A Biomechanical Study of the X-MESH™ Expandable Cage Implant

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ABSTRACT

Biomechanical testing was performed to evaluate the strength of the X-MESH™ Expandable Cage in compression and torsion as well as expulsion/migration resistance. Static test results indicate that the smallest X-MESH Expandable Cage has comparable strengths to the 10 mm x 50 mm Surgical Titanium Mesh in compression and torsion and to the OCELOT™ Stackable Cage System in a bench-top test of expulsion. In dynamic testing, the fatigue strengths of the X-MESH in axial compression and torsion were also comparable to that of the Surgical Titanium Mesh. Furthermore, the axial compression and torsional fatigue strengths of the X-MESH exceeded the highest *in vitro* and *in vivo* loads reported in the literature. The biomechanical tests indicate that the X-MESH cage is able to perform well against the biomechanical standards set by the Surgical Titanium Mesh and stackable cage.

PRODUCT BACKGROUND

Thoracolumbar corpectomies and vertebral body replacement procedures are typically indicated for spine trauma, tumors, and infections*. Common challenges in these procedural settings include: (1) developing an implant that fits the exact dimensions of the corpectomy defect, (2) distracting the surrounding vertebral bodies to restore normal height and sagittal alignment, (3) inserting the corpectomy device into a collapsed vertebral segment. Expandable cages provide an elegant solution to the issues above and for that reason have seen growing adoption in the spine community as corpectomy devices.

The X-MESH Expandable Cage system (DePuy Spine, Inc., Raynham, MA) is a new class of corpectomy device designed to provide a versatile solution for a broad range of corpectomy defects. The X-MESH device is comprised of two interfacing titanium sleeve components that can slide over each other, facilitating height adjustability. The height of the implant is locked with a pressure plate that attaches to both components.

Figure 1. Image of Expanded and Contracted X-MESH Cage

* Refer to full indications for use statement at the end of this document.

A set screw locks the pressure plate into preformed ridges on the inner sleeve of the implant.

The open graft window on the X-MESH cage allows for easy insertion of supplemental graft materials post expansion. The diamond mesh pattern on the sleeves of the X-MESH cage allow for vascularization and bony ingrowth. Spikes on the implant endplates surfaces are designed to stabilize the cage and prevent migration. The X-MESH implant comes in three configurations designed for 3 different approaches: Anterolateral, Direct Anterior, and Posterior.

The purpose of this evaluation was to assess the strength and viability of the X-MESH cage against corpectomy devices currently on the market including mesh and stackable products.

COMPRESSION TESTING

The primary purpose of an anterior intervertebral device is to maintain proper spinal height by resisting load on the anterior column. Therefore, a device placed here must be strong enough to withstand maximum body loads without sacrificing height. An ideal device will successfully resist loads which would normally break the vertebral body.

In order to assess the strength of the X-MESH Expandable Cage, the smallest and tallest device was selected: 16 mm in diameter and 130.5 mm long. Because this is the thinnest and longest device it will have the lowest strength and represents the "worst case scenario" for a cage in the X-MESH product family. This selection also meets FDA testing guidelines for spinal fixation.[1]

Figure 2. Test setup in Instron 5500R test frame for axial compression of X-MESH.

The device was expanded to its maximum length and compressed along its long axis to evaluate its strength (Figure 2). A calibrated Instron 5500R mechanical testing frame with a 10,000 lbs load cell was used to apply compression at a rate of 5 mm/min to the device. A Surgical Titanium Mesh (10 mm in diameter and 50 mm long) was also tested in the same way.

Normal daily living loads have been calculated to be close to 1,850 N.[2] Maximum body loads, produced by heavy lifting, may be closer to 4,000 N.[2] Similarly, Labrom et al found a maximum endplate strength of approximately 4,500 N (mean + 2 standard deviations) with a centrally located device.[3] Figure 3 shows the strength of these devices relative to Surgical Titanium Mesh as well as expected physiologic loads. The results shows that the smallest X-MESH™ Expandable Cage compares favorably to the 10 mm x 50 mm Surgical Titanium Mesh and other physiologic loads reported in the literature.

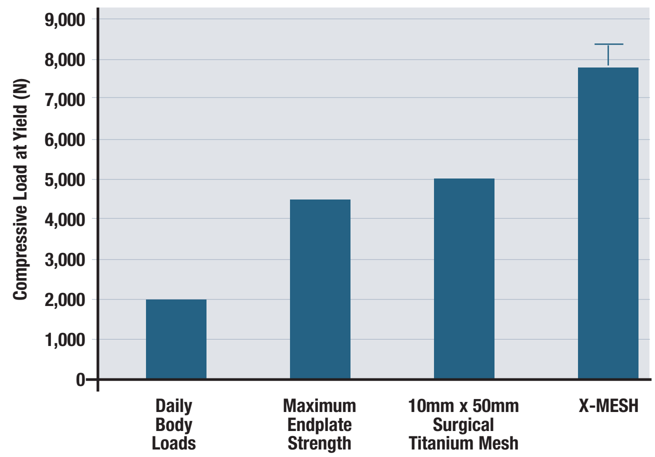

Figure 3. Mechanical strength of X-MESH relative to expected body loads and 10 mm x 50 mm Surgical Titanium Mesh.

Some implanted devices might fail by being overloaded in a single event, such as a fall down stairs. The testing above shows that in compression conditions the vertebral endplate is more likely to fail than the device, but should the device fail in a catastrophic event like this, it is helpful if the device can maintain structural integrity. Testing showed that the X-MESH Cage maintained rigidity after being loaded to failure in axial compression. At its maximum load, the pressure plate in the outer sleeve slipped to the next ridge on the interior component, remaining fixed.

However, some devices are more likely to fail by continued use, which fatigues the device and causes fracture after a lengthy implantation time. Of particular relevance with the X-MESH Cage is the pressure plate mechanism. A fatigue test was conducted to determine if the X-MESH Cage would fail in this way.

The device was placed in a phosphate buffered saline bath heated to 37° C in the same orientation as with the strength testing above. An MTS 858 Mini-Bionix test frame with a 20 kN load cell was used to apply a cyclic load. Load was cycled from a low magnitude (10% of maximum) to a high magnitude (maximum) to mimic extreme daily use. This test was conducted at 5 Hz. Although this is much faster than normal daily use, it may provide a worse case condition through frictional heating. The device was monitored for height loss throughout testing.

No fractures or height losses were found for loads up to the maximal body load estimate of 4000 N (900 lbs) for 5,000,000 cycles. To put this in perspective, it is estimated that maximum body loads occur less than 200 times per day, which is approximately once every 5 waking minutes, in normal healthy individuals.[4]

TORSION TESTING

In addition to compressing, the spine twists slightly – approximately two degrees in either direction per level for the lumbar spine, and slightly more for the thoracic spine. Normally this twisting is resisted by the intervertebral disc and facet joints, but in a fusion construct the device and graft are expected to resist twisting also.

In order to evaluate the strength of the X-MESH Cage in torsion, testing was done on a test frame similar to that done for compression testing (Figure 4). In this test, the X-MESH Cage is twisted along its long axis. The device was placed in metal blocks (Figure 5) with pockets the same shape as the X-MESH Cage endplates. These metal blocks provided a way to grip the device firmly. This setup was then placed in an MTS-858 Mini Bionix biaxial test frame and compressed to 500 N (112 lbs), which is consistent with standardized test method ASTM F 2077 -03 Test Methods For Intervertebral Body Fusion Devices.[5] While the entire construct was compressed, one end was then twisted clockwise at a rate of 1 degree per second while the resistance of the device was monitored. The test was stopped at 30 degrees, which is more rotation than the highest rotations expected in the body at the implanted levels.[6]

The test results showed continuously increasing resistance with applied twist. There was no drop in resistance throughout the test. This can be explained by the design. One advantage of the X-MESH Cage design is the "D" shaped cross section. As one component is twisted inside the other, the components bind together strongly and remain rigidly attached. The device was examined after testing and it was found to have a slight permanent twist, as would be expected after applying 30 degrees of angular displacement. In terms of relative performance, the X-MESH Cage withstood substantially more torque than can be expected in the body (Figure 6).[7,8]

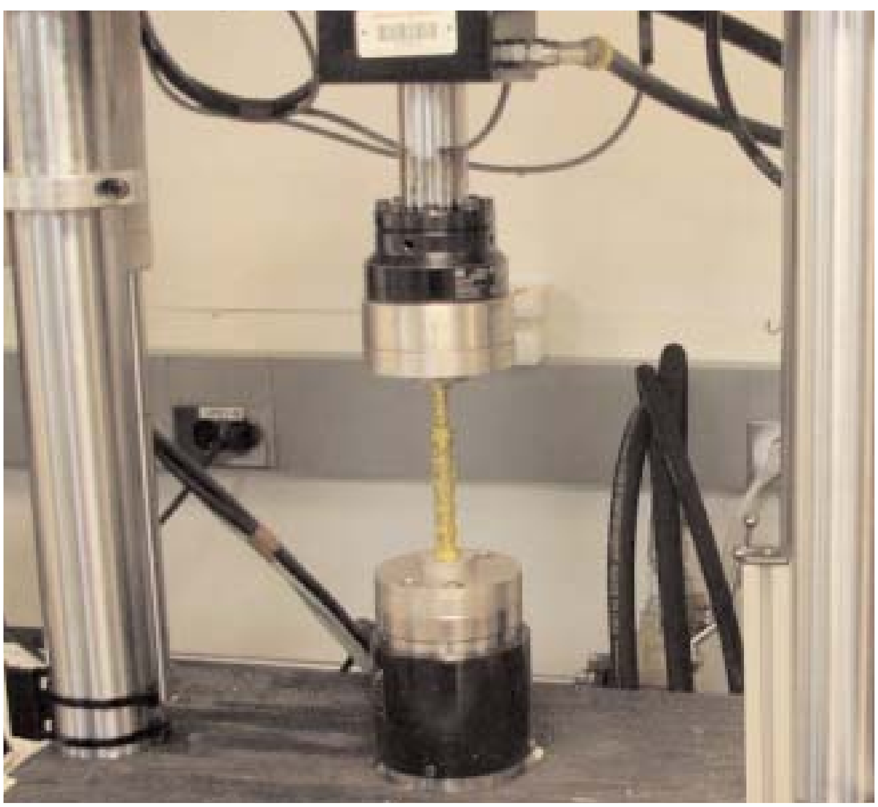

Figure 4. Test setup in MTS 858 Mini Bionix test frame for torsion of X-MESH.

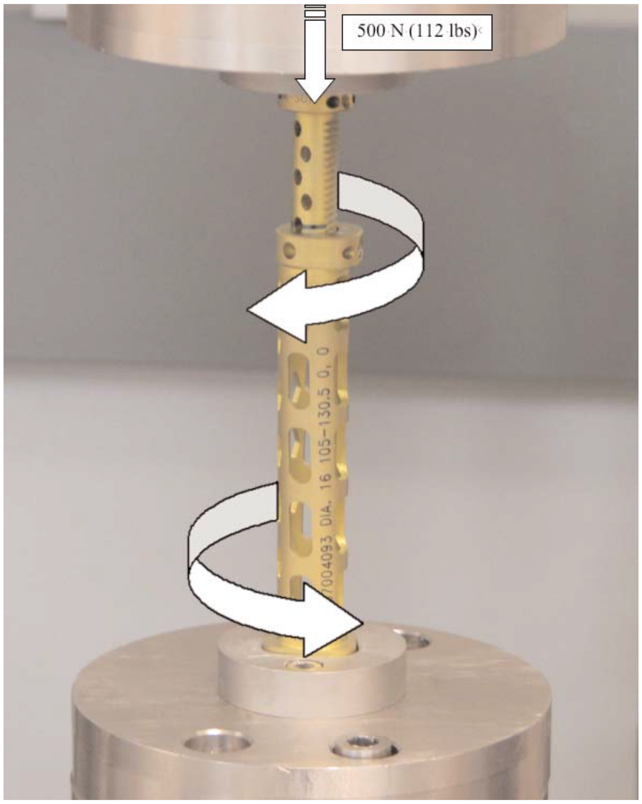

Figure 5. The X-MESH Cage was compressed with 500 N and then twisted 1 degree per second.

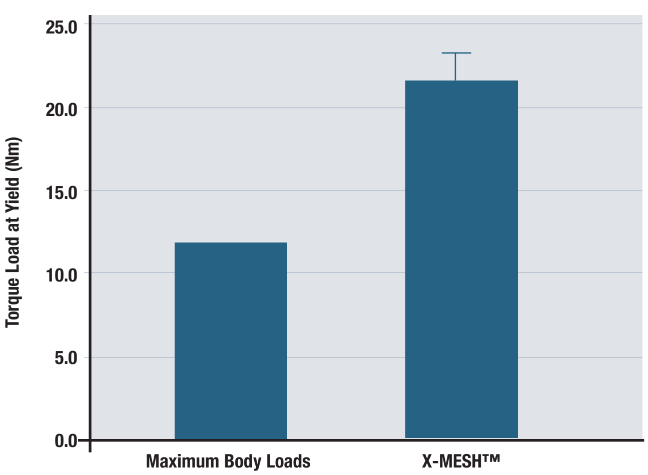

Figure 6. Static torque to yield the X-MESH Cage compared with normal maximum body load.

As with compression testing, a dynamic test was also performed to investigate the effects of repeated loading on the device. The device was again placed in a phosphate buffered saline bath heated to 37° C. An MTS 858 Mini-Bionix test frame was used to apply a cyclic load, which alternated between a maximum torque in one direction to a maximum torque in the other to mimic extreme use. This test was conducted for 5,000,000 cycles at 5 Hz, which again is much faster than normal daily use. The device was monitored for height loss throughout testing. Various loads were tested to determine the maximum fully reversed torque the X-MESH Cage could successfully withstand for 5,000,000 cycles.

The results of the torsional fatigue test suggest that the X-MESH Cage's fatigue strength meets the standard set by Surgical Titanium Mesh, just as with dynamic axial compression testing. While no dynamic failures were seen in axial compression, under large dynamic torsion loads the X-MESH Cage's inner component fractured while the pressure plate remained intact. This fracture region is expected because the inner component has the smallest cross-sectional area available to resist torsion. Larger and shorter X-MESH Cage devices are expected to have even greater torsional strength.

EXPULSION TESTING

The X-MESH Cage endplate has a serrated surface and three spikes to penetrate the bony endplate and resist migration. Benchtop testing was performed to compare the X-MESH Cage's endplate features with the OCELOT Stackable Cage's endplate features.

Solid rigid polyurethane foam biomechanical test blocks (Pacific Research Laboratories, 15 lbs/ft³) were used to evaluate the shear resistance of the devices. The devices were compressed between foam blocks with 400 N using a pneumatic actuator and a 5000 N Interface load cell. The devices were then pushed along the foam block faces by an Instron 5565 Mechanical Test Frame at a rate of 5 mm per minute. In this test a 0,24° angled X-MESH device was used because this presented the worst-case. Similarly, a construct made of ± 11° Large OCELOT Cage ends with spacers was used because it was the closest in size, shape, and indication to the X-MESH Cage.

The results (Figure 8) show that the 24° X-MESH met the threshold set by the OCELOT Stackable Cage for shear resistance in foam blocks. The tested block surface clearly showed the resistance of the spikes and rough endplate surface. A parallel (0°) X-MESH Cage is also shown for reference.

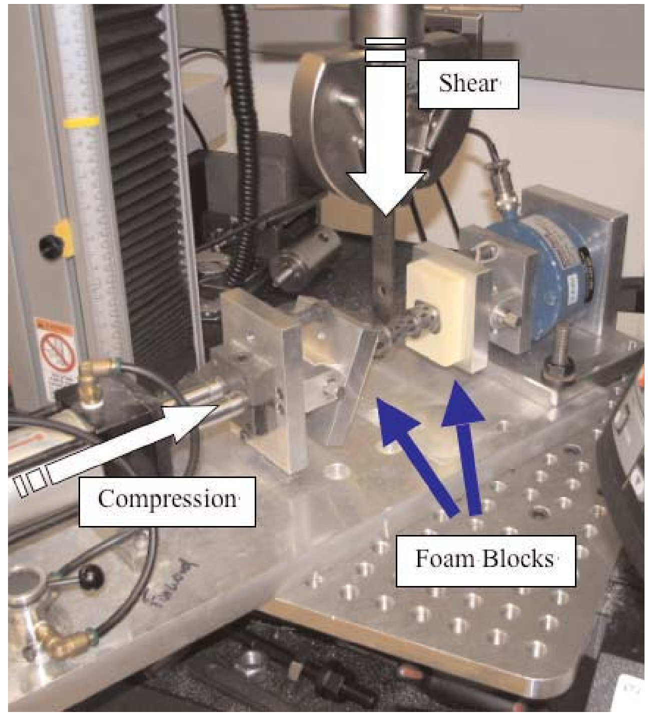

Figure 7. Test setup for expulsion testing.

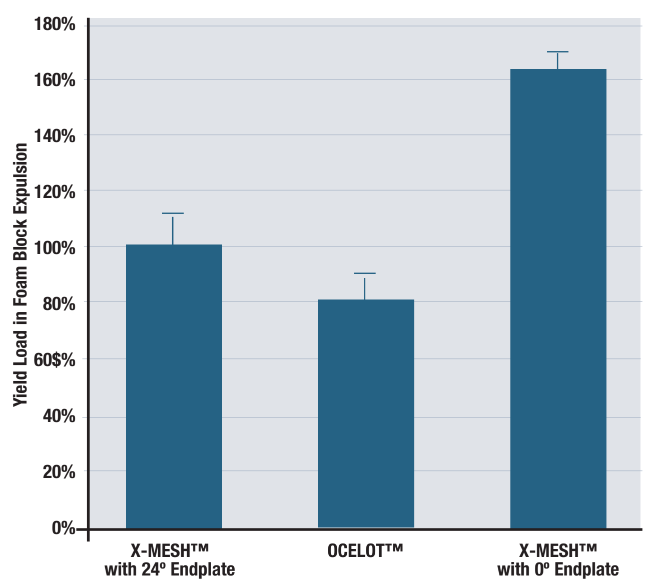

Figure 8. Relative expulsion resistances for X-MESH Cage and OCELOT Cage.

CONCLUSIONS

- X-MESH Cages demonstrate compression strength that far exceeds normal *in vivo* and *in vitro* loads reported in the literature. The X-MESH Cage's dynamic axial compression fatigue strength and static and dynamic torsion strength compared favorably to that of 10 mm x 50 mm Surgical Titanium Mesh, which has demonstrated clinical success for over a decade of use.

- X-MESH Cages meet the expulsion resistance threshold set by OCELOT Stackable Cages in benchtop testing. Their spikes and serrated roughened surfaces contribute favorably to their expulsion resistance.

REFERENCES

1. Center for Devices and Radiological Health, Guidance for Industry and FDA Staff: Spinal System 510(k)s. Document 636 FOD#2250, May 3, 2004.
2. White AA, and Panjabi MM, Clinical Biomechanics of the Spine, JB Lippincott: Philadelphia, 1990, p. 461.
3. Labrom RD, Tan JS, Reilly CW, Tredwell SJ, Fisher CG, Oxland TR. The effect of interbody cage positioning on lumbosacral vertebral endplate failure in compression. Spine. 2005 Oct 1;30(19):E556-61.
4. Zarda B, Dooris A, Bartish C, Fanger J. Estimation of Back Bending Cycles of Elementary School Teachers and Office Workers. Spine Arthroplasty Society, Miami, 2008.
5. American Society of Testing and Materials, International. F 2077-03 Test Methods for Interbody Fusion Devices. [F04.25] Spinal Devices Subcommittee.
6. White AA, and Panjabi MM, Clinical Biomechanics of the Spine, JB Lippincott: Philadelphia, 1990, p. 111.
7. Personal communication VK Goel, 2008.
8. Liu YK, Goel VK, Dejong A, Njus G, Nishiyama K, Buckwalter J. Torsional fatigue of the lumbar intervertebral joints. Spine. 1985 Dec;10(10):894-900.

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