

## Neurosurgical forum

### Letters to the editor

#### Lateral mass screw fixation in the cervical spine

TO THE EDITOR: We read with interest the article by Kawabata et al.<sup>15</sup> (Kawabata S, Watanabe K, Hosogane N, et al: Surgical correction of severe cervical kyphosis in patients with neurofibromatosis Type 1. Report of 3 cases. *J Neurosurg Spine* 18:274–279, March 2013). Reconstructive spinal surgery has undergone a tremendous transformation in the last several decades, with improvements in imaging, biologics, and implant technologies. Not uncommonly, the spine surgical community may abandon an older technique when it becomes evident that a new approach or technology is clearly safer or superior. Comparative clinical trials of older versus newer techniques are often limited to a small number of cases published over a short period of time and are typically not performed under the rigors of randomized controlled study sufficient to meet the standards set by governmental agencies to gain regulatory approval. Lateral mass screw fixation (LMSF) of the cervical spine, which has generally supplanted older wiring and hook cervical fixation methods, is one such technique. The article by Kawabata et al. published in this journal last year is a clear example of the use of cervical screw-rod fixation to treat complex deformity in a small series of patients with cervical kyphosis secondary to neurofibromatosis Type 1.<sup>15</sup> The severity of the deformity and the poor bone quality of the patients in this series would make any of the older fixation techniques clearly inadequate to maintain deformity correction and long-term stability.

Lateral mass screws have been implanted posteriorly in the cervical spine for nearly three-quarters of a century.<sup>10</sup> After first being reported in Europe by Roy-Camille in 1979, this technique of screw placement was modified by Magerl prior to its introduction in the United States in the 1980s.<sup>3,19,20</sup> Initial systems consisted of simple bone screws placed through holes or slots in plates.<sup>13,19,20</sup> This form of fixation has been studied extensively and found to be biomechanically superior to wiring techniques in various unstable spinal fusion models.<sup>6,23,24</sup> The Roy-Camille lateral mass screw-plate technique was introduced into the US by Paul Cooper, M.D. in the late 1980s, and the use of these systems in North America has grown steadily ever since.<sup>7,9</sup> In the 1990s, second-generation plating systems emerged, which allowed more versatility in screw position through the plate holes. Despite this evolution in the implant design, several disadvantages of lateral mass screw plating systems persisted. These include anatomical restraints of the plating system with fixed hole-hole

distances, a non-rigid connection of the screw to the plate, and the inability to compress or distract along the plate. Subsequent development of a screw-rod system solved these problems. Evolution of these LMSF systems occurred based upon an increasing body of clinical evidence and experience.<sup>1,4,8,9,12,14,16,22,26</sup> Despite this vast clinical experience, no system has been approved by the Food and Drug Administration (FDA) for “on label” usage in the subaxial cervical spine for the specific purpose of lateral mass fixation. Unfortunately this non-approval status constrains the ability of experienced spinal surgeons from educating others regarding appropriate surgical indications, techniques, and practices.

This non-FDA approval status of LMSF mirrors that of pedicle screw fixation in the thoracolumbar and lumbosacral spine.<sup>10,28</sup> The FDA denied the initial 510(k) applications for pedicle screws submitted in the mid-1980s and at the time was not convinced that there was a “pre-enactment” product on which to base a substantially equivalent claim. The FDA did, however, grant a 510(k) clearance for the use of “bone screws” in the sacrum and anterior vertebral bodies of the spine. As of 1994, the FDA had not granted any manufacturer a 510(k) clearance or pre-market approval (PMA) application for a bone screw indicated for pedicle fixation. Spinal implant companies were thus prohibited from marketing screws for this indication and were prohibited from supporting educational activities surrounding its application.<sup>10</sup> Similar to the current situation with lateral mass screws, this policy restricted a surgeon’s ability to teach pedicle screw implantation techniques, particularly under the auspices of corporate sponsorship from implant manufactures. This prevented corporate support of instructional courses sponsored by recognized academic spine societies including the Cervical Spine Research Society (CSRS), the North American Spine Society (NASS), the Scoliosis Research Society (SRS), American Association of Neurological Surgeons (AANS), and Congress of Neurological Surgeons (CNS). The International Meeting on Advanced Spine Techniques (IMAST) was initiated by the SRS in the early 1990s in order to support the free interchange of information on new spine technologies. All of the IMAST meetings to date have been outside of the US primarily to allow the discussion and teaching of newer technologies without the fear of reprisal from the FDA regarding promotion of “off-label” technologies.

To deal with this pedicle screw “dilemma,” a Scientific Committee was formed to develop and oversee the “Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar, and Sacral Spine Fusions.” The Scientific Committee consisted of representatives from

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NASS, the American Academy of Orthopaedic Surgeons (AAOS), the SRS, the AANS, and the CNS, as well as a biostatistician and an industry representative. The Committee's work was funded through a group of companies under the auspices of the Spinal Implant Manufacturers' Group (SIMG), which had no control over the expenditures, decisions regarding data acquisition, analysis, or reporting. Members of the FDA Office of Device Evaluation worked closely with the Scientific Committee and participated in all decisions. All data metrics were collected and validated by an independent biostatistician who assured the validity of the data and the accuracy of the data-processing analyses while protecting confidentiality for the patients and physicians. This unified effort between the FDA, medical societies, and industry was unprecedented. A special meeting of the FDA Orthopaedic and Rehabilitation Devices Advisory Panel was held in Gaithersburg, Maryland in July 1994. Members of the Committee as well as other interested parties were allowed to speak over the course of this meeting. Following this meeting the Advisory Panel unanimously recommended to the FDA that pedicle screw devices be reclassified from Class III to Class II for the treatment of degenerative spondylolisthesis and fractures.<sup>10</sup> This recommendation ultimately led to the full approval by the FDA for pedicle screw fixation devices for "conditions with significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion."<sup>18</sup>

While similar, the situation with LMSF is not identical to the pedicle screw fixation dilemma. Despite the focus in the thoracolumbar spine, there has been little effort to pursue strategies to obtain "down-classification" of LMSF devices for the "on-label" use in the subaxial cervical spine. The CSRS, other professional societies, orthopedic surgeons, neurosurgeons, and representatives from industry believe that the time has come for change regarding the regulatory status of LMSF devices. At the Spring Board Meeting of the CSRS in April, 2011, then CSRS President Sanford Emery, M.D., tasked the CSRS Special Projects Committee with performing a systematic review and/or meta-analysis of the existing literature regarding LMSF with the ultimate goal of achieving "on-label" classification for LMSF devices. This reclassification would allow experienced cervical spinal surgeons the freedom to educate our colleagues in the performance of LMSF, which has become the standard of care for stabilizing the cervical spine from a posterior approach for a variety of surgical indications. The CSRS Special Projects Committee asked that independent research organizations be contracted to perform this project. The CSRS board agreed with the recommendation. After requests for proposals were sought, the Committee recommended that Spectrum Research, Incorporated (SRI), an independent organization specializing in comparative-effectiveness reviews, be contracted to conduct this study. This recommendation was ratified by the board with funding from the CSRS Research Fund to support the study. This study was thus completed under the direction of Joseph

R. Dettori, M.P.H., Ph.D., of SRI with input from the Committee with regard to formulating the key questions and the PICO (patient, intervention, comparison, and outcomes) tables. The results were tabulated by the research staff from SRI. The Committee provided further input to refine any significant but unaddressed questions. The final decision regarding the inclusion and exclusion of the comparative literature, however, was determined by a priori criteria and evaluated independently by 3 investigators. The Committee believes that the results of this effort are a truly unbiased look at the best available evidence regarding LMSF.<sup>5</sup>

The most feared direct complications of LMSF are injuries to the vertebral arteries and nerve roots. Screw pull-out, implant disengagement, or fracture at the instrumented or adjacent segments are concerns, but they generally do not result in irreversible sequelae. The original lateral mass fixation technique as described by Roy-Camille involved a "straight ahead" trajectory in both the sagittal and axial planes,<sup>19</sup> with a starting point directly in the center of the lateral mass. The technique was unicortical to minimize the risk of neurovascular injury. Over time, Roy-Camille modified the technique with a 10° lateral angulation in the axial plane in order to further avoid neurovascular injuries.<sup>7</sup> Magerl described a more lateral (20°–30°) angulation and a slightly more medial and cephalad starting point with his technique. Additionally, a more superiorly angulated sagittal plane would maximize purchase, facilitate insertion, and further minimize the risk to the vertebral artery and nerve root.<sup>13</sup> When these techniques were critically compared in a cadaveric study, the Roy-Camille technique was typically more accurate with regard to zone of placement and possible nerve root risk than the Magerl technique.<sup>11</sup> Many others have since slightly modified the recommended insertion trajectory and starting points.<sup>2,3,26,27</sup> While nerve root injuries and secondary radiculopathy are reported with LMSF, most reports indicate resolution of any neurological deficit and pain with screw removal. Vertebral artery injury is extremely rare with lateral mass screw placement in the subaxial spine.

This systematic review is not without significant limitation. The papers included for review employ a variety of LMSF techniques for a variety of diagnoses with variable length of follow-up and variable outcome measures.<sup>5</sup> Post-operative CT scanning to evaluate screw placement accuracy was not performed routinely.<sup>1,14,22</sup> Stratification of complications in a manner meaningful to this review was challenging, with respect to comparison between papers and even stratification within papers. Furthermore, acceptable comparative trials with different posterior fusion techniques (wiring, clamps) were limited to only 2 studies.<sup>17,21</sup> Only one of these studies documented fusion rates.<sup>17</sup> This sole comparative trial, however, supported the hypothesis that fusion rates are at least equivalent, if not superior to control (posterior wiring) methods of internal fixation.<sup>17</sup> Despite these limitations, there is sufficient information in the CSRS systematic review to gain reasonable insight into the safety and effectiveness of LMSF.<sup>5</sup>

The results of the CSRS study show that LMSF using modern implant systems is safe, with an acceptably low incidence of neurovascular injury. There is no evidence

from this review that the incidence of infections, hematomas, deaths, or unspecified neurologic events is related to LMSF. Intuitively, the use of unicortical screw fixation would pose less risk to the neurovascular structures than bicortical fixation, at the cost of reduced screw purchase and increased incidence of screw failure. This study, however, was unable to establish evidence to support this hypothesis, as the data in the reviewed papers either did not specify the technique employed or did not stratify screw failure as a function of cortical purchase. While comparative data are relatively scant, it did not appear that LMSF techniques are any less or more effective than wire fixation techniques in achieving solid fusion.

On September 21, 2012, a meeting of the FDA's Orthopaedic and Rehabilitation Devices Panel was held in Gaithersburg, Maryland.<sup>25</sup> This meeting was held in response to a petition from the Orthopedic Surgical Manufacturers Association (OSMA) with testimony from OSMA presenters (Susan Krasny, Ph.D., member of the OSMA Board of Directors; John G. Heller, M.D.; Alexander J. Ghanayem, M.D.; and Sharon Starowicz, OSMA president), FDA presenters (Caroline Rhim, Ph.D., Vincent J. Devlin, M.D., and Genevieve Hill, B.S.) and 6 open public hearing speakers testifying on behalf of 6 professional societies and 1 research organization (Todd J. Albert, M.D., SRS; Paul A. Anderson, M.D., AAOS; William Welch, M.D., CNS and AANS; Gregory Przybylski, M.D., NASS; Lee H. Riley, M.D., CSRS; and Diana Zuckerman, Ph.D., National Research Center for Women and Families [NRCWF]).

Testimony began with a presentation by Susan Krasny outlining the history and current status of FDA regulation of pedicle screws. This was followed by a presentation from John Heller on the evolution and current status of LMSF techniques. He pointed out the lack of "equipoise" between LMSF and other fixation techniques in the posterior cervical spine, which rendered the performance of a randomized controlled trial of LMSF in comparison to other techniques essentially impossible to perform. This was followed by Alexander Ghanayem's presentation of OSMA's review of the published literature regarding the safety and effectiveness of cervical lateral mass and pedicle screws. The last section of the OSMA testimony was a presentation by Sharon Starowicz on the proposed regulatory controls for cervical screws.

The FDA representatives presented their own comprehensive review of cervical pedicle and lateral mass screws. They followed with a recommendation to down-classify lateral mass and pedicle screws used in the cervical spine to Class II devices. It was noted that lateral mass screws were heretofore considered non-classified (that is, not Class III) devices, as there were no predicate devices prior to 1976. Not only did the FDA testimony accept the OSMA petition's recommendation, they also expanded the recommendation to include pediatric age groups and include fixation to the upper thoracic spine and the use of screws in a variety of trajectories (C-2 pedicle, C-2 pars interarticularis, C-2 and C-7 intralaminar, and C1-2 transarticular). The use of posterior screws for limited non-fusion indications (tumors) was also recommended.

Testimony from CSRS, SRS, AAOS, AANS, CNS,

and NASS was in support of down-classifying cervical lateral mass and pedicle screws to Class II devices. Lee Riley III formally presented the results of the CSRS systematic review, and these same data were presented in summary form by Todd Albert. The only unsupportive testimony in the open public hearing section was from Diane Zuckerman from the NRCWF who testified that randomized controlled trials of cervical screw systems should be performed before reclassification to the Class II category. She supported her testimony with data from a single recent Japanese study that noted a high complication rate with the use of cervical pedicle screws.

During the several question and answer periods (as well as the panel deliberations), a lively discussion was held on several points. One of the questions concerned whether or not subaxial pedicle screws (C3-6) required special controls beyond that of lateral mass screws. Another question focused on the use of these devices in the pediatric population. Alvin H. Crawford, M.D., a pediatric orthopedic surgeon and a non-voting panel member, noted the paucity of data regarding the use of cervical screw fixation in children but nevertheless felt that reclassification was imperative in the pediatric population.

Finally, after several hours of open deliberation with comments from the panel members including non-voting member surgeons, a patient representative, an industry representative, and a consumer representative, the FDA panel unanimously voted to accept the FDA proposal to classify cervical pedicle screws as Class II devices with the recommendation to identify C3-6 pedicle screw placement as a "more challenging technique" than lateral mass screw placement. They also followed the recommendation that these devices were to be used as adjuncts to fusion only, with the limited exception of cases of advanced tumors where fixation could be achieved without mandating attempted fusion.

The next steps in reclassification will consist of a public posting of the proposed rule, marking the commencement of a 90-day public comment period. After closure of the comment period, the final rule classifying these devices will be issued. The time frame for this can be several months to several years. As of the writing of this letter, the public comment period has not yet begun. Of note, if the final rule classifies posterior cervical screw-rod fixation systems as Class II, FDA approval for future similar systems will follow the 510(k) process.

On the basis of this review, the CSRS Special Projects Review Committee does in fact believe that the data provide sufficient evidence for the FDA to consider down-classification of lateral mass fixation screws to Class II devices for the treatment of unstable cervical fractures and fracture dislocation, the stabilization of the cervical spine rendered unstable by cervical laminectomy, pseudarthrosis, and other indications. LMSF has become a standard technique in the armamentarium of most spine surgeons. Experienced and skilled spinal surgeons can use this technique safely to stabilize the cervical spine. The CSRS Special Projects Committee feels that it is imperative that these surgeons be given the ability to teach other less experienced surgeons LMSF techniques in order to optimize patient care. We agree with



the even broader recommendations of the FDA panel for the down-classification of LMSF systems as well as other cervical spine screw systems as described above.

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### Disclosure

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RESPONSE: We thank Dr. Coe and coauthors for referring to our work in their letter. We reported 3 cases of neurofibromatosis Type 1 presenting with severe cervical kyphosis and dystrophic changes, which were successfully managed by correction and fusion surgery. Reconstruction of severe cervical kyphosis in these cases posed tremendous technical challenges, particularly because the patients lacked osseous anchoring points for instrumentation due to severe dystrophic changes in lateral masses, laminae, and pedicles. We placed screws at levels where the lateral masses and pedicles seemed to accept screw placement and were able to achieve good correction of severe kyphosis. Conventional hooks and sublaminar wires placed on the thin laminae might not have been effective. Thus, as illustrated in our cases, lateral mass and pedicle screws are often effective and sometimes indispensable for fusion surgery in cases of cervical spinal disorders accompanied by instability and deformity.

We read with great interest Dr. Coe and colleagues' description of their effort to have cervical lateral mass and pedicle screws down-classified to Class II devices. We believe that lateral mass and pedicle screws can ben-

efit patients with cervical spinal disorders if they are appropriately used by well-trained surgeons.

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### Tubular retractor selection in minimally invasive spinal tumor resection

TO THE EDITOR: We read with great interest the article by Nzokou et al.<sup>5</sup> (Nzokou A, Weil AG, Shedid D: Minimally invasive removal of thoracic and lumbar spinal tumors using a nonexpandable tubular retractor. Clinical article. *J Neurosurg Spine* 19:708–715, December 2013). There has been tremendous advancement in minimally invasive surgery (MIS) techniques and technologies over the past 15 years.<sup>6</sup> Most spine surgeons today are familiar with MIS techniques, and many routinely perform MIS in their clinical practice to treat degenerative conditions of the spine. The application of MIS techniques in treating intradural spinal tumors was first reported by Tredway and colleagues<sup>7</sup> in 2006. Since then, several other reports have further demonstrated the safety and efficacy of MIS techniques when using expandable tubular retractors in selected groups of patients with intra- or extradural spinal neoplasms.<sup>1–4</sup> Nzokou et al. reported their experience in using 18-mm nonexpandable tubular retractors for spinal tumor resection in a series of 13 patients that included 4 intradural cases.

We applaud the excellent clinical results that the authors obtained using MIS techniques to treat these less common spinal pathologies. However, we would like to point out several potential issues with using 18-mm nonexpandable tubular retractors in the resection of spinal tumors. First, a fundamental principle for any operative approach—minimally invasive or open surgery—is the ability to provide a satisfactory exposure and an adequate surgical corridor to reach the intended pathology. This is no different when dealing with spinal tumor resection during MIS. The selection of tubular retractor should be based on the size, location, and type of the lesion. The ideal tubular retractor should provide adequate exposure and working space while minimizing tissue trauma. The authors illustrated a case of T12–L1 intradural schwannoma in Fig. 3; although not mentioned, the tubular retractor appears to be larger than 18 mm. The lack of full visualization of such an intradural tumor during resection may increase the risk of unnecessary retraction and manipulation of the tumor and, possibly, of the spinal cord if the lesion is located in the cervical or thoracic spine. Repositioning tubular retractors during tumor resection may also be hazardous to the patient, especially when treating intradural lesions with the spinal cord exposed. Second, restricted exposure typically results in intraleisional piecemeal tumor resection, which may be of little consequence when treating nerve sheath tumors but could