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# Mechanical Testing Summary
# The Aversion Pedicle Screw System

## 1. INTRODUCTION

The Aversion Pedicle Screw System consists of longitudinal members (rods – straight and pre-lordosed), anchors (polyaxial pedicle screws) and interconnections (crosslink connectors). These are available in a variety of sizes to accommodate differing patient anatomy. Testing of the devices was undertaken to characterize the mechanical properties of the system. [1,2] Those results are compared here to published data.[3,4,5]

## 2. MATERIALS AND METHODS

### a. Device description

The Aversion Pedicle Screw System consists of rods, polyaxial pedicle screws and crosslink connectors. These are available in a variety of sizes to accommodate differing patient anatomy. Rods are 5.5mm in diameter and are available in straight and curved versions in 35mm to 500mm lengths.

Regular and modified polyaxial screws are available in 5.5mm, 6.5mm, 7.5mm and 8.5mm diameters and in lengths ranging from 30mm to 55mm. Each is also offered having a reduction style tulip head. Regular screws have a standard thread profile while modified screws have unilateral non-threaded region at mid-section of the screw shaft (blue arrow, Figure 1). Crosslink connectors fasten the bilateral construct components. All implant components are manufactured from Ti6Al4V ELI according to ASTM F136.

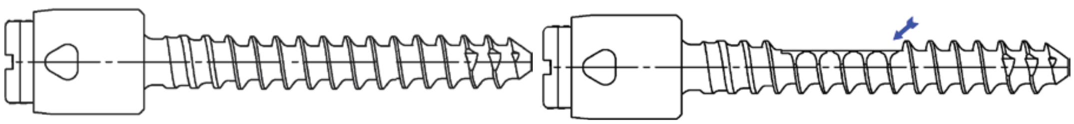

**Figure 1 Polyaxial Screws in regular and modified versions (left to right).**

### b. Selection of the test specimens

The smallest Aversion pedicle screw (5.5mm, part # AV5.5-40‡) was selected for testing. The rods are a single size (5.5mm) and offered in straight or pre-contoured versions. The straight rods (part # TR100-S) were tested as loading against the curvature of the lordotic rod artificially improves the construct stiffness. Crosslinks were attached for the static and dynamic compression bending testing only. The worst case construct is shown in Figure 2. Testing was performed at the Knight Mechanical Testing laboratory.

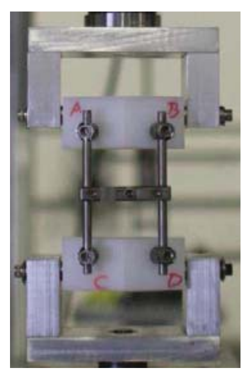


**Figure 2**

### c. Selection of the tests

Based upon the relevant FDA Guidance (*Guidance for Industry and FDA Staff, Spinal System 510(k)s 3 May 2004)*, the static and dynamic axial compression bending, and static torsion according to ASTM

‡ Note: the part number provided in the test report (AV40-5.5) was a provisional number which referenced the screw shaft. The part number above represents the assembled screw.

F1717[6] were chosen to evaluate the Aversion Pedicle Screw System.

In addition, because of the non-threaded region of the screw shaft, screw pullout was performed on the worst case, i.e., smallest diameter screw (5.5mm, part # AV40-5.5[‡]), following ASTM F543.[7]

## 3. Methods

Static compression bending tests were performed on six construct specimens under displacement control at 25mm per minute until contact of the screw housing and test block occurred. Static torsion tests were performed on six construct specimens under displacement control at 60° per minute until a maximum of 60° was reached. UHMWPE test blocks were constrained to prevent rotation about the loading hinge pin and a 0N axial compressive load was maintained throughout the test.

Compression bending fatigue tests were successfully conducted on six construct specimens at an R of 10 (for each load level). A specimen was dynamically loaded until a fracture or slippage of an implant component occurred, at which time the final cycle count was recorded. If failure had not occurred by runout (five million cycles) the test was stopped and the specimen recorded as a non-failure.

Screws were manually inserted to a depth of 35mm into a 20 pcf polyurethane foam block conforming to ASTM F1839.[8] A tensile axial displacement was applied to a rod affixed within the screw head at 5mm/minute until the screw was completely extracted from the block.

## 4. RESULTS

### a. Static compression bending

Means (± 1 standard deviation [SD]) for the compression test results are shown below in Figure 2 for the Aversion construct (**AV**)[1] and predicate systems as reported by Stanford et al[3] (where **MM-ti** ≡ titanium Moss® Miami, DePuy AcroMed – K992168 / K022623) and **Syn-o** ≡ Synergy VLS open screw, Interpore Cross International – K950099 / K974749 / K011437). Mean values are provided in the base of each column.

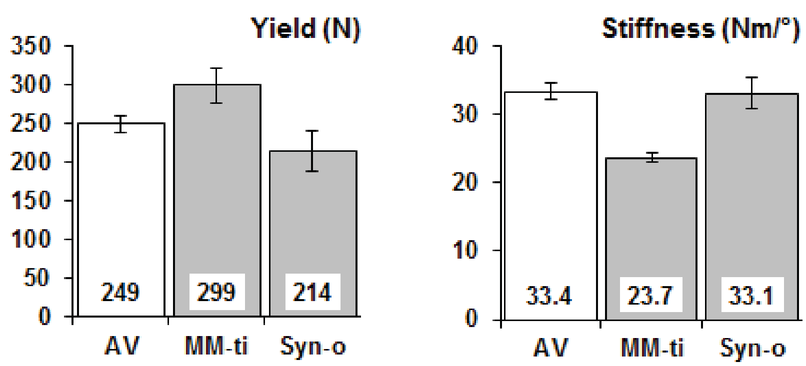


**Figure 3 Static compression bending results comparison for the K7 Aversion (AV) and predicate systems (white bar data from Ref. 1 and gray bar data from Ref. 3).**

## b. Dynamic compression bending

The endurance limit (5Mcyc runout) for the Aversion constructs was 180N (n=2).[1] The failure modes included both rod (n=3) and pedicle screw (n=1) fracture. No specimen failed by slippage.

The Aversion fatigue data with trendline (bold, dashed) is shown below in Figure 3. Note: the curve includes the censored data, i.e., all six of the data points were used. The testing reported by Stanford et al was performed on five specimens at three load levels for each system. The mean life at the tested load level is indicated by the respective solid markers; the standard deviation about that mean is given by the horizontal error bars. Arrows indicate at least one runout specimen. For completeness, the data point values used in Figure 3 are provided in Table 1 below for each system.

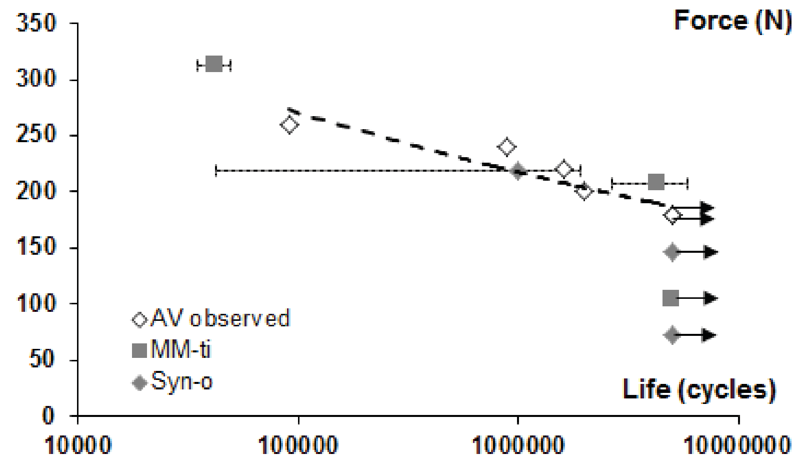


**Figure 4 Dynamic compression bending comparison (open marker [Aversion] data from Ref. 1 and solid marker data from Ref. 3)**

| System | Load level (N) | Mean cycle life (SD) |
|---|---|---|
| **Moss Miami - ti** | 312 | 42,000 (7,000) |
| | 208 | 4,280,000 (1,610,000) |
| | 104 | 5,000,000 (0) |
| **Synergy VLS (open)** | 219 | 987,000 (945,000) |
| | 146 | 5,000,000 (0) |
| | 73 | 5,000,000 (0) |
| **AV** | 260 | 90502 |
| | 240 | 891682 |
| | 220 | 1599793 |
| | 200 | 1987887 |
| | 180 | 5000000 (0) |

**Table 1 Raw data for the charted dynamic results**

## c. Static torsion

Means (± 1 SD) for the torsion test results are shown below in Figure 4 for the K7 Aversion construct (**AV**)[1] and predicate system CD Horizon M10 (Medtronic Sofamor Danek – K031655 / K041460) as reported by Mikles et al.[4] They evaluated the effect of bending moment arm length on construct stiffness. The "+0", i.e., standard length is shown here. Mean values are given in the base of each column.

The torsional yield of the Aversion system was found to be 10.1 ± 0.2Nm however because no published comparative information for this parameter could be found, it is not graphically presented here.

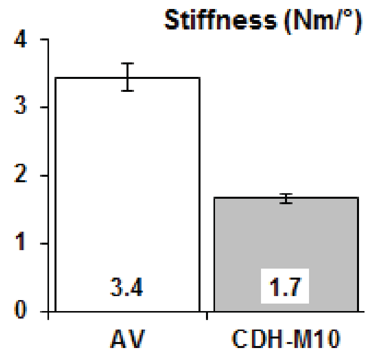


**Figure 5 Static torsion results comparison for Aversion and predicate CD Horizon M10 system.)**

## d. Pullout strength

Peak axial force means (+/- 1SD) for the pullout test results are shown below in Figure 3 for the Aversion modified and predicate pedicle screws as reported by Hsu et al.[5] In this paper the pullout strength of commercially available pedicle screws was evaluated. Screws were inserted to a depth of 35mm into a 20 pcf polyurethane foam block conforming to ASTM F1839. (where numbers indicate pedicle screw outer diameter and **AV** ≡ Aversion, **MM** ≡ Moss® Miami, DePuy AcroMed – K992168 / K022623) and **CD** ≡ CD Horizon, Medtronic Sofamor Danek – K031655 / K041460). Mean values are provided in the base of each column.

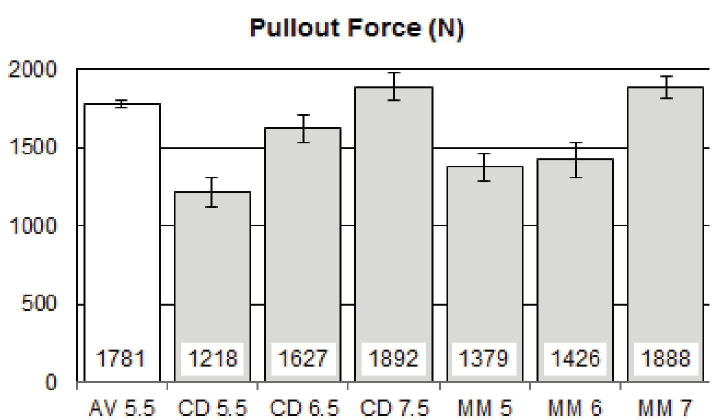


**Figure 6 Pullout strength results for the worst case Aversion modified screw (AV 5.5) compared to predicates. White bar data from Ref. 2 and gray bar data from Ref. 5.**

## 5. Discussion

Static and dynamic compression bending, and static torsion tests were used to characterize the mechanical properties of the worst case Aversion system constructs. Pullout testing was used to assess the effect of the non-threaded portion of the Aversion screw shaft.

The static compression bending results show the Aversion system has yield and stiffness properties comparable to cleared, predicate systems. The dynamic compression bending runout load levels for the Aversion Pedicle Screw System constructs were greater those reported for the both predicate systems. In static torsion, the Aversion system constructs had a greater stiffness than the predicate system. And in axial pullout the Aversion screw outperformed screws having a larger diameter which demonstrated no adverse effects due to the non-threaded region.

Overall, the results show the Aversion Pedicle Screw System to have properties comparable to or better than other commercially available posterior pedicle screw devices.

A few journal articles have been referenced in this summary to support the substantial equivalence of the subject device to predicate devices. The applicability of each of these is as follows:

| Reference | Applicability |
|---|---|
| 3. Stanford RE, Loefler AH, Stanford PM, Walsh WR: Multiaxial Pedicle Screw Designs: Static and Dynamic Mechanical Testing. Spine 29(4):367-375, 2004 | The predicate construct properties reported in these papers were established following earlier versions of the ASTM F1717 standard used for the Aversion system testing. Therefore they serve as direct and valid comparative references to the construct testing of the Aversion screws. |
| 4. Mikles MR, Asghar FA, Frankenburg EP, Scott DS, Graziano GP: Biomechanical Study for Lumbar Pedicle Screws in a Corpectomy Model Assessing Significance of Screw Height. J Spin Disord Tech 17(4):272-276, 2004 | |
| 5. Hsu C-C, Chao, C-K, Wang J-W, Hou S-M, Tsai Y-T, Lin J: Increase of pullout strength of spinal pedicle screws with conical core: biomechanical tests and finite element analyses. J Orthop Res 23(4):788-794, 2005 | The pullout strength of the Aversion screws was performed using the methodology (foam density, insertion depth and loading rate) described in this paper. Therefore it serves as a direct and valid comparative reference to the pullout results of the Aversion screws. |

## 6. Conclusions

In conclusion, this battery of testing has shown the mechanical properties of the Aversion Pedicle Screw System to be substantially equivalent to predicate devices and therefore sufficient for use in the thoracolumbosacral spine.

Karen E. Warden, PhD ______________________ 26 September 2013

President, BackRoads Consulting, Inc.

[1] Chadd N: 478KSL – K7 LLC Lumbar Pedicle Screw and Rod F1717 Final Report, KMT Project numbers: 478KSL1189, 478KSL1191 and 478KSL1193, 23 September 2013.

[2] Chadd N: 421KSL – K7 LLC Lumbar Pedicle Screw ASTM F543 Axial Pullout Final Report, KMT Project number: 421KSL1054, 23 September 2013.