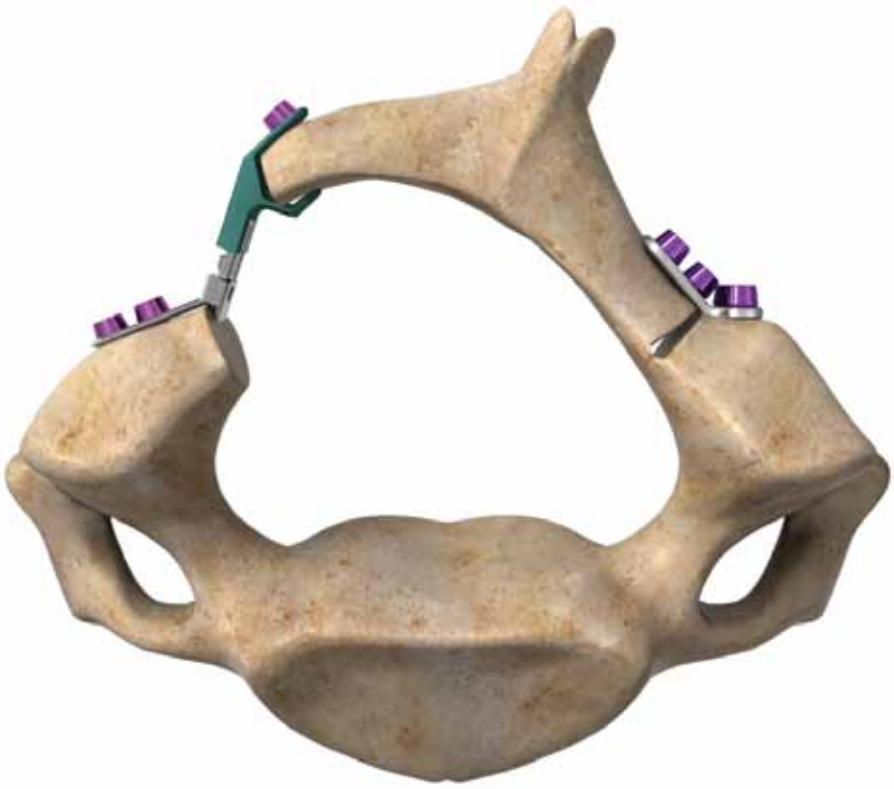
stryker®

Spine

Escalate™ Laminoplasty System

Technical Monograph

- Streamlined efficiency
- Engineered for safety
- Control through expansion



System Overview

The Escalate Laminoplasty System is a comprehensive set of implants and instruments designed for a systematic approach to cervical laminoplasty procedures. The system features an Expandable Laminoplasty Plate, a Base Laminoplasty Plate, Bone Screws for fixation, and a set of instruments to assist in implantation and removal of the device, if necessary.

Mechanical Testing

The Escalate Laminoplasty System provides a means by which the lamina may be opened to relieve cervical stenosis using a unique expandable plate. Escalate was designed to prevent lamina collapse.

The Escalate System was shown to be mechanically relevant in a series of tests designed to challenge its structural integrity. The Escalate System was compared to laminoplasty systems from Medtronic and Synthes. All systems were tested in accordance with the applicable ASTM standards.

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Prevention of Laminar Collapse

1. Design Challenge:

To design an implant that can adjust to a variety of heights and have enough strength to resist compressive loads.

2. Design Solution (Figure 1):

The triangular reinforced neck design of the Escalate Laminoplasty Plate is designed with increased rigidity of the mouth and greater lamina support. This feature was incorporated with consideration to the importance of maintaining an open lamina following the laminoplasty procedure.

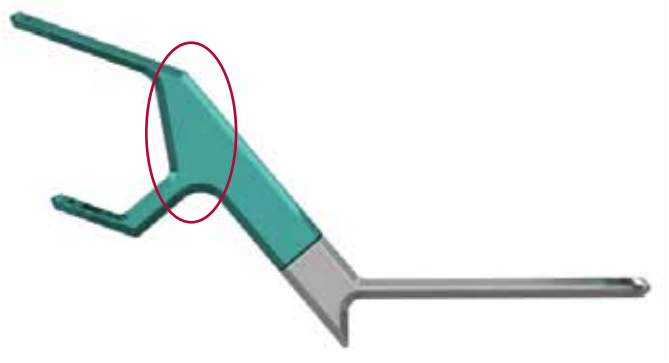

Figure 1
Escalate Laminoplasty Plate

3. Method (Figure 2):

The Laminoplasty Expandable Plate was expanded 12mm and its lateral mass and lamina mouth ends were attached to blocks of UHMWPE block. The lateral mass end UHMWPE block was pinned securely to a metal block and the metal block secured to the bottom of the test frame. A compressive load was applied at a rate of 10mm/minute until failure.

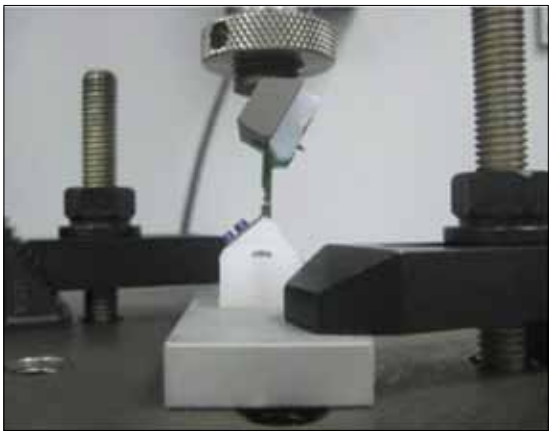

Figure 2
Escalate System Compressive Strength Testing Set-Up

4. Results (Figure 3):

- All values were normalized against the competitive component, denoted by 100%.*
- The Escalate System was found to be 115% stronger in plate compressive strength than the Medtronic Lateral Hole Plate system.†

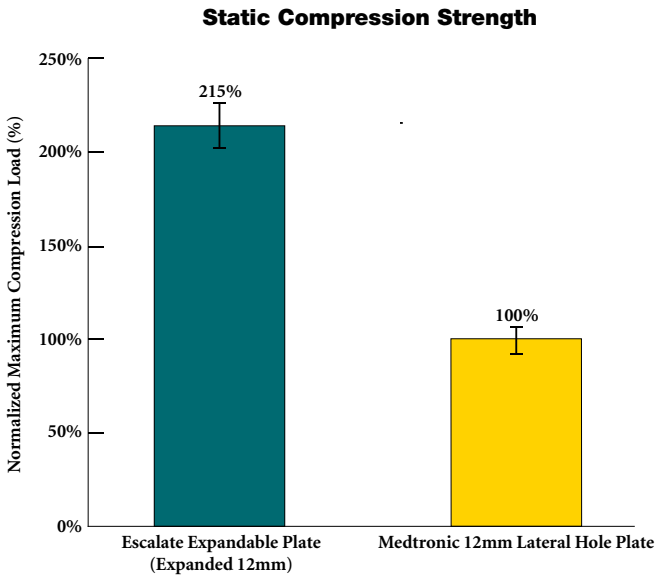

Figure 3
Laminoplasty Plate Compressive Strength

5. Conclusion:

The Escalate Plate was found to be more supportive than the comparable Medtronic plate when submitted to compressive loads.

Data on file at Stryker Spine.
*Report #: TREP0000025958
†Report #: TREP0000025961

Prevention of Bone Screw Pullout

1. Design Challenge:

To design a screw that is low profile and has the ability to resist pull out.

2. Design Solution:

By incorporating the well-known buttress thread design and promoting an environment that maximizes bone thread engagement, the Escalate bone screw is designed to increase resistance to implant backout and remain firmly in the lamina.

3. Method (Figure 4):

Testing followed ASTM F543-07 "Standard Specification and Test Methods for Metallic Medical Bone Screws." Ø2mm self drilling bone screws were inserted into 20 pcf foam a depth of 5mm. A tensile load was applied to the bone screw at a rate of 5mm/minute until the screw released from the foam block.

4. Results (Figure 5):

- All values were normalized against the competitive component, denoted by 100%.*
- The Escalate bone screw was found to be 39.4% stronger than the Synthes ARCH bone screw.†

5. Conclusion:

Escalate withstood higher loads than the comparable Synthes screw when submitted to this force.

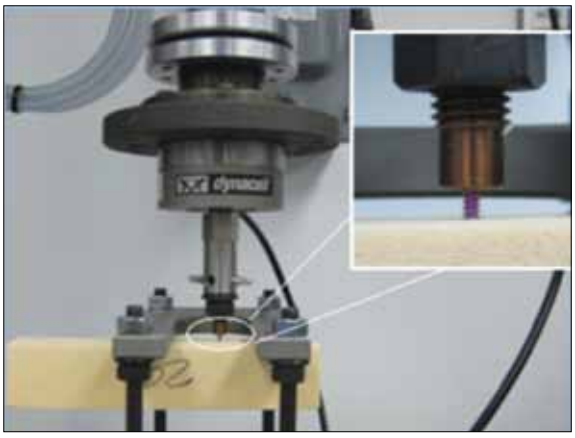

Figure 4
Escalate System Axial Pull Out Testing Set-Up

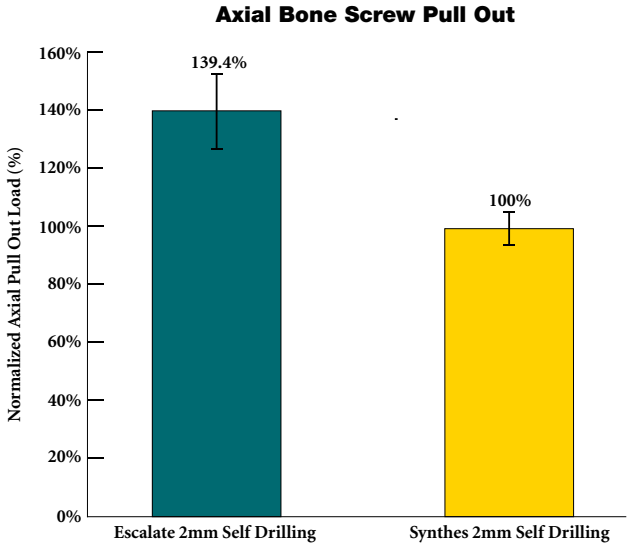

Figure 5
Axial Bone Screw Pull Out Resistance

Data on file at Stryker Spine.
*Report #: TREP0000025799
†Report #: TREP0000025894

Final Summary

The test results show that the mechanical strength of the Escalate Laminoplasty System exceeded the mechanical strength of the Medtronic and Synthes systems respectively when tested under the same conditions for:

Prevention of Laminar Collapse

Prevention of Bone Screw Pullout

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Reconstructive

Hips

Knees

Trauma & Extremities

Foot & Ankle

Joint Preservation

Orthobiologics & Biosurgery

MedSurg

Power Tools & Surgical Accessories

Computer Assisted Surgery

Endoscopic Surgical Solutions

Integrated Communications

Beds, Stretchers & EMS

Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial

Interventional Spine

Neurosurgical, Spine & ENT

Neurovascular

Spinal Implants

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Literature Number: **CVESCBR12090_US**
SC/GS 10/12