



Early Clinical Experience with a PEEK-OPTIMA™ HA Enhanced Device for Lumbar Fusion

▶ NASS 2016 Solution Showcase

PEEK-OPTIMA™ + HYDROXYAPATITE (HA)

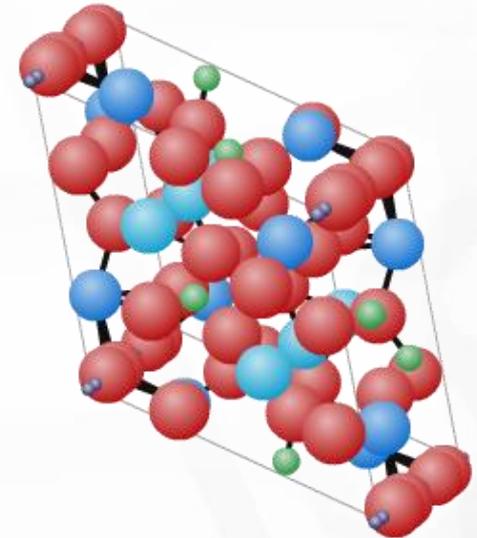
TWO PROVEN BIOMATERIALS. ONE SUPERIOR COMBINATION.

- Not a coating Technology
- 40-50% of human bone reinforced with apatite crystals
- Hydroxyapatite (HA) has a chemical and crystal structure similar to that found in bone
- HA compounded with PEEK-OPTIMA™

STRUCTURAL PROPERTIES OF PEEK + THE OSTEOCONDUCTIVE PROPERTIES OF HA

Invibio BIOMATERIAL
SOLUTIONS

Materials. Manufacturing. Knowledge.



Generic PEEK-OPTIMA™ HA Enhanced
cervical cages



These products are not cleared by
the FDA for distribution in the US.

Mechanical Properties Similar to PEEK-OPTIMA®

Property	Impact (Notched) (KJ/m ²)	Flex Strength (MPa)	Flex Modulus (GPa)	Tensile Strength (MPa)	Tensile Elongation at break (%)
PEEK-OPTIMA Natural	7.6	164	4.1	100	40
PEEK-OPTIMA® HA Enhanced	5.35	152.69	4.44	94.44	12.45
Cortical Bone	2-5 (un-notched)	173	18	80-150 (longitudinal)	1.4

Values stated are for evaluative purposes only and do not constitute product specifications.

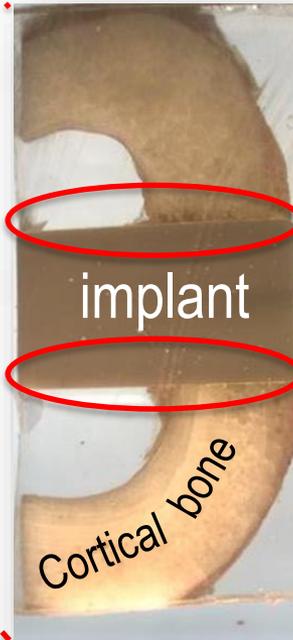
Ovine Study Design

Test group

PEEK-OPTIMA™ HA Enhanced Polymer



Medullary canal

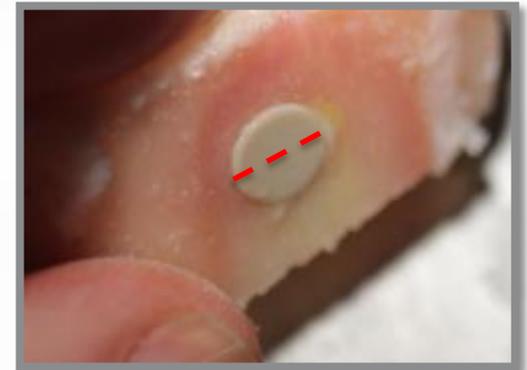


Interface

Trabecular Bone – Distal Femur, Proximal Tibia
Cortical Bone – Tibial diaphysis

Control group

PEEK-OPTIMA Natural



Implant *in situ*: 6mm x 25mm

Enhanced Bone Apposition

>75%

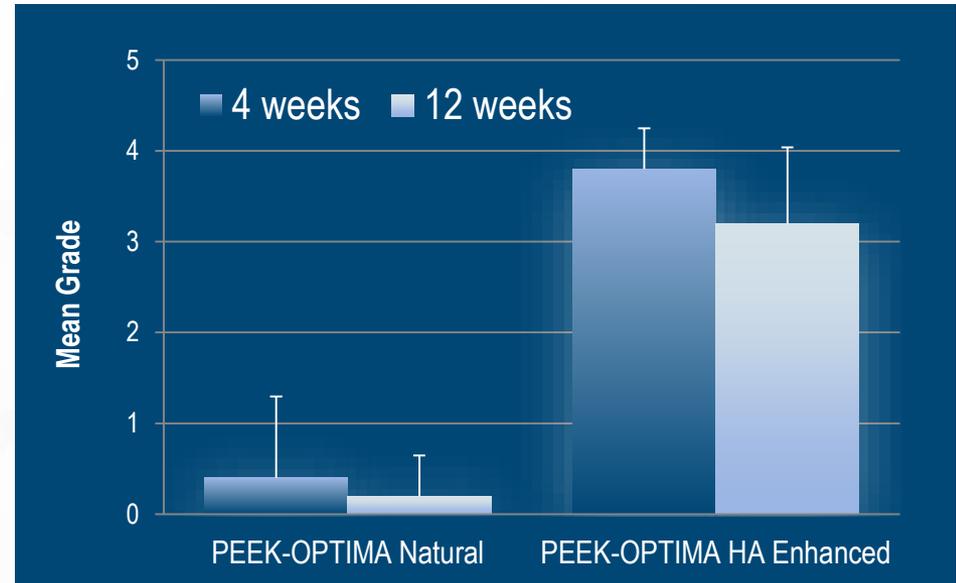
**Direct
Bone
Contact**

After 4 weeks[±]

[±]In an ovine model
Data on file with Invibio

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Grading of bone in contact:

4 = >75% contact

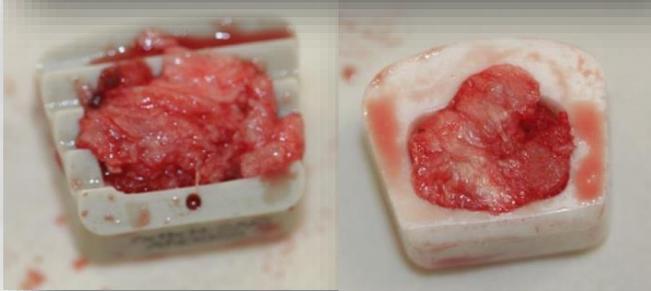
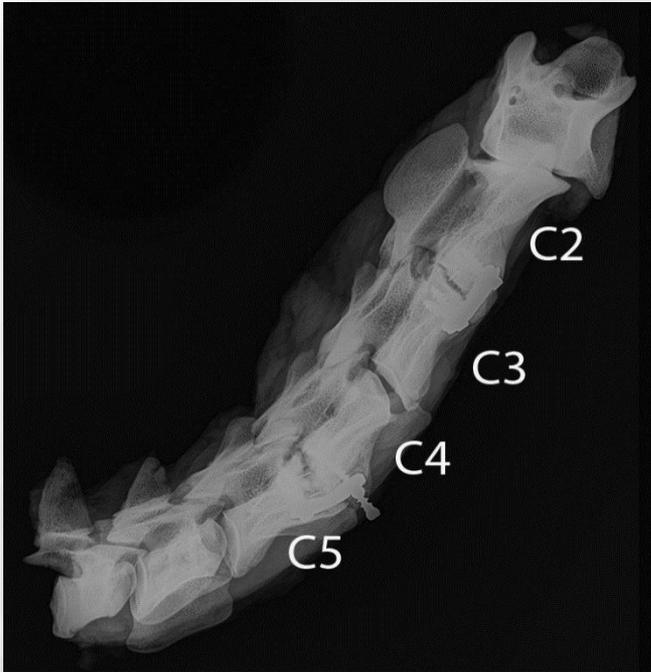
3 = 50%

2 = 25%

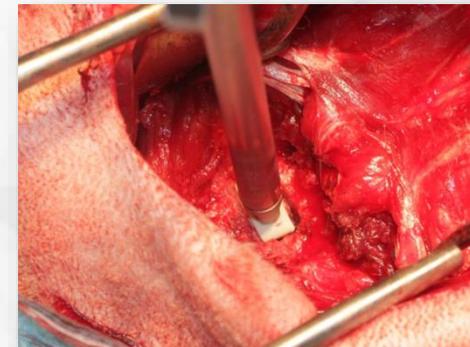
1 = <25%

0 = No direct contact

Cervical Fusion Study Design



- 2 level ovine cervical fusion model comparing:
 - Allograft bone
 - PEEK-OPTIMA™ Natural
 - PEEK-OPTIMA HA Enhanced
- 6, 12 and 26 week follow up*:
 - Radiography
 - Micro CT
 - Biomechanical testing
 - Histology

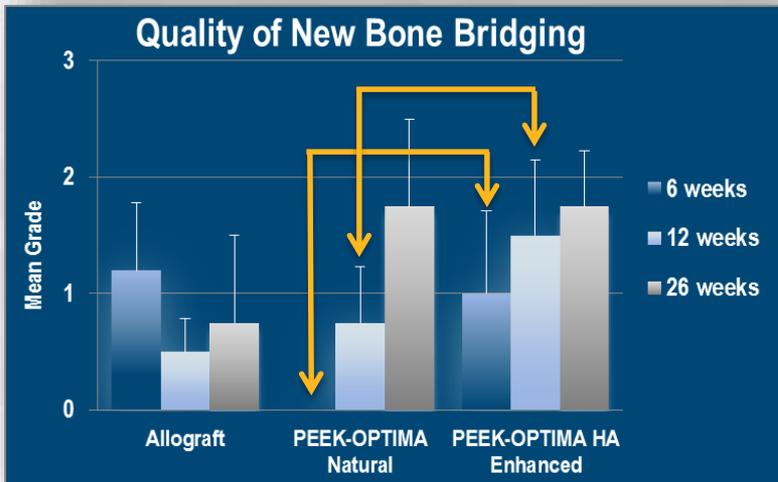
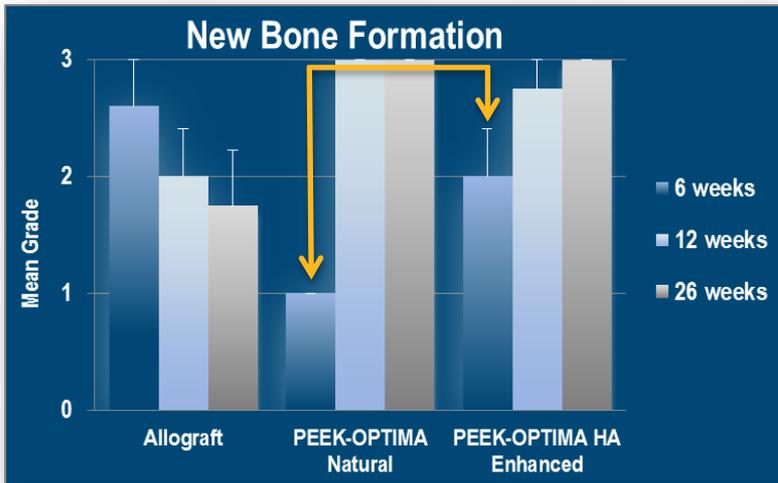


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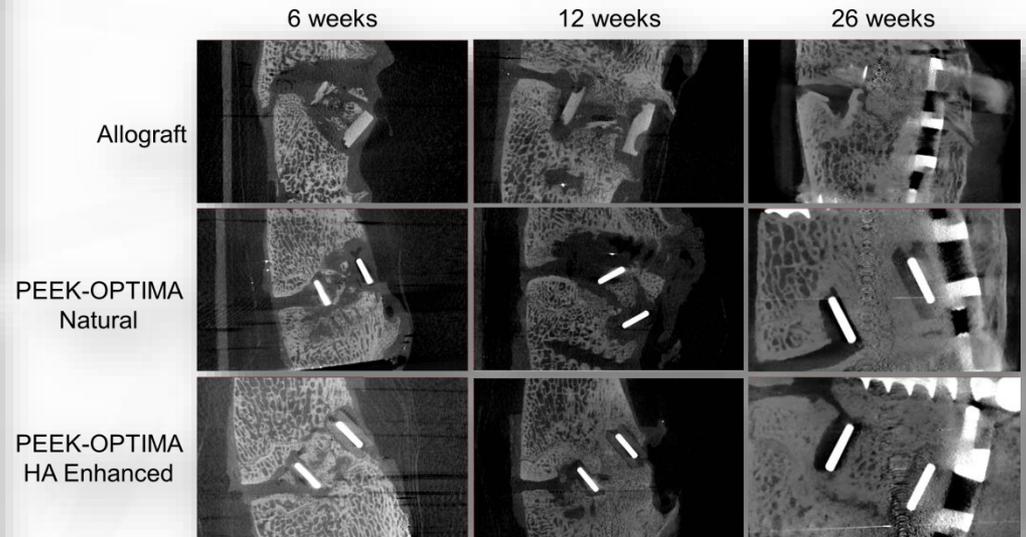
*n = 4 for each material per time point

Micro CT Evaluation



◀ Superior new bone formation:

PEEK-OPTIMA™ HA Enhanced polymer resulted in **greater new bone formation** at 6 weeks compared with PEEK-OPTIMA Natural



◀ Superior quality of new bone bridging:

PEEK-OPTIMA HA Enhanced resulted in a **higher quality of new bone bridging** at 6 and 12 weeks compared with PEEK-OPTIMA Natural.

Summary

▶ **Greater Bone Apposition:**

PEEK-OPTIMA™ HA Enhanced polymer resulted in over 75% direct bone contact after 4 weeks in a long bone ovine study.

▶ **Superior new bone formation:**

PEEK-OPTIMA HA Enhanced resulted in greater new bone formation at 6 weeks compared with PEEK-OPTIMA Natural in an ovine cervical fusion study.

▶ **Superior quality of new bone bridging:**

PEEK-OPTIMA HA Enhanced resulted in a higher quality of new bone bridging at 6 and 12 weeks compared with PEEK-OPTIMA Natural in an ovine cervical fusion study.

Clinical Case Series

Lumbar Interbody Fusion: PEEK-OPTIMA™ HA Enhanced

Dr. Timothy Bassett

SouthEastern Spine Specialists
Tuscaloosa, Alabama



Disclosures

- Product design royalties with Seaspine for ALIF, Cutting Edge Spine for PLIF/TLIF cages

Practice Overview

- 23rd year in private practice in Tuscaloosa, AL
- Primarily adult degenerative lumbar spine
- Most are spondylolisthesis/stenosis, failed fusion redos, some purely axial/disc related LBP
- Niche: Failed lumbar fusions
- Approximately 100 to 150 lumbar fusion annually
- TLIF, ALIF, XLIF, MIS, stand alone, facet, interspinous, Bone/titanium/PEEK, Allograft, bmp, dbm, msc, autograft
- Preferred method is unilateral PLIF approach, TLIF style banana cage, autograft

Rationale for Interbody Fusion

80% of my fusions are interbody based

- Primary goal is improving LBP
- Primary goal is leg pain improvement and patient has spondylolisthesis greater than 6 mm, or relative kyphosis
- Any form of failed prior fusion
- Asymmetrical disc space collapse on sx side

If F/E stable > Pedicle screw, Interspinous, Facet

If F/E greater than 3mm or kyphotic > pedicle screws

Surgical Technique

- Most of these patients require decompression as their primary procedure.
- Facets retained as much as possible lateral to the medial pedicle border
- Disc clearance usually one sided approach, symptomatic side, taking down across midline with curved curettes
- Endplates retained by using push down curettes
- Biconvex CES EVOS implant placed anteriorly, if possible, transversely to maximize graft area
- The best graft is placed in interbody area
- Pedicle screws highly triangulated, deep, locked in compression

EVOS HA Device



EVOSHA

The First PEEK-OPTIMA[®] HA Enhanced Lumbar Interbodies in the US

HYDROXYAPATITE IMPREGNATED PEEK-OPTIMA Natural

A GAME CHANGER

HA INTEGRATED INTO PEEK-OPTIMA[®] Natural



EVOSHA

1,857 FOOTPRINTS



- | CURVED |
|------------------------------|
| ▶ Chamfered leading edge |
| ▶ Biconvex or flat endplates |
| ▶ 0 or 6 degrees lordosis |



- | STRAIGHT |
|--|
| ▶ 3 Nose styles |
| ▶ Multiple sizes & forms, including true oblique lordotic design |
| ▶ Unilateral, bilateral, or oblique placement |



- | ROTATE |
|--|
| ▶ In situ distraction up to 4mm with ¼ turn |
| ▶ Multiple sizes & forms, including true oblique lordotic design |
| ▶ Unilateral, bilateral, or oblique placement |

STERILE PACKAGING

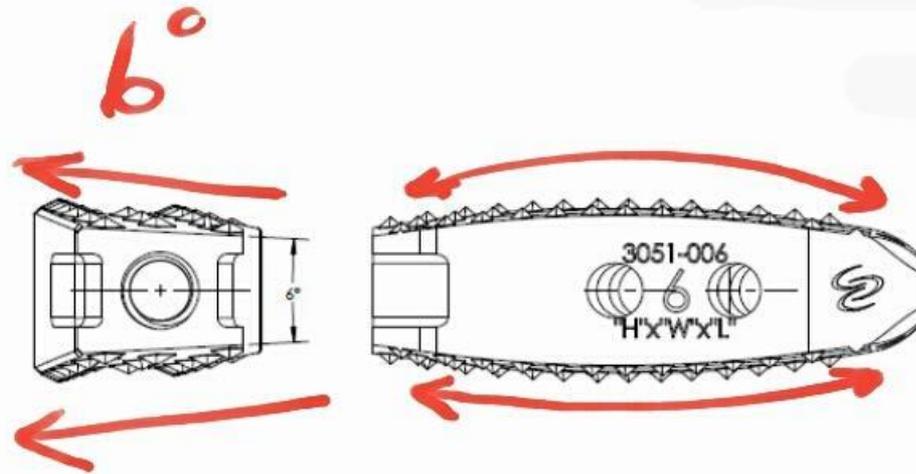
Increased Safety & Traceability

All EVOS implants are single-use, barcoded, and pre-sterilized.





Curved TLIF



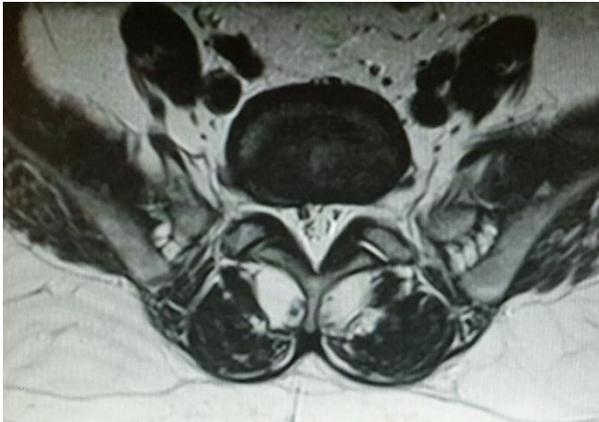
EVOS cage for biconvex design, strength, modulus match, rapid fusion ingrowth, ease of insertion with small exposure window

Case Series Overview

- Nine patients underwent 1-2 level lumbar fusion with the EVOS HA cage + autograft bone with posterior instrumentation
 - No biologics used in this series
 - Post-op no NSAIDS, caffeine, tobacco for 3 months
 - Two patients had Orthofix bone stimulator
- Evaluated clinical results
 - Pain VAS, opiate usage, functionality
 - Neurological Function, reoperations, complications
- Evaluated Fusion Results
 - AP, Lat X-rays at 6 weeks, 12 weeks
 - 6 month CT scan assessment

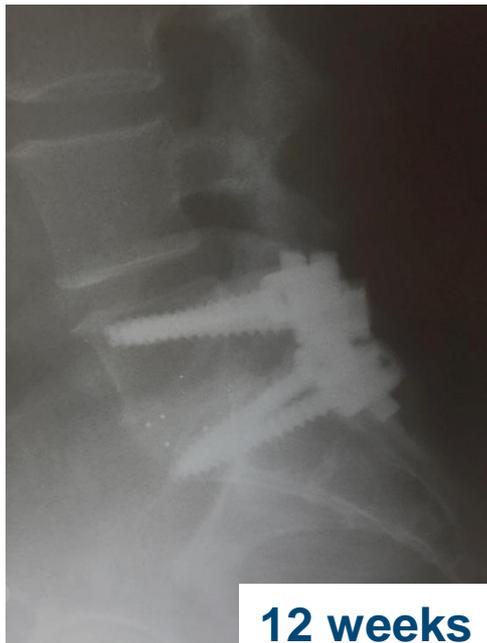
Patient 1

- 50 year old female, work comp, first patient Oct. 2015
- LBP, right L5 dermatomal pain secondary to lifting injury 6 months prior.
- VAS 7-10, Norco 3/day
- L5 bilateral pars defect, grade 1 slip with disc protrusion into foramen
- Right L5 weakness



Pt 1: Intervention

- L5-S1 Fusion
- EVOS HA cage + posterior instrumentation
- Autograft bone, no biologics



Pt 1: Outcome

- Solid L5-S1 fusion at 6 months on CT scan
- No leg pain
- >50 % improved LBP
- No pain meds
- Returned to same occupation



Patient 2

- 66 year old male farmer, smoker 1 ppd
- 2 year progressive lumbar pain radiating to left leg, neurogenic claudication.
- Gait tolerance 200 yards
- Fem-pop stent 2015, pacemaker, tobacco
- VAS 3-10, positional, tramadol
- Degenerative scoliosis L3-4, left
- Left L3 nerve root impingement with thigh pain



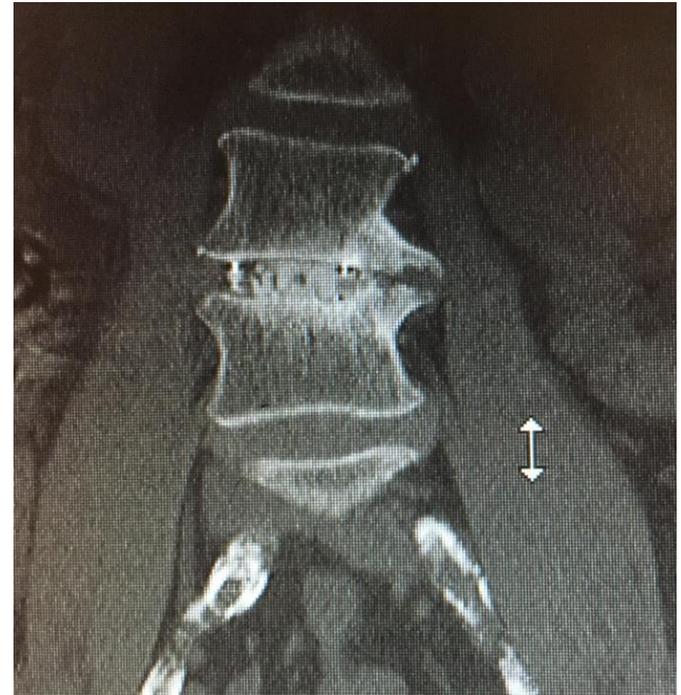
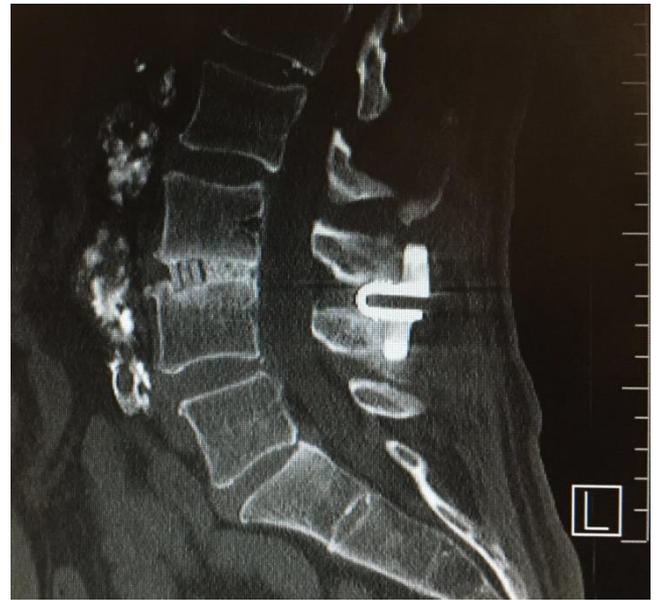
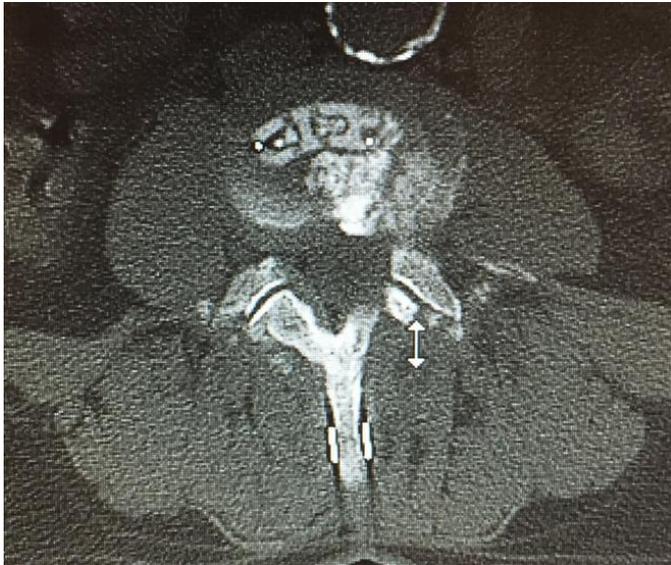
Pt 2: Intervention

- Left L3-4 foraminal decompression with L3-4 fusion
- EVOS HA cage + CoFlex ISP
- Autograft bone, no biologics
- Patient continued smoking



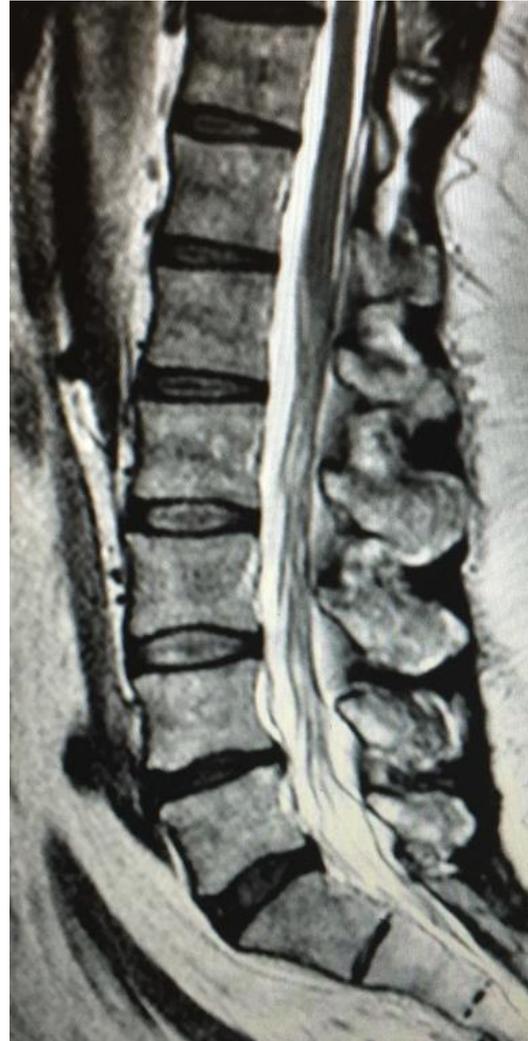
Pt 2: Outcome

- Hip wound dehiscence
- Fusion progressing at 6 months on CT scan
- Patient smokes 1 pack/day
- Returned to full activities farming, no residual leg pain
- Gait tolerance one-half mile
- Less than 25% residual LBP



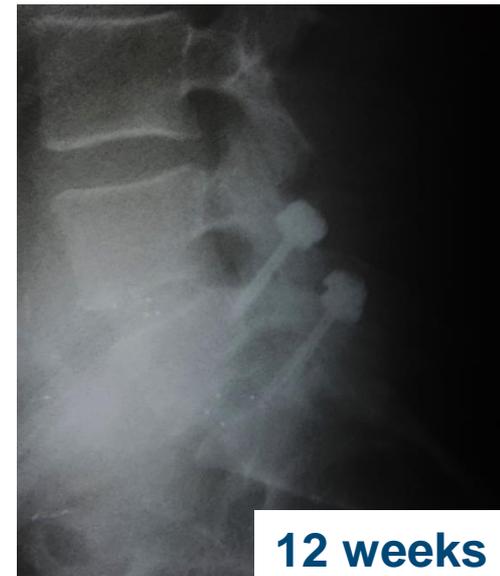
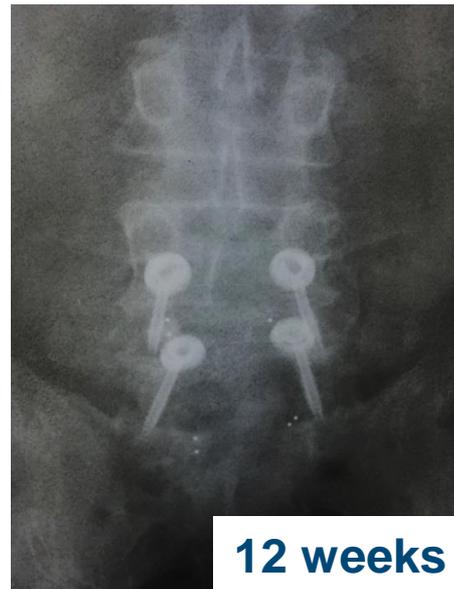
Patient 3

- 68 year old male non-smoker
- 2 year history low back pain
- Diabetic
- VAS 8-10
- No leg pain or weakness
- No gross instability
- Positive discogram L4-5, L5-S1, neg at L2-3, L3-4
- Chiropractic, physical therapy, four LEBs, pain meds



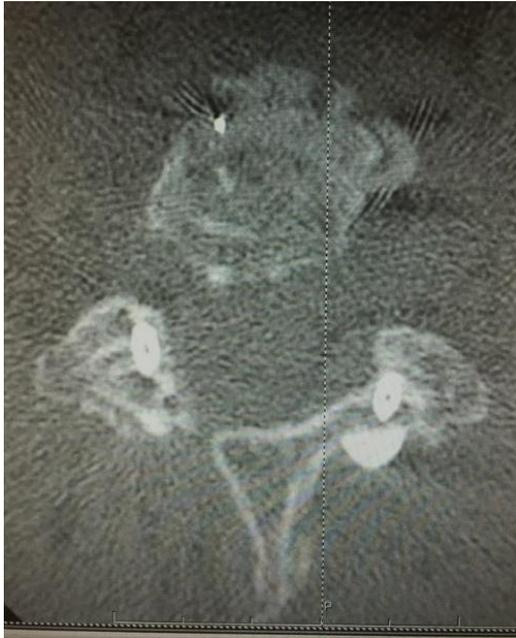
Pt 3: Intervention

- L4-S1 Fusion
- EVOS HA cage + Facet screws
- Autograft bone, no biologics
- Bone Stimulator +/- 12 weeks



Pt 3: Outcome

- Solid fusion at 6 months on CT scan
- Joined YMCA, exercising regularly
- No meds
- No back or leg pain



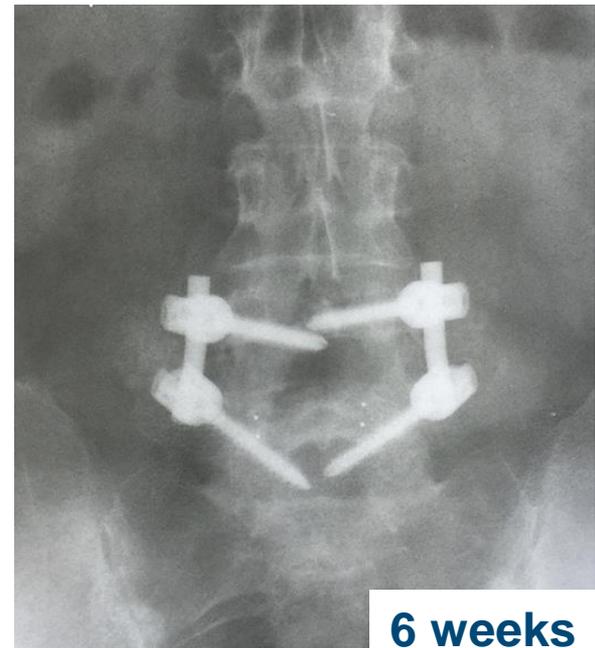
Patient 4

- 59 year old female non-smoker
- Hx Diabetes, PN, Cardiac stents
- Back and lower right L5 leg pain
- VAS 9-10
- Chiropractic, 3 LEBs
- 14 mm L4-5 Spondy with moderate stenosis



Pt 4: Intervention

- L4-5 decompression, fusion
- EVOS HA cage + posterior instrumentation
- Autograft bone, no biologics
- Orthofix Bone stim 6 weeks
- 6 week radiographs



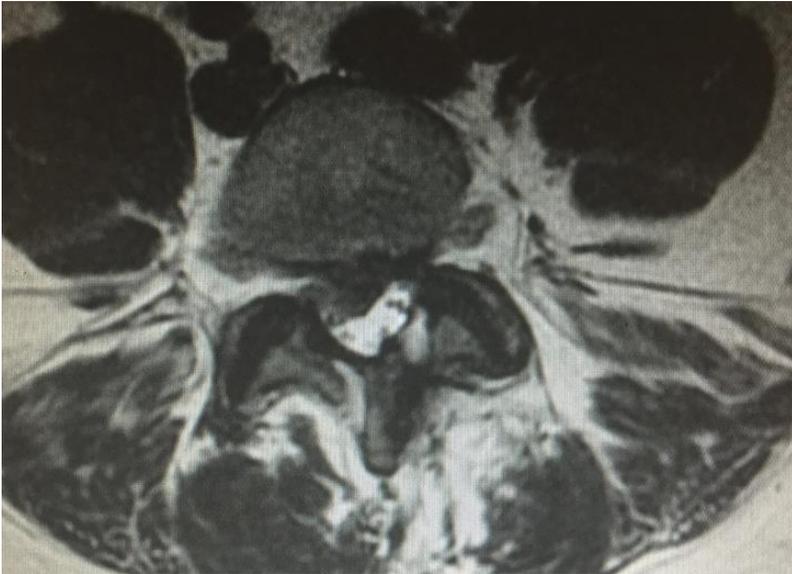
Pt 4: Outcome

- Spondylolisthesis corrected, lordotic
- Solid fusion at 6 months on CT scan
- No LBP. Some PN symptoms. No Radiculopathy



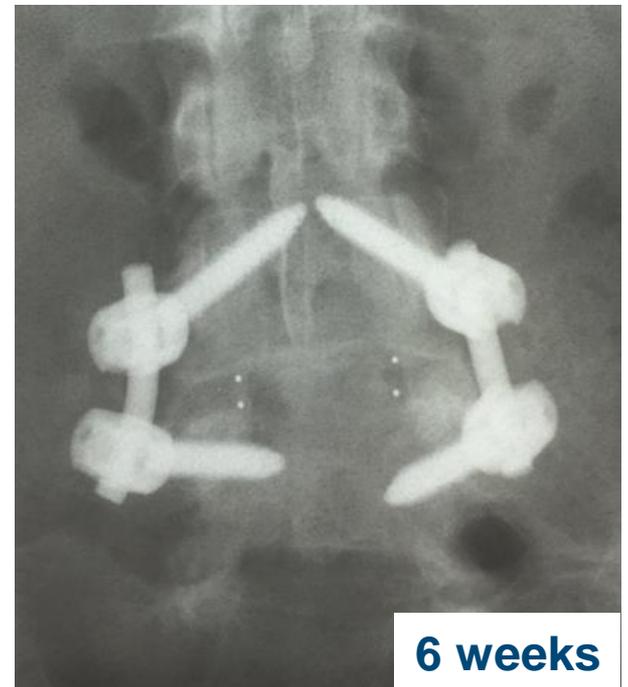
Patient 5

- 39 year old female
- Right S1 radiculopathy, weakness, LBP
- VAS 2-7, Tramadol
- Segmented S1-2
- Three previous discectomies with fourth disc rupture L5-S1
- Left L5 unilateral pars defect



Pt 5: Intervention

- L4-5 bilateral discectomy, fusion, interbody approach on pars defect side (L)
- EVOS HA cage + posterior instrumentation
- Autograft bone, no biologics



Pt 5: Outcome

- Solid fusion at 6 months on CT scan
- No back or leg pain VAS ZERO
- No meds
- No activity restrictions



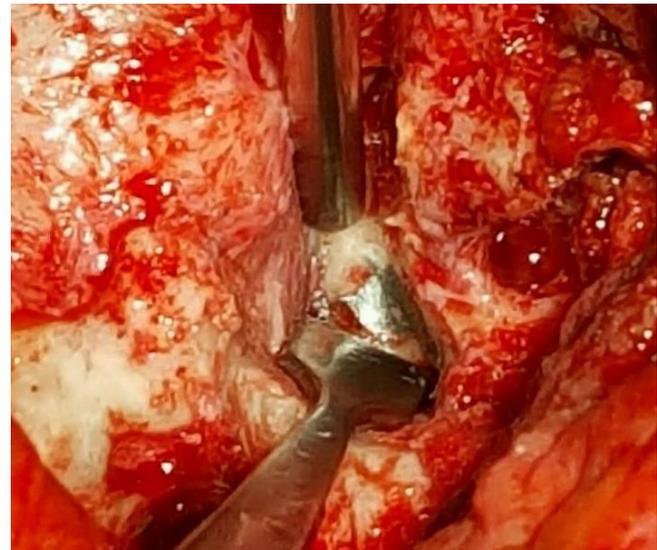
Patient 6

- 44 year old female
- Low back pain, hip pain, right S1 radiculopathy. Miserable
- Multiple blocks, Norco 3/day
- Prior failed L5-S1 Fusion with oblique PEEK cage, dbm, local
- S1 nerve root impingement with broken screw



Pt 6: Intervention

- L5-S1 Fusion, revision right S1 decomp, screw reduction
- EVOS HA cage + posterior instrumentation
- Autograft bone, no biologics



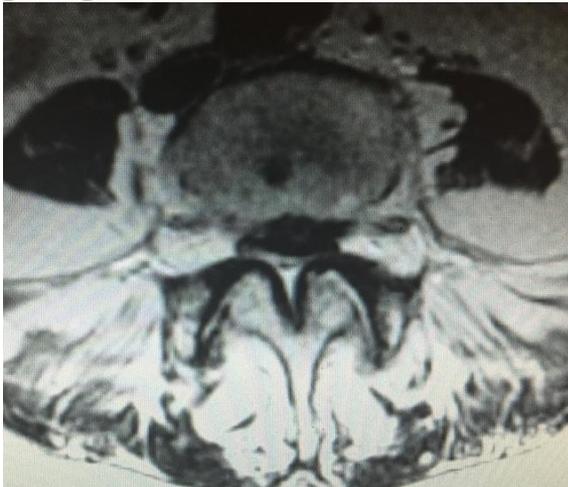
Pt 6: Outcome

- Fusion solid at 6 months on CT scan
- Off all pain meds
- Slight leg discomfort, Lyrica
- No LBP
- Going to gym regularly



Patient 7

- 76 year old female
- Leg pain, bilateral hip pain and posterior thigh pain. VAS 4-10, Oxycodone 2/day
- Neurogenic claudication hx, Gait tolerance less than 100 yards. Rapid pain relief upon sitting
- L4-5 Spondy (10mm) with high grade stenosis at L4-5



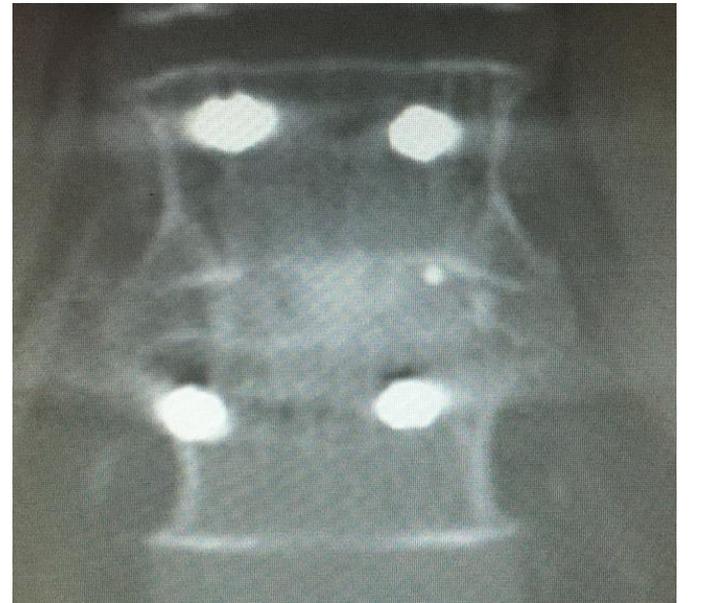
Pt 7: Intervention

- L4-L5 decompression, reduction with fusion
- EVOS HA cage + pedicle screw
- Autograft bone, no biologics



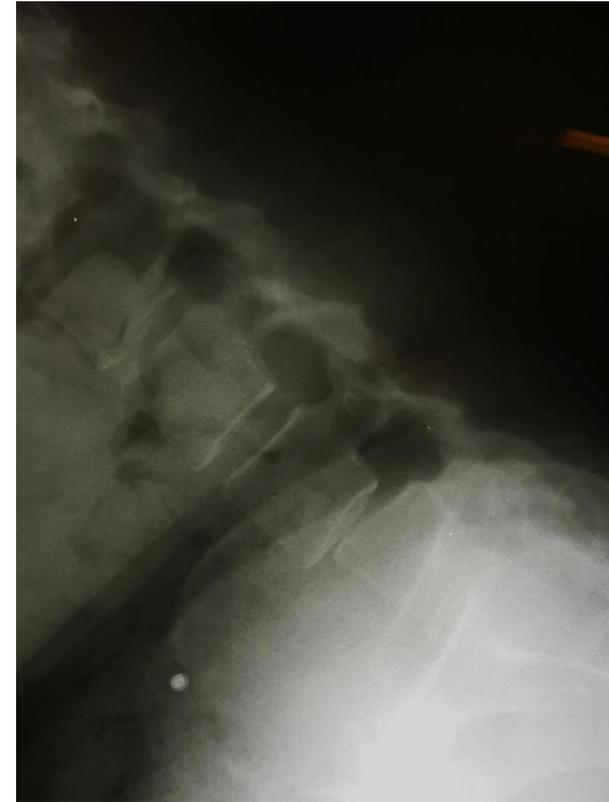
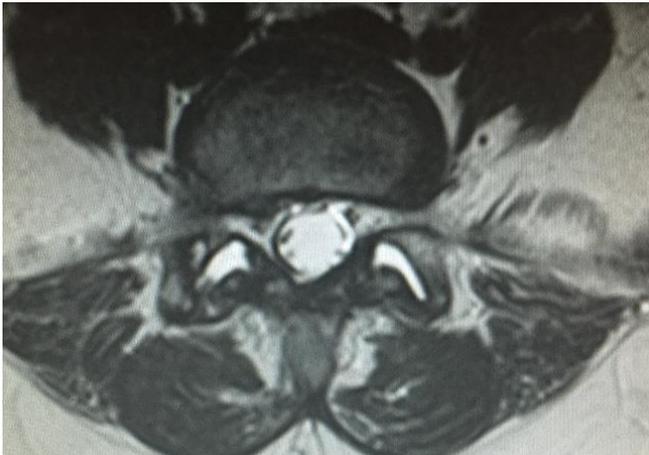
Pt 7: Outcome

- Fusion at 6 months on CT scan with bridging bone
- No leg pain
- No pain meds
- Walking daily for exercise, works out in gym 5 days per week



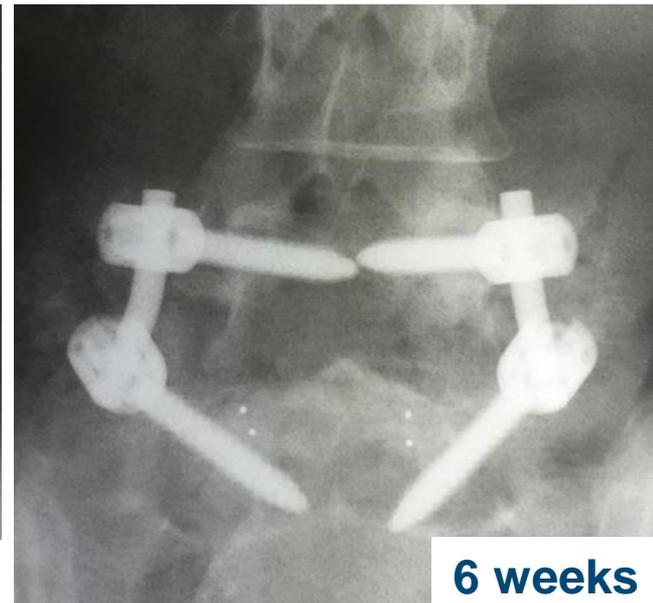
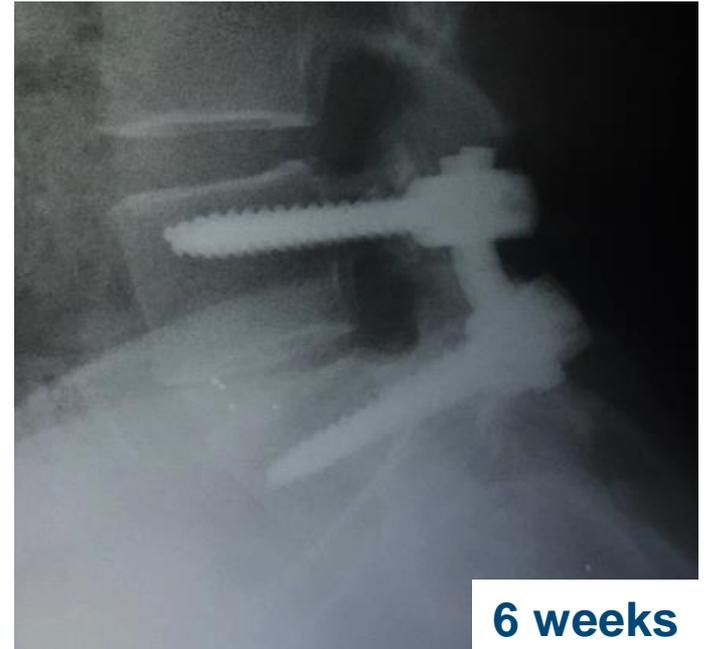
Patient 8

- 46 year old female
- Back and bilateral leg pain
- Rapid pain relief upon sitting
- Hx of fibromyalgia
- VAS 10/10 LBP
- Norco 4/day, Soma
- L4-5 Spondy with 5mm slip, sacralized L5-S1



Pt 8: Intervention

- L4-L5 reduction and fusion
- EVOS HA cage + pedicle screws
- Autograft bone, no biologics



Pt 8: Outcome

- Solid fusion at 6 months on CT scan with good bone abutment around cage
- Having some discomfort all over, likely due to history of fibromyalgia
- No specific LBP, leg pain
- No pain meds



Patient 9

- 53 year old female non-smoker
- Two separate prior MIS unilateral pedicle screw constructs with titanium cages, Infuse, dbx putty



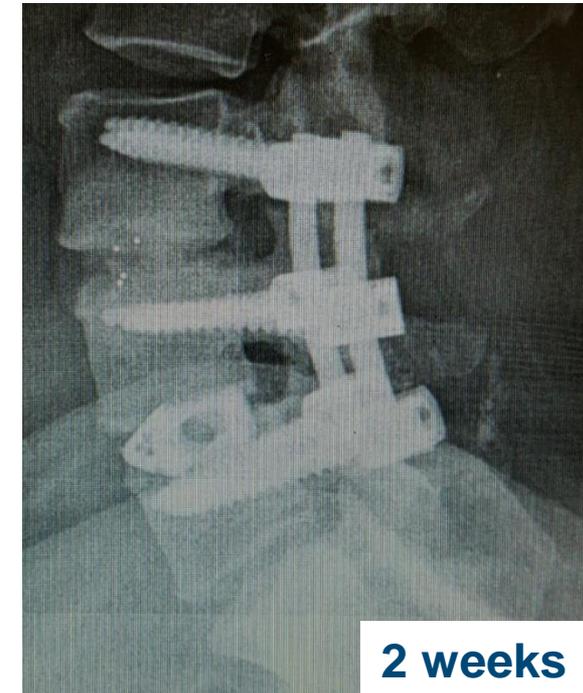
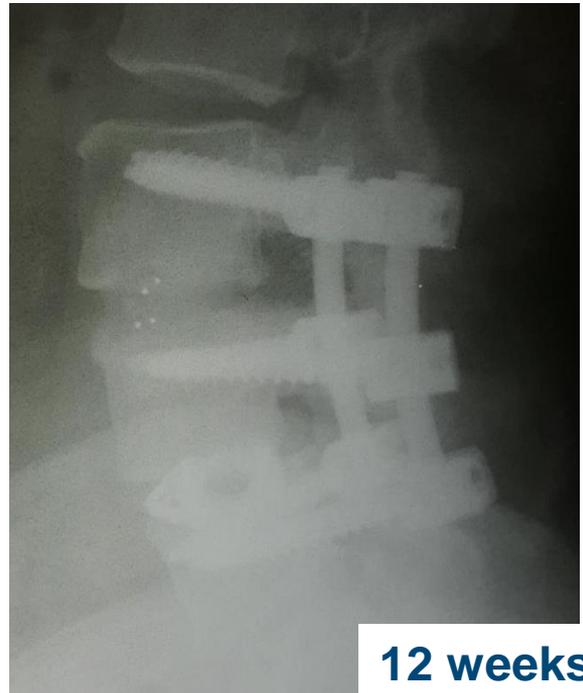
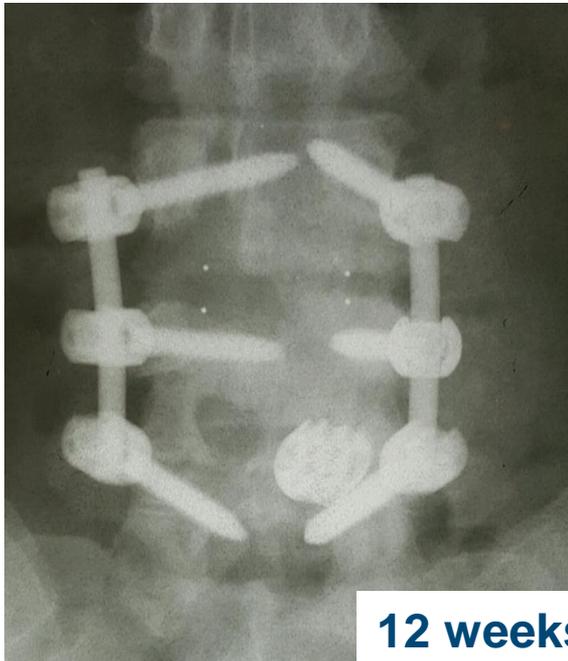
Patient 9

- Low back pain with severe left L3 leg pain and numbness secondary to foraminal bone overgrowth



Pt 9: Intervention

- Removal Ti cage at L3-4, left L3 decompression fusion with EVOS HA cage + bilat pedicle screws
- Autograft bone at L3-4, L4-5 disc spaces. No biologics
- Re-grafted L4-5, left Ti cage in place (non sx side)



Pt 9: Outcome

- Solid L3-4 fusion at 6 months on CT scan with good bone abutment around cage
- L4-5 fusion progressing but some gaps persist (coronal recon)
- Leg pain resolved, overall very good result



Clinical Results Summary

- Greater than 50% reduction in LBP in every patient
- Total or near total leg pain relief
- No neurologic sequelae
- No instrumentation failures
- No spine reoperations
- 9/10 fusions definitively solid on 6 month CT

Conclusion

- Very rapid visible bone fusion in the interbody region in six weeks on plain radiographs, correspondingly good clinical result
- Since October 2015, 51 patients with 70 levels. All TLIF biconvex cages, all autograft
- L1/2 (1), L2/3 (2), L3/4 (7), L4/5 (33), L5/S1 (27)
- 1 hip dehiscence, 2 lumbar wound dehiscences. No sequelae.
- 1 sacral fracture beneath L4-S1 fusion, required pelvic fixation
- No neurologic consequences beyond 6 weeks.
- No instrumentation failures. No implant migrations, no subsidence. No pseudoarthroses.

Thank you

The case studies and testimonial presented have been provided by a practicing orthopedic surgeon. His view and experiences are his own and do not necessarily reflect those of others. “Invibio” disclaims any liabilities or loss in connection with the information herein.