Lateral mass screw fixation in the cervical spine

To The Editor: We read with interest the article by Kawabata et al.13 (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 rigorous 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 I.15 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.10 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 1989, this technique of screw placement was modified by Roy-Camille in 1979, and this technique of screw placement was modified by Magerl prior to its introduction in the United States in 1989. Initial systems consisted of simple bone screws placed through holes or slots in plates.13,19,20 This form of fixation has been studied extensively and found to be biomechanically superior to wiring techniques in various unstable spinal fusion models.8,25,26 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.18 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.1,4,8,9,12,14,16,22,26 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.10,28 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 premarket 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.29 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 manufacturers. 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. 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.”

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 an 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.

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, 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. 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. 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. Many others have since slightly modified the recommended insertion trajectory and starting points. 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 limitations. 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. Postoperative CT scanning to evaluate screw placement accuracy was not performed routinely. 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. Only one of these studies documented fusion rates. 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. Despite these limitations, there is sufficient information in the CSRS systematic review to gain reasonable insight into the safety and effectiveness of LMSF.

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