CLINICAL PERFORMANCE EVALUATION OF A MODULAR INTERBODY FUSION DEVICE

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INTRODUCTION

Interbody Fusion Devices inserted from a posterior approach have historically been limited to only partial endplate coverage dictated by the dimensions of the posterior access channel. Many surgeons believe that a broader footprint would lead to greater stability, less subsidence, and a lower migration rate. The Vertebral Technologies, Inc. (VTI) InterFuse® implant is an FDA cleared interbody fusion device that uses several modules connected by rail and slot dovetailed junctions to build a full footprint implant horizontally across the endplates. Each module is about 8mm in the mediolateral dimension and can be placed through a unilateral PLIF approach, thus minimizing nerve root or dural irritation.

METHODS

We are reporting the results of imaging studies on the first 104 cases for which we have the imaging data. The patients are unselected except that they have had a CT scan and a flexion/extension x-ray performed six to nine months post operatively. Bone morphogenic protein was used in less than half of the patients. The films were read by an independent spine radiologist and evaluated for fusion, migration, subsidence, and hardware loosening. The criteria for fusion were based on stability and the presence of bridging bone. Migration was read as positive if more than 3mm of anterior/posterior displacement of any module was present. Subsidence was read as positive if more than 3mm of settling of the end plates had occurred and hardware loosening was determined by the presence of lucent lines around the screws.

RESULTS

Of the 104 cases with flexion/extension x-rays and CT scan, 101 were read as showing definite fusion. All 104 films and CT scans were read as negative for subsidence, migration or hardware loosening determined by the presence of lucent lines around the screws.

CONCLUSIONS

In this study the modular InterFuse® implant resulted in a high fusion rate and no subsidence, migration, or hardware loosening.