Lateral mass screw fixation in the cervical spine

To The Editor: We read with interest the article by Kawabata et al.[15] (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.[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 the 1980s.[3,19,20] 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.[6,23,24] 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.[7,9] 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.[10] 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

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.[10] 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."[18]

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 devises. 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.[5]

The most feared direct complications of LMSF are injuries to the vertebral arteries and nerve roots. Screw pullout, 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,[19] 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.[7] 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.[13] 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.[11] Many others have since slightly modified the recommended insertion trajectory and starting points.[2,3,26,27] 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.[5] Postoperative CT scanning to evaluate screw placement accuracy was not performed routinely.[1,14,22] 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.[17,21] Only one of these studies documented fusion rates.[17] 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.[17] Despite these limitations, there is sufficient information in the CSRS systematic review to gain reasonable insight into the safety and effectiveness of LMSF.[5]

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.[25] 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 follow 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 Ghaneyem'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 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.

Jeffrey D. Coe, M.D.
Silicon Valley Spine Institute
Campbell, CA
Alexander R. Vaccaro, M.D., Ph.D.
The Rothman Institute
Philadelphia, PA
Andrew T. Dailey, M.D.
University of Utah
Health Science Center
Salt Lake City, UT
Rick C. Sasso, M.D.
Indiana Spine Group
Carmel, IN
Steven C. Ludwig, M.D.
University of Maryland Medical System
Baltimore, MD
James S. Harrop, M.D.
Thomas Jefferson University Hospital
Philadelphia, PA
Joseph R. Dettori, M.P.H., Ph.D.
Spectrum Research, Inc.
Tacoma, WA
Christopher I. Shaffrey, M.D.
University of Virginia
Charlottesville, VA
Sanford E. Emery, M.D., M.B.A.
West Virginia University
Morgantown, WV
Michael G. Fehlings, M.D., Ph.D.
University of Toronto
Toronto, ON, Canada

Disclosure

Dr. Coe reports an ownership interest in Phygen, Implantium, and BASG; a consultant relationship with NuVasive, SI Bone, DePuy-Synthes, Medtronic, Trans1, and Benvenue Medical; receiving clinical or research support from NuVasive, Medtronic, NuTech, and CSRS. Dr. Vaccaro reports serving on the scientific advisory board, board of directors, and/or committees for AO Spine, Innovative Surgical Design, Association of Collaborative Spine Research, and Spinicity; receiving institutional or educational grants from Stryker Spine, NuVasive, and Cerapedics; receiving royalty payments from DePuy, Medtronic, Stryker Spine, Biomet Spine, Globus, Aesculap, NuVasive; acting as a consultant for Stout Medical, Gerson Lehrman Group, Guidepoint Global, MEDACorp, Innovative Surgical Design; and having direct stock ownership in Replication Medica, Globus, K-2 Medical, Paradigm Spine, Stout Medical, Spine Medica, Computational Biodynamics, Progressive Spinal Technologies, Spinology, Small Bone Innovations, Cross Current, Syndicom, In Vivo, Flagship Surgical, Advanced Spinal Intellectual Properties, Cytonics, Bonovo Orthopaedics, ElectroCore, Gamma Spine, Location Based Intelligence, FlowPharma, R.S.I., Rothman Institute and Related Properties, Innovative Surgical Design, and Spinicity. Dr. Dailey reports a consultant relationship with Biomet and receiving an honorarium for teaching from AO North America. Dr. Sasso reports a patent holder relationship with Medtronic. Dr. Ludwig reports a consultant relationship with DePuy Synthes Spine; a patent holder relationship with DePuy Spine and Globus Medical; and ownership in Spinicity, ASIP, and ISD. Dr. Harrop reports a consultant relationship with DePuy Spine. Dr. Shaffrey reports a consultant relationship with Biomet, Globus, Medtronic, NuVasive, and Stryker, and being a patent holder with and receiving royalties from Biomet and Medtronic. Dr. Fehlings reports that he acts as a consultant for, receives royalties from, and has been paid for presentations by DePuy Spine.

References

1. Al Barbarawi MM, Audat ZA, Obeidat MM, Qudsieh TM, Dabbas WF, Obaidat MH, et al: Decompressive cervical laminectomy and lateral mass screw-rod arthrodesis. Surgical analysis and outcome. **Scoliosis 6:**10, 2011
2. An HS, Gordin R, Renner K: Anatomic considerations for plate-screw fixation of the cervical spine. **Spine (Phila Pa 1976) 16 (10 Suppl):**S548–S551, 1991
3. Anderson PA, Henley MB, Grady MS, Montesano PX, Winn HR: Posterior cervical arthrodesis with AO reconstruction plates and bone graft. **Spine (Phila Pa 1976) 16 (3 Suppl):**S72–S79, 1991
4. Cabraja M, Abbushi A, Koeppen D, Kroppenstedt S, Woiciechowsky C: Comparison between anterior and posterior decompression with instrumentation for cervical spondylotic myelopathy: sagittal alignment and clinical outcome. **Neurosurg Focus 28(3):**E15, 2010
5. Coe JD, Vaccaro AR, Dailey AT, Skolasky RL, Sasso RC, Brodt ED, et al: Lateral mass screw fixation in the cervical spine: a systematic review. **J Bone Joint Surg Am 95:**2136–2143, 2013
6. Coe JD, Warden KE, Sutterlin CE III, McAfee PC: Biomechanical evaluation of cervical spinal stabilization methods in a human cadaveric model. **Spine (Phila Pa 1976) 14:**1122–1131, 1989
7. Cooper PR, Cohen A, Rosiello A, Koslow M: Posterior stabilization of cervical spine fractures and subluxations using plates and screws. **Neurosurgery 23:**300–306, 1988
8. Eubanks JD, Thorpe SW, Cheruvu VK, Braly BA, Kang JD: Does smoking influence fusion rates in posterior cervical arthrodesis with lateral mass instrumentation? **Clin Orthop Relat Res 469:**696–701, 2011
9. Fehlings MG, Cooper PR, Errico TJ: Posterior plates in the management of cervical instability: long-term results in 44 patients. **J Neurosurg 81:**341–349, 1994
10. Garfin SR: Historical cohort study of pedicle screw fixation in thoracic, lumbar, and sacral spine fusions. **Spine (Phila Pa 1976) 19 (20 Suppl):**2254S–2255S, 1994
11. Heller JG, Carlson GD, Abitbol JJ, Garfin SR: Anatomic comparison of the Roy-Camille and Magerl techniques for screw placement in the lower cervical spine. **Spine (Phila Pa 1976) 16 (10 Suppl):**S552–S557, 1991
12. Highsmith JM, Dhall SS, Haid RW Jr, Rodts GE Jr, Mummaneni PV: Treatment of cervical stenotic myelopathy: a cost and outcome comparison of laminoplasty versus laminectomy and lateral mass fusion. Clinical article. **J Neurosurg Spine 14:**619–625, 2011
13. Jeanneret B, Magerl F, Ward EH, Ward JC: Posterior stabilization of the cervical spine with hook plates. **Spine (Phila Pa 1976) 16 (3 Suppl):**S56–S63, 1991
14. Katonis P, Papadakis SA, Galanakos S, Paskou D, Bano A, Sapkas G, et al: Lateral mass screw complications: analysis of 1662 screws. **J Spinal Disord Tech 24:**415–420, 2011
15. Kawabata S, Watanabe K, Hosogane N, Ishii K, Nakamura M, Toyama Y, et al: Surgical correction of severe cervical kyphosis in patients with neurofibromatosis Type 1. Report of 3 cases. **J Neurosurg Spine 18:**274–279, 2013
16. Liu H, Ploumis A, Schwender JD, Garvey TA: Posterior cervical lateral mass screw fixation and fusion to treat pseudarthrosis of anterior cervical fusion. **J Spinal Disord Tech 25:** 138–141, 2012
17. Lowry DW, Lovely TJ, Rastogi P: Comparison of tension band wiring and lateral mass plating for subaxial posterior cervical fusion. **Surg Neurol 50:**323–332, 1998
18. Muehlbauer E: Spine and the law. Pedicle screws. **Spine J 1:** 152, 2001
19. Roy-Camille R, Saillant G, Bertreaux D, Marie-Anne S: Early management of spinal injuries, in McKibben B (ed): **Recent**

Advances in Orthopedics, ed 3. Edinburgh: Churchill-Livingstone, 1979, pp 57–87
20. Roy-Camille R, Saillant G, Mazel C: Internal fixation of the unstable cervical spine by a posterior osteosynthesis with plates and screws, in Cervical Spine Research Society Editorial Committee: **The Cervical Spine, ed 2.** Philadelphia: J.B. Lippincott, 1989, pp 390–403
21. Shapiro S, Snyder W, Kaufman K, Abel T: Outcome of 51 cases of unilateral locked cervical facets: interspinous braided cable for lateral mass plate fusion compared with interspinous wire and facet wiring with iliac crest. **J Neurosurg 91:**19–24, 1999
22. Stevens QE, Majd ME, Kattner KA, Jones CL, Holt RT: Use of spinous processes to determine the optimal trajectory for placement of lateral mass screws: technical note. **J Spinal Disord Tech 22:**347–352, 2009
23. Sutterlin CE III, McAfee PC, Warden KE, Rey RM Jr, Farey ID: A biomechanical evaluation of cervical spinal stabilization methods in a bovine model. Static and cyclical loading. **Spine (Phila Pa 1976) 13:**795–802, 1988
24. Ulrich C, Woersdoerfer O, Kalff R, Claes L, Wilke HJ: Biomechanics of fixation systems to the cervical spine. **Spine (Phila Pa 1976) 16 (3 Suppl):**S4–S9, 1991
25. US Food and Drug Administration: **Orthopaedic and Rehabilitation Devices Panel meeting transcript.** Annapolis, MD: Free State Reporting (http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM324390.pdf) [Accessed February 5, 2014]
26. Wu JC, Huang WC, Chen YC, Shih YH, Cheng H: Stabilization of subaxial cervical spines by lateral mass screw fixation with modified Magerl's technique. **Surg Neurol 70 Suppl 1:**S1:25–S1:33, 2008
27. Xu R, Haman SP, Ebraheim NA, Yeasting RA: The anatomic relation of lateral mass screws to the spinal nerves. A comparison of the Magerl, Anderson, and An techniques. **Spine (Phila Pa 1976) 24:**2057–2061, 1999
28. Yuan HA, Garfin SR, Dickman CA, Mardjetko SM: A historical cohort study of pedicle screw fixation in thoracic, lumbar, and sacral spinal fusions. Spine **(Phila Pa 1976) 19 (20 Suppl):**2279S–2296S, 1994

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

Morio Matsumoto, M.D.
Keio University
Tokyo, Japan

Please include this information when citing this paper: published online March 7, 2014; DOI: 10.3171/2013.11.SPINE13850.

Tubular retractor selection in minimally invasive spinal tumor resection

To The Editor: We read with great interest the article by Nzokou et al.[5] (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 techologies over the past 15 years.[6] 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[7] 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.[1–4] 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 intralesional piecemeal tumor resection, which may be of little consequence when treating nerve sheath tumors but could

have important consequences when treating myxopapillary ependymomas, which carry a significant risk of recurrence when removed in this manner. Finally, one of the most challenging aspects of MIS intradural surgery is dural closure. A watertight dural closure is paramount for an uncomplicated postoperative course when dealing with intradural pathologies. The 18-mm tubular retractor presents challenges to both adequate visualization of the intended durotomy site and instrument maneuverability during dural closure in MIS.

In our practice, we routinely use MIS techniques to treat intra- and extradural spinal tumors in carefully selected patients. In these cases, we typically prefer to use a tube diameter that is approximately 5–10 mm larger than the intended lesion, especially if the lesion is intradural. This gives us adequate access to the intended pathology and allows working room for both tumor resection and a watertight dural closure. Therefore, the selected tube diameter is slightly larger than the intended length of the durotomy, which is slightly larger than the length of the intradural pathology. In our own experience in using MIS to access intradural spinal pathology, we have used fixed diameter tubes ranging from 18 to 26 mm as well as expandable tubular retractors that can provide well over 4 cm of longitudinal exposure.

Techniques of MIS can be safely applied for resection of intradural and extradural spinal tumors in a selected group of patients, as Nzokou et al.[5] have nicely demonstrated. Proper selection of tubular retractor size, however, follows the basic principle of providing adequate exposure and a surgical corridor to reach the intended pathology. Keeping this in mind, the benefits of MIS techniques can be realized without compromising the surgical objective or increasing the risk of potential complications.

Lee A. Tan, M.D.
John E. O'Toole, M.D., M.S
Rush University Medical Center
Chicago, IL

Disclosure

Dr. O'Toole is a consultant to Pioneer Surgical Technology Inc. and Globus Medical Inc. Dr. Tan declares no potential conflicts of interest.

References

1. Gandhi RH, German JW: Minimally invasive approach for the treatment of intradural spinal pathology. **Neurosurgical Focus 35(2):**E5, 2013
2. Haji FA, Cenic A, Crevier L, Murty N, Reddy K: Minimally invasive approach for the resection of spinal neoplasm. **Spine (Phila Pa 1976) 36:**E1018–E1026, 2011
3. Lu DC, Chou D, Mummaneni PV: A comparison of mini-open and open approaches for resection of thoracolumbar intradural spinal tumors. Clinical article. **J Neurosurg Spine 14:**758–764, 2011
4. Mannion RJ, Nowitzke AM, Efendy J, Wood MJ: Safety and efficacy of intradural extramedullary spinal tumor removal using a minimally invasive approach. **Neurosurgery 68 (1 Suppl Operative):**208–216, 2011
5. 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, 2013
6. O'Toole JE: The future of minimally invasive spine surgery. **Neurosurgery 60 Suppl 1:**13–19, 2013
7. Tredway TL, Santiago P, Hrubes MR, Song JK, Christie SD, Fessler RG: Minimally invasive resection of intradural-extramedullary spinal neoplasms. **Neurosurgery 58:**ONS52–ONS58, 2006

Response: We thank Drs. Tan and O'Toole for their interest and valuable comments regarding our paper. They have correctly drawn our attention to an omission that appeared in the introduction to our paper. In our study of 13 patients who underwent minimally invasive removal of spinal tumors using nonexpandable tubular retractors, the size of these nonexpandable tubular retractors ranged from 18 to 24 mm, with 24-mm tubes used in 3 of the 4 intradural cases. Accordingly, the last sentence of the introduction was incorrect: it originally read,

> We report our experience with the minimally invasive removal of extradural foraminal and intradural-extramedullary tumors using the 18-mm nonexpandable Spotlight Access System (DePuy Spine).

This sentence has now been replaced with the following:

> We report our experience with minimally invasive removal of extradural foraminal and intradural-extramedullary tumors using the SPOTLIGHT Access System with nonexpandable tube retractors ranging from 18 to 24 mm (DePuy Spine).

This change is illustrated in the case shown in Fig. 3, in which a 24-mm tubular retractor was used in the resection of a T12–L1 intradural schwannoma. During our surgeries, incisions were the minimal length required to accommodate the varying sizes of the tubular retractors.

Drs. Tan and O'Toole bring forward an interesting discussion on the selection of tubular retractors. We fully agree with them that adequate exposure is imperative for minimally invasive resection of these tumors, especially when treating intradural tumors in which the entirety of the durotomy and tumor should be exposed with the tube. For extradural tumors, however, the size of the tumor can exceed the diameter of the tube 3- to 4-fold, and extradural nerve sheath tumors larger than 5 cm can be removed using an 18-mm tubular retractor (for example, Fig. 1, Case 12). Tumor resection in these larger extradural cases can be accomplished using standard microsurgical techniques of intracapsular debulking and extracapsular dissection combined with frequent repositioning of the tube, which is safe in the lumbar spine and has been safe in our limited experience when done carefully in the thoracic spine.

For intradural tumors, dural closure is among the more challenging aspects of this approach. Durotomy closure with interrupted or running suture, however, is rendered feasible using instruments such as a Castroviejo needle and a knot pusher. Although the numbers are too limited to draw firm conclusions, the combined experience described in the literature has found the rate of pseudomeningocele and CSF leak to be acceptable using these instruments and fibrin glue sealant.[1–3,5] Other alternatives, such as a dural graft or nonpenetrating titanium clips supplemented with fibrin glue sealant, have also been utilized with success.[3] This low rate of CSF leak

may be related to the minimally invasive nature of the exposure. The muscle-splitting approach allows the paramedian dead space to close on removal of the tube. This, combined with muscle fascia closure, helps prevent egress of CSF through the durotomy to the skin.[3–5] We agree that the risk-benefit ratio must be carefully assessed in each case and that limiting the operative exposure should not come at the cost of an increased risk of complications, which may lead to incomplete tumor resection or inadequate closure.

Andre Nzokou, M.D.
Alexander G. Weil, M.D., F.R.C.S.C.
Daniel Shedid, M.D., M.Sc., F.R.C.S.C.
University of Montreal
Montreal, QC, Canada

References

1. Haji FA, Cenic A, Crevier L, Murty N, Reddy K: Minimally invasive approach for the resection of spinal neoplasm. **Spine (Phila Pa 1976) 36:**E1018–E1026, 2011
2. Lu DC, Chou D, Mummaneni PV: A comparison of mini-open and open approaches for resection of thoracolumbar intradural spinal tumors. Clinical article. **J Neurosurg Spine 14:**758–764, 2011
3. Mannion RJ, Nowitzke AM, Efendy J, Wood MJ: Safety and efficacy of intradural extramedullary spinal tumor removal using a minimally invasive approach. **Neurosurgery 68 (1 Suppl Operative):**208–216, 2011
4. Than KD, Wang AC, Etame AB, La Marca F, Park P: Postoperative management of incidental durotomy in minimally invasive lumbar spinal surgery. **Minim Invasive Neurosurg 51:**263–266, 2008
5. Tredway TL, Santiago P, Hrubes MR, Song JK, Christie SD, Fessler RG: Minimally invasive resection of intradural-extramedullary spinal neoplasms. **Neurosurgery 58 (1 Suppl):** ONS52–ONS58, 2006

Please include this information when citing this paper: published online March 7, 2014; DOI: 10.3171/2013.10.SPINE13944.

Myxopapillary ependymomas

To The Editor: We found the article by Feldman et al.[3] (Feldman WB, Clark AJ, Safaee M, et al: Tumor control after surgery for spinal myxopapillary ependymomas: distinct outcomes in adults versus children. A systematic review. *J Neurosurg Spine 19:*471–476, October 2013) very interesting.

The authors performed a systematic review on the topic of tumor control after surgery for spinal myxopapillary ependymomas (MPEs).[3] They reported that the recurrence rate was lower after gross-total resection (GTR) (15.5%) than after subtotal resection (STR) (32.6%) ($p < 0.001$), and that GTR was more frequently achieved in filum terminale tumors (41 of 67) compared with tumors involving other neural elements (12 of 37, $p = 0.003$).[3] The addition of radiotherapy did not change the recurrence rates in patients who underwent GTR in the study population overall. As observed in clinical practice, the recurrence rate in pediatric patients was higher than in adults (40.5% vs 23.4%, respectively; $p = 0.02$, chi-square test) and recurrence occurred earlier in pediatric patients (median of 20.6 months in children compared with 75.1 months in adults). Of note, the authors stated that pediatric patients who underwent GTR without adjuvant radiotherapy had a high recurrence rate of 65% (recurrence occurring in 13 of 20 patients) compared with a rate of 7.6% (9 of 118 patients) in the adult population ($p < 0.001$, Fisher exact test). However, among patients who underwent STR and radiotherapy, the recurrence rate was 16.7% (2 of 12 patients) in children, compared with 37.7% (20 of 53 patients) in adults ($p = 0.20$, Fisher exact test), suggesting potential benefits of radiotherapy in pediatric patients. These data should be interpreted carefully. Based on this information obtained retrospectively with a small sample of patients, radiotherapy should be considered after surgery regardless of the extent of tumor resection in children. We emphasize that many other factors can influence MPE recurrence in children, such as tumor size at presentation (single- vs multilevel tumors), tumor infiltration of the nerve roots, dissemination through the foramen, piecemeal versus en bloc resection, and molecular and genetic characteristics, among many others. We emphasize that all these factors should be considered prior to undertaking radiotherapy in patients who have undergone GTR. In pediatric patients, radiotherapy can exacerbate pre-existing spinal deformities, decreasing the potential of cartilage growth and increasing the rate of postoperative kyphosis or scoliosis.[2,4] It can result in myelopathy or peripheral nerve injury, as well as exostoses.[5,7] Radiotherapy is also associated with radiation-induced tumors, such as meningiomas and sarcomas.[1,2] Finally, if patients have previously been treated with radiotherapy, additional surgery can be extremely challenging and entail more risk of neural injury.[6]

Considering all these points, we propose that prospective studies evaluating the role of radiotherapy after GTR in children are necessary. As stated by the authors, it is difficult to synthesize the available data of this complex disease, when the literature includes only case series with different methodologies and patient characteristics. The authors deserve our best congratulations for their carefully researched and interesting paper.

Andrei Fernandes Joaquim, M.D., Ph.D.
Enrico Ghizoni, M.D., Ph.D.
Helder Tedeschi, M.D., Ph.D.
State University of Campinas
Cidade Universitária Zeferino Vaz'
Campinas, Brazil
Centro Infantil Boldrini – Pediatric Oncologic Hospital
Campinas, Brazil

Disclosure

The authors report no conflict of interest.

References

1. Amirjamshidi A, Abbassioun K: Radiation-induced tumors of the central nervous system occurring in childhood and adolescence. Four unusual lesions in three patients and a review of the literature. **Childs Nerv Syst 16:**390–397, 2000
2. de Jonge T, Slullitel H, Dubousset J, Miladi L, Wicart P, Illés T: Late-onset spinal deformities in children treated by lami-

nectomy and radiation therapy for malignant tumours. **Eur Spine J 14:**765–771, 2005
3. Feldman WB, Clark AJ, Safaee M, Ames CP, Parsa AT: Tumor control after surgery for spinal myxopapillary ependymomas: distinct outcomes in adults versus children. A systematic review. **J Neurosurg Spine 19:**471–476, 2013
4. Joaquim AF, Cheng I, Patel AA: Post-operative spinal deformity after treatment of intracanal spine lesions. **Spine J 12:** 1067–1074, 2012
5. Joaquim AF, Santos MJ, Tedeschi H: Surgical management of intramedullary spinal ependymomas. **Arq Neuropsiquiatr 67:**284–289, 2009
6. Lee SH, Chung CK, Kim CH, Yoon SH, Hyun SJ, Kim KJ, et al: Long-term outcomes of surgical resection with or without adjuvant radiation therapy for treatment of spinal ependymoma: a retrospective multicenter study by the Korea Spinal Oncology Research Group. **Neuro Oncol 15:**921–929, 2013
7. Lunardi P, Licastro G, Missori P, Ferrante L, Fortuna A: Management of intramedullary tumors in children. **Acta Neurochir (Wien) 120:**59–65, 1993

Response: No response was received from the authors of the original article.

Please include this information when citing this paper: published online March 7, 2014; DOI: 10.3171/2013.11.SPINE13989.

Transsacral axial interbody fusion

To The Editor: We read with interest the article of Hofstetter et al.[3] (Hofstetter CP, Shin B, Tsiouris AJ, et al: Radiographic and clinical outcome after 1- and 2-level transsacral axial interbody fusion. Clinical article. *J Neurosurg Spine 19:*454–463, October 2013) that reported radiographic and clinical results in 38 patients who underwent single-level (n = 32) or 2-level (n = 6) transsacral axial interbody fusion. Through a mean follow-up of 26 months, mean back function improved by 19% and back pain decreased by 43%. Our group reported a mean 54% improvement in back function and a 63% improvement in back pain in 155 single-level presacral axial fusions and a 42% improvement in back function and a 56% improvement in back pain in a cohort of 52 two-level presacral axial fusions.[6,7] Additionally, Hofstetter et al. report fusion rates of 80% for single-level and 33% for L4–S1 axial fusions in 6 patients. In contrast, we reported a 94% fusion rate for single-level presacral axial fusion in 156 patients and 93% fusion confirmed by CT in 52 two-level AxiaLIF patients.

The reason for the discrepant results between studies is unknown, but the potential influence of confounding variables cannot be denied. In the Hofstetter study, the AxiaLIF device was part of a complex fusion construct in 42% of cases. Of further note is that 45% of patients had undergone previous instrumented or noninstrumented fusions. The authors failed to perform bilateral posterior instrumentation in nearly one-third of the patients. A biomechanical study by Erkan et al. confirmed the need for bilateral segmental posterior fixation at L-4, L-5, and S-1 to provide uniform stability across each motion segment and to decrease the load transfer to the fixation points of the anterior implant.[1] This might explain the prolonged operative times and as well as the inferior clinical outcomes in contrast to other reports.[2,5]

The lack of fusion in the 6 patients who underwent 2-level procedures might suggest less than adequate bone grafting of the interspace as well as a lack of posterior segmental fixation and posterior lateral fusion. Loss of disc height and subsidence of the AxiaLIF rod may result when excessive distraction is applied through the AxiaLIF implant.

The authors report a mean decrease of segmental lordosis of 5° and correlate this loss of lordosis with low fusion rates and poor clinical outcomes. We have found in a retrospective analysis of 52 patients who underwent L4–S1 lumbosacral fusion with AxiaLIF that there was no significant loss of global (L1–S1) or segmental (L4–S1) lordosis and that clinical outcomes and fusion rates were not compromised in the 5 patients that had a loss of lordosis of 5° or more.[4]

It is difficult to draw meaningful conclusions about the utility of the AxiaLIF implant given the complexity of the cases in the study of Hofstetter et al. Our multicenter study involving 52 patients demonstrates the safety and efficacy of the 2-level presacral fusion technique. This stands in sharp contrast to the current study, which is significantly limited by a small number of cases (6 two-level presacral fusions). Additional reports are needed to clarify the value of this technology.

William D. Tobler, M.D.
The Christ Hospital
Cincinnati, OH
Miguel A. Melgar, M.D., Ph.D.
Tulane University
New Orleans, LA
Thomas J. Raley, M.D.
Advanced Spine and Pain
Arlington, VA
W. Daniel Bradley, M.D.
Texas Back Institute
Denton, TX
Larry E. Miller, Ph.D.
Miller Scientific Consulting, Inc.
Asheville, NC
Richard J. Nasca, M.D.
Orthopaedic and Spine Surgery
Wilmington, NC

Disclosure

Drs. Nasca, Miller, Bradley, Tobler, and Melgar report consultant relationships with Baxano. Dr. Bradley also reports stock options with Baxano.

References

1. Erkan S, Wu C, Mehbod AA, Hsu B, Pahl DW, Transfeldt EE: Biomechanical evaluation of a new AxiaLIF technique for two-level lumbar fusions. **Eur Spine J 18:**807–814, 2009
2. Gerszten PC, Tobler WD, Raley TJ, Miller LE, Block JE, Nasca RJ: Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of lumbosacral isthmic spondylolisthesis. **J Spinal Disord Tech 25:**E36–E40, 2012
3. Hofstetter CP, Shin B, Tsiouris AJ, Elowitz E, Härtl R: Radiographic and clinical outcome after 1- and 2-level transsacral axial interbody fusion. Clinical article. **J Neurosurg Spine 19:** 454–463, 2013

4. Melgar MA, Tobler WD, Ernst R, Raley TJ, Anand N, Nasca RJ: Evaluation of lumbar lordosis in patients treated with the AxiaLIF 2 level implant and posterior instrumentation. Presented at the annual meeting of the **International Society for the Advancement of Spine Surgery**, Vancouver, 2013 (Abstract) (http://www.isass.org/abstracts/isass13_regular_posters/isass13-408-Evaluation-of-Lumbar-Lordosis-in-Patients-Treated-with-the-AxiaLIF-2-L.html) [Accessed January 29, 2014]
5. Tobler WD, Ferrara LA: The presacral retroperitoneal approach for axial lumbar interbody fusion: a prospective study of clinical outcomes complication and fusion rates at a follow-up of two years in 26 patients. **J Bone Joint Surg Br 7:**955–960, 2011
6. Tobler WD, Gerszten PC, Bradley WD, Raley TJ, Nasca RJ, Block JE: Minimally invasive axial presacral L5-S1 interbody fusion. **Spine (Phila Pa 1976) 36:**E1296–E1301, 2011
7. Tobler WD, Melgar MA, Raley TJ, Anand N, Miller LE, Nasca RJ: Clinical and radiographic outcomes with L4-S1 axial lumbar interbody fusion (AxiaLIF) and posterior instrumentation: a multicenter study. **Med Devices (Auckl) 6:**155–161, 2013

Response: We thank Dr. Tobler and colleagues for their thoughtful comments in response to our publication in the *Journal of Neurosurgery: Spine*.

In single-level L5–S1 AxiaLIF procedures that were not part of larger fusion constructs, our fusion rate was 87%, which is similar to the rate reported by Tobler and colleagues (94%),[6] Whang et al. (85%),[8] and Zeilstra et al. (88%).[9] Interestingly, the patients in our L5–S1 AxiaLIF cohort who did not achieve solid arthrodesis had indeed only unilateral pedicle-rod constructs. Biomechanical studies have compared stand-alone 1- or 2-level AxiaLIF constructs with different combinations of posterior instrumentation.[1,2] The authors of these 2 studies concluded that supplementary bilateral posterior instrumentation greatly increases construct stability. However, the effect of unilateral posterior instrumentation on construct stability has not been tested. Thus, we agree with Tobler and colleagues that it would be important to perform biomechanical testing on unilateral posterior instrumentation. Given our clinical results, we also agree that single-level AxiaLIF should be augmented with bilateral posterior instrumentation.

However, the failure of bilateral posterior instrumentation cannot be the explanation for the poor results in our 2-level AxiaLIF procedures, because all of these constructs were augmented with bilateral pedicle screw rod constructs. Our fusion rate in 2-level AxiaLIF cases was 33%, which is similar to the rate found by Marchi and colleagues (22%).[4] These fusion rates are dismal compared to the excellent results presented by Tobler and colleagues (93%).[7] As mentioned by the authors, there are a multitude of confounders that might have led to low fusion rates in our study and the study by Marchi and colleagues.[4] Calcium-based bone graft substitute was used in our study and by Marchi and colleagues.[4] While autologous bone remains the "gold standard" for grafting materials, calcium-based bone graft substitute has been demonstrated to support high union rates in the cervical and lumbar spine in common types of fixation.[5] Another difference between studies with low fusion rates[4] and those with high fusion rates[7] was the use of bone morphogenetic protein (BMP). However, the use of BMP has been demonstrated to lack statistically significant impact on fusion rates in fusion constructs using axial rods in a patient cohort of 99 patients.[3] The other difference was the type of transsacral rod that was used. Whereas we and Marchi et al. used a transscacral rod that was commercially available at the time of patient recruitment, Tobler and colleagues had access to the second-generation version of the axial rod, and this could have contributed to improved construct stability and higher fusion rates.

Loss of segmental lordosis at the level of the AxiaLIF procedure is the other concern we expressed. Marchi and colleagues also confirmed this finding.[4] In order to analyze whether too-excessive distraction of the disc space using the axial rod may have led to loss of disc height or loss of lordosis, we re-analyzed our data: In 38 patients, the AxiaLIF device achieved on average a 1.4-mm (range –2.6 to 4.4 mm) increase of disc height measured in the center of the L5–S1 interspace on immediate postoperative radiographs. This amount of distraction did not correlate with the loss of disc height (correlation coefficient 0.29, $p = 0.11$) or loss of segmental lordosis (correlation coefficient 0.17, $p = 0.37$) at the last follow-up. Therefore, we hypothesize that there might be other potential explanations for the failure of the AxiaLIF device to provide sufficient anterior column support. In particular, we suspect that the absence of a solid weight-bearing interbody graft is responsible for the collapse of the construct.

In conclusion, we thank Tobler and colleagues for their thoughtful comments. We admit that there are multiple variables that may lead to various outcomes, particularly in retrospective clinical case series. Our patient cohort included many patients who were undergoing revision surgeries, and frequently the AxiaLIF device was part of a larger fusion construct. However, we believe that our concerns are representative for those voiced by other surgeons who may have embraced this technology too enthusiastically and may have expanded its indications too quickly. Therefore, we believe that our study is a valuable contribution to the literature. AxiaLIF can be considered with the expectation of good clinical and radiographic success for 1-level instrumentation in a well-selected patient group when correction of lordosis and foraminal decompression is not the primary goal of the procedure. In our hands and using the hardware available at the time of our study the transsacral rod did not allow us to increase or maintain segmental lumbar lordosis and disc height. Therefore, we propose that this innovative and truly minimally invasive presacral approach should be further refined and evaluated.

Roger Härtl, M.D.
Weill Cornell Brain and Spine Institute
Weill Cornell Medical College
NewYork-Presbyterian Hospital
New York, NY

Disclosure

The author reports a consultant relationship with AOSpine, DePuy Synthes, BrainLAB, and Lanx and receiving study support from Baxter.

References

1. Akesen B, Wu C, Mehbod AA, Transfeldt EE: Biomechanical evaluation of paracoccygeal transsacral fixation. **J Spinal Disord Tech 21:**39–44, 2008

2. Erkan S, Wu C, Mehbod AA, Hsu B, Pahl DW, Transfeldt EE: Biomechanical evaluation of a new AxiaLIF technique for two-level lumbar fusion. **Eur Spine J 18:**807–814, 2009
3. Gerszten PC, Tobler WD, Nasca RJ: Retrospective analysis of L5-S1 axial lumbar interbody fusion (AxiaLIF): a comparison with and without the use of recombinant human bone morphogenetic protein-2. **Spine J 11:**1027–1032, 2011
4. Marchi L, Oliveira L, Coutinho E, Pimenta L: Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow-up. Clinical article. **J Neurosurg Spine 17:**187–192, 2012
5. Nagineni VV, James AR, Alimi M, Hofstetter C, Shin BJ, Njoku I Jr, et al: Silicate-substituted calcium phosphate ceramic bone graft replacement for spinal fusion procedures. **Spine (Phila Pa 1976) 37:**E1264–E1272, 2012
6. Tobler WD, Gerszten PC, Bradley WD, Raley TJ, Nasca RJ, Block JE: Minimally invasive axial presacral L5-S1 interbody fusion: two-year clinical and radiographic outcomes. **Spine (Phila Pa 1976) 36:**E1296–E1301, 2011
7. Tobler WD, Melgar MA, Raley TJ, Anand N, Miller LE, Nasca RJ: Clinical and radiographic outcomes with L4-S1 axial lumbar interbody fusion (AxiaLIF) and posterior instrumentation: a multicenter study. **Med Devices (Auckl) 6:**155–161, 2013
8. Whang PG, Sasso RC, Patel VV, Ali RM, Fischgrund JS: Comparison of axial and anterior interbody fusions of the L5-S1 segment: a retrospective cohort analysis. **J Spinal Disord Tech 26:**437–443, 2013
9. Zeilstra DJ, Miller LE, Block JE: Axial lumbar interbody fusion: a 6-year single-center experience. **Clin Interv Aging 8:** 1063–1069, 2013

Please include this information when citing this paper: published online March 14, 2014; DOI: 10.3171/2013.11.SPINE13981.