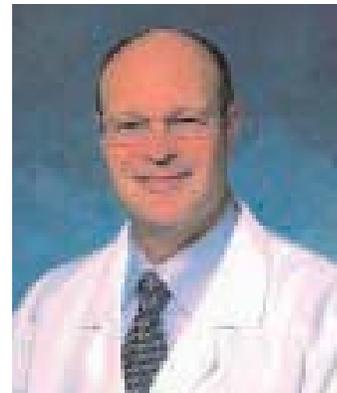


InterPlate™ Spine Fusion Device: Subsidence Control Without Stress Shielding



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The purpose of spinal fusion instrumentation is to maintain alignment after deformity correction, retain graft material, prevent graft collapse and kyphotic deformity, promote arthrodesis, allow early mobilization and prevent excessive post-op immobilization. Historically, fusion instrumentation has undergone generations of revision based on a progressive understanding of design biomechanics and evaluation of mechanical failures. These principles should be understood and applied to new implant designs.

One example is the evolution of cervical plates.¹ Early designs had unlocked bicortical screws. Excessive fluoroscopy increased risks to patients and operating room staff. Screw backout, fracture or migration were noted complications. Second-generation devices responded with rigid locking unicortical screws to introduce the box concept of stabilization. New failure modes were introduced, including graft stress shielding with resultant pseudoarthrosis, screw fracture or screw-bone interface failure. Rigid monoaxial screws still presented placement challenges.

Third-generation devices introduced polyaxial screws in round holes with partially compliant screw-locking mechanisms. While this increased placement options and reduced graft shielding, natural settling onto the graft during arthrosis caused the screw to pivot in a windshield wiper motion, with failure of the bone-screw interface.

Throughout this process, plate designers were striving for thinner profiles. The latest generation of plates is dynamic, with rotational and translational screws to control settling without loss of screw-bone interface. The optimal amount of screw constraint is open to discussion, and placement difficulties still remain a challenge.

On a separate path, the inherent design limitations of plates led to a trial of interbody devices. While interbody devices benefit from zero profile, studies have demonstrated that “stiff” devices produce stress shielding while “softer” devices may promote fusion.^{2,3,4} Displacement and expulsion can be problematic without any internal fixation mechanism, while incorporation of screws evoked challenges and failure modes similar to those of plates.

The search for the ideal fusion device continues. The InterPlate™ device was conceived as a vertebral body replacement (VBR or PVBR) and represents an attempt to incorporate the best features of plate and interbody concepts without the drawbacks. The basic design can serve as a platform for other applications including interbody devices. It is a near-zero profile, partially compliant, non-stress shielding device with a durable screw-bone interface. The device is easy to implant and allows for stackable use in adjacent levels, reducing the morbidity of adjacent-level operations. An attempt was made to address all potential failure modes. The basic design will have widespread application in the thoracolumbar spine and eventually the cervical spine as well.

The InterPlate, shown in Figure 1, features lateral wings that surround the graft. Two cephalad screws pivot through holes in the plate. A caudal screw is free to travel in a slot in the InterPlate tab. A cover prevents back-

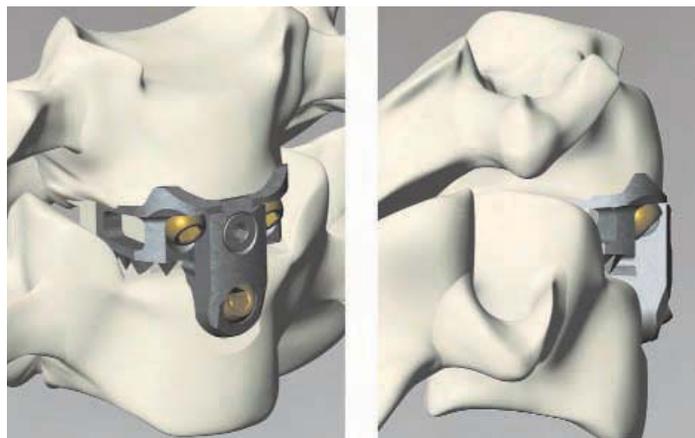


Figure 1: Anterior (left) and lateral (right) views of the InterPlate™ implanted in a spine model.

The dynamic performance of the device is unique. When load is applied to the construct, sharp teeth on the caudal surface of the InterPlate readily subside into the bone, preventing stress shielding of the graft. The tapered shape of the teeth has been designed to provide increasing resistance to subsidence. The tooth height is set at the average subsidence that occurs *in vivo*, and equal to the sliding distance allowed by the slot (Figure 2). When the teeth have fully embedded, flat surfaces on the caudal edge of the InterPlate are in contact with the bone surface, and the screw has reached the end of the slot. Resistance to subsidence continues to increase.

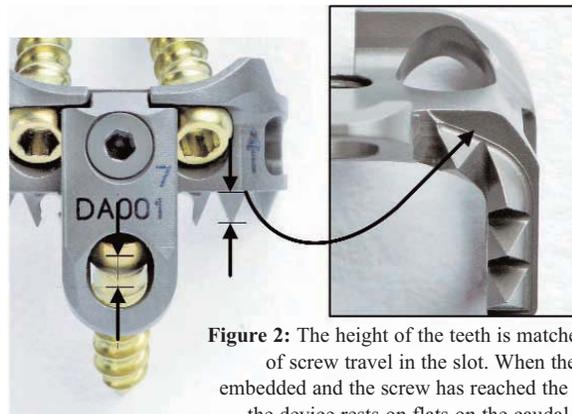


Figure 2: The height of the teeth is matched to the length of screw travel in the slot. When the teeth are fully embedded and the screw has reached the end of the slot, the device rests on flats on the caudal surface (inset).

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Note that materials like PEEK, which have a modulus close to that of cortical bone, have an insignificant effect on stress shielding in interbody applications. Device stiffness is a function of both material and structural properties. A PEEK interbody device modeled as a thin-walled box 11mm square by 6mm tall with a 2mm wall thickness would have an axial stiffness of about 50,000 N/mm. In tests conducted per ASTM standards, the actual subsidence resistance of similar-size metal devices was found to be 100 times lower, only 200-600 N/mm.⁵ By far, the primary source of deformation (load sharing) when compressive load is applied to an interbody device is penetration of the device into the bone, or localized bone fracture at the bone-implant interface, not axial shortening of the device itself. Put another way, compressive shortening of the device, regardless of whether it is metallic or PEEK, is insignificant relative to settling of the device/graft assembly into the host bone.

This design can serve as a platform for other applications, including a cervical interbody device (Figure 3), lumbar interbody device (Figure 4), and graft containment interbody device (Figure 5). With minor modifications, it could be manufactured from polymers such as PEEK or compos-

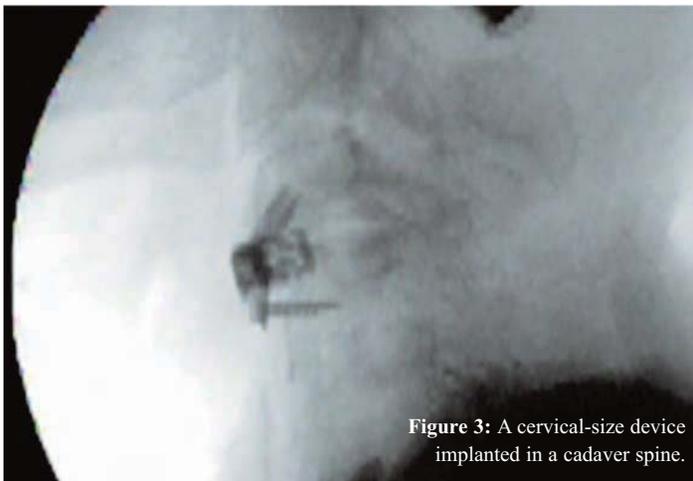


Figure 3: A cervical-size device implanted in a cadaver spine.

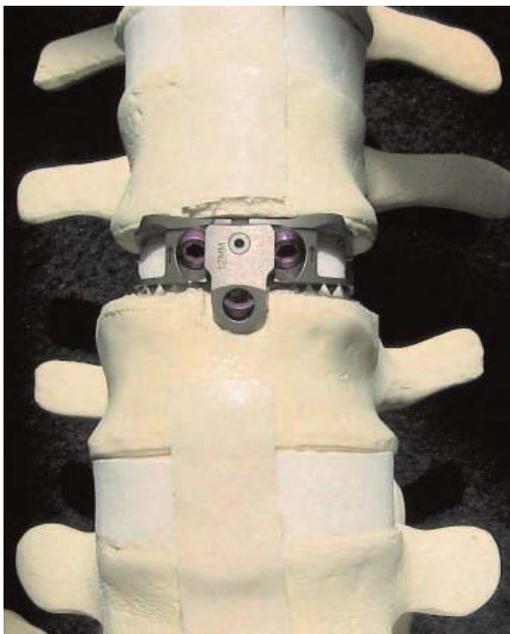


Figure 4: Lumbar interbody device prototype in a spine model.

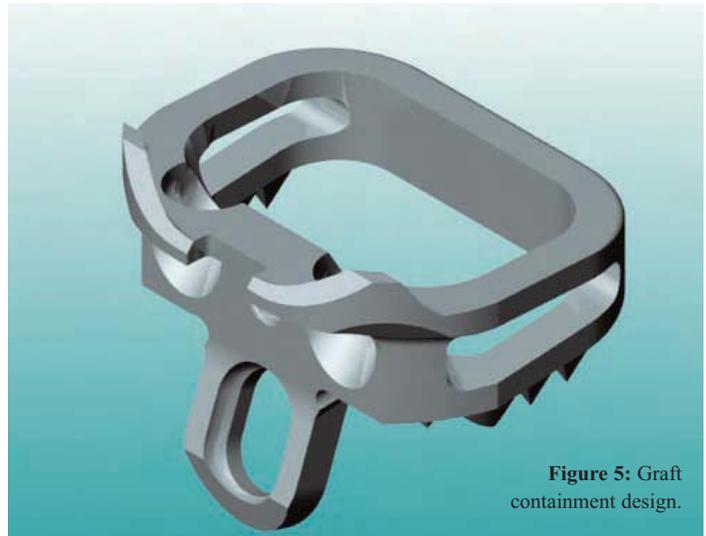


Figure 5: Graft containment design.

ites to provide radiotransparency. As noted in the previous paragraph, radiotransparency would be the sole benefit of PEEK. Stress shielding has been addressed through mechanical design of the bone-implant interaction.

A variation of the device that can be inserted postero-laterally in the lumbar spine is also under development.

Depending on the specific application, the InterPlate platform provides numerous benefits beyond stabilization without stress shielding, including:

Large graft volume. The InterPlate can accommodate a large graft volume between its wings. Even in the graft containment version, large open chambers are provided.

Virtually zero profile. The device is countersunk between the vertebrae. In cervical applications this is expected to reduce the amount of dissection required and minimize the occurrence of dysphagia.

Load transfer. The location of the InterPlate on the perimeter of the vertebral body facilitates load transfer to the cortical shell. Unlike cylindrical or cage interbody devices, the endplate does not need to be reamed to create a pocket matching the shape of the implant.

Screw fixation with backout prevention. The simple locking cover prevents backout of the fixation screws without inhibiting dynamic fixation characteristics.

Ease of implantation. Standard prep for graft placement is unchanged. Unlike plates, dissection is limited to the interbody space. A guide tube can be docked to the cover screw hole, facilitating through-the-tube screw placement. This ensures accurate screw placement and protects adjacent anatomic structures from injury. The screws are self-drilling and self-tapping.

Safety. If it becomes necessary to treat an adjacent level, the existing hardware does not need to be removed, avoiding the morbidity associated with re-operation.

There is currently strong interest in motion preservation devices. These same design principles should be applied to their development in order to prevent biomechanical failures. As we progress along the learning curve, it is likely that multiple generations of motion preservation devices will be

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needed to identify and resolve all of the issues. The most important parameter will be patient selection, and overuse will lead to clinical failures. Competition in the motion preservation segment is intense; entry costs are high and are rising, with new guidelines for Investigational Device Exemption studies and reimbursement being challenged by insurers. For these reasons, fusion of degenerative or traumatic segments in the spine will remain a mainstay of treatment. The InterPlate will likely find numerous applications, including a role in the salvage of failed Total Disc Replacement procedures.

A 510(k) application for InterPlate VBR and PVBR applications was approved in August 2006. An abbreviated 510(k) for the graft containment design is being prepared. Submissions for cervical and lumbar interbody indications will follow.

Patent Number 6,984,234. Other patents pending and applied for.

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