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American Academy of Orthopaedic Surgeons

Innovations in interbody materials

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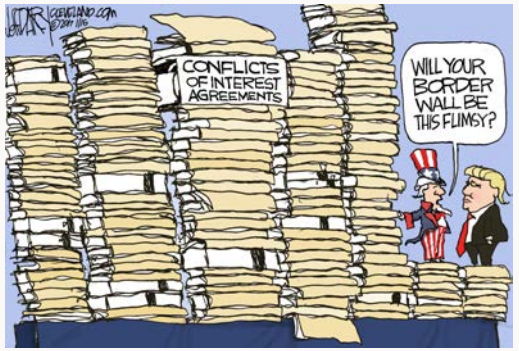
INNOVASIS
INNOVATE / INVOLVE / INVENT

Disclosures

- I believe in the utility of the full armamentarium of spine surgery
- Research support: DoD, Neilsen, Raisbeck foundation
- J&J teaching and consulting
- Globus teaching and consulting
- Joimax teaching and consulting
- Innovasis consulting



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PEEK

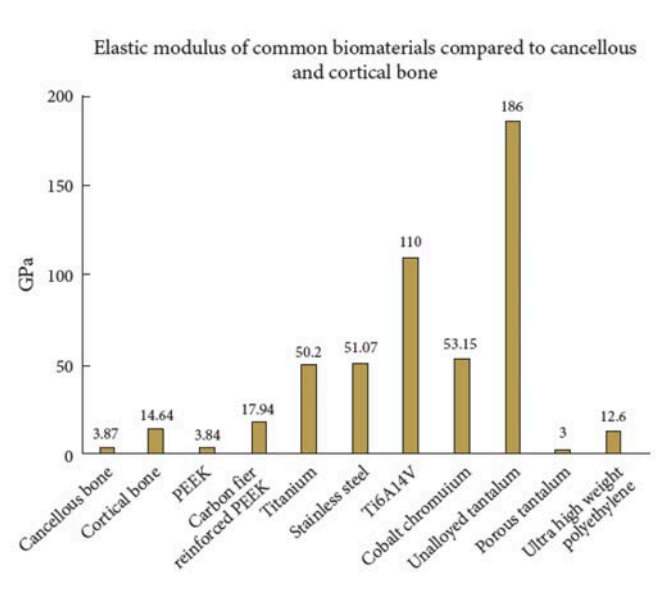
Polyether ether ketone (**PEEK**) is a colorless organic thermoplastic polymer in the polyaryletherketone family

Features

- Biocompatibility
- Young modulus comparable to bone
- Radiolucent
- Ease of manufacturing

Limitations

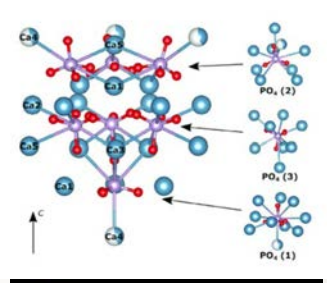
- Hydrophobic: lack of bone bonding ability



Long et al. 1998

Hydroxyapatite (HA)

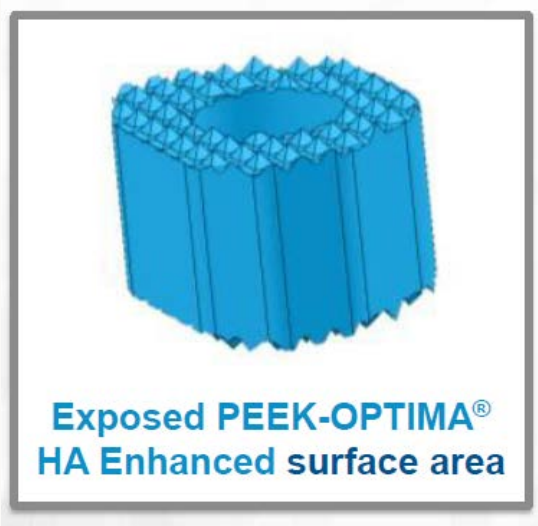
- Hydroxyapatite is a naturally occuring mineral form of calcium apatite $Ca_{10}(PO_4)_6(OH)_{2)}$
- Hydroxyl group of Hydroxyapatite can be replaced by fluride (fuoroapatite) or choride (chloroapatite)
- Main inorganic component of bone
- Bone: 70% HA, 25% organic, 5% water



Apatite is often mistaken for other minerals hence its name, (απατείν (apatein), which means *to deceive* or *to be misleading)*

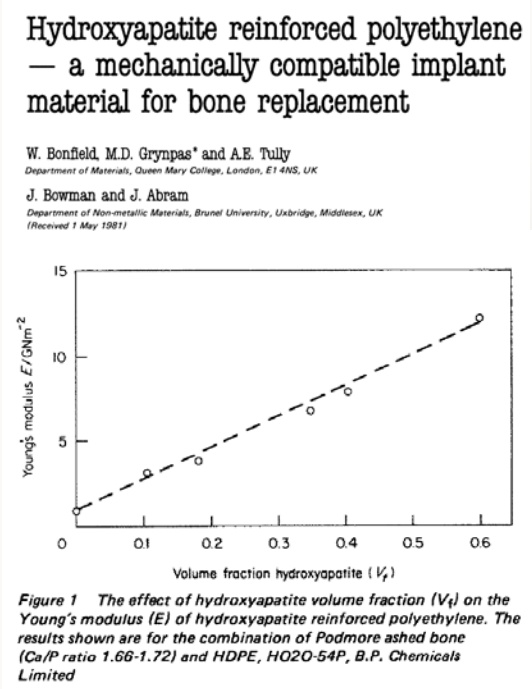
HA PEEK

- Composite material of 80% PEEK, 20% Hydroxyapatite integration
- Structural and mechanical properties of PEEK combined with osteoconductive properties of HA
- HA evenly distributed throughout PEEK
- No coatings or laminate



HA PEEK

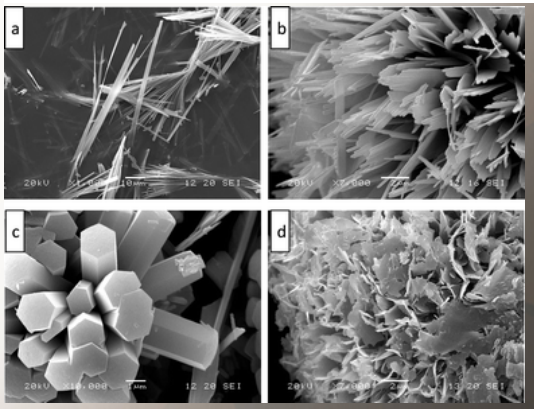
- HA mixed with polyethylene to create “artificial bone” void filler. With a Young’s modulus similar to bone (Bonfield et al. 1981)
- 20 –40% fractional volume HA showed increased bone on growth in rabbit models vs. inert polyethylene
- Osteoconductive biomaterial used to enhance bone apposition



Hydroxyapatite reinforced polyethylene — a mechanically compatible implant material for bone replacement

W. Bonfield, M.D. Grynpas* and A.E. Tully
Department of Materials, Queen Mary College, London, E1 4NS, UK
J. Bowman and J. Abram
Department of Non-metallic Materials, Brunel University, Uxbridge, Middlesex, UK
(Received 1 May 1981)

Figure 1 The effect of hydroxyapatite volume fraction (V_f) on the Young's modulus (E) of hydroxyapatite reinforced polyethylene. The results shown are for the combination of Podmore ashed bone (Ca/P ratio 1.66-1.72) and HDPE, HO2O-54P, B.P. Chemicals Limited



HA PEEK material properties

Property	Impact (Notched) (KJ/m²)	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

HA PEEK: Imaging properties

AXIAL VIEWPOINT OF DIFFERENT MATERIALS

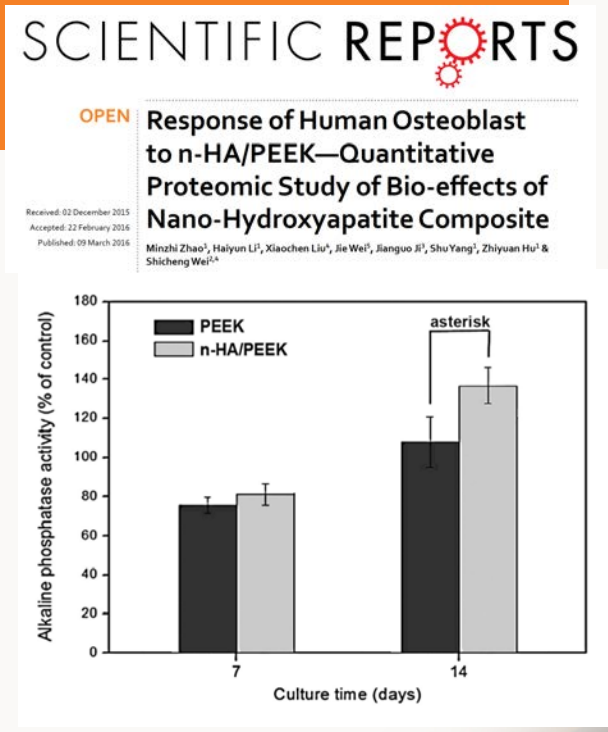
PRODUCT	FLUOROSCOPIC IMAGING	MRI: Magnetic resonance imaging	CT: Computer Tomography Imaging
METAL			
Titanium (Ti)			
316L Stainless steel (316L)			
Cobalt chromium steel (CoCr)			
Porous tantalum (Ta) hemi cylinder 1			
POLYMER			
Poly ether ether ketone (PEEK)			
Ultra high molecular weight polyethylene (UHMWPE)			
CERAMIC			
Silicon nitride (SiN)			
Alumina (Al)			
Zirconia toughened alumina (ZTA)			
Zirconia (Zr)			

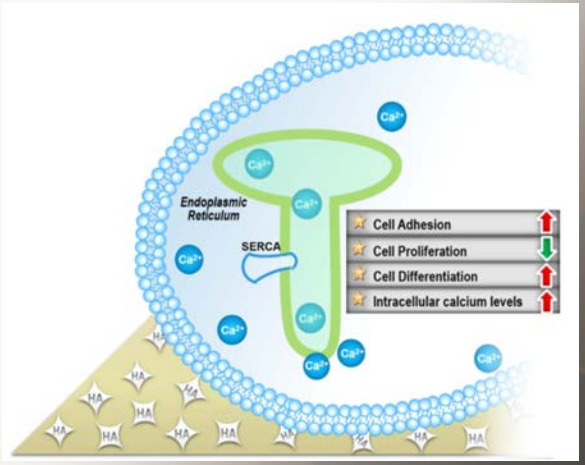
Innovasis Ax™ Stand Alone ALIF
6 month post operative

HA PEEK – material properties

In Vitro study of human osteoblast-like cells co-cultured either with PEEK or HA Peek

- No cell toxicity of nano-sized HA particles
- Osteoconductive surface allows bone ongrowth
- Promotes up-regulation of proteins related to calcium ion processes and cell adhesion in vitro
- Increase alkaline phosphate activity indicating increased osteoblast differentiation (Zhao et al. 2015)

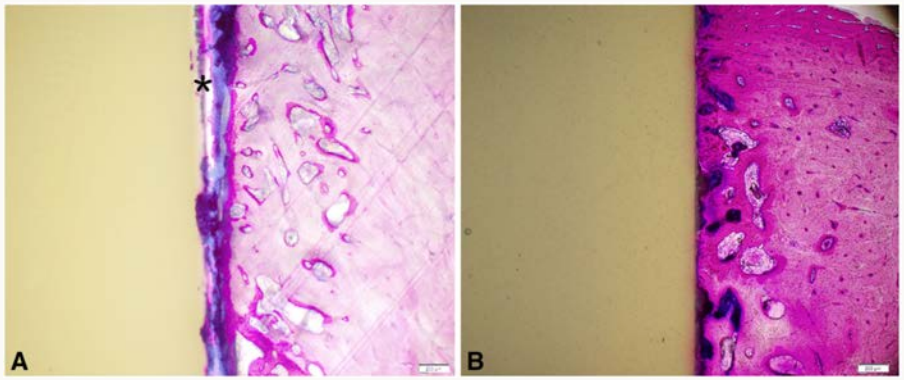




HA PEEK: Pre-clinical outcomes

PEEK-OPTIMA HA Enhanced has demonstrated performance advantages in a pre-clinical cervical spine fusion model in sheep at 6 and 12 weeks:

- More direct bone apposition
- Greater new bone formation at 6 weeks
- Higher quality new bone bridging at 6 and 12 weeks
- Bone ongrowth on the endplates and all faces of the interbody device (Wash et al. 2016)

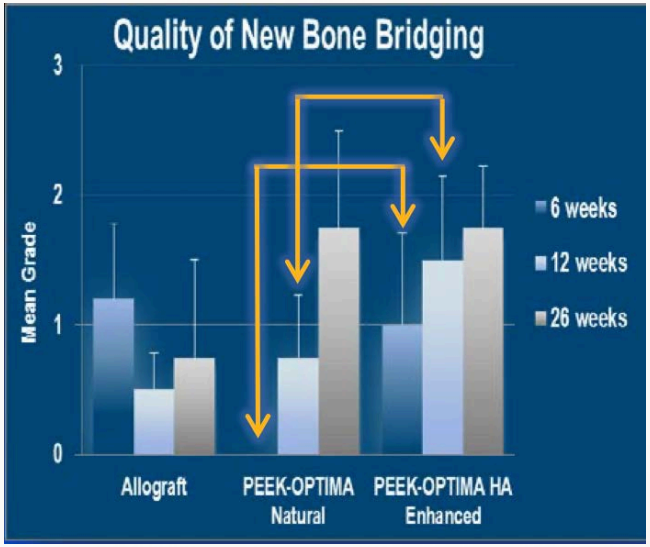


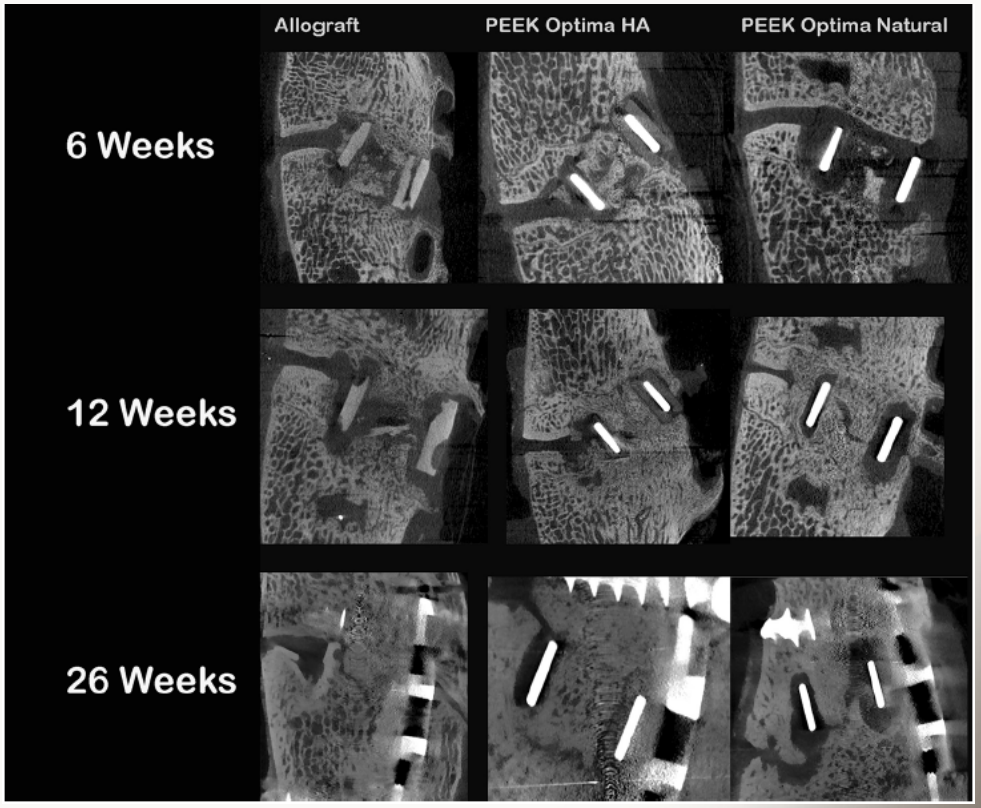
PEEK HA-PEEK

Walsh et al. 2016

HA PEEK: Pre-clinical outcomes

- Micro-CT showed direct bone contact at implant interface with HA PEEK
- More mature fusion histology with HA PEEK compared to PEEK or allograft implant.

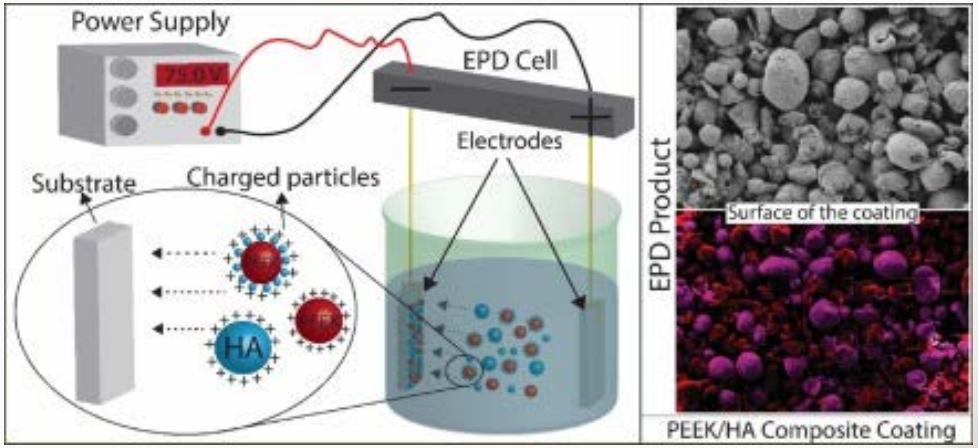




Walsh et al. 2016

HA PEEK: Possible future opportunities

- HA PEEK may be applied as composite coating



- Porous HA PEEK to enhance osteointegration

Table 1 — Elastic modulus and ultimate tensile strength

The elastic modulus (*E*) and ultimate tensile strength (*UTS*) of dense HA whisker reinforced PEEK composites was similar to that of human cortical bone tissue in the longitudinal anatomic direction, and the apparent compressive elastic modulus (*E*) and yield strength (*YS*) of porous HA whisker reinforced PEKK scaffolds was similar to that of human vertebral trabecular bone.

Uniaxial Tension	**Porosity (%)**	**Apatite Content (vol%)**	***E* (GPa)**	***UTS* (MPa)**
Dense HA whisker reinforced PEEK [9]	~0	0-40	4-19	25-118
Human cortical bone [11,12]	~5-10	~40	16-23	80-150
Uniaxial Compression	**Porosity (%)**	**Apatite Content (vol%)**	***E* (MPa)**	***YS* (MPa)**
Porous HA whisker reinforced PEKK [10]	75-90	0-40	1-190	0.002-2.7
Human vertebral trabecular bone [13,14]	~80-95	~40	20-500	0.5-4

Porous and Bioactive PEEK Implants for Interbody Spinal Fusion

Porous and bioactive PEEK interbody spinal fusion devices have been designed and manufactured to address a clinical need for enhanced osteointegration with the fusion mass.

Ryan K. Roeder, Ph.D.
University of Notre Dame

Stephen M. Smith, M.D.
North Central Neurosurgery

Timothy L. Conrad, Nathaniel J. Yanchak, Christina H. Merrill, and Gabriel L. Converse, Ph.D.
University of Notre Dame

Fig. 2 — Examples of commercially available cervical (left) and lumbar (right) PEEK interbody spinal fusion cages manufactured by Medtronic Sofamor Danek.

at least 5,000 interbody spinal fusion cages implanted each month in the U.S. alone [Ref. 2]. The total U.S. market for spinal fusion implants was valued at nearly $4 billion in 2008 [Ref. 3]. Interbody spinal fusion is used

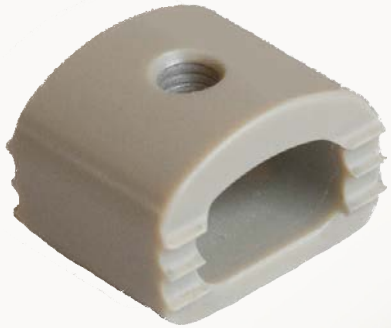
HA PEEK: Innovasis current Product Portfolio

PxHA
PLIF IBF System

TxHA
TLIF IBF System

Ax
Stand Alone ALIF

CxHA
Cervical IBF System



Innovative Interbody Technologies

Burden of Proof:

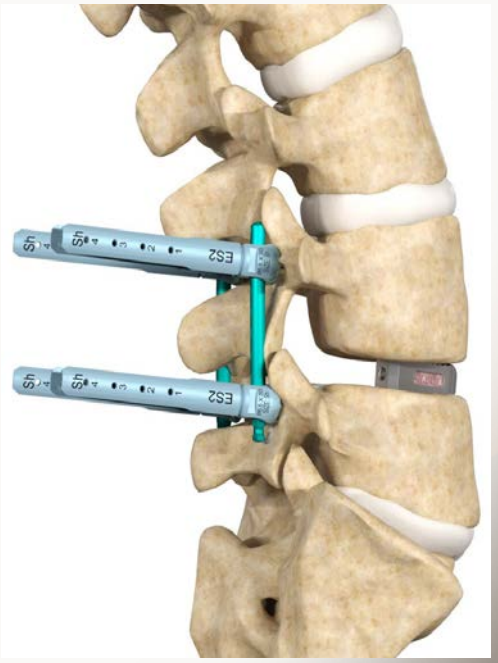
1) Improve Fusion Rates

2) Reduce Cage Subsidence

3) Reduce Cage Migration

4) Reduce Reoperations

5) Improve Clinical Outcomes



Conclusions

HA PEEK constitutes a favorable interbody material for spinal fusion procedures

- Facilitates bone ongrowth
- Images well across all modalities
- Has a modulus similar to bone
- Cost effective

Clinical cases

HA PEEK Clinical Case Series

48 year old female presented with a 3 year history of loss of upper extremity dexterity and progressive gait unsteadiness.

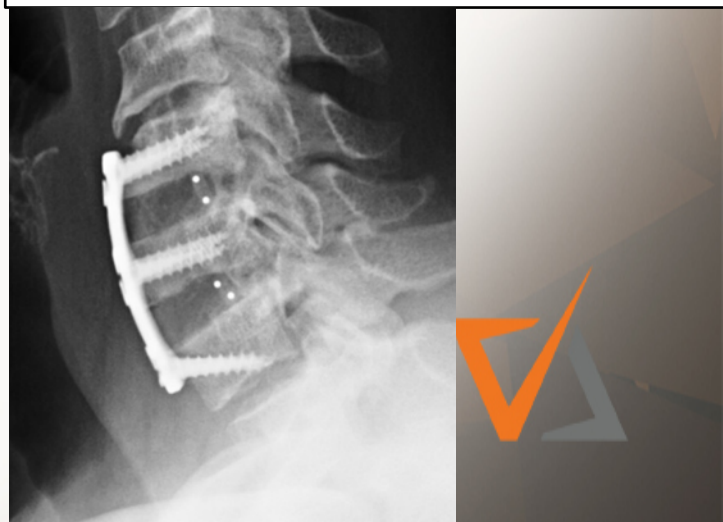
Neuro exam: left deltoid 3/5, hand intrinsic muscles 4/5, unsteady gait

Procedure: C5/6 and C6/7 ACDF with HA-PEEK cages with DBX and anterior plate

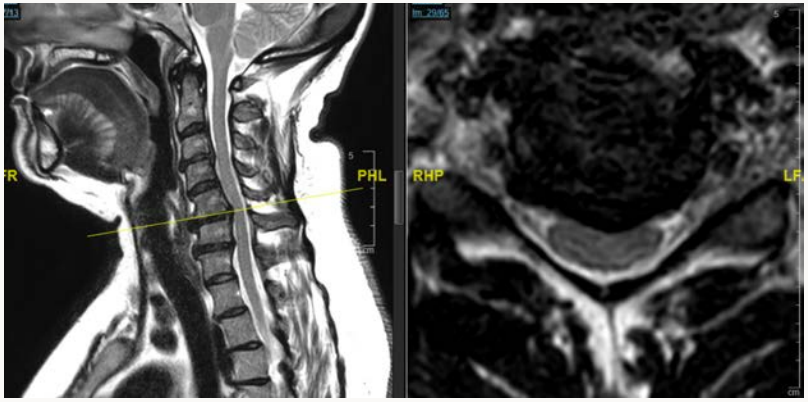
3 month follow up: left deltoid 4/5, hand intrinsic muscles 4+/5

Pre-operative

3 moth f/u



HA PEEK Clinical Case Series



51 year old female presented with loss of upper extremity dexterity and progressive gait unsteadiness.

Neuro exam: left hand intrinsic muscles 4/5, left positive Babinski, unsteady gait

Procedure: C5/6 and C6/7 ACDF with HA-PEEK cages with DBX and anterior plate

One year follow up

Pre-operative

1.	Neck Pain	(None)	0	1	2	3	4	5	6	(7)	8	9	10 (Unbearable)
2.	Left Shoulder Pain	(None)	0	1	2	3	4	5	6	7	8	(9)	10 (Unbearable)
3.	Right Shoulder Pain	(None)	0	1	2	3	4	5	6	(7)	8	9	10 (Unbearable)
4.	Left Arm Pain	(None)	0	1	2	3	4	5	6	7	8	9	10 (Unbearable)
5.	Right Arm Pain	(None)	0	1	2	3	4	5	6	7	8	9	10 (Unbearable)
6.	Back Pain	(None)	0	1	2	3	(4)	5	6	7	8	9	10 (Unbearable)
7.	Left Hip/Buttock Pain	(None)	0	1	2	3	4	5	(6)	7	8	9	10 (Unbearable)
8.	Right Hip/Buttock Pain	(None)	0	1	2	3	4	5	(6)	7	8	9	10 (Unbearable)
9.	Left Leg Pain	(None)	0	1	2	3	4	5	6	7	8	9	10 (Unbearable)
10.	Right Leg Pain	(None)	0	1	2	3	4	5	6	7	8	9	10 (Unbearable)

1 year f/u

1.	Neck Pain	(None)	0	1	(2)	3	4	5	6	7	8	9	10 (Unbearable)
2.	Left Shoulder Pain	(None)	0	1	2	(3)	4	5	6	7	8	9	10 (Unbearable)
3.	Right Shoulder Pain	(None)	0	1	2	(3)	4	5	6	7	8	9	10 (Unbearable)
4.	Left Arm Pain	(None)	0	1	2	3	4	5	6	7	8	9	10 (Unbearable)
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9.	Left Leg Pain	(None)	0	1	2	3	4	5	6	7	8	9	10 (Unbearable)
10.	Right Leg Pain	(None)	0	1	2	3	4	5	6	7	8	9	10 (Unbearable)

HA PEEK Clinical Case Series

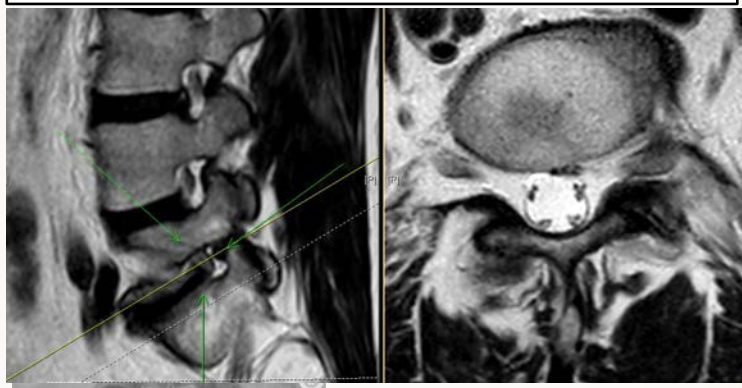
58 year old female presented with a 1 year history of left lower extremity radicular pain in an L5 distribution.

Neuro exam: neurologically intact

Procedure: L5/S1 ALIF with HA-PEEK cage

12 month follow up: patient is asymptomatic

Pre-operative



12 moth f/u