

Summary of Spine Specialty Day

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Disclosures

- **Consultant:** Stryker, Depuy, Alphatec
- **Fellowship Support:** OREF, Synthes, Biomet

Controversies

Vertebroplasty and Kyphoplasty

The Literature

PubMed



- Vertebroplasty first paper March 1985
- 1887 papers published from 1985 to August 2011 = 9.5 papers per month

Literature Review

- Ploeg WT, Percutaneous **vertebroplasty** as a treatment for osteoporotic vertebral compression fractures: a systematic review. *Eur Spine J.* 2006 Dec;15(12):1749-58.
 - Medline, Embase and The Cochrane Controlled Trials Register
 - fifteen studies, eleven prospective, three retrospective and one controlled trial
 - VAS: 7.8 to 3.1
 - few adverse effects were reported (mean 2.4%)
 - “Insufficient data...assessing the efficacy of percutaneous vertebroplasty requires controlled trials”

Literature Review

- Afzal S, et al. Percutaneous vertebroplasty for osteoporotic fractures. *Pain Physician*. 2007 Jul;10(4):559-63.
 - Prospective cohort study
 - 30 patients
 - No control group
 - VAS score was 8.91 compared to a score of 2.02 at follow up

Literature Review

- Barr JD, et al. Percutaneous vertebroplasty for pain relief and spinal stabilization. Spine (Phila Pa 1976). 2000 Apr 15;25(8):923-8.
 - Retrospective cohort study
 - 47 patients
 - No control group
 - 24 (63%) had marked to complete pain relief, 12 (32%) moderate relief and 2 (5%) no significant change

Literature Review

- Retrospective reviews
- Case series
- Limited numbers
- “Significant improvement” defined as post-operative pain 2-4.

Literature Review

- Kallmes DF, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N Engl J Med. 2009 Aug 6;361(6):569-79.
 - Prospective randomized trial
 - Multi-center
 - 131 patients
 - Vertebroplasty compared against sham procedure
 - No significant difference at 1 month or 3 months
 - 1 month: 3.9 versus 4.6

Literature Review

- Buchbinder R, A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. N Engl J Med. 2009 Aug 6;361(6):557-68.
 - Prospective randomized trial
 - Multi-center
 - 78 patients
 - Vertebroplasty compared against sham procedure
 - At 3 months, VAS for the vertebroplasty and control groups were 2.6 and 1.9



AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

**THE TREATMENT OF SYMPTOMATIC
OSTEOPOROTIC SPINAL COMPRESSION
FRACTURES**

GUIDELINE AND EVIDENCE REPORT

Adopted by the American Academy of Orthopaedic Surgeons
Board of Directors
September 24, 2010

RECOMMENDATION 8

We recommend against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Quality of Evidence	Quantity of Evidence	Applicability Downgrade	Critical Outcome(s)
Level I	2 studies	No	Pain, Function
Level II	3 studies		

Strength of Recommendation: Strong

■ AAOS: Weak recommendation for
kyphoplasty

Buchbinder et al & Kallmes et al Critique

- Not a sham procedure
- F/U too short
- Acuity of fracture

Buchbinder et al.

- **Selection bias;**
78 patients enrolled out of 468,
25 % of patients excluded because no fracture,
- **Quality of diagnosis;**
origin of pain? low back pain for less than
12 months and presence of one or two recent
vertebral fracture?
- **Quality of intervention;**
9.5 cases per center over 54 months = 0.73 per month
per center

Kallmes et al

- **Selection bias;**
131 patients enrolled out of 1813 fractures screened
recruitment issues thus lowered VAS threshold < 3
- **Quality of diagnosis;**
11 % (201/1813) no fracture found,
404 patients excluded for no reported reason
No initial proof of fracture.
- **Quality of intervention**
43% crossover sham to vertebroplasty in 1 month

Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial.

Klazen et al. Lancet, Vol 376, Sept, 2010

- Prospective randomized trial
- Bone edema on MRI
- Pain for 6 weeks or less, and a VAS >5
- 431 eligible patients
- Difference in mean VAS score between baseline and 1 month was -5.2 after vertebroplasty and -2.7 after conservative treatment
- 1 year was -5.7 (-6.22 to -4.98) after vertebroplasty and -3.7 (-4.35 to -3.05) after conservative treatment.

Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial.

Klazen et al. Lancet, Vol 376, Sept, 2010

- **Conclusions;** in patients with acute VCF and persistent pain, percutaneous vertebroplasty is effective and safe.
- Pain relief after vertebroplasty is immediate, is sustained for at least a year, and is significantly greater than that achieved with conservative treatment

Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial.

Klazen et al. Lancet, Vol 376, Sept, 2010

- vertebroplasty appears to be a cost effective: QALY compared to conservative treatment was €22,685 or approximately \$36,000

Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. Farrokhi et al, J Neurosurg Spine. 2011 Mar 4.

- 105 patients with acute osteoporotic VCFs
- 40 patients underwent PV and 42 received OMT.
- **Conclusions:** The PV group had statistically significant improvements in visual analog scale and QOL scores maintained over 24 months, improved VBH maintained over 36 months, and fewer adjacent-level fractures compared with the OMT group.

Have referral patterns for vertebroplasty changed since publication of the placebo controlled trials.
Luetmer MT & Kallmes DF. AM J Neuroradiol Feb, 2011

- Patients treated before the NEJM trials vs after
 - Referrals per month; Pre 18.9, Post 11.3
 - Percentage undergoing vertebroplasty; Pre 67.3 %, post 76.0 %
- Conclusions; The number of vertebroplasty referrals at our center has decreased significantly since publication of INVEST and the Australian trial, yet we continue to offer the procedure to a high proportion of referred patients

Mortality risk for operated and non-operated vertebral fracture patients in a medicare population

Ediden et al, J Bone Min R, Jan 2011

- Survival using Kaplan Meir method and mortality using Cox regression between operated and non-operated VCF patients estimated from medicare dataset over years 2005 – 2008
- 858,978 patients identified,
182,946 underwent vertebral augmentation
- Conclusions: Vertebral augmentation group were 37% less likely to die and had higher survival rate 60.8% vs 50.0%

Literature Summary

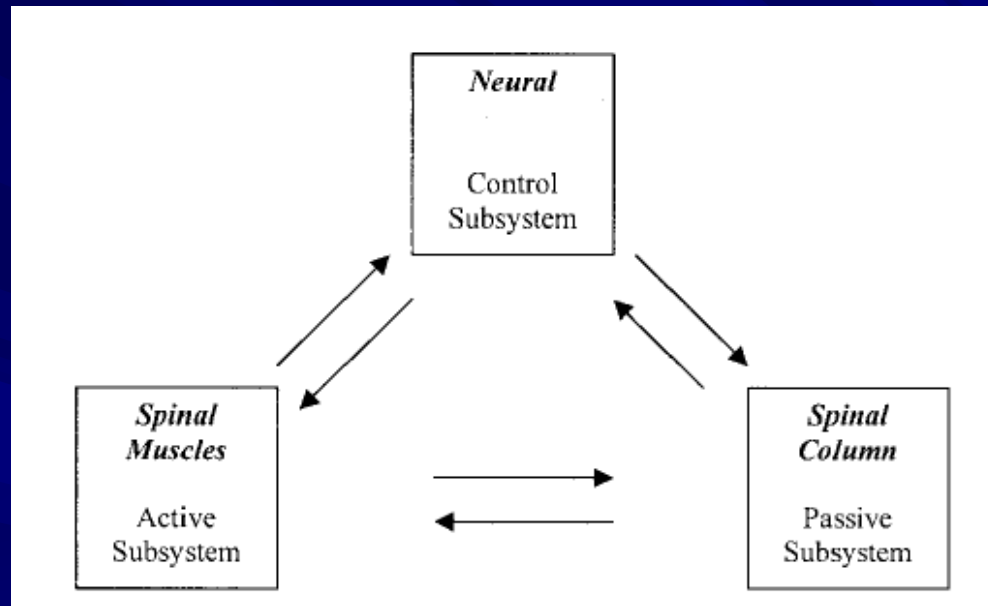
- VCFs have a significant impact QOL
- Outcomes of controlled vertebroplasty studies are mixed
- Supportive safety and effectiveness data exists for Vertebroplasty
- Unanswered questions and call for RCTs

Lumbar Spine Fusion versus Disk Replacement

Lumbar Degeneration

- Significant cause of disability among adults
- Lifetime incidence – 60-80%
- Affects 50 million people in United States
- Major socioeconomic costs
 - 50-100 billion dollars/year

Pathomechanics of LBP



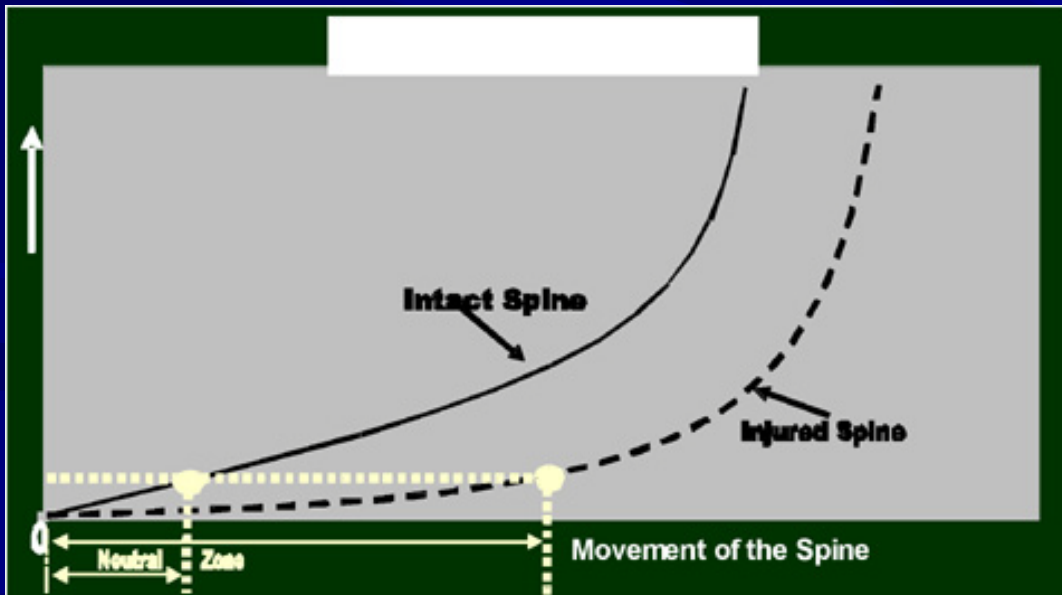
Yue JJ et al.: *Neurosurg Focus* 2007;22:E12

■ “Neutral zone”

- First proposed by Panjabi
- Spinal segment normally moves within a given set of biomechanical parameters
- Clinically relevant measure of spinal stability

Pathomechanics of LBP

- Degeneration increases biomechanical limits of motion segment
 - Pathologic laxity
 - Abnormal load sharing
- Widening of NZ may result in mechanical LBP



Yue JJ et al.: *Neurosurg Focus* 2007;22:E12

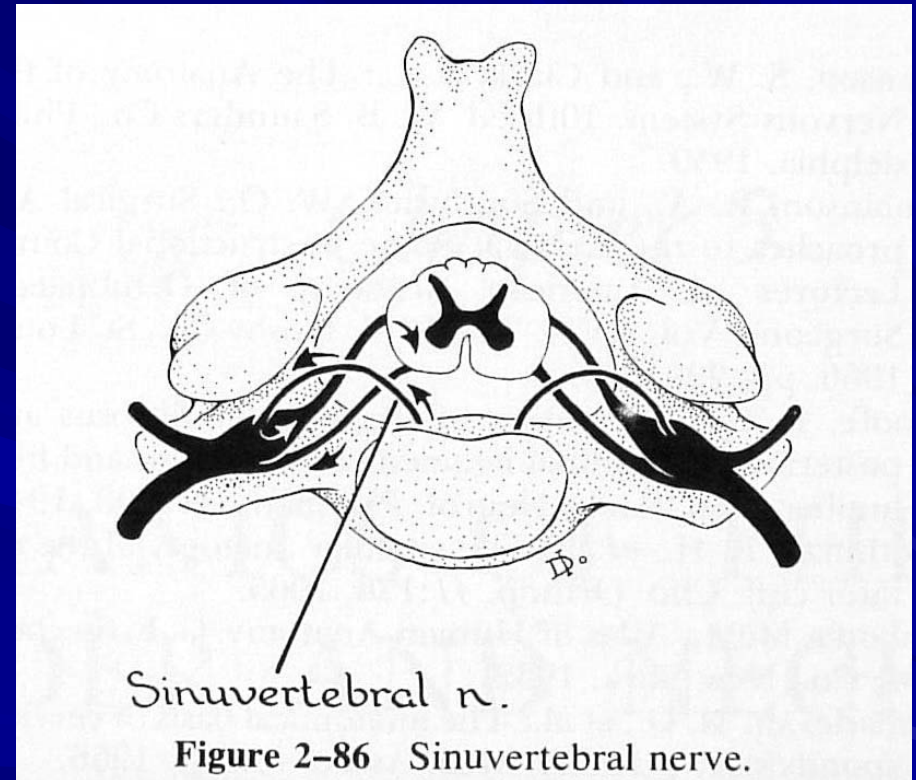
Pathomechanics of LBP

- Symptoms of degeneration result from abnormal loading rather than “instability”



Pathophysiology

- The disc receives sensory innervation from the sinuvertebral nerve which is believed to be the culprit in discogenic back pain.



Spinal Fusion

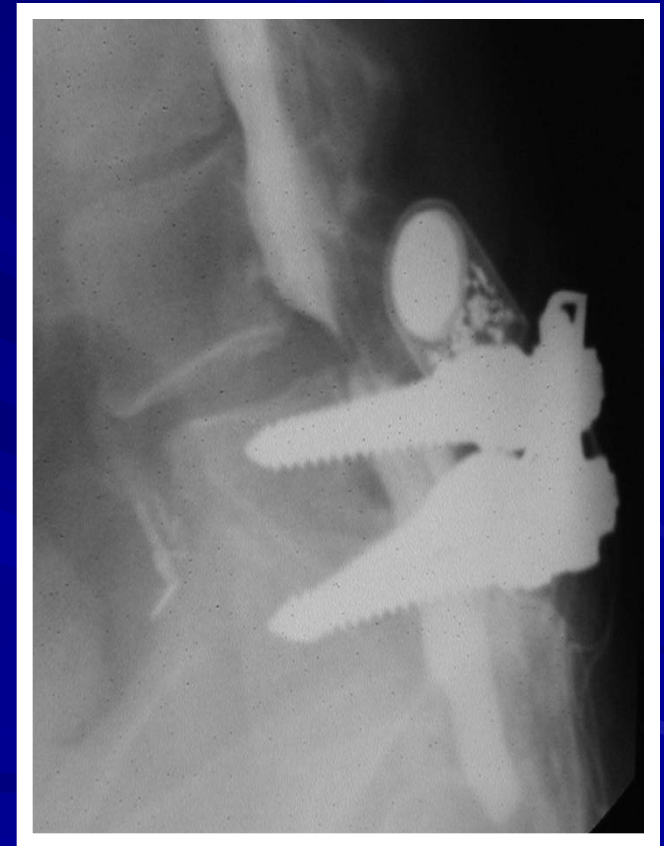
- “Gold standard” surgical treatment for symptomatic lumbar degenerative disease
 - Diminish pathologic motion
 - Reduce/prevent deformity
 - Compensate for iatrogenic instability

Spinal Fusion

- Fritzell P, Hägg O, Wessberg P, Nordwall A; Swedish Lumbar Spine Study Group. 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine*. 2001 Dec 1;26(23):2521-32
 - 294 patients with 2 year follow up
 - Randomized, prospective study
 - Pain reduced 33% in the operative group versus 7% in non-operative group
 - 63% reported improvement in the operative group versus 29% in the non-operative group
 - 36% returned to work in the operative group versus 13% in the non-operative group

Detrimental Effects of Fusion

- Risk of pseudarthrosis
- Need for bone graft
- Fixed sagittal alignment
- Adjacent segment degeneration



Background

■ Spine Fusion

- 200,000 every year
- **O'Beirne J, O'Neill D, Gallagher J, Williams DH. Spinal fusion for back pain: a clinical and radiological review. *J Spinal Disord.* 1992 Mar;5(1):32-38.**
 - 34% pseudoarthrosis rate
 - 74% satisfaction rate

? ADVANCEMENTS ?

■ Cages

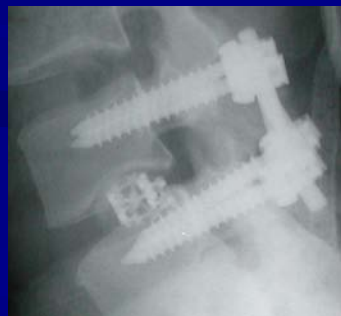
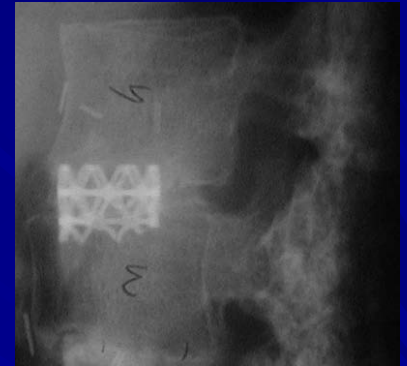
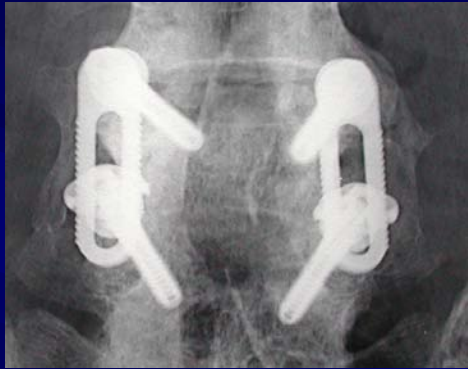
■ Pedicle Screws

■ PLIF/TLIF/ALIF

■ Allograft

■ DBM

■ BMP



Operative Treatment

■ Fusion

- Longest track record
- Good fusion rates \neq good clinical success
 - Zucherman Spine 1992
 - 89% fusion vs. 60% clinical success
 - Jackson Spine 1985
 - 87% fusion vs. 58% clinical success
 - Zdeblick Spine 1993
 - 93% fusion vs. 64% clinical success
 - Followed prospectively

Detrimental Effects of Fusion

- Silber JS, Anderson DG, Daffner SD, Brislin BT, Leland JM, Hilibrand AS, Vaccaro AR, Albert TJ. Donor site morbidity after anterior iliac crest bone harvest for single-level anterior cervical discectomy and fusion. *Spine*. 2003 Jan 15;28(2):134-9.
 - persistent drainage, 3.7%, wound dehiscence, 2.2%
 - 26.1% chronic pain
 - 11.2% required chronic pain meds
 - 5.2% reported discomfort with clothing
 - Ambulation 12.7%
 - activities of daily living 8.2%
 - sexual activity 7.5%

Detrimental Effects of Fusion

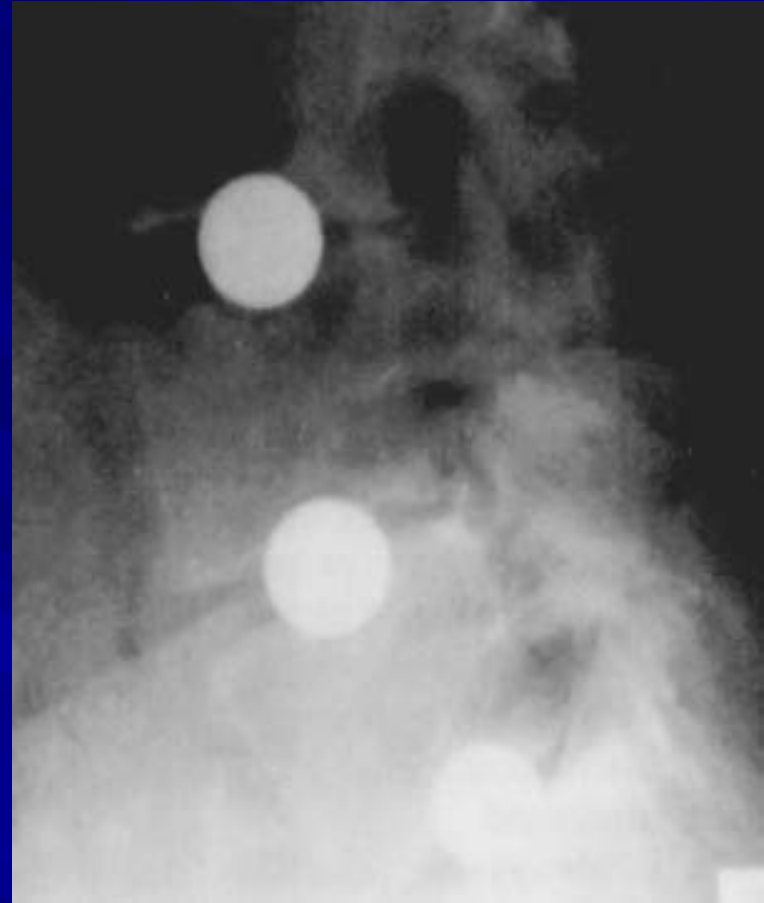
- Ghiselli G, Wang JC, Bhatia NN, Hsu WK, Dawson EG. Adjacent segment degeneration in the lumbar spine. *J Bone Joint Surg Am.* 2004 Jul;86-A(7):1497-503.
 - Retrospective review
 - 215 patients
 - 59/215 (27.4%) patients had evidence of degeneration at the adjacent levels and elected to have an additional decompression (fifteen patients) or arthrodesis (forty-four patients).

Hx of Artificial Discs

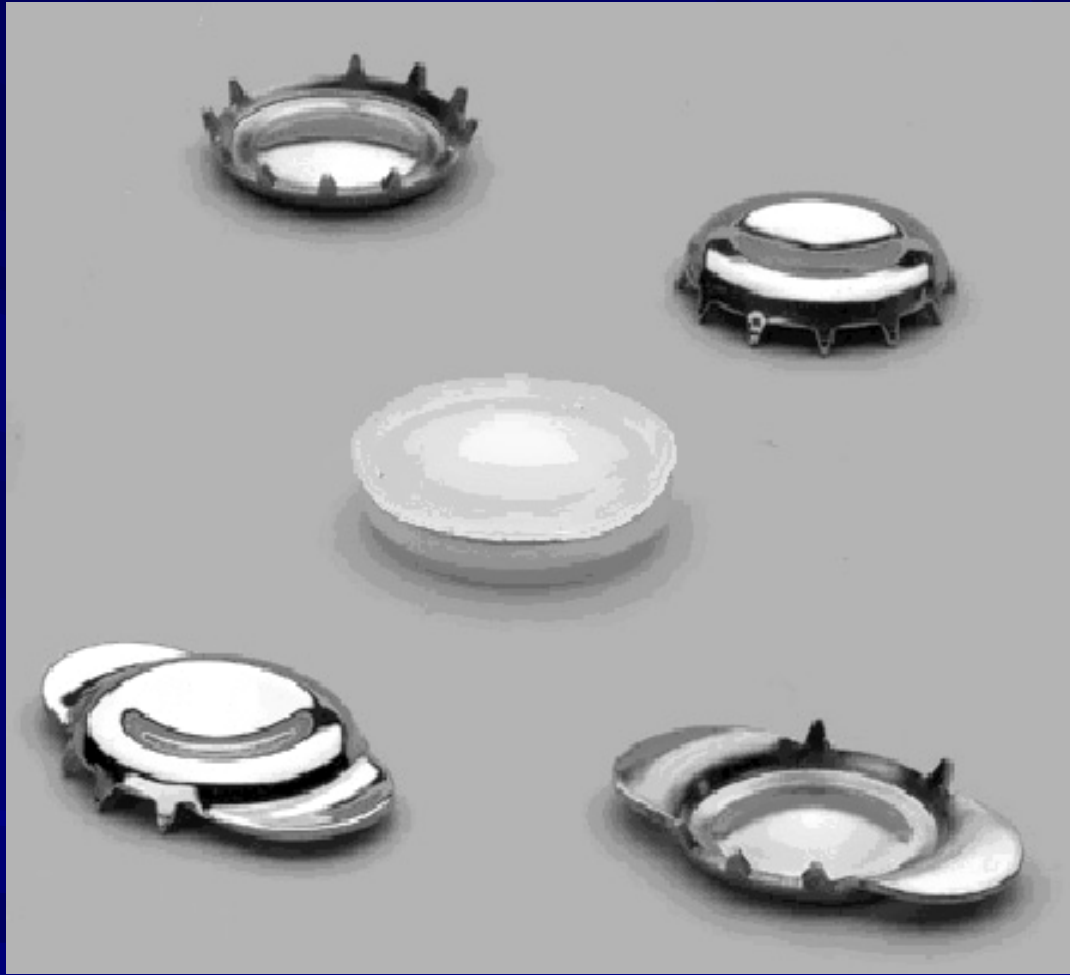
- Ball bearings in disc **Fernström 1950's**
- Implanted rubber core between flat titanium plates **Steffee 1980's**
- Polyethylene core in two curved plates **Brittner-Janz, Marnay**

History

1960's Ulf Fernstrom of Sweden implanted stainless steel spheres in 125 pts. 88% of his patients demonstrated subsidence at 4-7 yr followup.



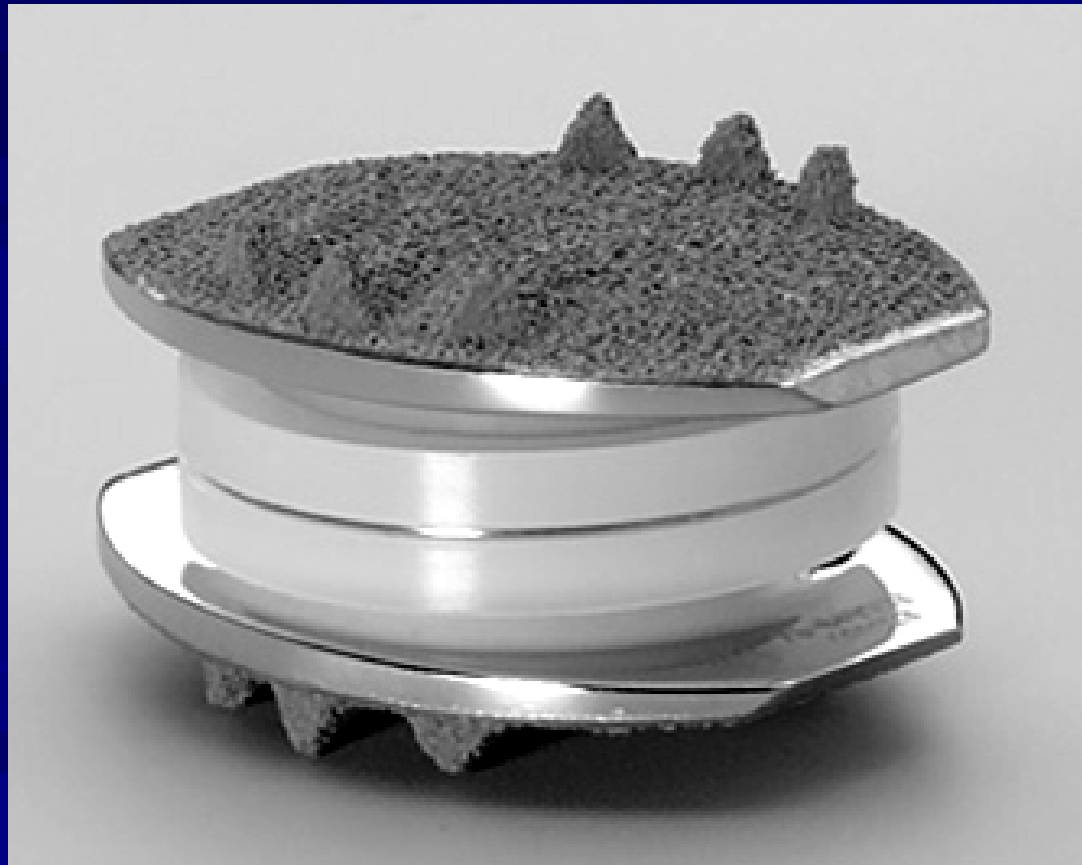
SB Charité I and II (Link)



**Early Designs
(Implanted
Early 1980s)**

SB Charité III (Link)

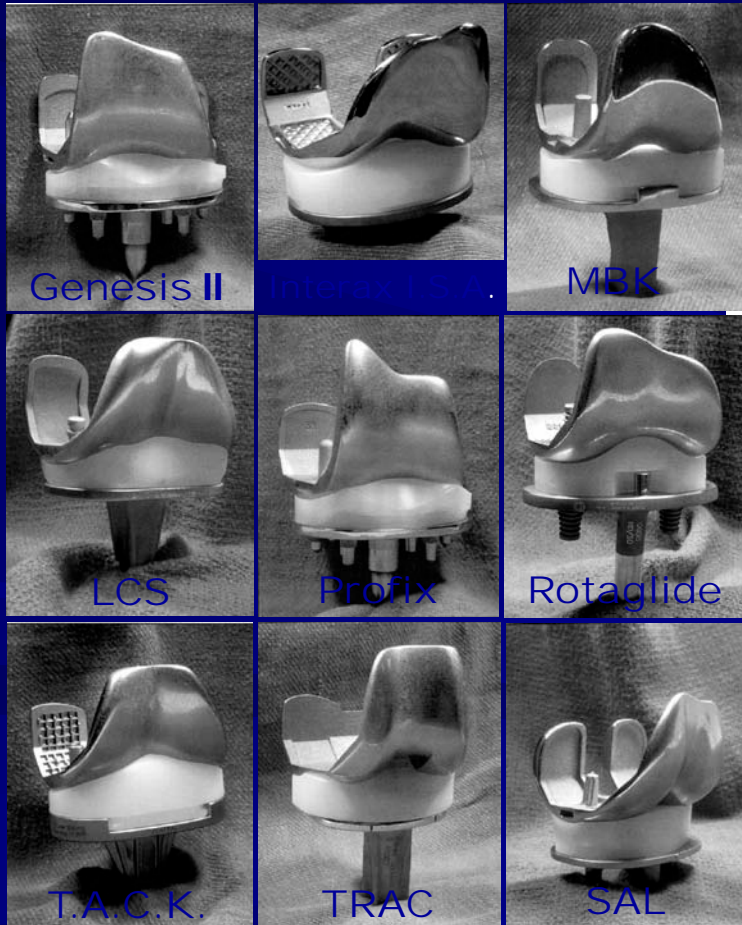
An Unconstrained Anatomic Disc Replacement



Biomechanics

The “Mobile Sliding Core“ Artificial Disc

Just like the contemporary „mobile bearing knee“ designs ...



Gemini MK II



SB Charité

... the SB Charité artificial Disc
has a “Mobile Sliding Core“,
which...

Biomechanics

The “Mobile Sliding Core“ Artificial Disc

... results in a
physiologic restoration
of the lumbar motion segment.

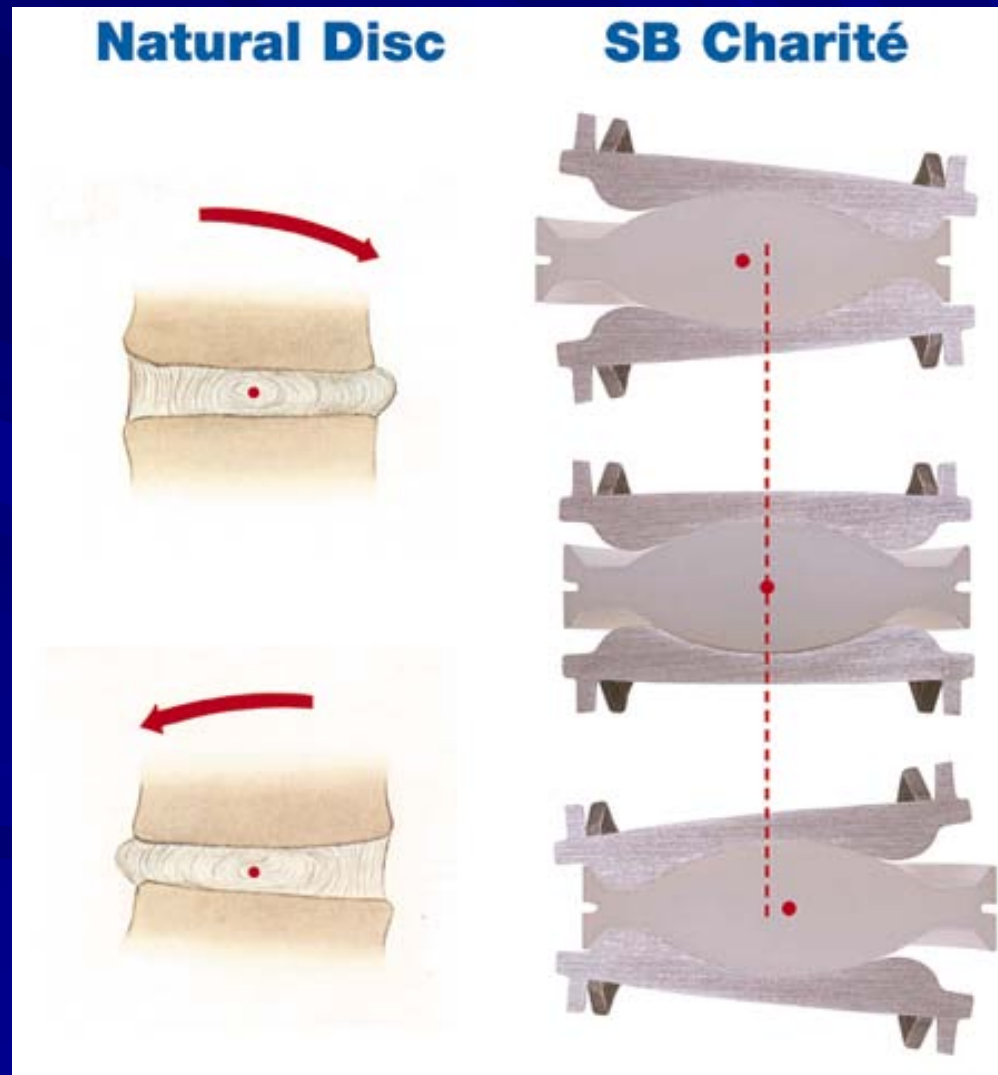
Biomechanics: Sliding Core Mimicks Normal Disc

Flexion

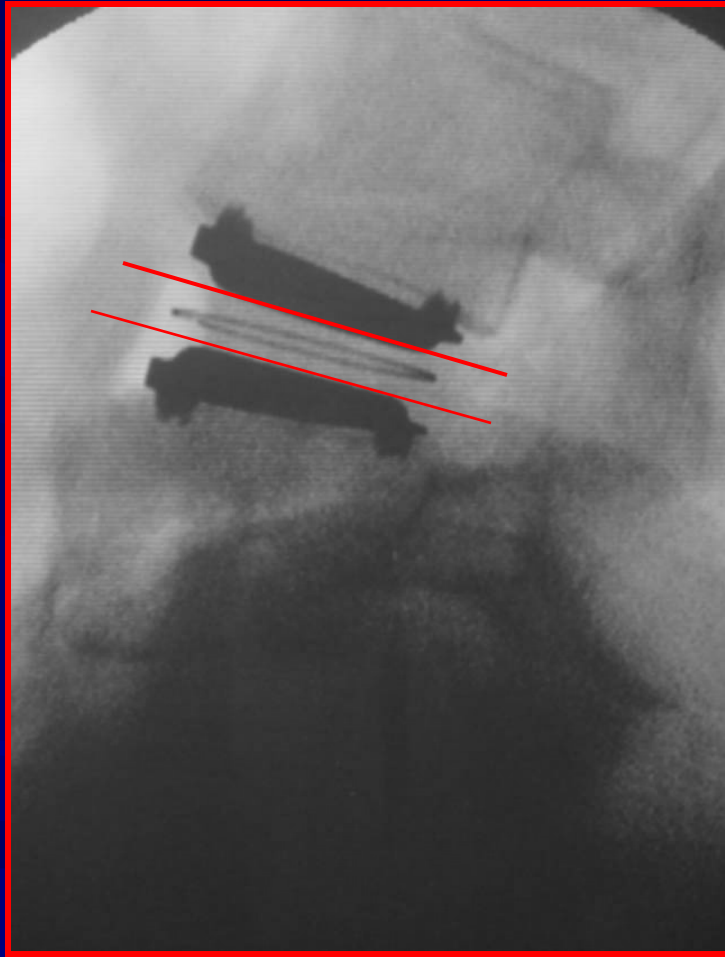
Center of
Nucleus
Moves
Posteriorly

Extension

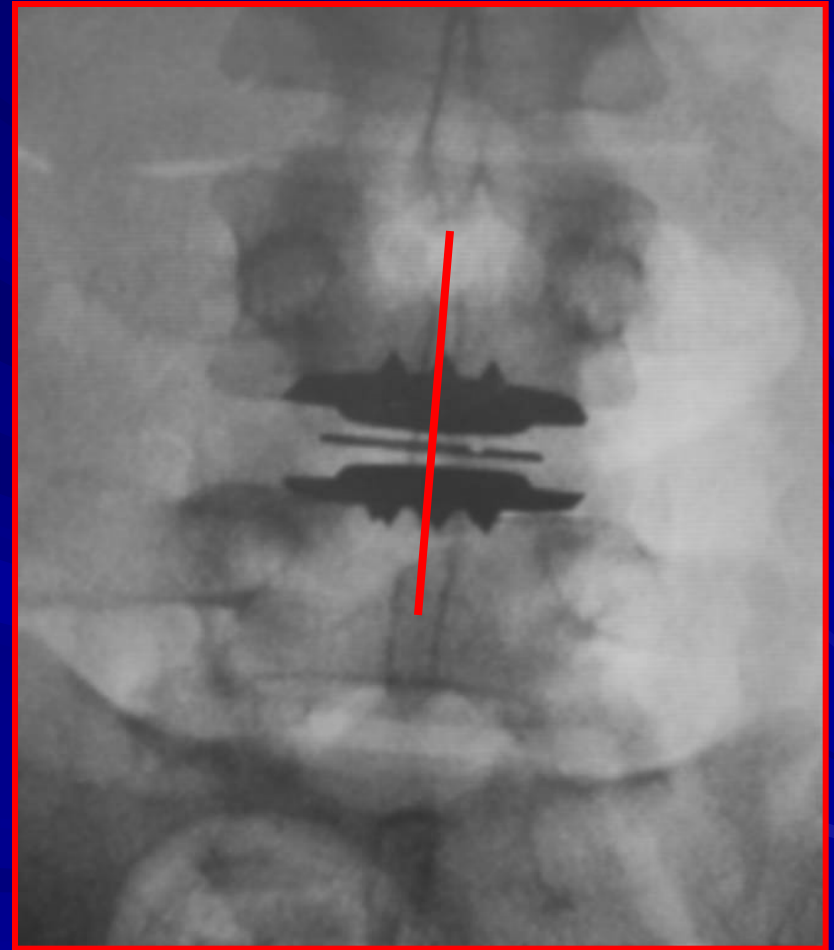
Center of
Nucleus
Moves
Anteriorly



Endplates Parallel



Aligned with Spinous Process



Charité

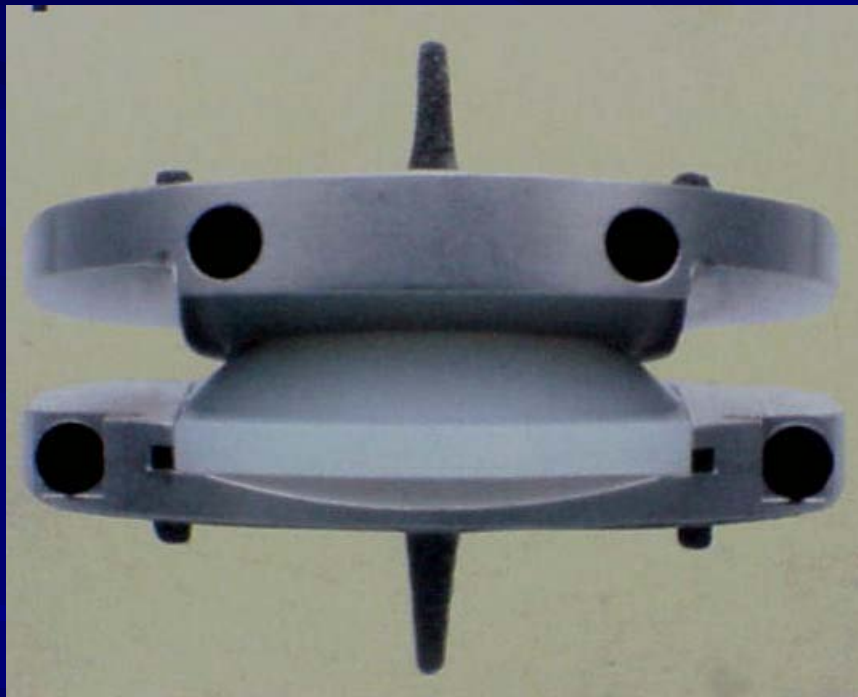
- Lemaire et al., CORR 1997.
 - 51 mos ave follow up in 105 patients
 - 79% good to excellent results
 - 13° motion at L4-5, 9° at L5-S1
 - No device related failures

Charité

- Blumenthal S. et al., Spine 2005
 - 2 year follow up of FDA trial.
 - 304 patients at 14 centers.
 - Charité versus ALIF
 - 73.7% versus 53.1% rate of satisfaction

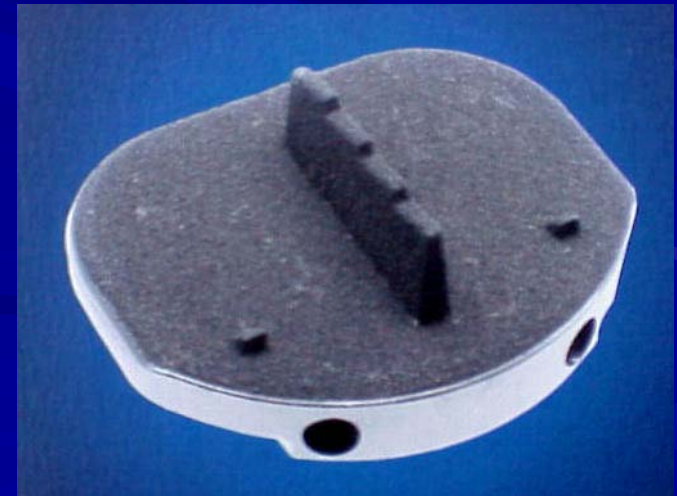
PRODISC

Total Disc Replacement



■ ROM matches physiologic norms

- 13 degrees of flexion
- 7 degrees of extension
- 10 degrees of lateral bending
- 3 degrees of axial rotation





Prodisc

- Delamarter et al., NASS 2006 abstract
 - 242 patients at 2 year follow up.
 - ProDisc (162 patients) or fusion (80 patients)
 - 64% success rate in the ProDisc group, 45% in the fusion group
 - By stricter FDA criteria, 53% success rate in the ProDisc group and 41% in the fusion group

Disc Replacement

- Lemaire JP, Carrier H, Sariali el-H, Skalli W, Lavaste F. Clinical and radiological outcomes with the Charité artificial disc: a 10-year minimum follow-up. *J Spinal Disord Tech.* 2005 Aug;18(4):353-9.
 - Retrospective review
 - 107 patients
 - 90% good or excellent outcome
 - 91.5 % returned to work

Disc Replacement

- Punt IM, Visser VM, van Rhijn LW, Kurtz SM, Antonis J, Schurink GW, van Ooij A. Complications and reoperations of the SB Charité lumbar disc prosthesis: experience in 75 patients. Eur Spine J. 2008 Jan;17(1):36-43.

Disc Replacement

- Putzier M, Funk JF, Schneider SV, Gross C, Tohtz SW, Khodadadyan-Klostermann C, Perka C, Kandziora F. Charité total disc replacement--clinical and radiographical results after an average follow-up of 17 years. *Eur Spine J.* 2006 Feb;15(2):183-95.
 - 53 patients
 - 60% rate of spontaneous ankylosis after 17 years
 - Although no adjacent segment degeneration was observed in the functional implants (17%), these patients were significantly less satisfied than those with spontaneous ankylosis

Challenges

Diagnosis?

Is it warranted?

Will it last?

What about facets?

What about natural history?

Disc Replacement

- Zindrick MR, Tzermiadianos MN, Voronov LI, et al. An evidence-based medicine approach in determining factors that may affect outcome in lumbar total disc replacement. *Spine*. 2008 May 15;33(11):1262-9.
 - The majority of studies found were level IV (Case series)
 - Decreased rates of adjacent segment degeneration

Disc Replacement

- Guyer RD, Siddiqui S, Zigler JE, et al. Lumbar spinal arthroplasty: analysis of one center's twenty best and twenty worst clinical outcomes. *Spine*. 2008 Nov 1;33(23):2566-9.
 - Retrospective review 20 patients
 - Percentage change in VAS and Oswestry scores looked at to evaluate the 10 best and 10 worst cases
 - Patients who were off work for shorter durations, or not at all, were more likely to be in the best-outcome group
 - No additional factors related to the best/worst classification were identified in the current study.

Disc Replacement

- Rohan MX Jr, Ohnmeiss DD, Guyer RD, et al. Relationship between the length of time off work preoperatively and clinical outcome at 24-month follow-up in patients undergoing total disc replacement or fusion. *Spine J.* 2009 May;9(5):360-5
 - 232 patients
 - 52 received a Charité, 111 received a ProDisc, 27 underwent a combined anterior/posterior instrumented fusion, and 14 underwent anterior lumbar interbody fusion
 - The length of time off work preoperatively was more strongly related to outcome than was surgery type, insurance type, job demand, or preoperative VAS and Oswestry scores.

Summary

Many different devices

Still unproven

Diagnosis is key

Remain cautiously optimistic

BMP-2

Cervical Spine

FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion

Issued: July 1, 2008

Dear Healthcare Practitioner:

This is to alert you to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the **cervical spine**. Note that the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by FDA for this use.

BMP-2 complications

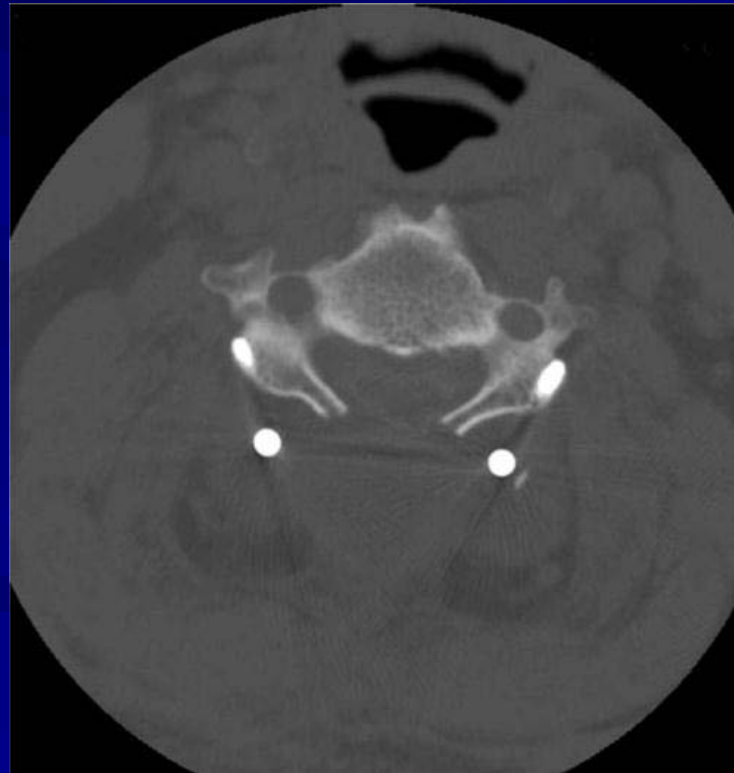
- Williams BJ, et al. Does bone morphogenetic protein increase the incidence of perioperative complications in spinal fusion? A comparison of 55,862 cases of spinal fusion with and without bone morphogenetic protein. **Spine** (Phila Pa 1976). 2011 Sep 15;36(20):1685-91.
 - 55,862 cases of spinal fusion were identified with BMP used in 21% (11,933) of the cases
 - Anterior cervical fusions with BMP were associated with more overall complications (5.8% vs. 2.4%; $P < 0.001$) and more wound infections (2.1% vs. 0.4%; $P < 0.001$)

BMP-2 complications

- Anderson DW, et al. Postoperative **cervical** myelopathy and cord compression associated with the use of recombinant bone morphogenetic protein-2 in posterior **cervical** decompression, instrumentation, and arthrodesis: a report of two cases. **Spine** (Phila Pa 1976). 2011 May 1;36(10):E682-6.
 - 2 cases where BMP-2 was used resulting in cord compression and neurologic decline
 - Both patients were found to have a moderate-to-large seroma causing severe compression on the spinal cord and were urgently taken to an operating room for evacuation of the seromas.

BMP-2 complications

- Image of fluid collection posterior causing moderate to severe cord compression



BMP-2 complications

- Myelogram



BMP-2 complications

- Yaremchuk K, et al. Acute airway obstruction associated with the use of bone-morphogenetic protein in **cervical** spinal fusion. *Laryngoscope*. 2010;120 Suppl 4:S140.
 - Retrospective study of 260 patients
 - Compared to a cohort of 520 patients where BMP-2 was not used
 - Patients that underwent cervical procedures with BMP were noted to have significantly longer hospital stays (7.2 ± 11.1 days vs. 4.3 ± 5.2 days, $p < 0.001$), and greater costs (\$129,483 versus \$74,974, $p < 0.001$)
 - Tracheotomies (Odds Ratio = 3.79, p -value = 0.021), unplanned intubations after surgery (2.81, 0.008), dysphagia (8.94, 0.001), dyspnea (2.43, 0.001), and respiratory failure (3.35, 0.001) were all significantly associated with the BMP group
 - In addition, hospital readmissions (1.96, 0.040), ICU admissions (3.05, 0.001), and 90 day mortality rates (Hazard Ratio = 2.44, $p = 0.047$) were significantly worse for the BMP group.

BMP-2 complications

- Cahill KS, et al. Prevalence, complications, and hospital charges associated with use of bone-morphogenetic proteins in spinal fusion procedures. *JAMA*. 2009 Jul 1;302(1):58-66.
 - Retrospective cohort study of 328,468 patients
 - no differences were seen for lumbar, thoracic, or posterior cervical procedures
 - Use of BMP in anterior cervical fusion procedures was associated with a higher rate of complication occurrence (7.09% with BMP vs 4.68% without BMP)
 - Increases seen in wound-related complications (1.22% with BMP vs 0.65% without BMP) and dysphagia or hoarseness (4.35% with BMP vs 2.45% without BMP)
 - Increases between 11% and 41% of total hospital charges were reported, with the greatest percentage increase seen for anterior cervical fusion

BMP-2 complications

- Buttermann GR. Prospective nonrandomized comparison of an allograft with bone morphogenic protein versus an iliac-crest autograft in anterior **cervical** discectomy and fusion. **Spine J.** 2008 May-Jun;8(3):426-35. Epub 2007 Mar 7.
 - ACDF with either iliac-crest bone autograft (n=36) or BMP-allograft (n=30)
 - In the BMP-allograft group, one patient had a pseudarthrosis, but 50% had neck swelling presenting as dysphagia which was substantially more common than the 14% present in the iliac bone graft group

BMP-2 complications



BMP-2 complications

- Smucker JD, et al. Increased swelling complications associated with off-label usage of rhBMP-2 in the anterior cervical spine. *Spine (Phila Pa 1976)*. 2006 Nov 15;31(24):2813-9.
 - 234 consecutive patients (ages 12-82 years) undergoing anterior cervical fusion with and without rhBMP-2 over a 2-year period
 - 69 of whom underwent anterior cervical spine fusions using rhBMP-2; 27.5% of those patients in the rhBMP-2 group had a clinically significant swelling event versus only 3.6% of patients in the non-rhBMP-2 group

BMP-2 complications



Preoperative



Postoperative day 4



Postoperative week 6

Lumbar Spine

BMP

- Boden SD, Kang J, Sandhu H, Heller JG.
Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar spine fusion in humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies.
Spine. 2002 Dec 1;27(23):2662-73.
 - 25 patients undergoing lumbar arthrodesis
 - Autograft with instrumentation, and rhBMP-2 with and without instrumentation
 - radiographic fusion 40% autograft with instrumentation
 - 100% with rhBMP-2 group with or without internal fixation (= 0.004).

BMP

- Carreon LY, Glassman SD, Djurasovic M, et al. RhBMP-2 versus iliac crest bone graft for lumbar spine fusion in patients over 60 years of age: a cost-utility study. Spine (Phila Pa 1976). 2009 Feb 1;34(3):238-43.
 - Retrospective review
 - 52 ICBG, 50 rhBMP-2
 - \$34,235 in the ICBG group and \$36,530 in the rhBMP-2
 - rhBMP-2/ACS was \$39,967 and for ICBG the cost was \$42,286

BMP

- Carreon LY, Glassman SD, Djurasovic M, et al. RhBMP-2 versus iliac crest bone graft for lumbar spine fusion in patients over 60 years of age: a cost-utility study. *Spine (Phila Pa 1976)*. 2009 Feb 1;34(3):238-43.
 - In the ICBG group, 8 patients had complications; 20 had additional interventions, 5 of whom required revision for nonunion.
 - In the rhBMP-2/ACS group, 6 patients had complications, 10 had additional interventions, and 1 required revision for nonunion.

BMP

- Carragee EJ, Mitsunaga KA, Hurwitz EL, et al. Retrograde ejaculation after anterior lumbar interbody fusion using rhBMP-2: a cohort controlled study. Spine J. 2011 Jun;11(6):511-6.
 - Retrospective reviews
 - ALIF
 - 69 with BMP-2, 174 without
 - five RE events (7.2%) reported in the rhBMP-2 group and 1 (0.6%) in the control group.

BMP

- Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J.* 2011 Jun;11(6):471-91.
 - Systemic review
 - 13 studies, 780 patients
 - No reported complications
 - Revised adverse events

BMP

- Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J.* 2011 Jun;11(6):471-91.
 - 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.

BMP

- Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J.* 2011 Jun;11(6):471-91.
 - anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls.

BMP

- Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J.* 2011 Jun;11(6):471-91.
 - Posterior lumbar interbody fusion use was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes.

Summary

- Recommendations against BMP-2 in cervical spine
- Increasing concerns in lumbar spine
- Informed consent

Thank You