Minimally Invasive Spinal Fusion Using a Transdiscal Screw System

A new minimally invasive transdiscal screw system has been tested on cadaver spines and found to be as effective at stabilization as the currently used bilateral pedicle screw system. When fusing two vertebrate together, the transdiscal screw system only uses two screws as compared to the bilateral pedicle screw system that uses four screws and two rods. Moreover, the transdiscal screw system could be done as a percutaneous surgery, whereas the pedicle screw system fusion is typically done as an open surgery. The transdiscal screw system percutaneous surgery could result in less blood loss, less tissue disruption, less scarring, shorter operation times, as well as shorter recovery times, which makes the device a potential candidate for use in an outpatient setting.

COMMERCIAL OPPORTUNITY

- Traditional spinal fusion has estimated sales of $6B annually, and the bilateral pedicle screw system comprises the largest market share.
- The Spine Industry is attractive as evidenced by the market having a number of players including Johnson & Johnson/Depuy spine/Synthes, Medtronic, Nuvasive, Globus Medical, Stryker, Zimmer, and a number of smaller companies.
- The transdiscal screw allows decompression and compression. Decompression can alleviate pain and pressure on an encroached nerve by lengthening the screw, and compression balances the curvature of the spine by shortening the screw.
- The transdiscal screw system can be placed using a minimally invasive percutaneous procedure. The system can be a stand-alone device or used in combination with an interspinous fusion device, and once placed in the patient would have fewer parts resulting in a lower likelihood of failure.
- Testing has begun for a 510(k) regulatory filing with the FDA.

TECHNOLOGY

To evaluate the feasibility of a novel transdiscal screw in spinal fixation as an alternative to the bilateral pedicle screw system (BPSS) in non-spondylolisthesis cases, an in vitro biomechanical study in lumbar cadaveric spines was completed. Twelve lumbar cadaveric segments (L4-S1) were tested under flexion-extension (FE), lateral bending (LB), and axial rotation (AR). Four treatments were simulated as follows: (1) intact, (2) bilateral facetectomy at L4-L5, (3) transdiscal screw system and (4) BPSS. Range of motion (ROM) and neutral zone stiffness (NZS) were statistically compared among conditions (alpha=0.05). Both fixation constructs significantly reduced ROM and increased NZS ($p<.01$) during LB and AR motion. There was not enough evidence to show any difference between the constructs in terms of ROM and stiffness ($p>0.20$). This preliminary study shows comparable in vitro biomechanical performance of the transdiscal system to the “gold standard” technique BPSS in the immediate stabilization of a complete bilateral facetectomy, which suggests the transdiscal screw would be an alternative to BPSS in the treatment of certain spinal conditions.

PUBLICATION/PATENT

- PCT patent application filed 10/5/12 for Dr. Vrionis, Dr. Aghayev, Ms. Gonzalez-Blohm, and Mr. Doulgeris
- FD Vironis et al., *Spine Journal*, November 2013 published online

CONTACT

Haskell Adler PhD MBA
Senior Licensing Manager
Haskell.Adler@Moffitt.org
(813) 745-6596

LICENSING OPPORTUNITY

MOFFITT CANCER CENTER

11MA021.2014.02