

Comparative Study Finds Performance Advantages with PEEK-OPTIMA™ HA Enhanced Polymer

Invivo has previously demonstrated that PEEK-OPTIMA HA Enhanced polymer leads to increased bone apposition compared with PEEK-OPTIMA™ Natural polymer in a bone defect sheep model, as early as 4 weeks following implantation.¹ Now, Invivo has commissioned an independent cervical fusion study in sheep to compare outcomes between implants composed of PEEK-OPTIMA HA Enhanced, PEEK-OPTIMA Natural and allograft bone. Results indicate that PEEK-OPTIMA HA Enhanced may provide advantages in mechanical performance, new bone formation and graft quality.²

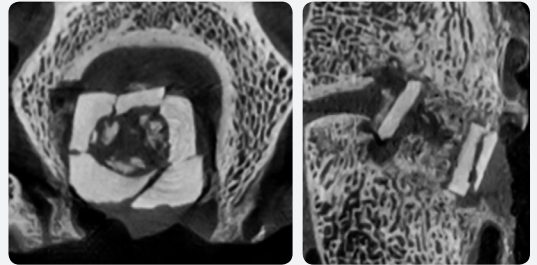
Results²

The study highlights the advantages of integrating PEEK-OPTIMA with Hydroxyapatite (HA), a well-known osteoconductive material for direct bone ongrowth, not only at the endplates, but on all faces of an interbody device. PEEK-OPTIMA HA Enhanced implants demonstrated the following performance advantages:

► Superior Mechanical Performance

PEEK-OPTIMA HA Enhanced devices outperformed allograft, with fracture of allograft devices in 6/13 (46%) instances.

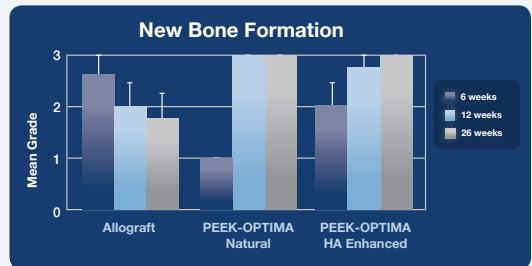
Despite the ability of the allograft spacers to support direct bone-implant contact, fracture of the implants was frequently observed, even at early time points. ►



► Greater New Bone Formation

PEEK-OPTIMA HA Enhanced resulted in greater new bone formation at 6 weeks compared with PEEK-OPTIMA Natural.

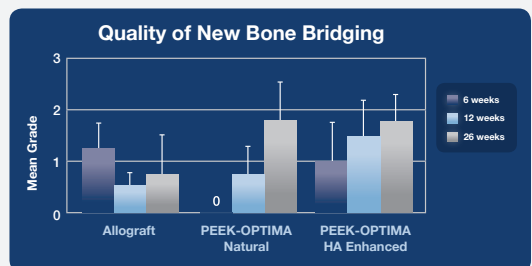
New bone formation at an early time point with PEEK-OPTIMA HA Enhanced (based on μ CT grading). ►

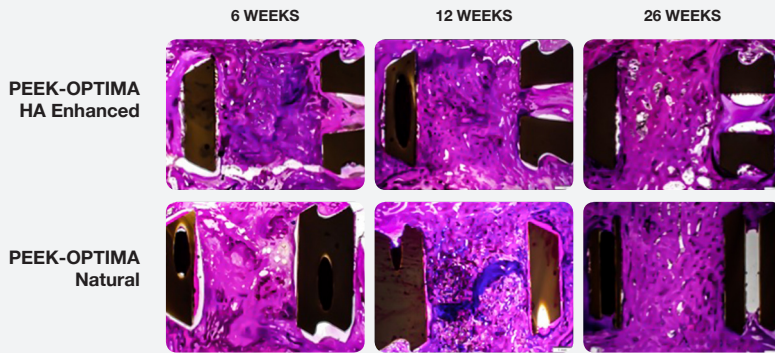


► Higher Quality of New Bone Bridging

PEEK-OPTIMA HA Enhanced devices resulted in a higher quality of new bone bridging at 6 and 12 weeks compared with PEEK-OPTIMA Natural.

PEEK-OPTIMA HA Enhanced provides a more favorable environment for new bone formation (based on μ CT grading). ►





▶ *PEEK-OPTIMA HA Enhanced provides a more favorable environment for bone graft compared with PEEK-OPTIMA Natural, resulting in a more robust fusion mass.*

Study Design²

Fully mature female sheep underwent surgery at two non-adjacent cervical spine levels. Eighteen animals were used in the in vivo study (6 animals each at 6, 12 and 26 weeks), and a further 6 animals were used for time zero biomechanical testing. Sheep were implanted with cervical spacers of identical design and randomly assigned to one of 3 test groups: PEEK-OPTIMA HA Enhanced v. allograft, PEEK-OPTIMA Natural v. allograft or PEEK-OPTIMA HA Enhanced v. PEEK-OPTIMA Natural. Local bone saturated with BMA was used as the graft material in all cases.

Radiographs were obtained following surgery and at time of sacrifice and micro computed tomography (μ CT) was performed at time of sacrifice. Specimens were also assessed for range of motion and histology of the treated levels. A semi-quantitative grading system was used to score new bone formation, quality of new bone bridging, new bone-implant contact, residual graft material in the graft space, fibrotic tissue formation and inflammation.

The Latest Material Development for Interbody Fusion.

PEEK-OPTIMA HA Enhanced polymer is fully integrated with Hydroxyapatite (HA), not coated, making it available on all surfaces of a finished device. This unique material combination has the potential to improve bone apposition and provide surgeons and implant manufacturers with a more advanced material for interbody fusion.

▶ [Download white paper at InvibioSpine.com](http://InvibioSpine.com)

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REFERENCES

1. Study evaluated the bone ongrowth of PEEK-OPTIMA and PEEK-OPTIMA HA Enhanced in a bone defect model in sheep. Data on file at Invibio. This has not been correlated with human clinical experience.
2. Study evaluated the in vivo response to PEEK-OPTIMA Natural, PEEK-OPTIMA HA Enhanced and allograft in a cervical spine fusion model in sheep. Data on file at Invibio. This has not been correlated with human clinical experience.

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