

# Novel Surface Technologies: The Evidence Supporting HA PEEK

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# Hydroxyapatite

- HA defined:  $\text{Ca}_{10}(\text{PO}_4)_6\text{OH}_2$   
It is the main inorganic component of bone and tooth enamel
- Bone 70% HA, 25% organic, 5% water
- Bonfield, et al, in 1981 mixed HA with polyethylene to create “artificial bone” void filler. 20 – 40% fractional volume HA showed increased bone ongrowth in rabbit models vs inert polyethylene.
- In the 1990's, Ti/HA hip implants, survivability 98% at > 20 years

# Polyetheretherketone

- Introduced in 1980's by Victrex (Invibio)
- PEEK used in spinal fusion predominantly in the form of a load bearing interbody cage for approx 15 years.

## Advantages

- >Mechanical strength
- >Modulus similar to cortical bone
- >Imaging compatibility
- >Biocompatibility
- >Ease of manufacturing

## Disadvantages

- >Hydrophobic, inert. Bone does not directly bond to the PEEK, creates a fibrous layer. Concern for nonunion.

# PEEK-OPTIMA™ HA Enhanced

- PEEK-OPTIMA + HYDROXYAPATITE (HA)
- Not a coating technology
- Formed by heat extrusion into rods
- Hydroxyapatite (HA) has a chemical and crystal structure similar to that found in bone
- HA evenly distributed throughout PEEK



**STRUCTURAL PROPERTIES OF PEEK +  
THE OSTEOCONDUCTIVE PROPERTIES OF HA**

# PEEK-OPTIMA™ HA Enhanced

- Typical Material Properties



Property	Impact (Notched) (KJ/m <sup>2</sup> )	Flex Strength (MPa)	Flex Modulus (GPa)	Tensile Strength (MPa)	Tensile Elongation at break (%)
PEEK-OPTIMA Natural	4.7	170	4.0	115	20
PEEK-OPTIMA® HA Enhanced	4.4	178	5.5	103	8
Cortical Bone	2-5 (un-notched)	173	18	80-150 (longitudinal)	1.4

20% fractional volume HA

# Basic Science Study 1

- “Response of human osteoblast to nano HA-PEEK – Quantitative proteomic study of bioeffects of nano-HA composite”  
Scientific Reports 3/2016 Zhao, et al

Study looked at 40% by volume nano-HA coating

- Found no toxicity of nano sized HA particles
- Cell attachment test demonstrated that the number of cells attached to n-HA/PEEK is significantly higher vs PEEK
- Alk phosphatase activity increase signifying increased osteoblast differentiation

# Basic Science Study 2

- “Preparation methods for improving PEEK’s bioactivity for ortho and dental applications: A review”  
Int J of Biomaterials 2016 Almasi, et al
- Increasing the volume fraction of HA increases the Young’s modulus, though strength and strain at fracture point decreases. Range 20 to 40%
- Best bioactivity approx 29%

# Pre-Clinical Study 1

- “Does PEEK HA enhance bone formation compared with PEEK in a sheep cervical fusion model?”  
CORR 11/2016 Walsh, et al
- Result: “Incorporating HA into the PEEK matrix resulted in more direct bone apposition as opposed to the fibrous tissue interface with PEEK alone.”



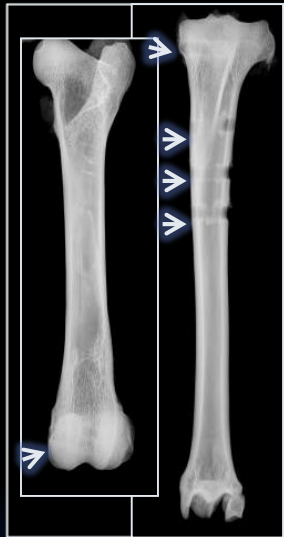
## ■ Ovine Study Design

### Test Group

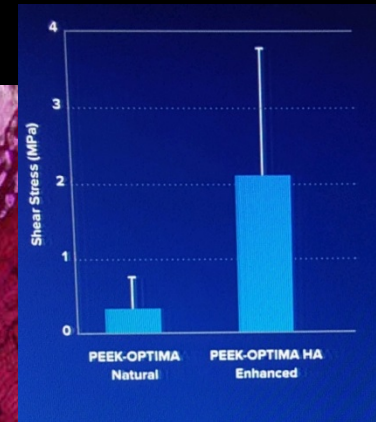
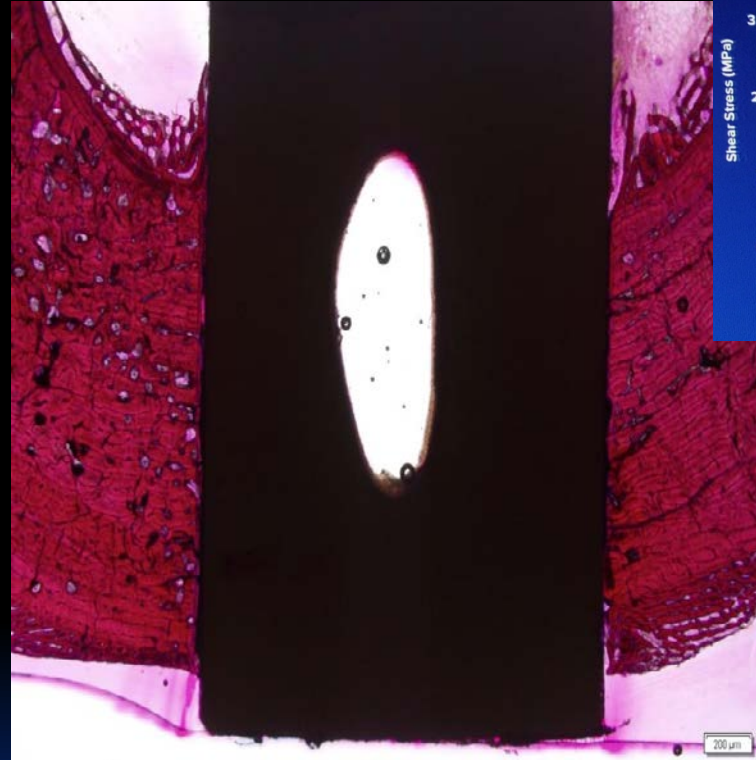
PEEK-OPTIMA HA Enhanced Polymer

### Control Group

PEEK-OPTIMA Natural

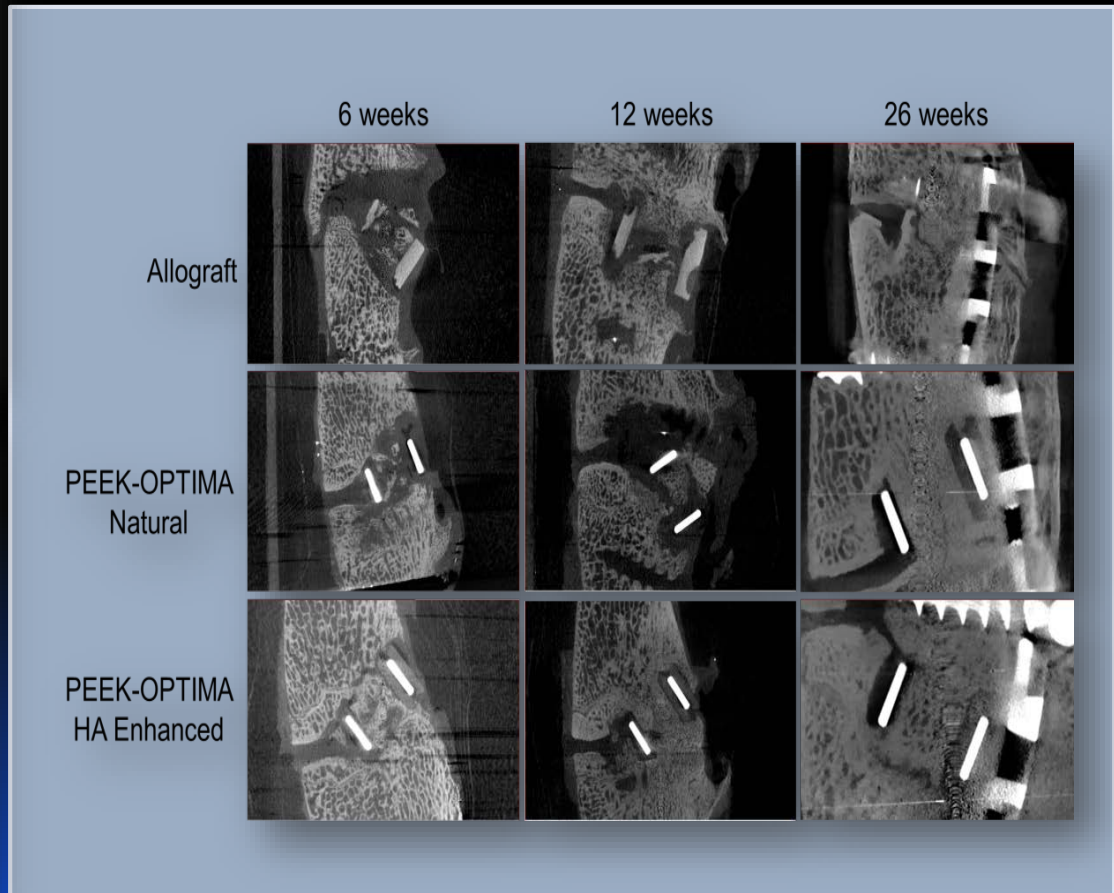
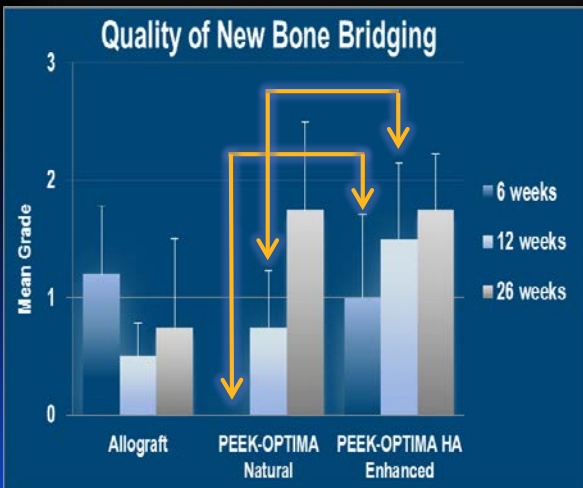
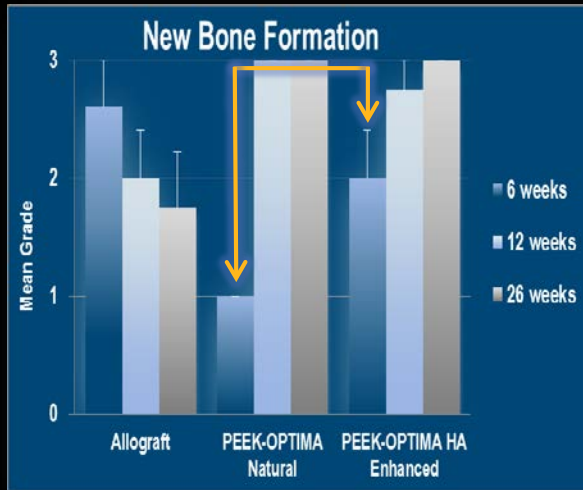


Implant in situ: 6mm x 25mm



**TRABECULAR BONE – DISTAL FEMUR,  
PROXIMAL TIBIA  
CORTICAL BONE – TIBIAL DIAPHYSIS**

# Pre-Clinical 1



# Pre-Clinical Study 2

- “PEEK implants achieve increased bone fusion when coated with nano-sized HA: A histomorphometric study in rabbit bone”

Int j Nanomedicine 11/2016

Johansson, et al

- Result: “Nano-sized HA coating on PEEK implants in rabbit femur significantly improved the bone-implant contact and demonstrated strong osteoconductive properties inside the implant”



# Pre-Clinical 2

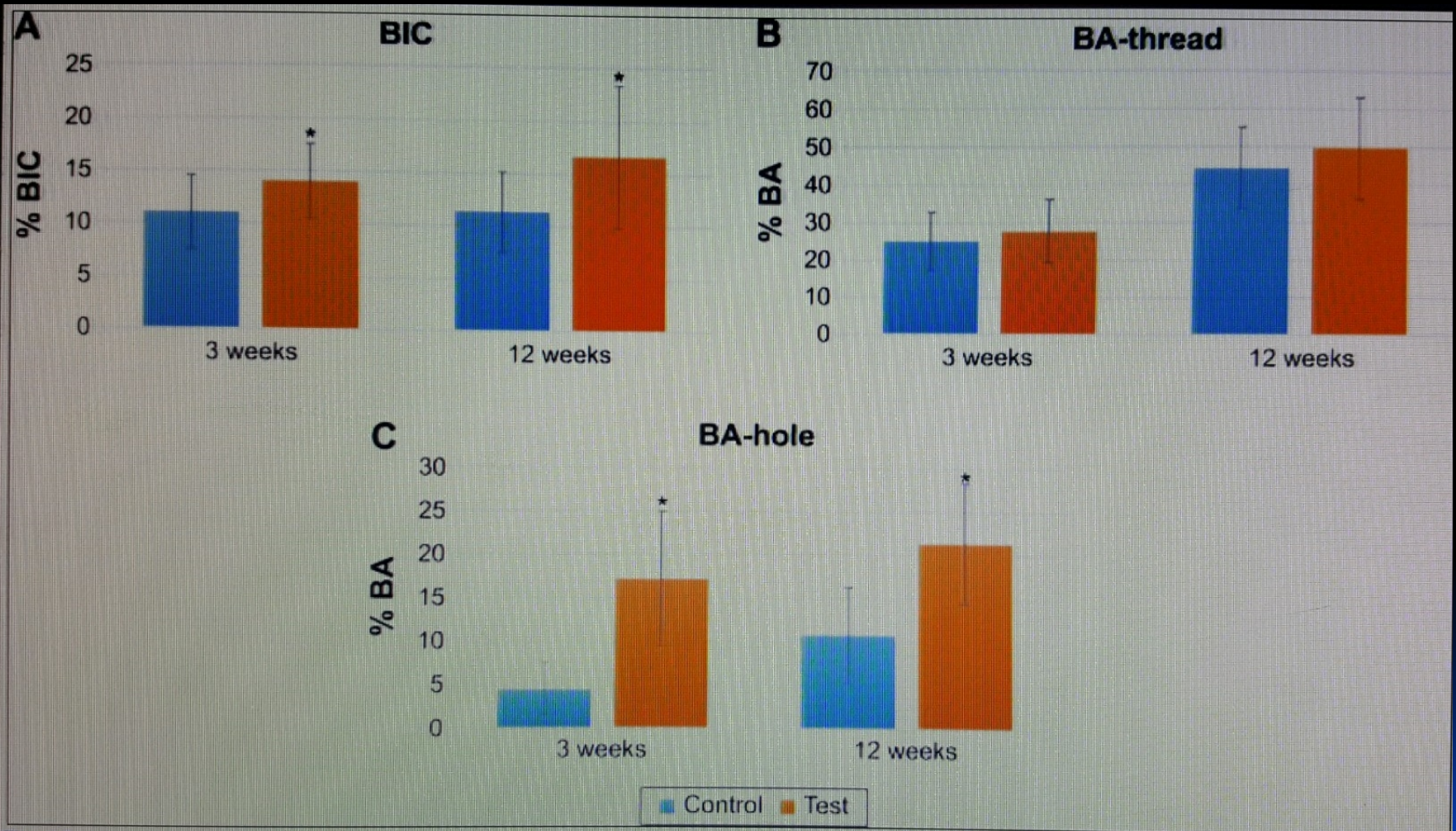


Figure 6

Graphs presenting the bone-implant contact (A), bone area (B), and bone area inside the perforating hole (C) at 3 weeks and 12 weeks of healing.

# Surgical Experience

- First PEEK-HA implants for spine surgery available in the US October 2015.
- First case series was nine patients done between Oct 2015 and Jan 2016.
- Later added eleven patients done Feb 2017 to March 2017
- Presented at NASS 2016, 2017

# Case Series Overview

- PEEK-HA TLIF cage with autograft iliac crest with either pedicle screw, facet screw, ISP fixation
  - No biologics used in this series
  - Post op no NSAIDS, caffeine, tobacco
- Evaluated clinical results
  - Pain VAS, opiate usage, neurologic recovery
  - Functional recovery, reoperations, complications
- Evaluated Fusion Results
  - AP, Lat X-rays at 6 weeks, 12 weeks
  - 6 month CT scan assessment
  - **Only patients who underwent the required 6 month post op CT scan were included**

# Rationale for Interbody Fusion

- 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 fixation,  
Facet screws

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

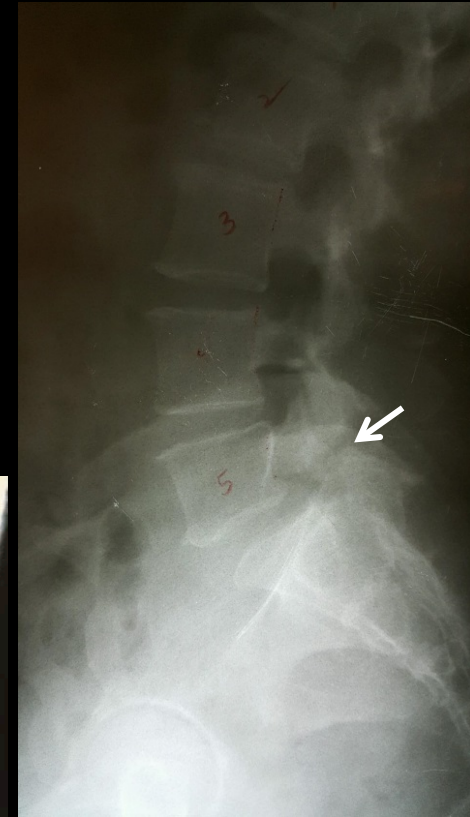
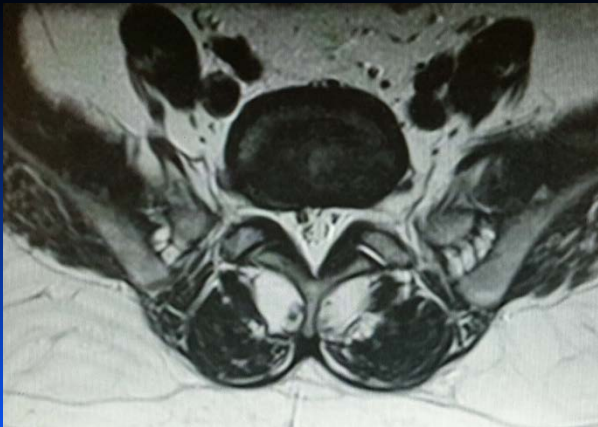
# Surgical Technique

- Most of these patients require decompression as their primary procedure.
- Disc clearance usually on the more symptomatic side, taking down across midline with reverse/angled/push down curettes
- Endplates retained
- Facets typically retained as much as possible lateral to medial pedicle line
- PEEK-HA TLIF style implant placed transversely and anteriorly, if possible, to maximize graft area
- Pedicle screws triangulated, deep, locked in compression



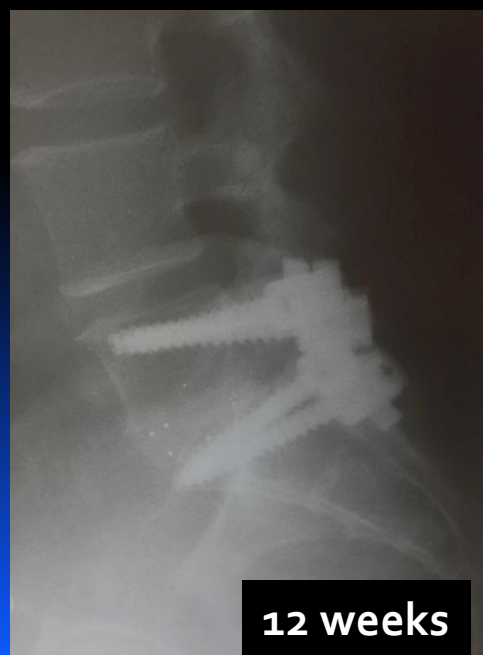
# TLIF Case 1

- 50 year old female, work comp, first patient
- 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

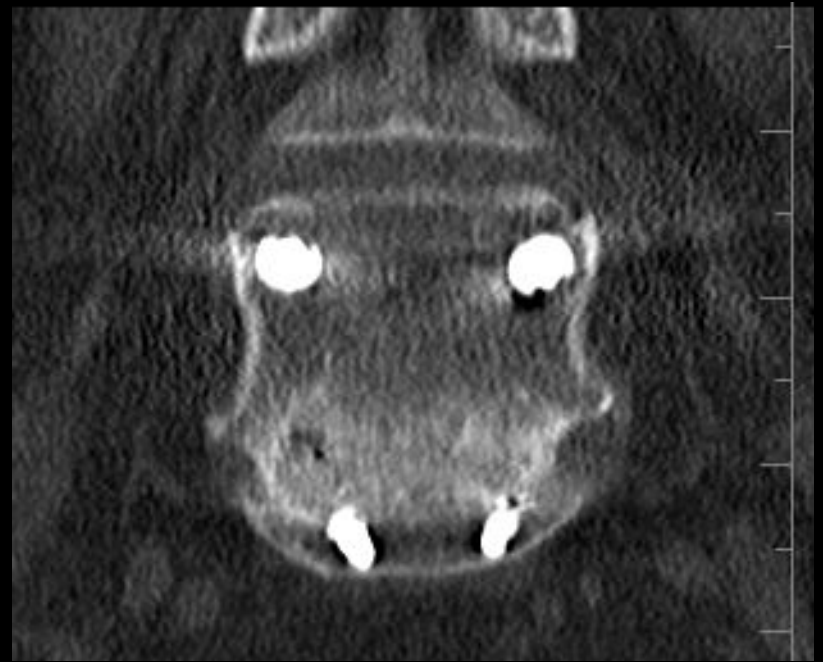
- L5-S1 Fusion, Gill lam
- EVOS PEEK HA cage + posterior instrumentation
- Autograft bone, no biologics





## Pt 1: Outcome

- Solid L5-S1 fusion at 6 months on CT scan
- No leg pain
- >50 % improved LBP
- Returned to work without job modifications



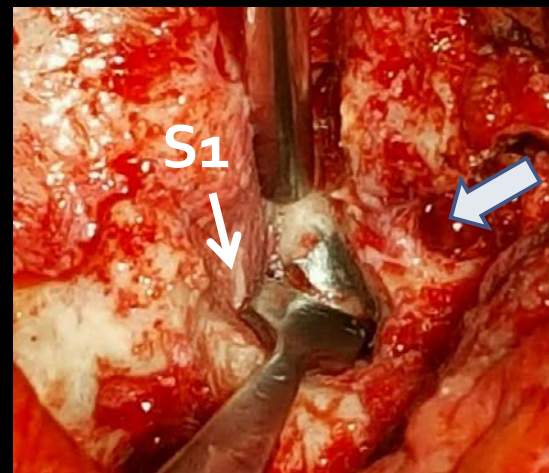
# TLIF Case 2

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



## Pt 2: Intervention

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



12 weeks



12 weeks



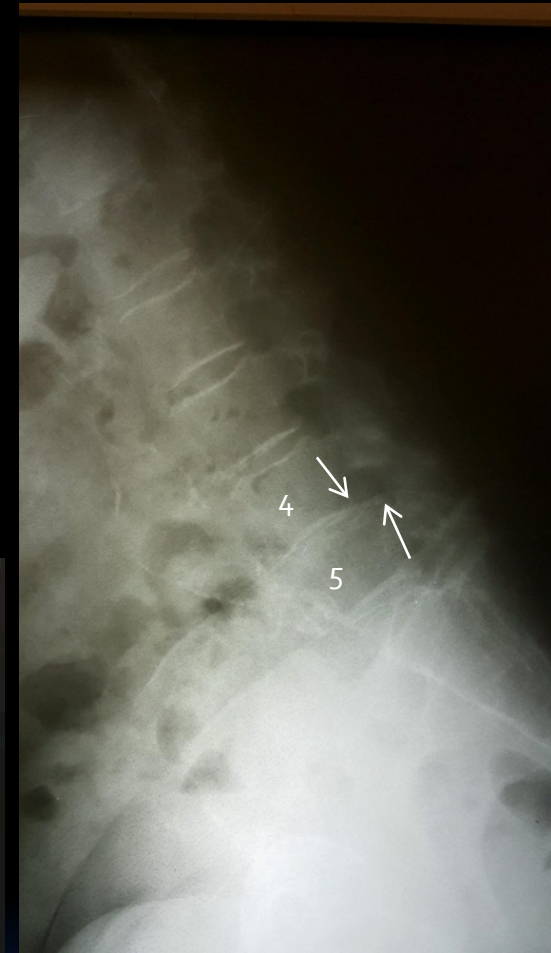
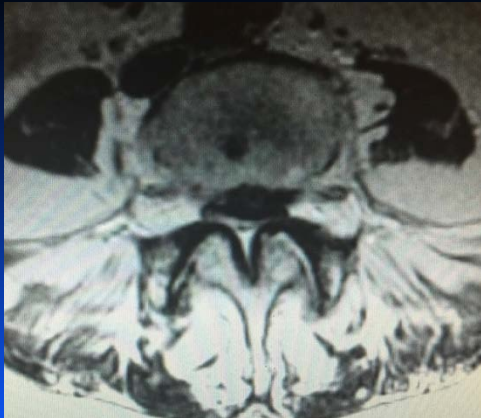
## Pt 2: Outcome

- Fusion solid at 132 days on CT scan
- Off all pain meds
- Slight leg discomfort
- Going to gym regularly
- Full bone apposition at implant



# TLIF Case 3

- 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 3: Intervention

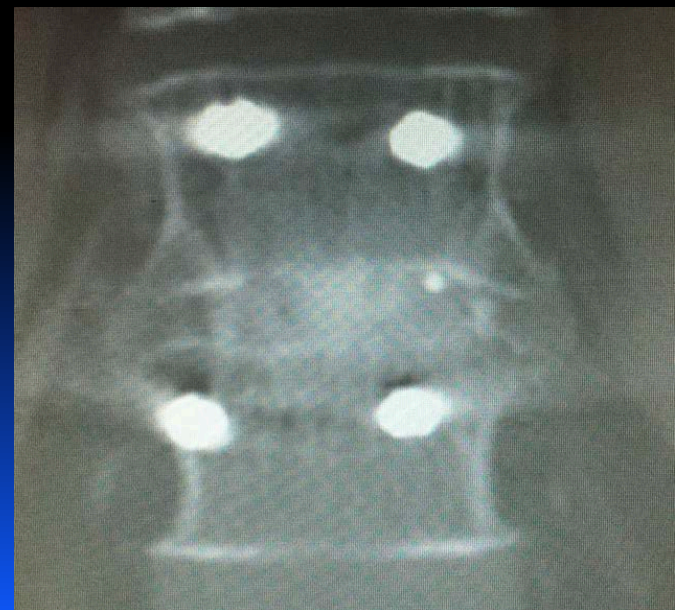
- L4-L5 decompression, reduction with fusion
- EVOS PEEK HA cage + pedicle screws
- Autograft bone, no biologics





## Pt 3: Outcome

- Fusion at 163 days on CT scan with bridging bone
- No leg pain
- Walking daily for exercise, works out in gym 5 days per week
- Dense apposition at implant



# ACDF Case 1

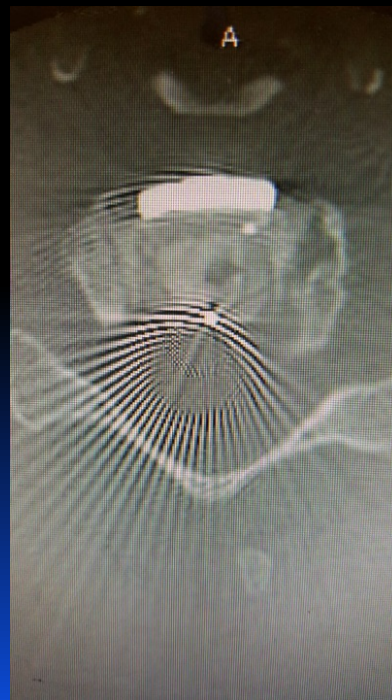
- 59 yo mechanic, ex smoker
- Neck pain, headaches, arm numbness
- VAS 4-10
- Daily Norco, Ambien





# ACDF Case 1

- 3 level PEEK-HA
- CT at 6 months
- Excellent pain relief



# ALIF Case 1

- 47 yo nurse. Chronic LBP
- L5/S1 discectomy 2010
- Nonsurgical management 2 years
- Discogram concordant at L5/S1
- VAS 3-8



# ALIF Case 1

- Stand alone PEEK-HA ALIF
- Early two month xray follow up
- 95 % pain reduction





# TLIF Clinical Series

- Patients treated with one and two level lumbar fusions between October 2015 and March 2017
- Purpose: To assess the 6 month post-op CT scan results in regards to the health of the interbody fusion using PEEK-HA TLIF implants
- All patients had TLIF implants with iliac crest bone graft. No biologic adjuvants and no other graft sources were used
- Twenty total patients with 23 total fusion levels.

# Demographics

## Clinical

- Male 5 Female 15
- Total patients = 20
- Tobacco 4 opiates 13 DM 1  
steroids 1
- Age distribution
  - Age 30-39 2
  - Age 40-49 5
  - Age 50-59 5
  - Age 60-69 6
  - Age 70-79 2
- Pre-op diagnosis
  - Spondylolysis 1
  - Degen S-listhesis 7
  - Failed Lam/HNP 5
  - Discogenic, DDD 3
  - Failed fusion 2
  - Adjacent Segment 2

## Surgical

- One level fusion 17 two level 3
- Total implant levels = 23
- Unilateral discectomy 15 bilateral 8
- Pedicle screws 14 ISP 3 Facet 3
- TLIF level distribution
  - L2/3 1
  - L3/4 4
  - L4/5 11
  - L5/S1 7
- Primary vs Revision
  - Primary operation 11
  - Rev lam/disc 7
  - Rev fusion (implant) 2

# Data Evaluation

## Clinical

- VAS Back pain % reduction
- VAS Leg pain % reduction
- Opiate Usage at 6 months



## CT Scan

- CT average = 189 days post-op (6 month, 6 days)
- Volume of nucleus filled
- Gap size between implant/endplate
- Gap size between implant/bone graft
- Subsidence of implant





# Clinical Results

- Lumbar pain VAS % reduction (n=20)

100 %	15
75 %	1
50 %	4
25 %	0

- Leg pain VAS % reduction (n=16)

100 %	15
75 %	0
50 %	1
25 %	0

- Opiate Usage

Pre-op	13
6 month	1

- Complications: 1 graft site, 1 lumbar incision wound dehiscence treated dressing changes only

# CT Scan Results

- Nucleus volume filling (n=23)

100 %	18
75 %	3
50 %	2
25 %	0
- Implant/endplate gap (n=23)

<0.5 mm	18
0.5-2 mm	5
>2mm	0
- Implant/graft gap (n=23)

<0.5mm	19
0.5-2mm	4
>2mm	0
- Subsidence (n=23) 1



14/23

# CT Scan Results

- Complete fusion (n=17)

- < 0.5 mm gaps, full disc space volume, no subsidence

Unilateral (n=15)	12
Bilateral (n=8)	5

Primary op(n=14)	11
Rev lam/disc (n=7)	4
Rev fusion (n=2)	2

- Incomplete fusion (n=6)

- At least one parameter present

Unilateral (n=15)	3
Bilateral (n=8)	3

Primary op (n=14)	3
Rev lam/disc (n=7)	3
Rev fusion (n=2)	0

# Conclusion

- From the basic science, pre-clinical animal studies, and from my own surgical experience, it would appear that the addition of HA to PEEK interbody implants improves the early stability of the implants, possibly enhancing an earlier and more robust fusion
- In the series presented on TLIF PEEK HA implants, 15 of the 20 patients having complete back pain relief. Leg pain relief occurred completely in 15 of 16 preoperatively symptomatic patients.
- Absolute fusion at 6 months average was confirmed on CT scan in 17 of, meeting all parameters.
- 14 of 23 levels showed robust dense bone formation at the immediate margins of the implant.
- Since October 2015, 95 TLIF patients with 124 levels  
26 ACDF patients with 45 levels  
3 single level ALIF stand alone.
- One revision. Zero planned revisions

President Donald Trump Rally in Phoenix, Arizona 8/22/17 Trump Phoenix Arizona Speech

