TECHNICAL BRIEF – TRUSS IMPLANT TECHNOLOGY

LATERAL DEVICE RESISTANCE TO SUBSIDENCE

QUICK FACTS

- The 4WEB® LSTS implants were compared to an annular CFR implant for resistance to subsidence
- To mimic osteroporotic through normal bone, 5, 10, 15 and 20 PCF SawBone® blocks were utilized for testing
- 4WEB® 18W device resisted subsidence better than the 21W annular cage for all length combinations
- The 4WEB® 18W x 60L performed 67% better than the annular 21W x 60L
- The 4WEB® 18W cage out-performed the 21W annular cage for all density foam blocks
- The 4WEB® 18W cage resisted subsidence better than the 21W annular cage for all depths of subsidence (1-4mm)

INTRODUCTION

Lateral interbody fusion is a common and generally successful procedure. However, subsidence of the supportive interbody implant remains a well known occurance. Literature shows longer construct length and narrower cage width correlate with increasing subsidence rates.[1,2] The need for improved fusion and disc height restoration led to developing an implant utilizing a proprietary truss-based web technology. Truss based web technology increases resistance to subsidence and optimizes mechanobiological dynamic responses for stimulating bone on-growth, through-growth and subsequent implant fusion.

PURPOSE

The purpose of this technical brief is to describe the subsidence resistance properties of the 4WEB® Lateral Spine Truss System™ (LSTS™, 4WEB® Medical, Frisco, TX) interbody fusion device versus those of a slimilar predicate annular carbon fiber (CFR) device.

METHODS

- To mimic osteoporotic through normal bone, 5, 10, 15 and 20 PCF SawBone® blocks were utilized for testing.
- Each test block consisted of the loading fixture, the LSTS™ implant and the SawBone® specimen, and was tested using an MTS® test system in uni-axial compression.
- Compressive load was applied to the superior endplate of each cage under a displacement-control loading protocol with the displacement rate of 5mm/min.
- The test was repeated 6 times for each block combination and subsidence was measured following each experiment.

FIG 1A

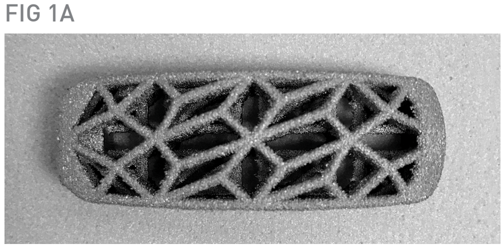


FIG 1B

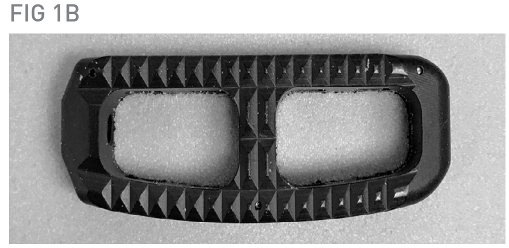
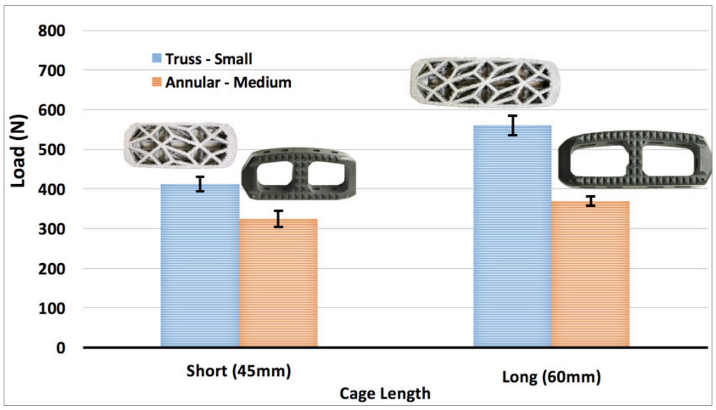


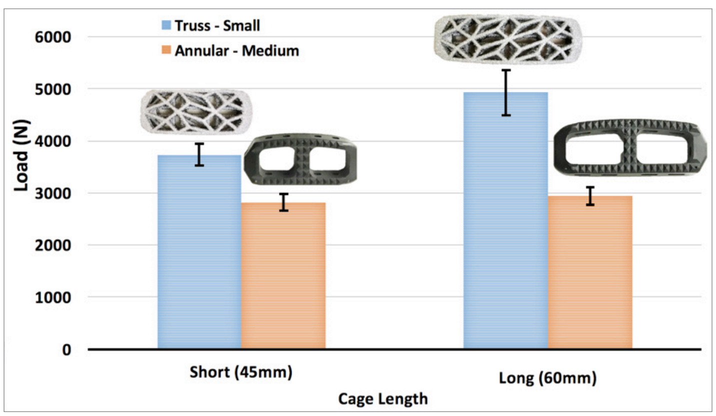
Figure 1A: 4WEB® LSTS™ implant 18mm (W) x 50mm (L) x 12mm (H)
Figure 1B: CFR Annular implant 21mm (W) x 50mm (L) x 12mm (H)

RESULTS

- The subsidence resistance at 1, 2, 3, & 4mm was greater for the 4WEB® LSTS™ small device (18W) than the corresponding annular medium device (21W) across all implant lengths and all density foam blocks.
- The 4WEB® LSTS™ 18mm (W) x 60mm (L) performed 67% better than the annular 21mm (W) x 60mm (L) implant.
- The 4WEB® LSTS™ 18mm (W) x 45mm (L) outperformed the annular 21mm (W) x 60mm (L) across all bone density models.



5PCF (OSTEOPOROTIC BONE)-1MM SUBSIDENCE



20PCF (NORMAL BONE)-1MM SUBSIDENCE

Figure 2. Comparison of the load necessary to achieve 1mm subsidence for a small footprint truss implant versus a medium footprint annular implant in SawBone® blocks of 5-PCF (osteoporotic bone) and 20-PCF (normal bone).

SUMMARY

In conclusion, the 4WEB® LSTS™ implant out-performed the annular carbon-fiber LLIF implant across all test combinations.[3] These results are indicative of the optimized load distribution inherent to the 4WEB® LSTS truss-based web technology. The truss design maximizes endplate contact and subsidence resistance while providing an open architecture for bone formation and subsequent fusion.

REFERENCES:

1. Le T, Baaj A, Dakwar E, Burkett C, Murray G, Smith D, Uribe J: Subsidence of Polyetheretherketone Intervertebral Cages in Minimally Invasive Lateral Retroperitoneal Transpsoas Lumbar Interbody Fusion. Spine 2012;37(14):1268-1273
2. Marchi L, Abdala N, Oliveira L, Amaral R, Coutinho E, Pimenta L: Radiographic and clinical evaluation of cage subsidence after stand-alone lateral interbody fusion. J Neurosurg Spine 2013; 19: 110-118
3. Kiapour, A. Evaluation and Comparison of Subsidence Properties of 4WEB Lateral Device versus an Annular Lateral Device.