

STALIF MIDLINE® BIOMECHANICAL STUDY

STUDY OBJECTIVES

Quantify multidirectional flexibility properties of the **STALIF TT™** vs. **STALIF MIDLINE®** devices using non-destructive and destructive investigative methods.

BACKGROUND

A 2005 study was undertaken to compare the non-destructive multi-directional flexibility properties of Centinel Spine's **STALIF TT™** against 3 selected types of interbody fixation: LT PEEK Cages Alone, LT Cages with Pyramid Anterior Plate, and LT Cages with ISOLA Pedicle Screws / Rod Instrumentation.

The original study concluded that anterior reconstruction using the **STALIF TT™** device with 3 or 4 screws was shown to reduce segmental motion to levels similar to that produced using circumferential pedicle-screw based spinal arthrodesis.¹

The current study was performed to compare the **STALIF TT™** results from the 2005 study with the **STALIF MIDLINE®** 3 screw construct. The objectives were to:

- 01.** Quantify and compare the changes in non-destructive multidirectional flexibility properties of the **STALIF TT™** using both 3 and 4 screw configurations versus the **STALIF MIDLINE®** device with 3 integrated screws.
- 02.** Determine and compare the peak moment of failure under destructive extension loading of the **STALIF TT™** using 4 screws versus the **STALIF MIDLINE®** device with 3 integrated screws.

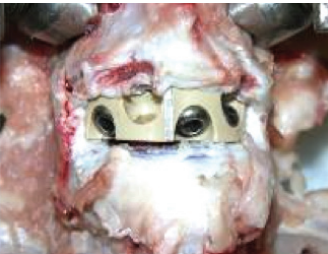
MATERIALS & METHODS

A total of 14 fresh-frozen calf lumbar spine specimens (L3-L6) were utilized in this latest investigation and equally randomized into two groups (n=7 per group) based on reconstruction condition. The 3 screw **STALIF MIDLINE®** construct was tested against the 3 and 4 screw **STALIF TT™** constructs in all 6 degrees of motion. Testing to destructive failure was performed with the **STALIF MIDLINE®** being compared to the 4 screw **STALIF TT™** construct.

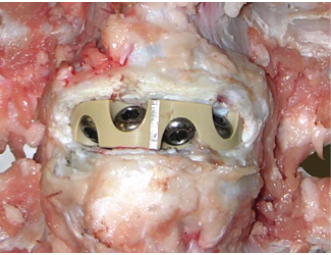
A. INTACT SPINE



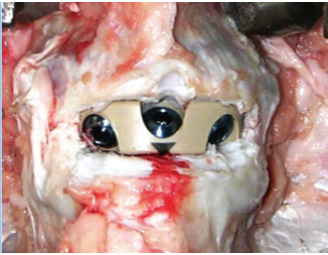
B. STALIF TT™ 3 SCREWS



C. STALIF TT™ 4 SCREWS



D. STALIF MIDLINE®



CONCLUSION

This study provides statistically significant evidence that the **STALIF MIDLINE®** 3-screw construct has equivalent biomechanical properties to the **STALIF TT™** with either 3 or 4 screw fixation.²

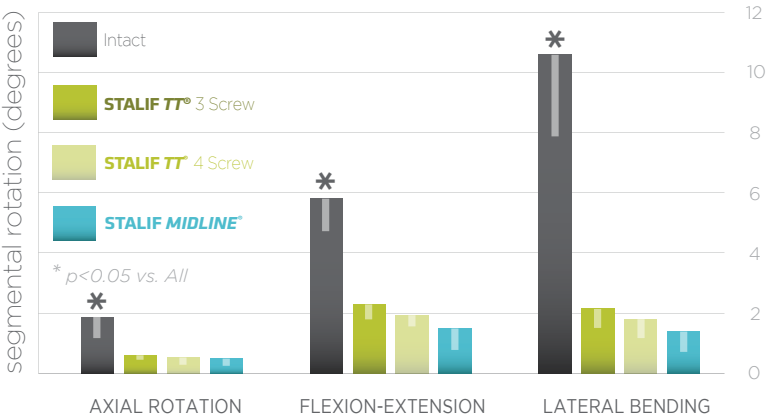
¹ Cappuccino A, MD; Cunningham BW - Multi-directional flexibility properties of the **STALIF TT™** device versus circumferential spinal arthrodesis: an in-vitro spine model presentation, SAS6, Montreal, May 2006.

² Cappuccino A, MD, SAS 11, Las Vegas, NV April 2011.

THE DETAILS

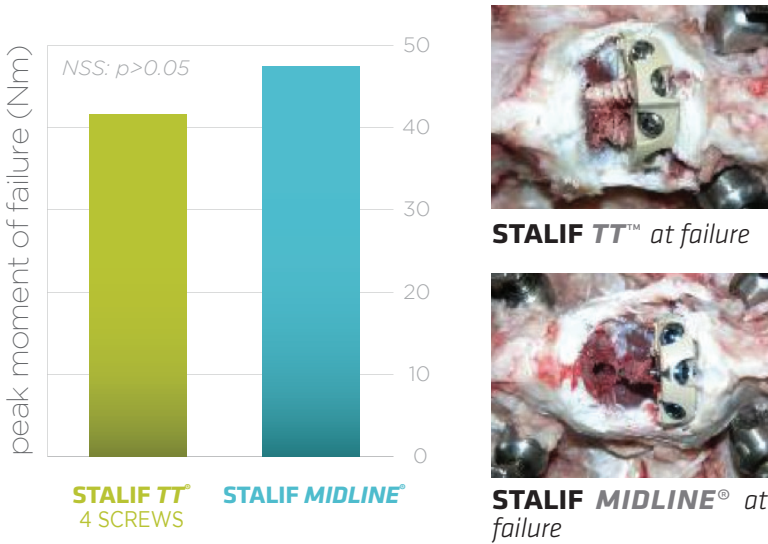
NON-DESTRUCTIVE MULTIDIRECTIONAL FLEXIBILITY TESTING

Based on the non-destructive kinematics, comparison of the operative segmental range of motions produced under all three loading modes – axial rotation, flexion-extension and lateral bending - exhibited no significant differences between the various treatments ($p>0.05$). However, all groups demonstrated decreased segmental motion compared to the intact control ($p<0.05$).



DESTRUCTIVE EXTENSION TESTING

This test demonstrated the peak destructive extension moments at failure for the **STALIF TT™** with four integrated screws was statistically equivalent to the **STALIF MIDLINE®** with three integrated screws. Failure mechanisms for all reconstructions were secondary to screw pullout from the vertebral endplate combined with annular tearing / disruption at the operative disc level. In the case of the **STALIF MIDLINE®**, the single inferior screw was the pullout location in all cases (n=7).



THE DESIGN OBJECTIVES

STALIF MIDLINE® perfectly balances its litany of complex objectives with a single, elegant, and unparalleled solution.

01. STABLE FIXATION OF MOTION SEGMENT

- Avoidance of posterior surgery.
- Solid compressive fixation of the motion segment to enhance fusion.
- Resistance to axial, torsional, and bending movement.

02. LARGE BONE GRAFT SURFACE AREA

- Graft/endplate surface compression gives best opportunity for fusion.

03. RADIOLUCENCY

- Allows for graft and fusion bed to be assessed.

04. RESTORATION OF DISC HEIGHT

- Indirectly opens neural foramen relieving nerve root impingement and pain.

05. RESTORATION OF LORDOSIS / SAGITTAL BALANCE

- Relieves musculoskeletal pain.

06. OPTIMAL LOAD TRANSFER

- Complies with Wolff's law to afford superior fusion outcomes.
- Footprint allows contact on cortical rim.