Biomechanics of Interspinous Process Fixation and Lateral Modular Plate Fixation to Support Lateral Lumbar Interbody Fusion (LLIF)

Jason Inzana, PhD\(^1\); Anup Gandhi, PhD\(^1\); Ryan DenHaese, MD\(^2\); Chris Wagener, MD\(^3\); Randall Porter, MD\(^4\)

\(^1\)Zimmer Biomet Spine, Broomfield, CO; \(^2\)AXIS Neurosurgery and Spine, Williamsville, NY
\(^3\)Coordinated Health Systems, Bethlehem, PA; \(^4\)Barrow Neurological Institute, Phoenix, AZ
Disclosures

• In support of their research or for preparation of this work, Ryan DenHaese, MD; Chris Wagener, MD; Randall Porter, MD have received remuneration from Zimmer Biomet.

• Jason Inzana and Anup Gandhi are salaried employees of Zimmer Biomet.

• ©2016 Zimmer Biomet Spine.

• The surgeon presenter is a paid consultant of Zimmer Biomet Spine. The information being presented is of a general nature and does not represent or constitute medical advice or recommendations and is for medical education purposes only. The information includes descriptions of conditions that a surgeon may encounter and treatment options that may be considered for those conditions.

• Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this information does not replace the need for such examination and/or advice in whole or in part. Zimmer Biomet Spine does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

• All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Zimmer Biomet Spine or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Zimmer Biomet Spine. This material is intended for healthcare professionals. Distribution to any other recipient is prohibited. For product information, including indications, contraindications, warnings, precautions, potential adverse effects, and patient counseling information, see the package insert and www.zimmerbiomet.com.
When used as a lumbar intervertebral body fusion device, the Timberline MPF System is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (“DDD”) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants with 20 degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least one integrated fixation screw. The Timberline MPF System is to be combined with supplemental fixation (except as noted below). Approved supplemental fixation systems include the Biomet® Spinal Fixation System.
The Alpine XC™ Adjustable Fusion System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The system is intended for use with autograft or allograft. The Alpine XC™ Adjustable Fusion System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and failed previous fusion. The Alpine XC™ Adjustable Fusion System device is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: DDD; spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Alpine XC™ Adjustable Fusion System device is intended for use with bone graft material, not intended for stand-alone use.
Biomechanics of Adjustable Interspinous Process Fixation:

Interbody Cage Load & Lordosis Correction
Biomechanics of Interspinous Process Fixation: Cage Load & Lordosis Angle

STUDY OBJECTIVE: Evaluate interbody cage loading and lordosis correction as a function of device compression/distraction

Alpine XC™ Adjustable Fusion System
(Zimmer Biomet, Inc. Broomfield, CO)

Silverton® System (Zimmer Biomet, Inc. Broomfield, CO)

Lordosis Correction

Interbody Loading

Subsidence

Migration
Biomechanics of Interspinous Process Fixation: Cage Load & Lordosis Angle

METHODS:

**Specimen**
- Human cadaveric lumbar spines
  - L1-Sac; n = 2 spines, n = 8 levels

**Posterior Prep**
- Bilateral pedicle screws (no rods) L1-L5

**Interbody Prep**
- Partial Discectomy
  - Lateral Approach
- Custom lateral cage with two compression load cells
- Sized to fit each level
METHODS (Cont'd):

Biomechanical Testing

Prepared Specimen

Randomized

ISPFI

Pedicle Screws

X-ray

X-ray

X-ray

Fixation

8 mm Compression

205 N Force Compression

160 N Force Compression

4 mm Distraction

Clinically Relevant Effort

Compression

Neutral

Distraction

a

b

c
RESULTS:

Alpine XC achieves 5° increase in lordosis with 8 mm compression
RESULTS:

Interbody load increases with both ISP compression and distraction to match bilateral pedicle screw fixation (BPSF)

*Denotes statistical significance; \( p < 0.05 \)
RESULTS:

Interbody compression during distraction likely results from posterior ligaments acting as a tensile fulcrum
RESULTS:

Loads on the spinous processes remain in a safe range

CONCLUSIONS

• Interbody loading stabilizes the spacer in both compression & distraction

• ISPF achieves at least as much lordosis correction (5°) as BPSF

*Denotes statistical significance; p < 0.05
Biomechanics of Adjustable Interspinous Process Fixation:

Spine Range of Motion with and without Lateral Modular Plate Fixation
STUDY OBJECTIVE:
Evaluate the rigidity of interspinous process fixation to support LLIF as well as the effect of lateral modular plate fixation

Alpine XC™ Adjustable Fusion System (Zimmer Biomet, Inc. Broomfield, CO)

TIMBERLINE® MPF System (Zimmer Biomet, Inc. Broomfield, CO)
Biomechanics of Interspinous Process Fixation: Range of Motion

METHODS:

Specimen
- Human Cadaveric Lumbar Spines (L1-L4; n = 7)

Posterior Fixation at L2-L3
- Bilateral pedicle screw fixation (BPSF)
- Alpine XC interspinous process fixation (ISPF)

Interbody Spacer at L2-L3
- Timberline® lateral cage ± 4 screw modular plate fixation

Alpine + LLIF

Alpine + LLIF + 4S MPF

BPSF + LLIF
Biomechanics of Interspinous Process Fixation: Range of Motion

METHODS (Cont'd):

**Biomechanical Testing**
- Loading to 7.5 Nm pure moment
  - Flexion-Extension
  - Lateral Bending
  - Axial Rotation
- Randomized testing order

**Motion Tracking**
- 3D motion tracking sensors at L1-L4
Biomechanics of Interspinous Process Fixation: Range of Motion

RESULTS: Flexion-Extension

ISPF with a lateral cage is as rigid as BPSF with a lateral cage

*Denotes statistical significance; p < 0.05
RESULTS: Lateral Bending

ISPF with a lateral cage + MPF is as rigid as BPSF with a lateral cage

*Denotes statistical significance; p < 0.05
RESULTS: Axial Rotation

ISPF with a lateral cage + MPF is as rigid as BPSF with a lateral cage.

*Denotes statistical significance; p < 0.05
CONCLUSIONS

• ISPF provides rigid stability, matching BPSF, in flexion-extension

• Fixation stability with ISPF can match BPSF in lateral bending and axial rotation when adding a lateral modular plate

*Equivalent operative time, fluoroscopy time, and blood loss with MPF – Denhaese et al. SMISS 2015.
Thank You

Broomfield, CO

Rocky Mountain National Park, CO