Carbon-Fiber Reinforced Polymer for Spinal Intervertebral Fusion

"Are All Radiolucent Cages Created Equal?"

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Advances in interbody fusion technology have led to the creation of radiolucent cages for lumbar interbody fusion. Radiolucent cages allow for the visualization of bone remodeling within the interbody space and the presence or absence of solid fusion using plain radiographs. This is a great benefit for spine surgeons who have struggled for years attempting to determine the status of their patients' interbody fusion with metal cages in the absence of gross instability. Though advances in CT scan technology have given spine surgeons another radiographic tool to assess lumbar interbody fusion, there are two significant drawbacks to this method. The first is the scatter effect of certain metals, which often produces a suboptimal scan. Even the use of sagittal reconstruction scans can yield ambiguous results. The second drawback concerns the presence of a fibrous non-union within the cage that is difficult to differentiate from a bony union on CT scan.

The first radiolucent lumbar interbody cage approved for use specifically for interbody fusion, was the Jaguar JaguarSystem (DePuy Spine, Raynham, MA). The JaguarJaguar is manufactured from Polyetheretherketone (PEEK) reinforced with 30% Carbon Fiber (CF) which yields a new compound of Carbon Fiber Reinforced Polymer (CFRP) (Figure 1, JaguarJaguar). Utilized through a PLIF approach and in combination with transpedicular fixation, the Jaguar demonstrated a solid fusion rate of 98.9% in 178 patients with minimum two-year follow-up[1].

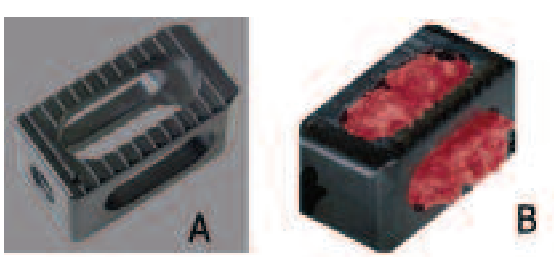

Figure 1: Carbon fiber reinforced PEEK interbody fusion cage before and after filling the cage with graft bone.

Other radiolucent interbody cages currently on the market and available for use are manufactured in 100% PEEK without the carbon fiber reinforcement.

There are differences between a CFRP cage and 100% PEEK product. The question is, are those differences relevant for lumbar interbody fusion? Mechanical testing was performed on both CFRP and PEEK materials. With the addition of 30% carbon fiber reinforcement, the stiffness of CFRP is five times greater than PEEK, matching the material's stiffness to that of cortical bone. The strength of CFRP is more than 200% higher than that of PEEK in both compression and tension[2].

In a physiologic loading scenario, (where the load is distributed across the surface of the cage), the CFRP cage had a greater compressive strength than the maximum *in-vivo* load of the lumbar spine (3.4kN) as first described by White and Panjabi[3]. However, the PEEK product failed at well below the maximum (44.1% and 32.4% below, respectively) *in-vivo* load (Figure 2B). This means a CFRP open cage design is adequate to withstand the compressive physiologic forces of the lumbar spine, but PEEK open cage design may not. This may be why PEEK products currently on the market incorporate only small lateral openings.

The finite element model testing was repeated for the same cage sizes with a closed cage design (i.e., the lateral aspect of the cage are solid). Under the physiological loading scenario, the PEEK product achieved sufficient compressive strength before failure, at or above the maximum *in-vivo* load of 3.4kN, which is equivalent to the open CFRP cage. However, the stiffness of the closed PEEK product was 636% and 512% greater than the open CFRP cage for the 9x9x25mm and 11x11x25mm sizes respectively (Figure 2A). So a closed PEEK cage has adequate compressive strength to withstand the physiologic loads of the lumbar spine. However, the increased stiffness, which is the tradeoff of a closed vs. open design, may lead to unintended results.

As the stiffness of internal fixation such as transpedicular screw constructs have increased over the past two decades, spine surgeons have encountered a near linear increase in solid fusion rates. This has led to the axiom that "the more stiff, the better." But while "the more stiff, the better" holds true for instrumented posterolateral fusion that is not necessarily the case for interbody fusion. Though it is counterintuitive to think in this manner, based on prior experience, some interbody fusion devices such as the closed cage designs manufactured in PEEK may be too stiff. If a cage is too stiff it may shield the load transfer for bony healing, thus reducing the bone formation as indicated by Wolff's law of adaptive bone remodeling. The other inherent problem with a closed cage design is that it does not allow for lateral bone growth through the interbody space. When using an open cage design most of the surgeon preference is to pack bone and/or bone graft materials in between and around the cages. This allows full biological potential available with an open cage. This technique is not possible with a closed cage design.

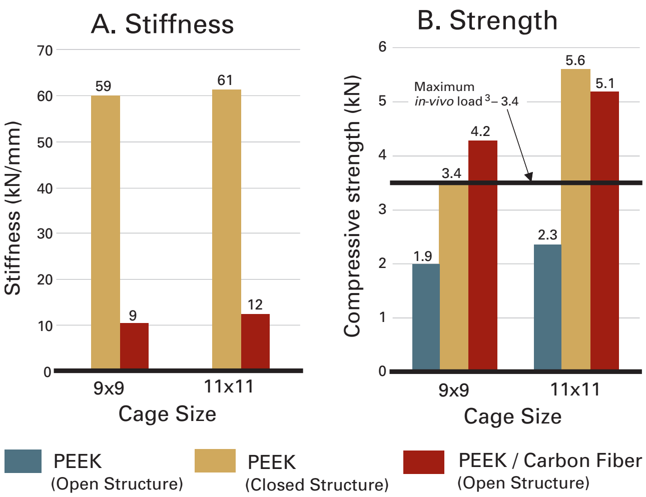

Figure 2: Axial Compression – Finite Element Analysis Results.

In conclusion, radiolucent lumbar cages are not equal. CFRP is adequate for an open interbody fusion cage design, but PEEK may not be. Though a closed PEEK design may provide adequate strength, the excessive stiffness may lead to stress shielding of the bony healing and eliminate the option of maximizing the biology of bony ingrowth within the interbody space.

REFERENCES

1. Brantigan JW, Steffee AD., Lewis ML., Quinn LM., Persenaire JM. *Lumbar interbody fusion using the Brantigan I/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system: two-year results from a Food and Drug Administration investigational device exemption clinical trial.* Spine 2000; 25(11): 1437-46.
2. William, DF., McNamara, A., Turner, RM. *Potential of polyetheretherketone (PEEK) and carbon fiber-reinforced PEEK in medical application.* Journal of Material Science Letters; 6, 1987; 188-190.
3. White, III, AA., Panjabi, MM. *Clinical Biomechanics of the Spine, 2nd Edition;* Philadelphia, Lippincott, JB., 1990, pp. 461.