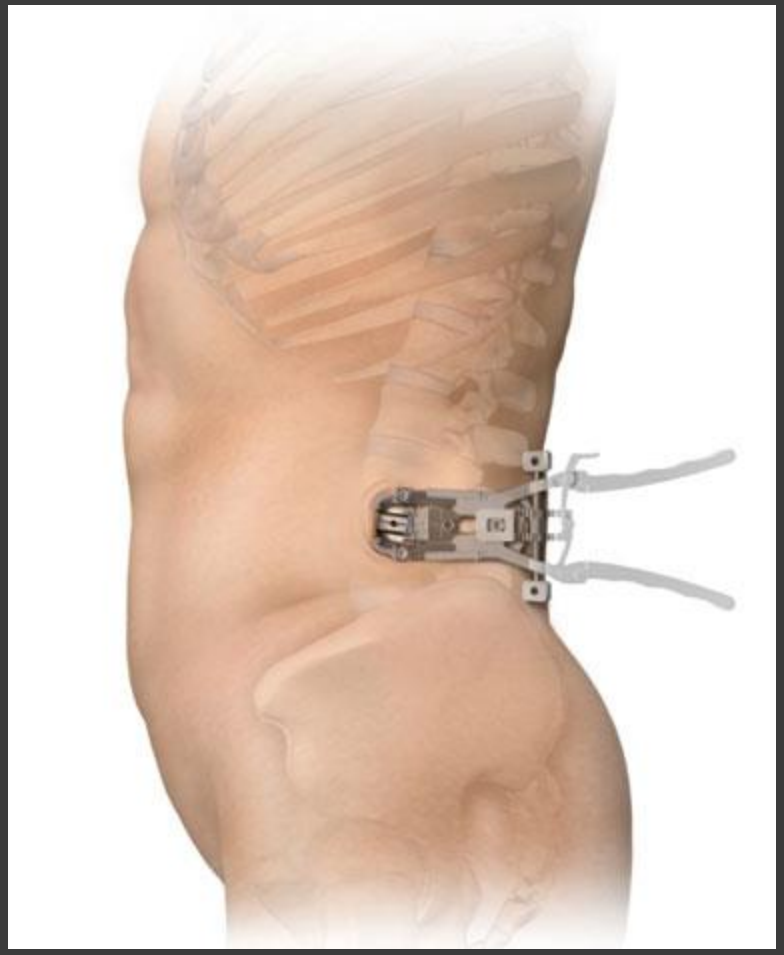
Osteotomies in the posterior-only treatment of complex adult spinal deformity: a comparative review

Ian G. Dorward [1] and Lawrence G. Lenke [2]

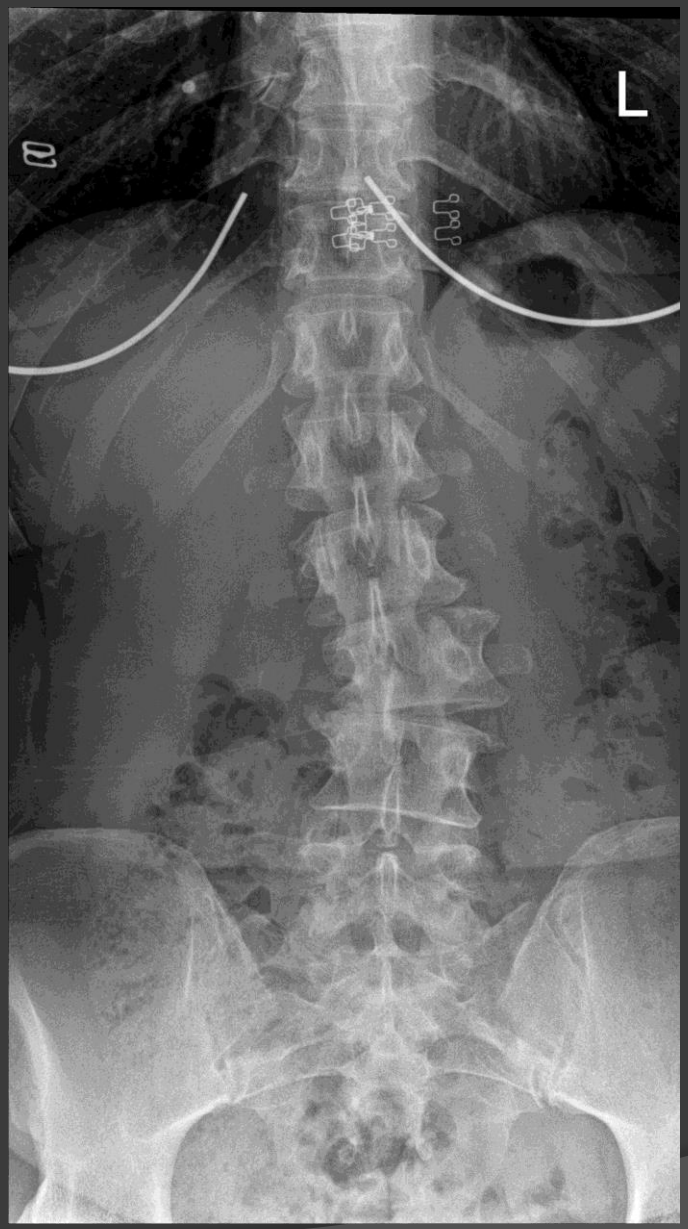
VIEW MORE +

DOI: https://doi.org/10.3171/2009.12.FOCUS09259

ABSTRACT FULL TEXT PDF




TLIF
PLIF
XLIF/ALIF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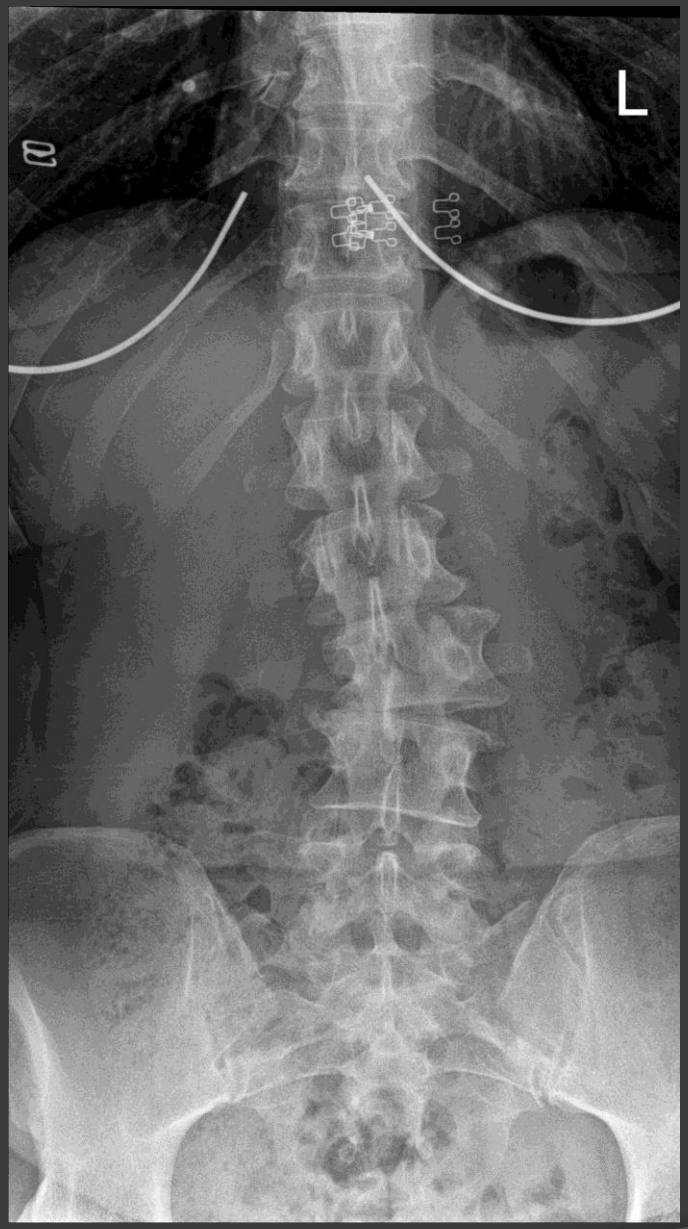
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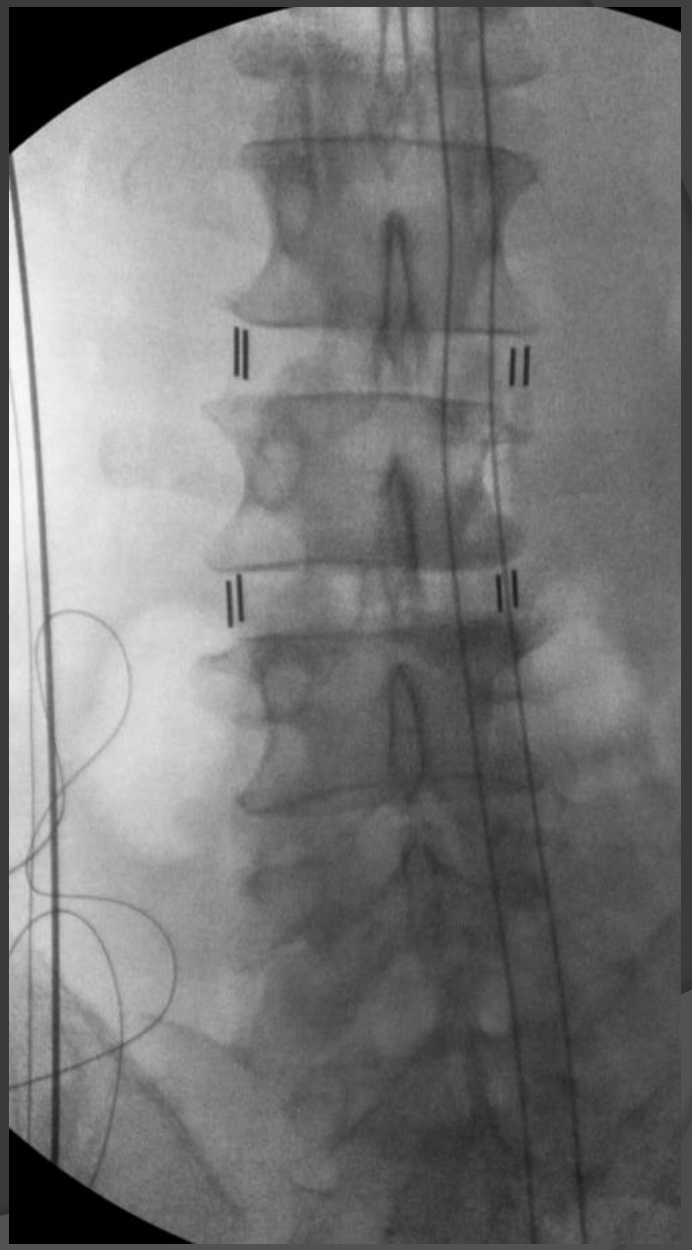

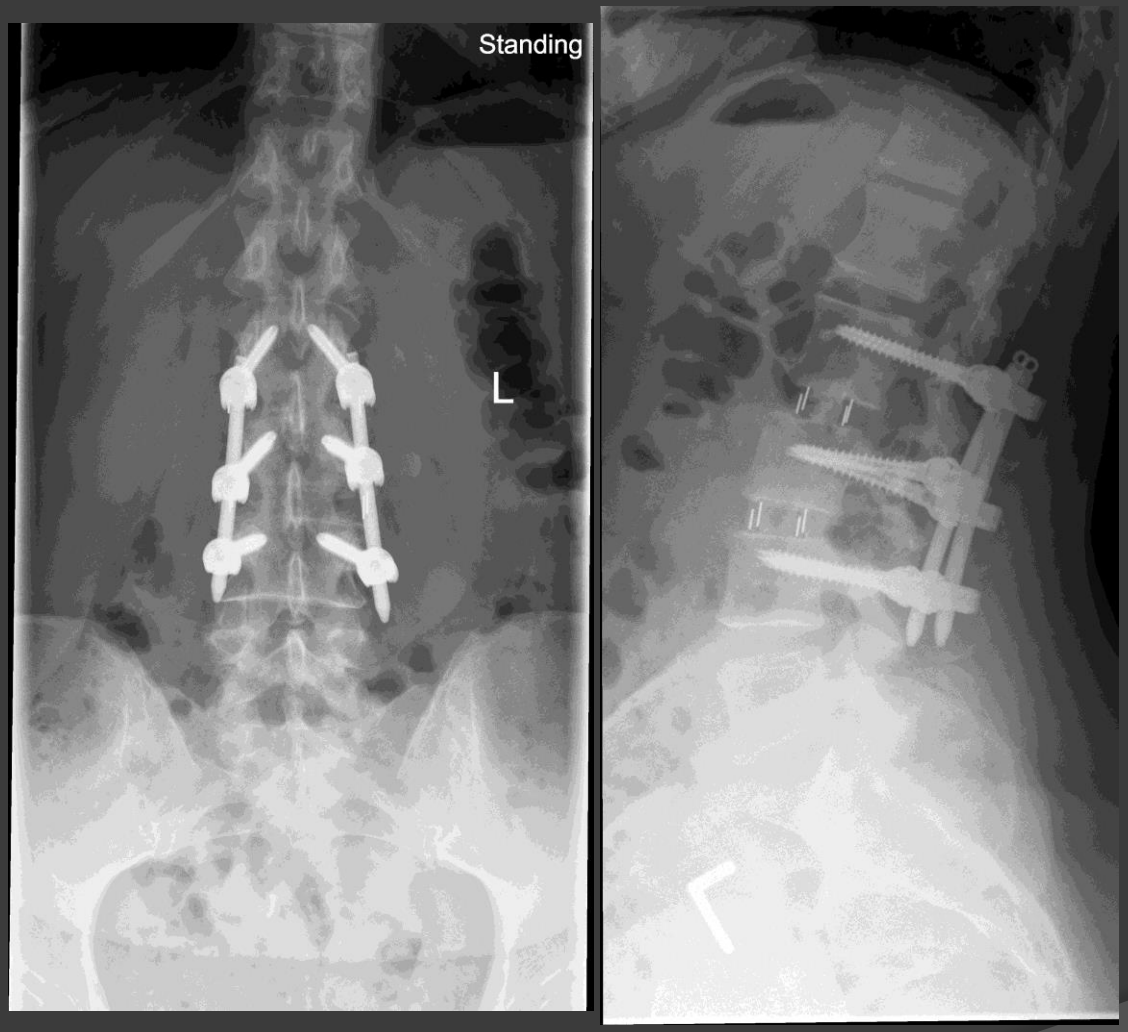
Standing
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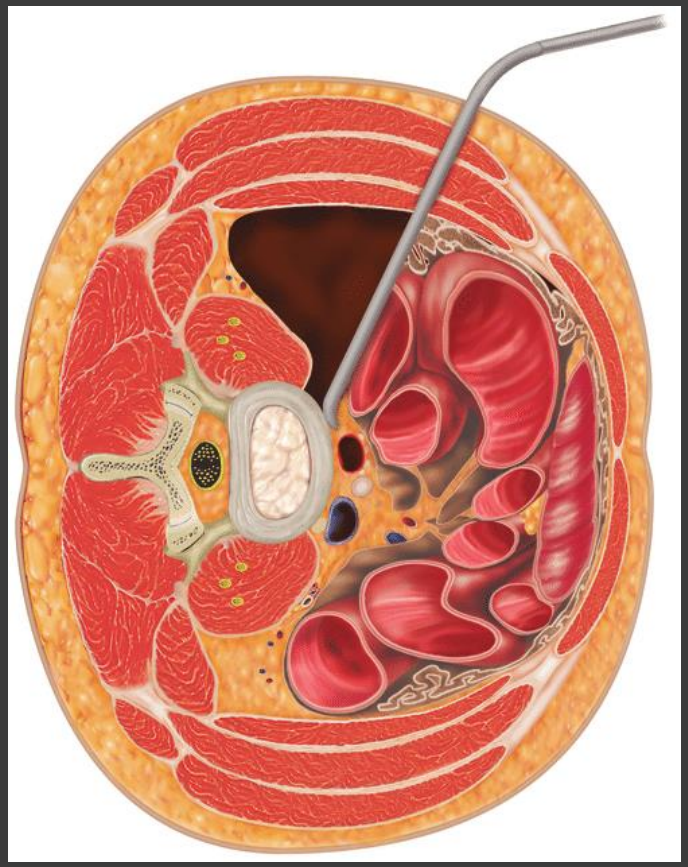
ATP/OLIF Future?



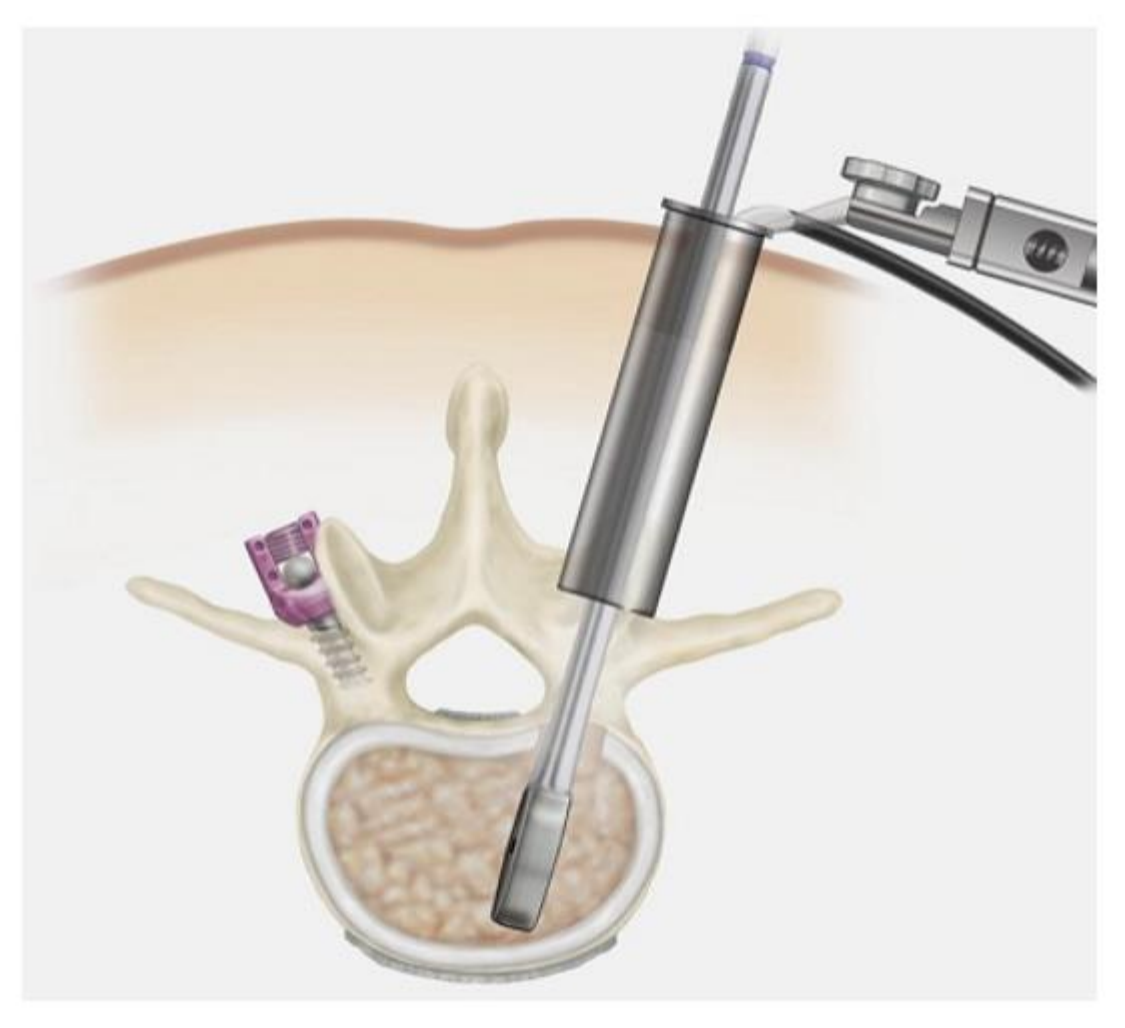
Author reference Year	Surgery Other	Surgery Other	Recommendation Observations	Findings Other	Conclusions Risks Complications Other
Youssef[30] 2010	84 MIS XLIF	Followed average 15.7 months	68 (81%) fused No subsidence CT/Dynamic X-rays	2.4% perioperative complications	6.1% postoperative Complications
Oliveira[20] 2010	21 MIS XLIF X-ray MR Study	21 XLIF 43 levels 47 minute surgery	Improvement MR/X-ray 41.9% disc height 13.5% foraminal height 24.7% foraminal area 33.1% central canal diameter	Average age 67.6 Degenerative lumbar stenosis	Complications 3 (14.3%) iliopsoas weakness 2 Reoperations: (9.5%) posterior decompression/ instrumentation
Isaacs[15] 2010	107 patients MIS XLIF With/without posterior fusion	Degenerative scoliosis	Average age 68 Average 4.4 levels per patient	75.7% of patients, 5.6% had lateral fixation, and 18.7% had stand-alone XLIF	Major complications: 13 (12.1%) 2 (1.9%) medical 12 (11.2%) surgical
Arnold[2] 2012	Review of teohnique of MIS XLIF	Fluoroscopy to identify mid position of disc	True lateral positioning	Larger implants with XLIF vs. TLIF and PLIF	Complications: neural injuries, psoas weakness, and thigh numbness
Caputo[8] 2013	30 MIS XLIF Degenerative scoliosis	14.3 month follow up Evaluation with X-ray and CT	Improvement Foraminal width 7.4% Disc height 116.7% Lordosis 14.1%	Correction; Cobb angle 72.3% Apical translation 59.7% Foraminal height 80.3%	Complications 11.8 pseudarthrosis 1 lateral hernia 2 ruptures ALL 2 wound breakdown 1 pedicle fracture 1 nonunion secondary fusions
Spivak[24] 2013	Lumbar MIS XLIF	XLIF Retractor Placement	Place XLIF Retractor Anterior Half of Disc	Psoas coverage increased 80–85% from L2-L4	Place retractor in anterior half of disc to avoid neural/ plexus injury
Meredith[18] 2013	18 MIS XLIF Thoracic Thoraco-lumbar	XLIF 32 levels 12 Anterior posterior procedures	Most at thoracolumbar junction Medical complications: 2 pulmonary effusions	Medical complications 2 cardiac arrhythmias 1 death 1 metastatic disease	Surgical complications 2 durotomy 1 infection 1 instrument pull-out
Tohmeh[27] 2014	140 Patients 223 MIS XLIF Levels	Pedicle screw fixation Lateral plating Evaluated cage settling for interbody devices	Followed average 15.5 months At 12 months Disability better 44% Low back pain 49% leg pain 48% QUALY 50%	Cage settling 62% at 1 year Reduced with wider/ longer cages Lateral plates reduced cage settling more the pedicle screws	Increase foraminal height 15.7 to 21.2 mm Disc height 4.6 to 9.4 mm discal lordosis 4 to 8.1 mm segmental lordosis 10.7 to 13.7 mm
Lykissas[17] 2014	6 years MIS XLIF wit BMP (72 patients)	Vs. XLIF without BMP (72 patients)	Long term sensory deficits 29 with vs. 20 without BMP	Persistent motor deficits 35 with vs. 17 without BMP	Anterior thigh/groin pain 8 with vs. 0 without BMP
Wang[29] 2014	21 patients over 30 months MIS XLIF alone	No screws Spacers without pedicle screws for adjacent level disease	No infection No trauma No prior pedicle screws 17-1 level 4-2 level XLIF	Patients followed average 23.6 mos. Setting 1.7 mm All fused on CT	Used BMP in all interbody XLIF No major complications 1 delayed reoperation
Malham[16] 2014	52 patients 79 level MIS XLIF	Assess foraminal/ arthrotic facet decompression with CT	Average age 66.4 89% > posterior disc height 38% > foraminal height	45.1%> foraminal area	XLIF significantly indirectly decompressed the neural foramen
Fogel[13] 2014	7 Cadavers MIS XLIF	Models of XLIF at L4-L5 with DS	Combinations of Models with XLIF cages	Lateral plate Unilateral or Bilateral screws	Bilateral pedicle screws most effectively reduced A-P displacement with XLIF cage
Burić[6] 2015	29 Patients MIS XLIF (47 levels)	All prior lumbar surgery DDD SS Average age 59	Average 1.6 level XLIF	Use MR to assess psoas dimensions; determine susceptibility to neural deficits	10 (34%) Postoperative anterior thigh/groin pain (24 Hours postop); 3 most only 1 still symptomatic
Sembrano[22] 2015	MIS LLIF ALIF	147 Fusions at 212 levels	Overall lumbar lordosis changes: ALiF 4.2	No significant changes in adjacent level lordosis except for ALIF	Conclusion: LLIF comparably improved sagittal balance

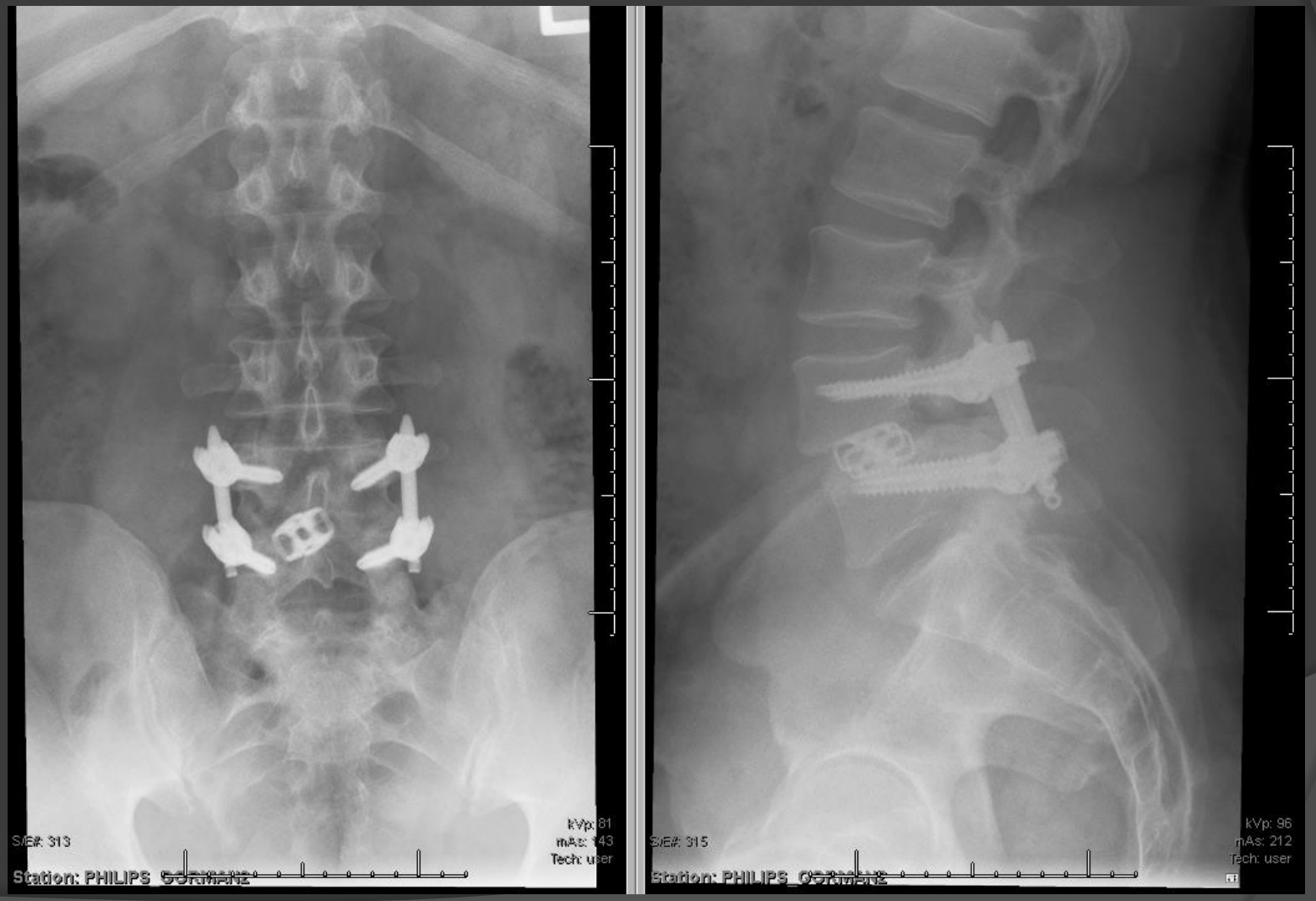
Cost effectiveness

- Deluzio et al. JSAS 2010
  - Open vs transpoas approach
  - Fewer complications, shorter LOS and 10% less cost

  National data 66,000 patients 13% compilation after open posterior lumbar surgery, re-operation rate 9.5-19%

MIS Technologies

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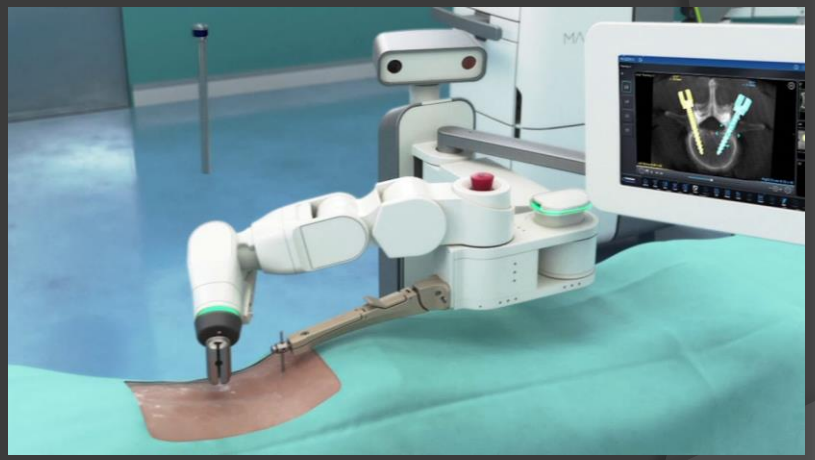
kVp: 81
mAs: 143
Tech: user
S/E#: 315
kVp: 96
mAs: 212
Tech: user

Society of Minimally Invasive Spine Surgery Annual Forum 2016

- There were 705 patients included in the study; 403 robotic guided procedures, 224 fluoroscopic guided procedures and 78 freehand procedures.

- • Robotic guidance: 4 percent
  • Fluoroscopic guidance: 5.4 percent
  • Freehand: 12.8 percent

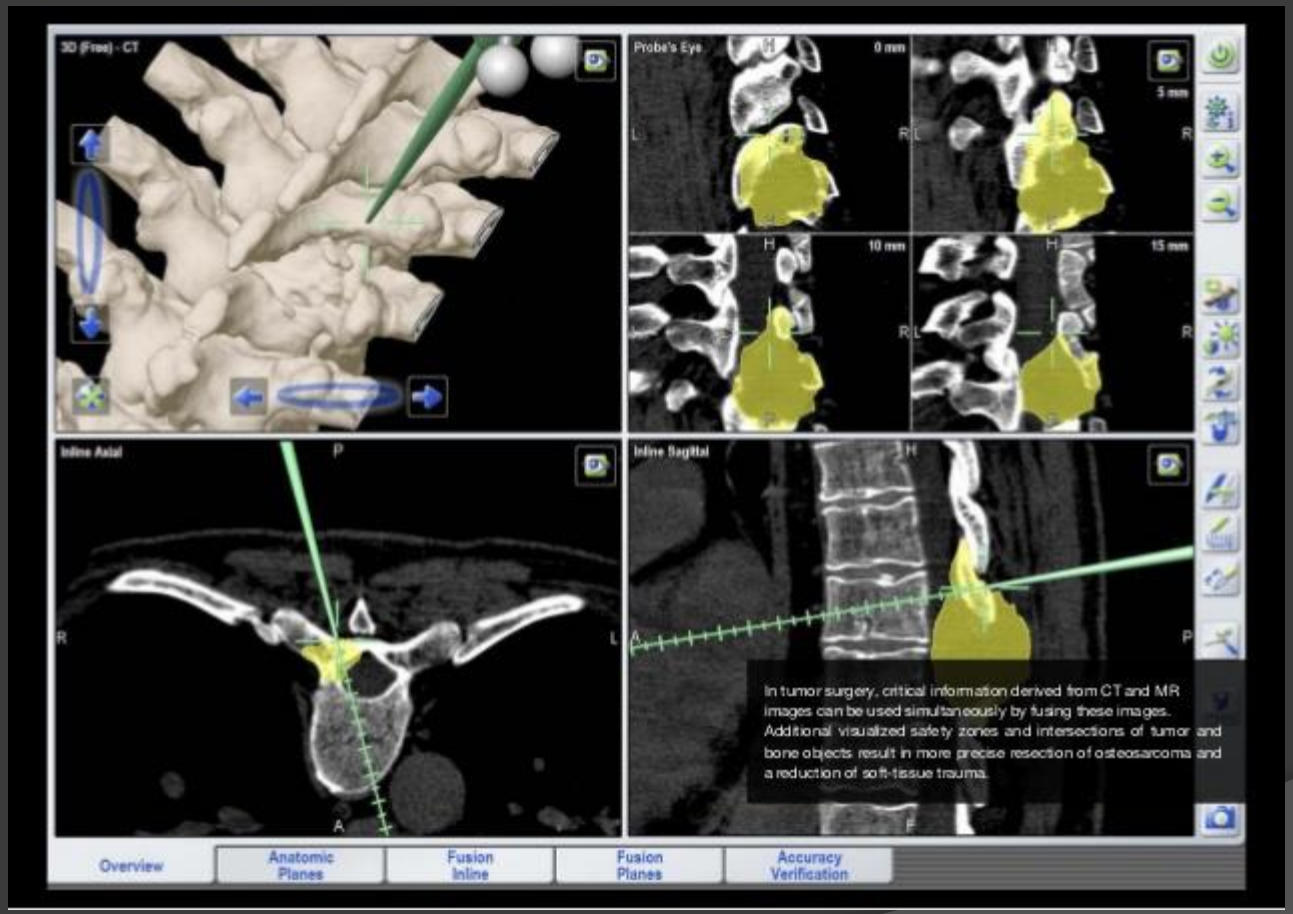
- 2. The revision rate was similar between the robotic and fluoroscopic guidance groups — 3.8 vs 7.7 per cent respectively



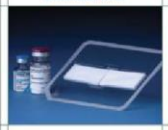
Costs of MIS vs Open

- Parker et al. 2014
  - MIS versus open TLIF was associated with a reduction in mean hospital cost of $1758, indirect cost of $8474, and total 2-year societal cost of $9295 (*P* = 0.03)
- Wang et al. J Neurospine 2011
  - Mean LOS 3.9 vs 4.8
  - MIS 70,159 vs 78,444 open
  - Complication rate 4.3 vs 13.4%

Future navigation robotics?



BMP-2

TOTAL GRAFT VOLUME	2.8 cc	5.6 cc	8.0 cc	8.0 cc
ORDER NUMBER	7510200 SMALL KIT	7510400 MEDIUM KIT	7510600 LARGE KIT	7510800 LARGE KIT II
INFUSE® Bone Graft Kits				
Sterile Absorbable Collagen Sponge (ACS)	(2) ACS 1" x 2" (2.54 cm x 5.08 cm)	(4) ACS 1" x 2" (2.54 cm x 5.08 cm)	(6) ACS 1" x 2" (2.54 cm x 5.08 cm)	(1) ACS 3" x 4" (7.62 cm x 10.16 cm)
				
mg rhBMP-2	4.2 mg	8.4 mg	12.0 mg	12.0 mg
Concentration rhBMP-2	1.5 mg/cc	1.5 mg/cc	1.5 mg/cc	1.5 mg/cc

RETRACTED ARTICLE

See: Retraction Notice

J Bone Joint Surg Br. 2008 Aug;90(8):1068-72. doi: 10.1302/0301-620X.90B8.20349.

Recombinant human bone morphogenetic protein-2 for grade III open segmental tibial fractures from combat injuries in Iraq.

Kuklo TR[1], Groth AT, Anderson RC, Frisch HM, Islinger RB.

Author information

Retraction in

Withdrawal of a paper. [J Bone Joint Surg Br. 2009]

Abstract

This is a retrospective consecutive case series of 138 Gustillo-Anderson type IIIB and IIIC segmental tibial fractures treated at Walter Reed Army Medical Center in soldiers injured in Iraq between March 2003 and March 2005. Five patients with a head injury and four who were lost to follow-up were excluded. The patients were treated definitively with either a ringed external fixator or a reamed intramedullary nail, evaluated in terms of supplementary bone grafting with either autogenous bone (group 1, 67 patients) or recombinant human bone morphogenetic protein-2 at 1.50 mg/ml applied to an absorbable collagen sponge (group 2, 62 patients). The mechanism of injury, defect size and classification, associated injuries, presence of infection, preliminary treatment/fixation, number of procedures before definitive management, time to and details of definitive management, subsequent infection, re-operation, smoking history and other complications were noted. Radiographs were assessed for union, delayed union or nonunion by an independent investigator. All the patients were male. Their mean age was 26.6 years (20 to 42) and the mean follow-up was for 15.6 months (12 to 32). Group 2 had a slightly higher profile of concomitant injuries and a slightly worse fracture classification, but these were not significant. The rate of union was 76% (51 of 67) for group 1 and 92% for group 2 (57 of 62; p = 0.015). There was also a higher rate of subsequent infection in group 1 (14.9%) compared with group 2 (3.2%; p = 0.001) and a higher rate of re-operation (28%) in group 1 (p = 0.003). There were no observed hypersensitivity reactions to the recombinant human bone morphogenetic protein-2 implant.

PMID: 18669965 DOI: 10.1302/0301-620X.90B8.20349

[Indexed for MEDLINE]

2011 BMP bomb

Spine J. 2011 Jun;11(6):471-91. doi: 10.1016/j.spinee.2011.04.023.

A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned.

Carragee EJ[1], Hurwitz EL, Weiner BK.

⊕ Author information

Abstract

BACKGROUND CONTEXT: Increasingly, reports of frequent and occasionally catastrophic complications associated with use of recombinant human bone morphogenetic protein-2 (rhBMP-2) in spinal fusion surgeries are being published. In the original peer review, industry-sponsored publications describing the use of rhBMP-2 in spinal fusion, adverse events of these types and frequency were either not reported at all or not reported to be associated with rhBMP-2 use. Some authors and investigators have suggested that these discrepancies were related to inadequate peer review and editorial oversight.

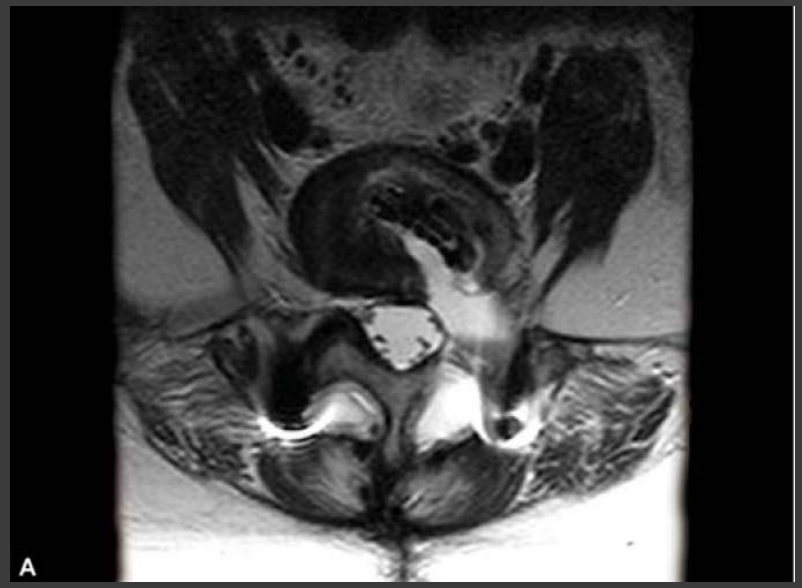
PURPOSE: To compare the conclusions regarding the safety and related efficacy published in the original rhBMP-2 industry-sponsored trials with subsequently available Food and Drug Administration (FDA) data summaries, follow-up publications, and administrative and organizational databases.

STUDY DESIGN: Systematic review.

METHODS: Results and conclusions from original industry-sponsored rhBMP-2 publications regarding safety and related efficacy were compared with available FDA data summaries, follow-up publications, and administrative and organizational database analyses.

RESULTS: There were 13 original industry-sponsored rhBMP-2 publications regarding safety and efficacy, including reports and analyses of 780 patients receiving rhBMP-2 within prospective controlled study protocols. No rhBMP-2-associated adverse events (0%) were reported in any of these studies (99% confidence interval of adverse event rate <0.5%). The study designs of the industry-sponsored rhBMP-2 trials for use in posterolateral fusions and posterior lateral interbody fusion were found to have potential methodological bias against the control group. The reported morbidity of iliac crest donor site pain was also found to have serious potential design bias. Comparative review of FDA documents and subsequent publications revealed originally unpublished adverse events and internal inconsistencies. From this review, we suggest an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach. Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. Posterior lumbar interbody fusion use was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes. In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy.

CONCLUSIONS: Level I and Level II evidence from original FDA summaries, original published data, and subsequent studies suggest possible study design bias in the original trials, as well as a clear increased risk of complications and adverse events to patients receiving rhBMP-2 in spinal fusion. This risk of adverse events associated with rhBMP-2 is 10 to 50 times the original estimates reported in the industry-sponsored peer-reviewed publications.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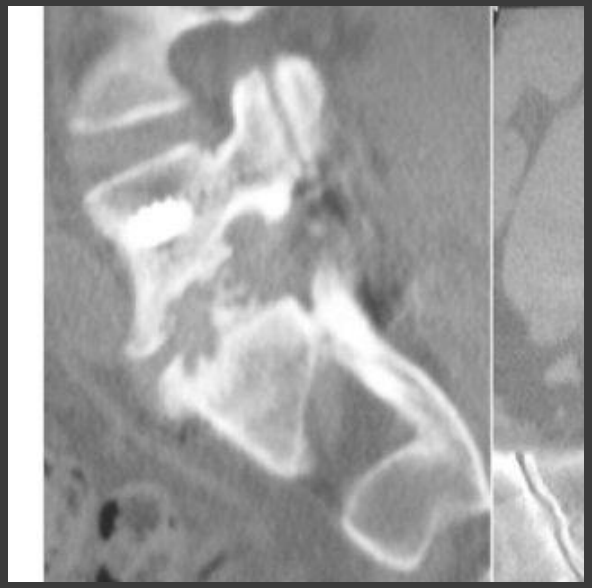

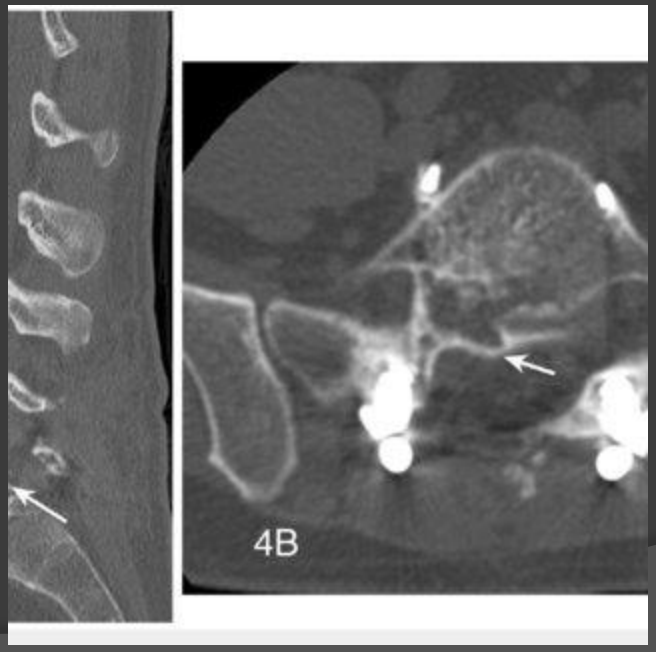
4B

Clin Spine Surg. 2016 Feb;29(1):E28-33. doi: 10.1097/BSD.0000000000000079.

Cost-Utility Analysis of 1- and 2-Level Dorsal Lumbar Fusions With and Without Recombinant Human Bone Morphogenic Protein-2 at 1-Year Follow-Up.

Alvin MD[1], Derakhshan A, Lubelski D, Abdullah KG, Whitmore RG, Benzel EC, Mroz TE.

- Retrospective review cost analysis
  - 33 bmp-2 and 44 local bone/allograft
  - Autograft cost effective at $71,625/QALY
  - BMP-2 $136,207/QALY gained

Clin Spine Surg. 2017 Jul;30(6):E720-E724. doi: 10.1097/BSD.0000000000000273.

Counting the Cost of Failed Spinal Fusion for Relief of Low Back Pain: Does Primary Fusion With Bone Morphogenetic Protein Make Economic Sense From a Primary Payer Perspective?

Lloyd AP[1].

  - If BMP-2 were cheaper would it make sense to use it primarily.
  - Mean cost with failed fusion and re-operation with infuse $47,734 per patient
  - Conclusion not cost effective

Thank you