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August 28, 2012

Sara J. Anderson,
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave.
Building 66, Rm. 1611
Silver Spring, MD 20993-0002

RE: Classification of posterior cervical screws, including pedicle and lateral mass screws [Docket No. FDA-2012-N-0001] FDA Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

Dear Ms. Anderson:

The American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves appreciate the opportunity to provide comments to the Food and Drug Administration in advance of the meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Committee regarding the classification of posterior cervical screws.

Currently, these screw devices are approved for use in the thoracic spine and are classified as a Class II device. Their use in the posterior cervical spine is considered off-label, with respect to the products' FDA-approval and labeling. Given the benefits to neurosurgical patients -- due to the anatomical and biomechanical advantages over current FDA approved techniques -- the posterior cervical screws have become the standard of care in managing trauma, degenerative disease, and deformity. **We therefore request that posterior cervical screws, including pedicle and lateral mass screws, remain FDA Class II devices. Additionally, we recommend that the manufacturers provide data to the FDA for on-label use of these screw devices in the posterior cervical spine.**

We would like to review what we feel are the key advantages of the posterior cervical screw, not only from an anatomical and biomechanical perspective, but in the broader context of the experience in the literature. Introduced and popularized by Roy-Camille and Magerl in the 1970's, posterior cervical screws have been rapidly adopted in the ensuing decades by spine surgeons in the U.S. and across the globe for stabilization and arthrodesis of the cervical spine. The current FDA-approved cervical fixation techniques include spinal wiring and laminar hooks. While both of these techniques allow for stabilization of the spine for arthrodesis, they limit the capacity to decompress the neural elements, require more spinal levels to be operated on, and do not offer 360-degree stabilization. The very nature of both of these techniques mandates preservation of the lamina; laminar removal is often needed for spinal decompression, for a point of fixation. Posterior cervical screws provide the capacity for the surgeon to perform a wide decompression of the spinal cord and nerve roots without compromising a primary fixation point. It is a tremendous advantage to the surgeon to simultaneously perform a wide decompression without compromising the ability to achieve rigid fixation.

With regard to biomechanics, the cervical screw within either the lateral mass or the pedicle is more effective in resisting lateral bending and axial rotation than laminar hooks(6). Maintaining rigidity optimizes an environment for arthrodesis and minimizes the risk of a subsequent need for revision. Collectively, the ability to decompress and stabilize the cervical spine simultaneously from the posterior approach has revolutionized our treatment of the cervical spine. Many studies have confirmed the utility and safety of posterior cervical screws (1, 2, 8, 11, 16).

One of the larger studies by Heller et al. in 1995(8) reported the use of 654 lateral mass screws in 78 patients, with two-year follow-up. Complication rates as a function of the number of screws inserted included: nerve root injury, 0.6%; facet violations, 0.2%; vertebral artery injury, 0%; broken screw, 0.3%; screw avulsion, 0.2%; and screw loosening 1.1%. Complications as a percentage of the number of cases performed included: spinal cord injury, 2.6%; iatrogenic foraminal stenosis, 2.6%; broken plate, 1.3%; lost reduction, 2.6%; adjacent segment degeneration, 3.8%; infection, 1.3%; and pseudoarthrosis, 1.4%. These complication rates are consistent with standard protocols in the overall treatment of cervical spine disease. Wellman et al. in 1998(16) reported the use of 281 lateral mass screws in 43 consecutive patients. These authors did not identify either nerve injuries or vertebral artery injuries.

Regarding cervical pedicle screws, a large study was reported by Abumi et al. in 2000(3), with 712 cervical pedicle screws used in 180 consecutive patients. In this series there was a sole vertebral artery injury that did not result in a neurological deficit, and 3 cases of radiculopathy. This further corroborates the evidence that cervical pedicle screws may be safely utilized.

The use of this technique has led to the rapid acceptance of posterior C1-C2 fusions for atlantoaxial instability. Numerous studies report successful use of C1 lateral mass screws and C2 pars/pedicle screws (4, 7, 10, 12). For the elderly patient with an acute, unstable odontoid fracture, posterior fixation has become more popular than any other technique in Level 1 Trauma Centers and has been associated with fewer complications.(15)

Technical advances have led to the popular use of cervical translaminar screws (5, 9, 13, 14). When the anatomy makes it feasible, especially at the C2 level, C2 translaminar screws have proven to be useful and may reduce the risk of neurovascular injury with solid fixation.

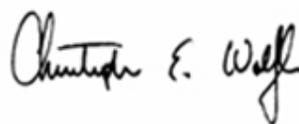
In summary, the anatomical and biomechanical advantages, the current body of literature and the experience in current clinical practice collectively demonstrate that posterior cervical screws have become the standard of care when instrumenting the posterior cervical spine. **We respectfully request that posterior cervical screws, including pedicle and lateral mass screws, remain FDA Class II devices and request that the manufacturers provide data to the FDA for on-label use of these screw devices in the posterior cervical spine.**

Again, thank you for this opportunity to comment. If you have any questions, please feel free to contact Joseph Cheng, MD (joseph.cheng@vanderbilt.edu), Chairperson, AANS/CNS Section on Disorders of the Spine and Peripheral Nerves.

Sincerely,



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References

1. Abumi K, Itoh H, Taneichi H, Kaneda K: Transpedicular screw fixation for traumatic lesions of the middle and lower cervical spine: description of the techniques and preliminary report. **J Spinal Disord** 7:19-28, 1994.
2. Abumi K, Kaneda K: Pedicle screw fixation for nontraumatic lesions of the cervical spine. **Spine (Phila Pa 1976)** 22:1853-1863, 1997.
3. Abumi K, Shono Y, Ito M, Taneichi H, Kotani Y, Kaneda K: Complications of pedicle screw fixation in reconstructive surgery of the cervical spine. **Spine (Phila Pa 1976)** 25:962-969, 2000.
4. Campanelli M, Kattner KA, Stroink A, Gupta K, West S: Posterior C1-C2 transarticular screw fixation in the treatment of displaced type II odontoid fractures in the geriatric population--review of seven cases. **Surg Neurol** 51:596-600; discussion 600-591, 1999.
5. Dorward IG, Wright NM: Seven years of experience with C2 translaminar screw fixation: clinical series and review of the literature. **Neurosurgery** 68:1491-1499; discussion 1499.
6. Espinoza-Larios A, Ames CP, Chamberlain RH, Sonntag VK, Dickman CA, Crawford NR: Biomechanical comparison of two-level cervical locking posterior screw/rod and hook/rod techniques. **Spine J** 7:194-204, 2007.
7. Hamilton DK, Smith JS, Sansur CA, Dumont AS, Shaffrey CI: C-2 neurectomy during atlantoaxial instrumented fusion in the elderly: patient satisfaction and surgical outcome. **J Neurosurg Spine** 15:3-8.

8. Heller JG, Silcox DH, 3rd, Sutterlin CE, 3rd: Complications of posterior cervical plating. **Spine (Phila Pa 1976)** 20:2442-2448, 1995.
9. Jea A, Sheth RN, Vanni S, Green BA, Levi AD: Modification of Wright's technique for placement of bilateral crossing C2 translaminar screws: technical note. **Spine J** 8:656-660, 2008.
10. Jeanneret B, Magerl F: Primary posterior fusion C1/2 in odontoid fractures: indications, technique, and results of transarticular screw fixation. **J Spinal Disord** 5:464-475, 1992.
11. Kotani Y, Cunningham BW, Abumi K, McAfee PC: Biomechanical analysis of cervical stabilization systems. An assessment of transpedicular screw fixation in the cervical spine. **Spine (Phila Pa 1976)** 19:2529-2539, 1994.
12. Mummaneni PV, Lu DC, Dhall SS, Mummaneni VP, Chou D: C1 lateral mass fixation: a comparison of constructs. **Neurosurgery** 66:153-160.
13. O'Brien JR, Gokaslan ZL, Riley LH, 3rd, Suk I, Wolinsky JP: Open reduction of C1-C2 subluxation with the use of C1 lateral mass and C2 translaminar screws. **Neurosurgery** 63:ONS95-98; discussion ONS98-99, 2008.
14. Parker SL, McGirt MJ, Garces-Ambrossi GL, Mehta VA, Sciubba DM, Witham TF, Gokaslan ZL, Wolinsky JP: Translaminar versus pedicle screw fixation of C2: comparison of surgical morbidity and accuracy of 313 consecutive screws. **Neurosurgery** 64:343-348; discussion 348-349, 2009.
15. Smith HE, Vaccaro AR, Maltenfort M, Albert TJ, Hilibrand AS, Anderson DG, Harrop J, Fehlings MG, Kopjar B, Brodke DS, Arnold PM, Shaffrey CI: Trends in surgical management for type II odontoid fracture: 20 years of experience at a regional spinal cord injury center. **Orthopedics** 31:650, 2008.
16. Wellman BJ, Follett KA, Traynelis VC: Complications of posterior articular mass plate fixation of the subaxial cervical spine in 43 consecutive patients. **Spine (Phila Pa 1976)** 23:193-200, 1998.