PEEK-OPTIMA® Rods: a literature and clinical cases review

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Presentation Objectives

To review the main papers available on the literature treating about PEEK spinal rod systems

Paper 1 and 2: Biomechanical evaluations of PEEK rod systems

Paper 3, 4, 5 and 6: Clinical cases review
Biomechanical evaluation and comparison of polyetheretherketone rod system to traditional titanium rod fixation

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• **Method**
  
  — **Cadaveric testing:**
    - L1-S1 segment
    - Static flexion / extension, lateral bending and axial rotation
    - Intact segment, destabilized segment, Posterolateral fusion with PEEK rod and titanium rod with and without Posterior Lumbar Interbody Fusion device
    - Motion (angular displacement) measured

  — **Corpectomy testing (ASTM 1717-04):**
    - Static compression bending in displacement control
    - Static torsion under rotation controlled
    - Dynamic compression, sinusoidal displacement control, two run-out
• Results
  – Cadaveric testing:
    • Range of motion significantly reduced with PEEK rods (PLF or PLIF)
    • No significant difference between PEEK and Titanium rod constructs
  – Corpectomy testing:
    • Static compression bending: 67 degrees
    • Static torsion: 30 degrees
    • Dynamic compression: 23 degrees, two run-out, 5M cycles @ 5 Hz

• Conclusion
  – PEEK provide comparable stability than titanium rods
  – PEEK rods can withstand beyond normal physiological range of motion
Biomechanical Assessment of a PEEK Rod System for Semi-Rigid Fixation of Lumbar Fusion Constructs

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Method

- Axial grip characteristic of the PEEK rod system (ASTM 1798-97):
  - Evaluate the force required to push the PEEK rod through the screw head

- Corpectomy testing (ASTM 1717-04):
  - Static compression bending in load control
  - Dynamic compression, sinusoidal load control

- A/P shear testing:
  - Custom fatigue test protocol: dynamic compression, sinusoidal load control

- Cadaveric testing:
  - L1-Sacrum segment
  - Normal bone
  - Static flexion / extension, lateral bending and axial rotation
  - Intact segment, destabilized segment, Posterolateral fusion with PEEK rod and titanium rod without interbody fusion device
  - Motion (angular displacement) measured
Results

- Axial grip characteristic of the PEEK rod system (ASTM1798-97):
  - Force required to push the PEEK rod through the screw head: 35% higher than the one for Ø5.5 mm Ti rod

- Corpectomy testing (ASTM 1717-04):
  - Static compression bending: stiffness is lower for PEEK rod than titanium rod
  - Dynamic compression: run out value = 135 N, 5M cycles @ 4 Hz

- A/P shear testing:
  - Run out value = 225 N, 10M cycles @ 4 Hz

- Cadaveric testing:
  - Reduction of the range of motion
  - No significant difference between Titanium and PEEK construct

- Finite element analysis:
  - Intradiscal pressure calculated is higher with PEEK than Titanium rods

Conclusion

- Stability equivalent to metal construct
- Better antero-posterior load sharing
- Decreased forces and strains induced at the bone screw / interface
Flexible rods and the case for dynamic stabilization

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Paper 3: Flexible rods and the case for dynamic stabilization

- 3 cases
  - Case 1:
    - Re-operation at 8 months following a instrumented L3-L5 fusion with severe stenosis at L2-L3, severe ligamentum flavum hypertrophy and facet overgrowth
    - PEEK rods placed from L2 to L3
  - Case 2:
    - Young patient with severe degenerative disc disease at L5-S1, with marked stenosis at L4-L5
    - PEEK rods placed from L4-S1 with TLIF at L5-S1
  - Case 3:
    - 80 yo woman with neurogenic claudication and minimal back pain, severe L4-L5 stenosis and Grade I spondylolisthesis
    - Laminectomy + L3-L4 PEEK rod construct for stabilization

- Conclusion
  - The PEEK rods bridge the gap between dynamic constructs and rigid fixation systems
  - The use of PEEK rods in fusion of the lumbar spine potentially addresses the causal factors of adjacent-segment disease
Eur Spine J
DOI 10.1007/s00586-012-2219-x

ORIGINAL ARTICLE

Posterior lumbar fusion by peek rods in degenerative spine: preliminary report on 30 cases

F. De Iure · G. Bosco · M. Cappuccio · S. Paderni · L. Amendola

Received: 14 February 2012 / Accepted: 19 February 2012
Paper 4: Posterior lumbar fusion by peek rods in degenerative spine: preliminary report on 30 cases

• Material and method
  – From Oct. 2008 to Sept. 2010: 30 patients operated for degenerative lumbar spine disease (multilevel spinal stenosis with claudication, symptomatic low-grade spondylolisthesis, sciatic and back pain)
  – PEEK rods + PEEK cages performed in 22 patients
  – Patients controlled at 1 month, 3 months, 6 months, 12 months, 18 months

• Results
  – No intraoperative complications
  – 2 complications: superficial wound dehiscence, one deep infection
  – 1 cranial screw mobilization at 8 months (reoperation)
  – 22 patients (those with IBD) fused at 12 months
  – 7 of 8 remaining fused at 12 months
  – 1 patient still suffering of low back pain at 18 months

• Discussion and conclusion
  – Fusion rate similar or even higher than classical rigid fixation system at 18 months follow up
  – Effect on adjacent level to be evaluated in a longer term
Polyetheretherketone (PEEK) Rods in Lumbar Spine Degenerative Disease: A Case Series

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Paper 5: Polyetheretherketone (PEEK) Rods in Lumbar Spine Degenerative Disease: A Case Series

• Material and method
  – 42 consecutive patients underwent instrumented fusion using PEEK rods for degenerative lumbar spinal disease from January 2007 to June 2009
  – Indications for surgery included axial back pain with or without radiculopathy and lower extremity weakness.
  – The standard open technique for lumbar decompression and fusion was used.
  – The degenerated disc was replaced with an interbody spacer

• Results
  – 8 of the 42 patients with PEEK rods required reoperation. Reasons for reoperation mainly included ASD (5/8) and non-union with cage migration (3/8).
  – Radiographically documented fusion rate was 86%.
  – Mean follow up was 31.4 months.
  – No statistical differences were found in fusion rates or reoperation between age over 55 and younger than 55 (p=1.00), male and female (p=0.110), single or multilevel fusion (p=0.67), and fusion with and without interbody graft (p=0.69).

• Discussion and conclusion
  – PEEK rods demonstrate a similar fusion and reoperation rate in comparison to other instrumentation modalities in the treatment of degenerative lumbar spine disease.
Comparative effectiveness of PEEK rods versus titanium alloy rods in lumbar fusion: A preliminary report

Lei Qi · Mu Li · Shuai Zhang · Jingsong Xue · Haipeng Si

Received: 30 January 2013 / Accepted: 13 May 2013
Paper 6: Comparative effectiveness of PEEK rods versus titanium alloy rods in lumbar fusion: A preliminary report

• Material and method
  – From August 2010 and July 2011, 41 patients enrolled, randomly treated for fusion
  – 21 patients treated with titanium rods system (Weigao, Shandong, China)
  – 20 patients treated with PEEK rod systems (Dingkian, Changzhou, China)
  – Indications: single-level, lumbar degenerative disease
  – All cases underwent single-level posterior lumbar inter-body fusion.

• Results
  – Clinical VAS-BP, VAS-LP and JOA scores were significantly improved at 3 months, 6 months, and 1 year postoperatively as compared with preoperative scores in both groups (p<0.05), with similar levels of improvement observed at the same time points postoperatively between the two groups.
  – The overall fusion rate was 100% at the 1-year follow-up for both groups with no implant failure
  – No significant differences in lumbar, lordosis angle were found preoperatively, 1 week and 1 year postoperatively in both groups (p>0.05).
  – The postoperative increase of disc space height and loss of disc space height during the follow-up showed a similar extent of change between both groups (p>0.05).
  – Complications: No surgical site infection, 1 superficial wound dehiscence at 6 days (Ti group), 1 leakage of cerebrospinal fluid, 1 neurological deficit postoperatively, 2 urinary retention (1 Ti group and 1 PEEK group), 2 respiratory tract infection (2 PEEK group), 1 deep vein thrombosis (PEEK group)

• Discussion and conclusion
  – The PEEK rod system provides intervertebral stability comparable to that of titanium lumbar fusion constructs
  – The loss of disc space height could be found during the follow-up in PEEK group, but the extent of loss was similar to TI group.
  – PEEK rods offer a similar radiological and clinical efficacy as titanium alloy rods.
  – PEEK rods, as a semi rigid implant with unique characteristics, may be an effective alternative treatment option for degenerative lumbar disease in lumbar fusion.
Conclusion
Conclusion

- PEEK Optima® rods can perform as well as titanium rods
- **Clinical advantages of PEEK Optima® rods systems:**
  - No fretting or corrosion like metal implant
  - Better anterior column load sharing profile
  - Reduce stress at the bone / screw interface
  - Radiolucency (image friendly)
  - Reduce implant failure (lower re-intervention rate)
  - PEEK Young modulus similar to bone
  - Rigid constructs are probably far more rigid than needed to augment fusion
- PEEK Optima® rods systems fill the gap between soft and rigid constructs as a “semi-rigid” fixation
Conclusion

- **Other key Literature**
  - **Biomechanical and in vivo models**
  - **Pre-Clinical/Clinical Research**
    - Pasciak, PEEK Plastic Rods Versus Titanium Stiff Rods in Transpedicular Lumbar Stabilisation. Clinical Comparison of Short Term Results
    - Galler, CNS 2011, The Use of PEEK Rods in the Stabilisation of the Lumbar Spine
  - **Test Methods**
    - Siskey, Validation of a Test Method for Evaluation of the Fatigue Performance of PEEK Spinal Fusion Rod Systems
Thank you for your attention!