CASE SERIES: PEEK-OPTIMA™ HA Enhanced Polymer Shows Early Clinical Success in Interbody Spinal Fusions

North American Spine Society (NASS) Annual Meeting Presentation of Findings, October 2016

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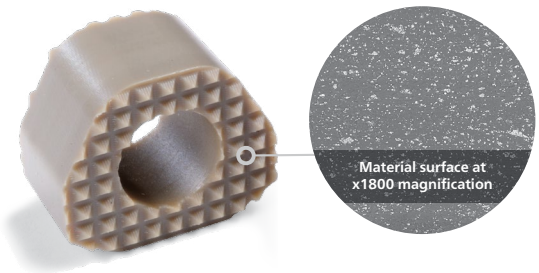
After years of research, development and pre-clinical studies by Invibio, early clinical results have shown PEEK-OPTIMA HA Enhanced Polymer may optimize bony ongrowth, osteointegration and fusion in interbody spinal fusions. The polymer, which was introduced to the market in 2013, combines PEEK-OPTIMA Natural with hydroxyapatite (HA), a well-known osteoconductive material with a bone-like chemical and crystalline structure that promotes bone remodeling and fusion.

One of the unique aspects of PEEK-OPTIMA HA Enhanced is that it addresses the entire interbody environment. Unlike roughened-metal or coated-metal technologies, HA crystals in PEEK-OPTIMA HA Enhanced are fully integrated, not coated, into the PEEK-OPTIMA matrix, making it available on all surfaces of a finished device. Consequently, both inter-cage and outer-cage graft material are exposed to hydroxyapatite, resulting in enhanced osteoconductivity.



Interbody Fusion Device examples. These products are not cleared for distribution and implantation.

HA crystals in PEEK-OPTIMA HA Enhanced are fully integrated, not coated, making it available on all surfaces of a finished device.

PEEK-OPTIMA HA Enhanced maintains the properties that have made PEEK-OPTIMA Natural, one of the leading interbody fusion biomaterials over the last 15 years; a modulus similar to cortical bone, reduced stress shielding, artifact-free imaging, biocompatibility and processing adaptability. In contrast, titanium can stress shield the bone graft, creating stress concentrations between implants and endplates, resulting in subsidence.

Pre-clinical studies with PEEK-OPTIMA HA Enhanced have indicated greater osteointegrative benefits compared to PEEK-OPTIMA Natural including:

- Enhanced bone apposition, with > 75% direct bone contact after 4 weeks[1]
- Greater new bone formation at 6 weeks[2]
- Higher quality bone bridging at 6 and 12 weeks[2]

Our early clinical experiences using PEEK-OPTIMA HA Enhanced Interbody Fusion Devices for lumbar and cervical fusion demonstrates similar, positive clinical outcomes. Several cases exhibiting these successes, as presented at the 2016 North American Spine Society (NASS) Annual Meeting, are highlighted on the following pages.

Early Clinical Experience - Lumbar Fusions, Timothy Bassett, MD

9-Patient Case Series

Patients in my series included males and females aged 39-76 with varying levels of health, pre-existing diseases or conditions and previous surgeries. Patients also had various combinations of leg pain, cramping and weakness, and back pain necessitating lumbar fusion.

To track and compare clinical results, I took anteroposterior and lateral x-rays at six- and twelve-weeks post-op and CT scans at six-months post-op.

All nine patients underwent a one- or two-level lumbar fusion utilizing the same EVOS-HA Interbody Device from Cutting Edge Spine, cage setup and pure iliac crest bone graft. All devices were made with PEEK-OPTIMA HA Enhanced Polymer by Invibio Biomaterial Solutions. No biologics were used. Post-op anti-inflammatory, caffeine and tobacco* usage was restricted for at least three months. Two patients had Orthofix bone stimulators.

*Patient 2 continued smoking throughout and after treatment

Radiographic Fusion Results

Six-month, post-op CT showed solid fusion for eight** of nine patients; One-year radiographs showed solid fusion in all nine patients.

**Solid fusion at one year in-patient with history of heart problems and smoking

Neurologic Function Results

- No neurologic sequelae

Clinical Results

- More than 50% back pain reduction
- Nearly all leg pain resolved
- No instrumentation failures
- No reoperations

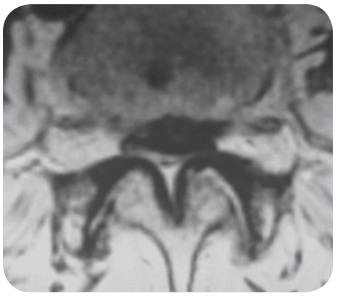
I have selected two cases to illustrate typical clinical and radiographic results from this 9-patient series.

Lumbar Fusion Case Study – Patient 7

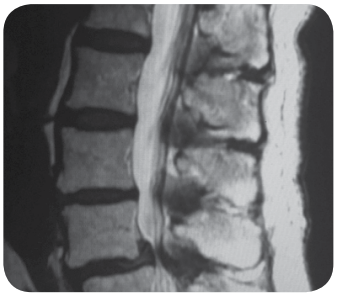
Patient Symptoms and Diagnosis

A 76-year-old female, presented with leg, bilateral hip and posterior thigh pain, and neurogenic claudication with less than 100-yard mobility was diagnosed with severe lumbar stenosis with subluxation.

Pre-operative Images



Axial MRI view showing high grade stenosis at L4-5



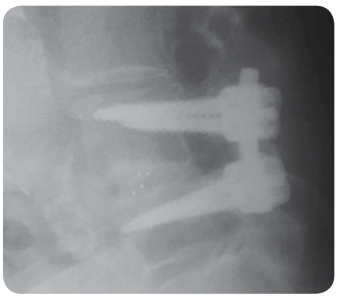
Sagittal MRI view showing L4-5 spondylolisthesis (10mm)

Surgical Procedure Performed

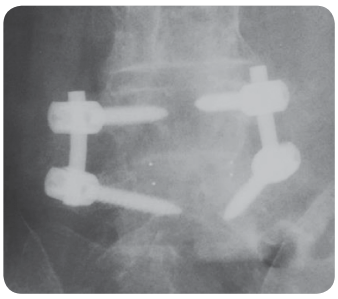
I performed a biologic-free, standard interbody L4-L5 decompression, reduction with fusion utilizing EVOS-HA Interbody Device by Cutting Edge Spine with iliac crest graft and pedicle screw. The device was made with PEEK-OPTIMA HA Enhanced Polymer from Invibio Biomaterial Solutions.

Radiographic Results

Early Follow Up Results

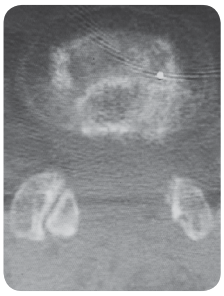


12-week sagittal view radiograph of EVOS-HA cage and pedicle screws

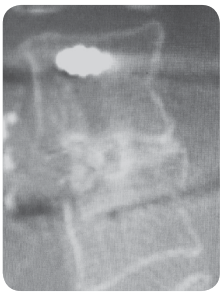


12-week coronal view radiograph of EVOS HA cage and pedicle screws

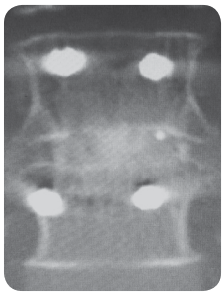
Six-Month Results



6-month axial CT scan showing dense bone apposition around the EVOS HA cage



6-month sagittal CT scan showing dense bone apposition around the cage



6-month coronal CT scan showing solid bone bridging and areas of dense bone

Clinical Results

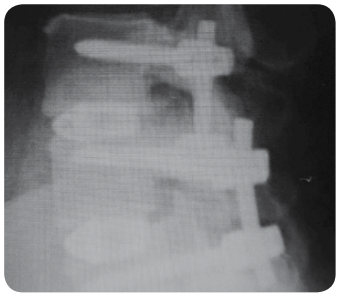
The patient reported no further leg pain and resumed full pre-surgical activity, including daily walks and a 5-day per week workout regimen.

Lumbar Fusion Case Study – Patient 9

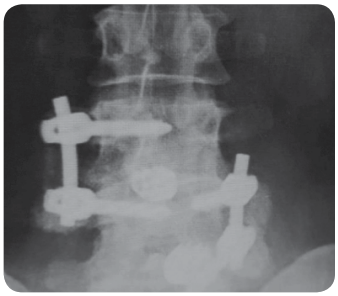
Patient Symptoms and Diagnosis

A female who had two previous, two-level MIS procedures with pedicle screw constructs, titanium cages, infuse bone morphogenetic (BMP) and dbx putty. Both failed. She presented with severe left side back and L3 leg pain, and secondary numbness from BMP foramenal bone overgrowth and non-union.

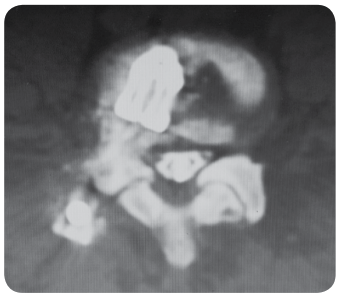
Pre-operative Images



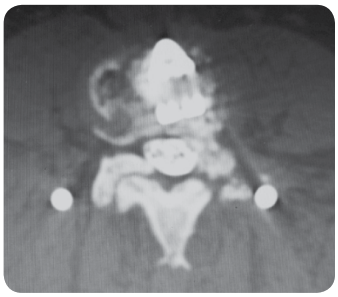
Sagittal radiograph of failed titanium cages



Coronal radiograph of failed titanium cages



Axial CT scan showing foramenal overgrowth from BMP, L3-4



Axial CT scan showing foramenal overgrowth from BMP, L4-5

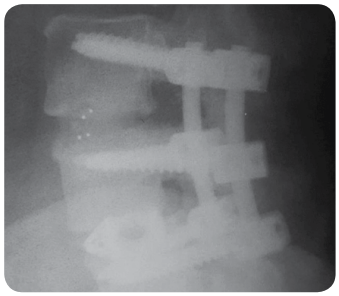
Surgical Procedure Performed

In this case, I performed a wide foramenectomy to remove the extra bone growth and explanted the titanium cage at L3-L4 on the symptomatic side. Fusion was performed at L3-L4 and L4-L5 utilizing EVOS-HA Interbody Device from Cutting Edge Spine with iliac crest graft. The device was made with PEEK-OPTIMA HA Enhanced Polymer from Invibio. Due to explant difficulties and to prevent future nerve pain, I only partially removed the asymptomatic side cage and regrafted using iliac crest craft around the L4-L5 space.

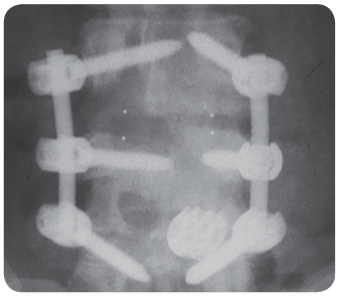
Radiographic Results

Post-op radiographic imagery shows solid L3-L4 fusion and bone growth with good bone abutment and dense bone-cage apposition. Although L4-L5 was progressing, some gaps remained (coronal recon).

Early Follow Up Results

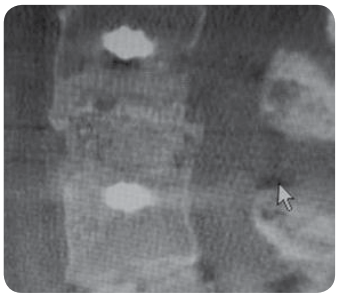


12-week sagittal radiograph with EVOS HA at L3-4 and Titanium cage at L4-5

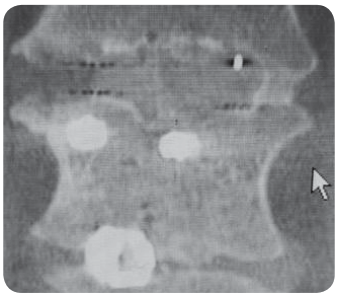


12-week coronal radiograph with EVOS HA at L3-4 and Titanium cage at L4-5

Six-Month Results



6-month sagittal CT scan showing bone bridging and fusion with EVOS HA cage



6-month coronal CT scan showing dense bone apposition around EVOS HA cage and delayed union with titanium cage

Clinical Results

The patient reported no further leg pain and the case was deemed successful.

Conclusion

PEEK-OPTIMA HA Enhanced Polymer shows exciting potential for use in spinal lumbar fusions. In all nine cases, the PEEK-OPTIMA HA Enhanced Interbody Fusion Device exhibited rapid bone fusion in the interbody region and very dense bone growth around the implant as early as six weeks, typically unseen with pure PEEK. With PEEK-OPTIMA HA Enhanced Polymer I can conduct standard format procedures on challenging cases with greater certainty that rapid fusion without instrumentation failure will result. Even at 18-month follow up, no subsidence has occurred. As a result of HA's quick bond, patients are less likely to require anterior posterior reconstructions and can return to everyday function and exercise regimes sooner and with greater confidence.

Early Clinical Experience - Cervical Fusions, Brad Prybis, MD

8-Patient Case Series

In my eight-patient cervical spine case series, I tested whether PEEK-OPTIMA HA Enhanced provides better bony ongrowth and fusion. I observed pain and neurologic function, and took anteroposterior, lateral and flexion extension radiographs at six-months post-op.

Patients included males and females aged 43-66 with chronic neck, arm, hand and finger pain, numbness and weakness. Some patients also reported loss of control, coordination and balance in the affected areas. Diagnoses included various levels and combinations of cervical radiculopathy, cervical myelopathy, myeloradiculopathy, central stenosis with spinal cord impingement, foramenal stenosis and chronic pain.

All eight patients underwent a two-level Anterior Cervical Discectomy and Fusion (ACDF) with devices made with PEEK-OPTIMA HA Enhanced polymer.

I utilized the standard ACDF left-sided discectomy and decompression approach, and removed the posterior longitudinal ligament. Utilizing a high-speed burr to maintain good bone-cage contact and some endplate bleed, I prepared the endplates for a PEEK-OPTIMA HA Enhanced spacer. I then filled the spacer with both local vertebra autograft, including bone marrow aspirate, and Vitoss BA synthetic bone graft. Last, I placed the anterior plate to secure the levels.

Radiographic Fusion Results

Six-month, post-op follow up showed solid fusion at 17 of the 17 levels.

Neurologic Function Results

- Improved neurologic function in all 8 patients
- Residual numbness in 3 of 8 patients
- Residual weakness in 1 of 8 patients

Clinical Results

- Arm pain resolved in all 8 patients
- Neck pain resolved in 5 of 8 patients
- Neck pain improved in 7 of 8 patients
- Neck pain unresolved in 1 patient

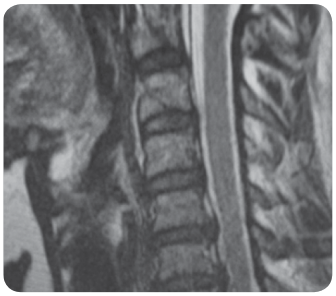
I have selected two cases to illustrate the typical clinical and radiographic results with PEEK-OPTIMA HA Enhanced Devices.

Cervical Fusion Case Study – Patient 1

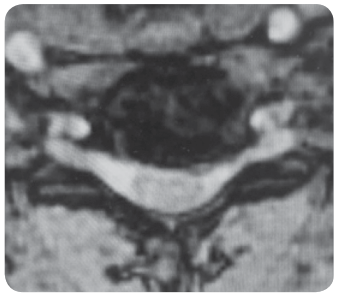
Patient Symptoms and Diagnosis

A 49-year-old female school teacher, presented with mostly left arm pain and numbness, loss of hand sensation and left thumb weakness. She was diagnosed with cervical radiculopathy.

Pre-operative Images



Sagittal MRI showing osteophyte and disc caused stenosis



Axial MRI showing foramenal stenosis and nerve root encroachment

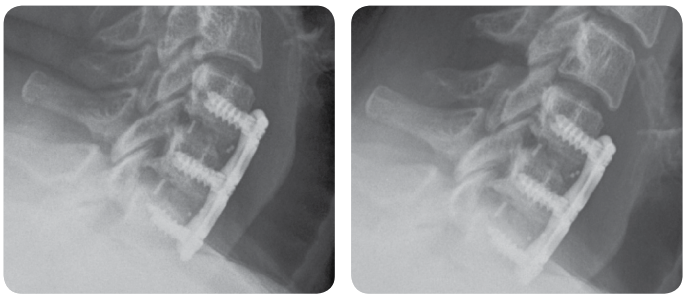
Surgical Procedure Performed

I performed an anterior cervical discectomy and fusion at C5-C7 utilizing a PEEK-OPTIMA HA Enhanced Interbody Fusion Device.

Radiographic Results

Post-op radiographic imagery shows solid, 2-level fusion at 6 months.

Six-Month Results



6-month Flexion Extension radiographs demonstrating solid fusion

Clinical Results

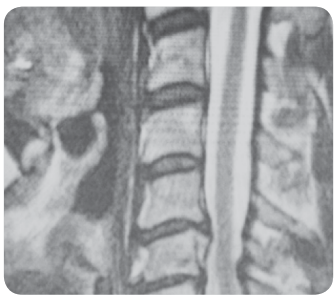
The patient resumed work as a teacher after two weeks, and reported no further neck and arm pain with only mild residual left thumb numbness.

Cervical Fusion Case Study - Patient 2

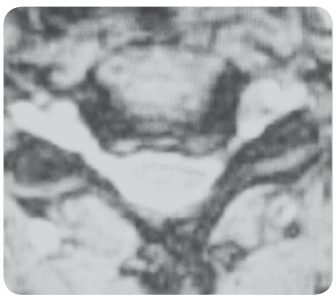
Patient Symptoms and Diagnosis

A 57-year-old male bucket truck worker, presented with neck pain radiating into the left arm and hand, decreased left thumb and index sensation, and thumb weakness. He was diagnosed with cervical radiculopathy.

Pre-operative Images



Sagittal MRI showing osteophyte and disc caused stenosis



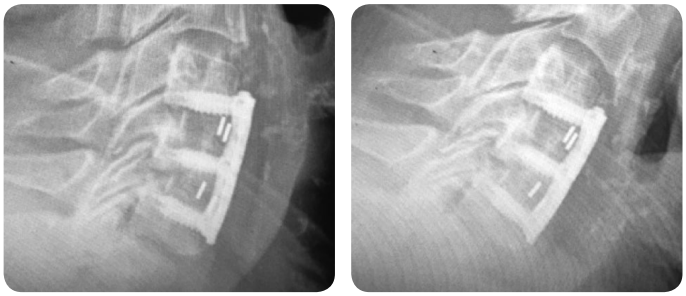
Axial MRI showing foramenal stenosis and nerve root encroachment

Surgical Procedure Performed

I performed an anterior cervical discectomy and fusion at C5-C7 utilizing a PEEK-OPTIMA HA Enhanced Interbody Device.

Radiographic Results

Post-op radiographic imagery shows solid fusion at both disc levels, and bridging between Vertebrae C5-C7 with no lucency, halo or motion between the spinous processes.



6-month Flexion Extension radiographs demonstrating solid fusion

Six-Month Results

Clinical Results

The patient resumed bucket truck work after eight weeks, and reported no further neck and arm pain with only mild residual left index finger numbness.

Conclusion

Overall, I am more confident using PEEK-OPTIMA HA enhanced interbody fusion devices than traditional PEEK devices. All eight cases utilizing the HA enhanced devices provided as good or better clinical and radiographic results than traditional PEEK Interbody Fusion Devices. Patients healed quicker and could return to normal activity after only two weeks. I'm convinced that HA integration does make a big difference in clinical outcomes.

Summary

Fifteen years of surgical implant use shows Invibio's PEEK-OPTIMA Natural is structurally sound and delivers excellent clinical results, including bone remodeling and fusion in interbody spinal fusion. The advanced polymer, PEEK-OPTIMA HA Enhanced, has shown the potential for the same material efficacy with additional osteoconductive benefits and growing case evidence of rapid bone apposition and dense bony ongrowth in interbody spinal fusions. Although, more studies are warranted, the early successes are promising. ▲

ABOUT THE AUTHORS

Timothy Bassett, MD

Dr Timothy Bassett is a board-certified orthopedic surgeon at The SouthEastern Spine Specialist Clinic in Tuscaloosa, Alabama. He earned a medical doctorate from the University of Florida, completed his residency in orthopedic surgery at the University of South Carolina, and did his one-year fellowship in adult and pediatric spinal disorders and reconstruction at the University of Wisconsin-Madison. Dr Bassett specializes in cervical and lumbar spine problems with primary focus on adult degenerative lumbar spine problems and failed lumbar fusions. He also has over 23 years-experience using interbody implants and grafts.[3]

Brad Prybis, MD

Dr Brad Prybis is a board-certified orthopedic surgeon at Carrollton Orthopaedic Clinic in Carrollton, Georgia. He earned a medical engineering degree from Georgia Tech and medical doctorate from the Medical College of Georgia. Later Dr Prybis completed his residency in orthopedic surgery at the University of South Carolina and one-year fellowship in spine surgery at the renowned Scoliosis and Spine Center in Baltimore, Maryland. He specializes in spine, neck and back pain, scoliosis, herniated discs, degeneration, injuries and tumors.[4]

REFERENCES

1. Invibio Data on File. Unloaded Long Bone Ovine Model, Bone Implant Interface Study. Data has not been correlated with human clinical data.
2. Invibio Data on File. Loaded Cervical Fusion Ovine Model, Functional Biomechanics Material Impact Study. Data has not been correlated with human clinical data.
3. Since 2016, Timothy Bassett, MD has provided ad hoc consultancy services to Invibio Ltd.
4. During 2016 to 2017, Brad Prybis, MD provided ad hoc consultancy services to Invibio Ltd.

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