Single- to Dual-Lead Pedicle Screws Pose No Advantage in Fixation Strength: An investigation of biomechanical pullout strength and cyclic toggle to failure in a cadaver model

Amy A. Claeson PhD[1], Anup A. Gandhi PhD[2], Amir A. Mehbod MD[3]

1. Highridge Medical, Westminster, CO
2. Zimmer Biomet Spine, Westminster, CO
3. Twin Cities Spine Center, Minneapolis, MN

Presented at:
• Global Spine Congress 2019 Annual Meeting, Toronto, ON, CA
• NASS 2019 Annual Meeting, Chicago, IL, USA

Introduction

Thread form design aims to maximize screw purchase over the spectrum of bone quality to provide superior fixation strength and resistance to loosening. This biomechanical cadaver study assesses the fixation strength of the Vitality® Spinal Fixation System's dual-lead pedicle screws against pedicle screws of Medtronic's CD Horizon® Solera™ Spinal System with the single- to dual-lead OSTEOGRIP® thread form (Figure 1).

VITAL VITALITY

VITAL / VITALITY	CD HORIZON SOLERA / TSRH-3Dx / OSTEOGRIP
Dual-Lead	Single- to Dual-Lead Cortico-Cancellous (Osteogrip)
Polyaxial Pedicle Screw	
Ø6.5 mm x 45 mm L	
Shaft: Ti-alloy	Shaft: Ti-alloy
Pitch: 2.7 mm	Pitch: 4.0 mm, 2.0 mm

CD HORIZON SOLERA TSRH-3DX

Fig. 1 *Pedicle screws of Highridge Medical's Vital™ Spinal Fixation System and Vitality® Spinal Fixation System share the same dual-lead thread form. Pedicle screws of Medtronic's CD Horizon® Solera™ Spinal System and TSRH-3Dx™ Spinal System share the single- to dual-lead, cortico-cancellous, OSTEOGRIP® thread form. All screws pictured are Ø6.5 mm x 45 mm except the TSRH-3Dx pedicle screw is Ø6.5 mm x 35 mm.*

Materials and Methods

Specimen Distribution

Fresh-frozen cadaveric vertebrae (T12-L5, n=32) were isolated and cleared of all soft tissue and stratified into groups based on bone quality (non-osteoporotic, osteoporotic) and test method (axial pullout, cyclic toggle to failure) as follows:

- Non-osteoporotic – axial pullout (n=8, BMD>0.80g/cm²)
- Non-osteoporotic – toggle to failure (n=8, BMD>0.80g/cm²)
- Osteoporotic – axial pullout (n=8, BMD<0.70g/cm²)
- Osteoporotic – toggle to failure (n=8, BMD<0.70g/cm²)

Specimen Preparation

Pedicle preparation followed standard technique for the Vitality spinal fixation system and that of the CD Horizon Solera system. The pedicle trajectory was created with a Lenke probe and the trajectory was undertapped by Ø1.0 mm with the respective tap from each system: Vitality Ø5.5 mm tap (dual-lead, PN:07.02088.005), CD Horizon Solera Ø5.5 mm tap (single-lead, PN:8350424). One Vitality pedicle screw (Ø6.5 mm x 45 mm L, PN:07.02000.075) and one Osteogrip pedicle screw (Ø6.5 mm x 45 mm L, PN:54840006545) was bilaterally placed in each prepared pedicle which yielded bone quality and internal control. Both trajectory and placement were confirmed by fluoroscopy (Figure 2).

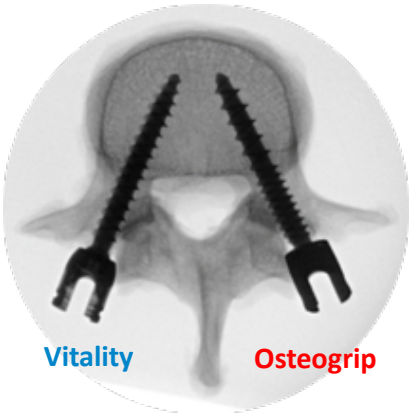

Fig. 2 *Axial fluoroscopic image of bilateral pedicle screw instrumentation*

AXIAL PULLOUT – Biomechanical Test Method

- Secure vertebra in test setup, couple screw to actuator (Figure 3)
- Displace actuator upwards at 5 mm/min for minimum of 10 mm
- OUTCOME METRIC: Maximum load (N)

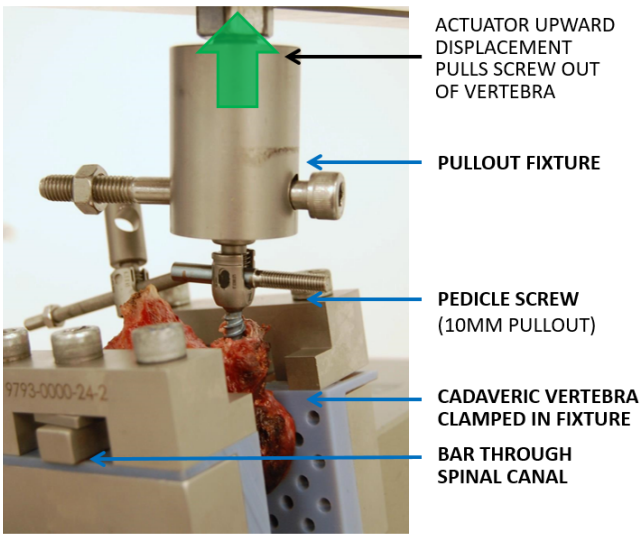

Fig. 3 *Axial pullout biomechanical test setup*

CYCLIC TOGGLE TO FAILURE – Biomechanical Test Method

- Secure vertebra in test setup, couple screw to actuator (Figure 4)
- Sinusoidal waveform at 2Hz applies compressive loading (Figure 5)
  - Start: -10N/-100N
  - Each 200 cycles, compressive load increases -5N/-50N to failure
- Failure defined as -4 mm of actuator deflection
- OUTCOME METRIC: Load at failure (N)

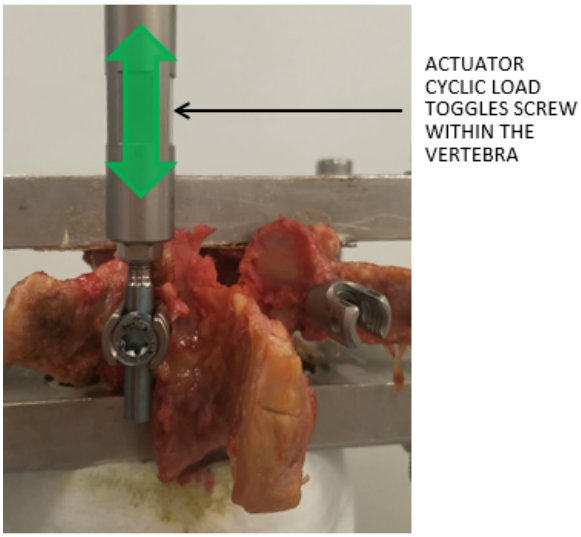

Fig. 4 *Cyclic toggle to failure biomechanical test setup*

Data Analyses

- Difference in screw outcomes within a bone-quality group: paired t-test or Wilcox signed rank test
- Difference in screw outcomes across bone-quality groups: unpaired t-test or Mann-Whitney-U test
- Data normalized by outcome metrics of Vitality in non-osteoporotic vertebrae
- Significance for all statistical tests set to $p<0.5$

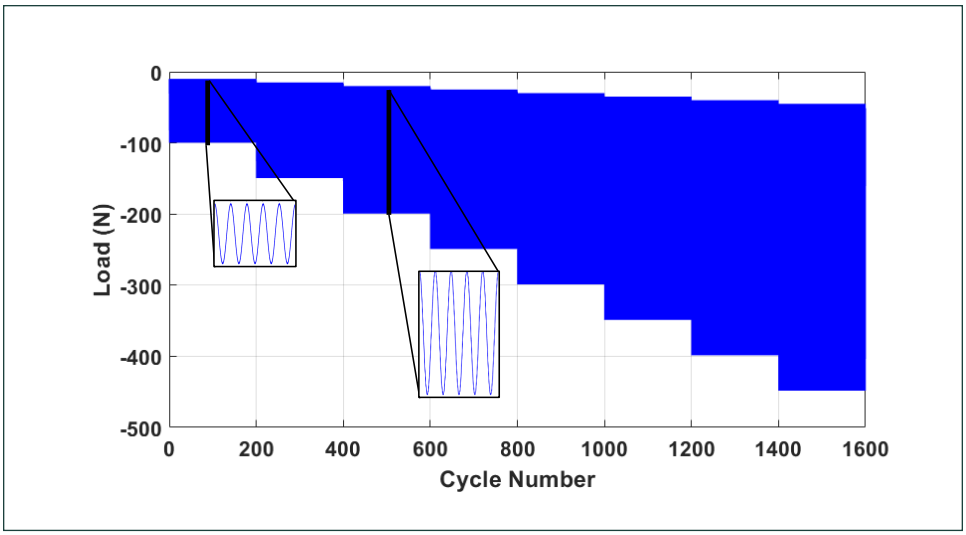

Fig. 5 *Loading protocol used for cyclic toggle to failure biomechanical testing*

Results

- Vitality pedicle screws exhibit equivalent fixation strength ($p>0.05$, Figure 6) compared to that of Osteogrip in:
  - Non-osteoporotic vertebrae – axial pullout
  - Osteoporotic vertebrae – axial pullout
  - Non-osteoporotic vertebrae – cyclic toggle to failure
  - Osteoporotic vertebrae – cyclic toggle to failure
- Axial pullout strength of Vitality is 33% greater than that of Osteogrip in non-osteoporotic vertebrae, though not significantly greater ($p>0.05$, Figure 6)
- Both pedicle screws fail at significantly larger loads in non-osteoporotic vertebrae compared to osteoporotic vertebrae ($p<0.05$)

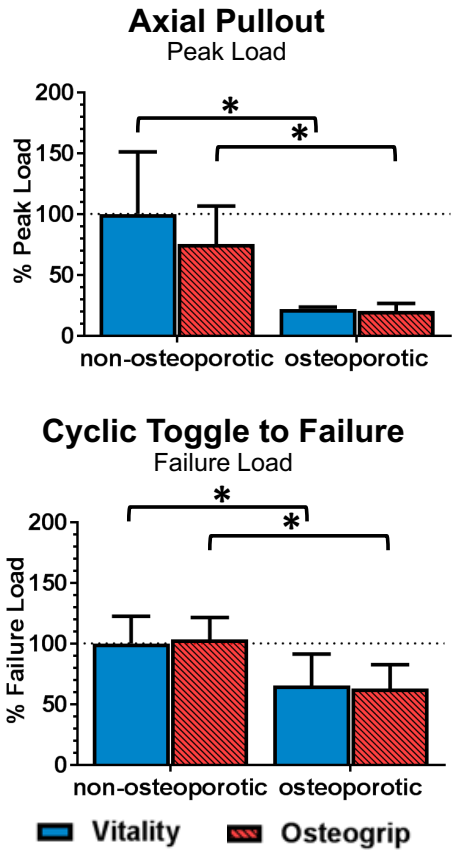

Fig. 6 *Biomechanical outcomes; data normalized to non-osteoporotic Vitality outcomes. All error bars denote standard deviation. Significance * = $p<0.05$*

CONCLUSION

Vitality dual-lead pedicle screws have equivalent fixation strength to the single- to dual-lead Osteogrip thread form of Medtronic's CD Horizon Solera System in failure modes of axial pullout and cyclic toggle to failure. Single- to dual-lead pedicle screws posed no advantage in fixation strength in this non-clinical cadaver study.

Pedicle screws of Highridge Medical's Vital Spinal Fixation System and Vitality Spinal Fixation System share the same dual-lead thread form.

Pedicle screws of Medtronic's CD Horizon Solera Spinal System and TSRH-3Dx Spinal System share the single- to dual-lead, cortico-cancellous, OSTEOGRIP thread form.

Data on file.

Publications:

Claeson, A., Gandhi, A., & Mehbod, A. A. (2019). 293. Biomechanical assessment of pedicle screw fixation strength in nonosteoporotic and osteoporotic pedicles: comparison of straight dual-lead vs single-to dual-lead threadforms. The Spine Journal, 19(9), S142-S143.

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