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# ASK THE EXPERTS

## Part 3: PEEK material and spinal implants

**Assess PEEK material for use in spinal implant.**

**Literature review.**

***PEEK invitro and in vivo studies.***

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Since their biocompatibility was established (1) polyaryletherketones (PAEK) have become widely in implant manufacturing and more specially in spine surgery.

One PAEK polymer became the most commonly encountered in practical use, poly-aryl-ether-ether-ketone widely referred as PEEK.

The structure of those polyaromatic ketones gives them resistance to temperature (up to 300°C), radiation and allows compatibility with other compounds in order to reinforce the construct such as carbon fibers or even glass (2).

Their modulus of elasticity can be further tailored by being carbon fiber reinforced using different fiber length and/or orientation (4).

The resistance of PEEK to radiation and heat makes it easy to sterilize by gamma radiation and if needed by autoclaving.

PEEK is a radiolucent material (9) and is then Magnetic Resonance Imaging (MRI) safe (10).

All those properties make them well adapted to the manufacturing of spinal implants and, indeed, the first such interbody cages appeared in the early 90's.

A number of finite elements analysis (FEA) and in vitro studies have investigated the mechanical properties of PEEK spinal implants, such as elastic modulus, compression resistance and creep behavior. Most of those works compared PEEK to similarly shaped titanium (Ti) implants.

The long-term mechanical stability of PEEK Optima was investigated by Ferguson et al. by in vitro mechanical testing and FEA (4). The loading was of 10 MPa for 2000 hours and showed a creep of less than 0.1%. The FEA analysis comparing with Ti showed that the metallic implant resulted in increased areas of higher strains on the adjacent vertebra under compression loading.

The modulus of elasticity (ME) and thus stiffness, was very thoroughly investigated in vitro by Heary RF et al (5).

The authors compared the ME of cancellous bone, cortical bone, PEEK, carbon fiber reinforced PEEK (CFRP), Ti, stainless steel and CrCo steel. The materials were tested under pure compression at a 2mm/min rate at a maximal compressive force of 45 kilonewtons (KN) and load-displacement plots were calculated and enabled to determine Young's ME and thus stiffness expressed in Gigapascals (GPa).

Their results showed that PEEK and cancellous bone had similar ME (3.84 and 3.78 GPa), while cortical bone and CFRP were measured at 14.64 and 17.94 GPa while all metallic implants where over 50 GPa and was little difference between Ti and stainless steels. This demonstrates that PEEK is more adapted to surrounding bone and less disruptive, which is important not only in interbody cages but also in intrabody vertebral augmentation devices.

In a FEA, Vadapalli et al. (6) showed that not only PEEK cages decreased centroidal stresses on the endplates compared to Ti, potentially decreasing risk of subsidence, but that the load on the graft inside the cage was augmented thus favorizing application of Wolff's law (13). This continuous graft loading decreases stress shielding.

PEEK has been tested as an alternative to Ti in posterior union rods. An in vitro study by Agarwal A et al (7) compared PEEK and Ti rods by subjecting different constructs to fatigue loading. They showed that post-fatigue motion and thus loads increased at the index level increased significantly with Ti as compared to PEEK indicating higher sustained loads.

In another in vitro study fatigue loading procedure, Chou WK et al (8), compared the effect PEEK and Ti (and with a non-instrumented sample) rods on the screw bone interface and on the cranial and caudal adjacent levels. The height of adjacent levels was decreased with Ti rods whereas there remained similar those of the non-instrumental sample. Likewise, the stress at the bone/screw interface was significantly lower with PEEK rods. This again indicated the increased loads induced by Ti implants.

Another major advantage of PEEK is its radiolucency. Krätzig T et al (9) compared, in vitro, CFR PEEK screw/rod constructs with Ti ones. They used CT as well as MRI. In CT artifacts were precisely measured as voxel gray scales in Hounsfield units while MRI were assessed qualitatively by a set of observers. In both CT and MRI the Ti implants yielded significantly artifacts.

Fleege C et al (10) compared CFR PEEK pedicular screws and Ti screws in two groups of patients fused for lumbar spondylolisthesis. An MRI was performed within the first postoperative month. For each segment the surface of artifact free vertebral body area was assessed as a percentage of that whole area ($p < 0.001$). The assessment of all anatomical structures (spinal canal and foramens) as well that of the screws themselves were graded from 1 (very good) to 5 (very poor). The artifact area in the PEEK groups was significantly higher (67% vs 48%). The grading scores for the canal and foramen were, in average, twice better in the PEEK group.

Several clinical studies compared Ti and PEEK cages. The quality of those studies is very unequal, so we looked at two metanalysis of the relevant literature.

Zhi-Jun Li et al (11) looked at PEEK vs Ti cages in ACDF. They found two randomized and two non-randomized trials. There was a total of 107 patients (184 levels) in the PEEK cage group and 128 patients (211 levels) in the Ti group. The meta-analysis showed no difference in clinical or radiographic fusion results although there was more cage subsidence in the Ti group than in the PEEK (15.6 % vs 6%, $p<0.001$).

Seaman S et al (12) conducted a meta-analysis on 6 studies and 410 patients (Ti 228, PEEK 182) and 587 levels (Ti 327, PEEK 260), 4 anterior cervical discectomy and fusion (ACDF) (395 levels) and two in transforaminal lumbar interbody fusion (TLIF) (192 levels). Three studies were class IV, two class III and one class II). The results showed that rate of fusion showed no statistical difference but that the rate of cage subsidence in cervical (20% vs 6%) as well as in lumbar region (35% vs 28%) was higher for Ti cages and this reached statistical significance (p=0.015).

All this data shows clearly that PEEK is more bone compliant than titanium. PEEK implants have a modulus of elasticity close to that of cancellous bone and this lower stiffness compared to metal will induce less surface stress and adjacent structure stress. Those increased loads phenomenon associated with metallic implants is prone to induce complications and additional damages. This makes them especially adapted not only for interbody cages but also for intravertebral augmentation devices.

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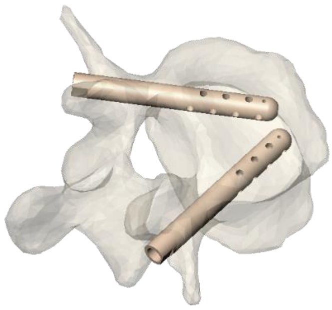
**About V-STRUT© Vertebral Implant**

Hyprevention has developed V-STRUT© Vertebral Implant indicated to treat vertebral fracture due to osteoporosis or bone metastasis.

The medical device reinforces the full vertebrae thanks to a PEEK implant providing a unique pedicle anchorage and allowing to share loading between the anterior and posterior column to limit subsequent and adjacent fracture.



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