

Interventional News: A New Course
By Jayson S. Brower, MD
Radiology Today
Vol. 21 No. 1 P. 6

Steerable technology enhances percutaneous vertebroplasty and kyphoplasty procedures.

Achieving success with vertebroplasty or kyphoplasty is multifactorial, encompassing proper patient selection, thorough understanding of spinal anatomy—including an ability to “read the anatomy” during the procedure and adjust as necessary—and a certain comfort level in performing these techniques, something gained through experience and training. To a great extent, outcomes are operator dependent, and, to a lesser degree, they rely on the ability of the tools used to navigate the anatomy. Thus, the equipment and tools used during vertebroplasty and kyphoplasty have a definite role in ensuring patients realize maximal benefit.

Technological Advances

The fundamental objective of vertebroplasty and kyphoplasty procedures is delivery of polymethyl methacrylate (PMMA) bone cement inside the vertebral body at the site of the fracture. Ideally, the PMMA fills a space from end plate to end plate and from pedicle to pedicle. Achieving that goal can be technically challenging, however, as the operator is navigating in a 3D fashion, often in the setting of complicated and variable anatomy. Intuitively, improving the ability to navigate to the site and facilitate accurate deployment of PMMA would increase the ability to achieve successful outcomes.

The majority of the needle options for vertebroplasty and kyphoplasty procedures are designed with a fixed, straight shape. Through careful insertion and manipulation, the tip is navigated as close to the fracture location as possible, although the operator is limited in the ability to bend, twist, or turn the tip during this critical but delicate part of the procedure. In this setting, completing cement delivery to the desired location may necessitate use of a bipedicular approach, which is associated with equal biomechanical strength compared with unipedicular approaches but longer procedure time and increased cost.¹⁻³

More recently, precurved needles constructed of flexible nickel titanium (nitinol) have been introduced. With this needle, the tip is straightened to fit through a rigid introducer to get through the skin and vertebral body; once inside the bone, the tip is extended beyond the tip of the introducer and forms its natural curve. This design provides comparatively better steerability than a fixed-shape device but is still limited in terms of truly accurate localization.

The most recent advance in needle technology is a concept referred to as steerable technology, where the tip of the vertebral needle or osteotome—a chisel without a bevel that is used for cutting bone—articulates. With this technology, the operator gains the ability to navigate in a curvilinear fashion through 3D space. As such, steerable technology confers a few theoretical benefits. First, the articulating feature can be used to create channels for later introduction of the cement, thereby ensuring more stable fixation. Second, these particular devices may be more accurate than fixed-shape devices for navigation, and certainly so as the operator gains experience with making minor adjustments. Third, the articulation provides greater access to the entire vertebral body, thus making it more likely that a unipedicular approach will be sufficient. Fourth, and for all the reasons stated above, procedure times may be shorter, which translates to lower requirement for anesthesia and less time that the operator and patient are exposed to radiation from imaging.

The breadth of steerable technology instruments already available allows operators a variety of options to customize the procedure. Steerable balloon technology is available as an option, although our practice typically uses steerable osteotomes for targeted cavity creation. Our thought process is that the improved maneuverability with a robust steerable osteotome allows us to selectively but efficiently achieve space in a fashion analogous to kyphoplasty, but while sparing native trabecular bone within the vertebral body to act as a scaffold within which cement can interdigitate. More recently, a steerable needle has been released that provides the ability to inject the cement from the end of the needle. In my hands, this tool kit significantly enhances confidence in being able

to achieve a successful resolution in a wider variety of cases, even including very difficult anatomy, such as vertebral plana or an asymmetrically compressed vertebral body.

PMMA Formulation and Delivery

One of the proposed benefits of greater interdigitation with the vertebral needle or osteotome is that more accurate placement of the cement will reduce the potential for extravasation. This may well be the case; however, the most significant factor in reducing cement leakage outside the vertebral body is the design of more viscous PMMA formulations.

The risk of cement leakage is multifactorial. Local tissue morphology has been suggested to impact cement infiltration, which may be difficult for the operator to overcome. On the other hand, use of higher-viscosity PMMA has been shown to lower the risk of leakage, both in vitro^{4,5} and in situ.^{6,7} However, growing evidence that viscosity increases during polymerization of the PMMA agent suggests that the timing and mechanism of delivery should be considered.⁸ Specifically, it appears optimal that the injection occur when the agent is at or near peak viscosity, which, in turn, may require a higher injection force than what manual injection mechanisms can reliably deliver.⁹ The latter hypothesis seems to be supported by in vitro models showing a positive correlation between cement viscosity and the injection force required for delivery.¹⁰ Overall, these data suggest that mechanical injection devices offer utility for even, consistent delivery of the PMMA to the intended site.

One of the features of the steerable platform is that it is available with versions that allow either manual or mechanical delivery. With the latter, high-viscosity bone cement is polymerized by radiofrequency (RF) energy as it passes through an RF cartridge; onboard software adjusts the RF energy delivery to increase cement viscosity at the onset and then tapers it over time to assure the same high-viscosity cement over an extended working time. Of note, the delivery can be administered with a remote control up to 20 feet away, distancing the operator from the imaging equipment and reducing radiation exposure. The manually delivered version, likewise, employs high-viscosity PMMA but does not depend on RF energy delivery, thus giving operators who prefer tactile response during delivery an option that still provides extended working time.

Conclusions

Successful percutaneous vertebroplasty or kyphoplasty hinges on a number of factors. The role of an experienced, well-trained operator cannot be discounted. Learning to navigate often challenging anatomy, particularly in the setting of osteoporosis, is associated with a modest learning curve. Once those skills have been mastered, incremental improvements to the procedure can be made through use of various devices and equipment. As the ultimate goal of each of these procedures is dependent on returning stability to the fractured vertebra, advances in the science and formulation of PMMA have been critical. Targeted cavity creation and cement delivery using steerable technology and higher-viscosity cements, whether delivered manually or mechanically, provides the operator one additional variable that can be controlled during the procedure to achieve the desired outcome.

— Jayson S. Brower, MD, is president of Inland Imaging and past chief of staff at Providence Holy Family Hospital in Spokane, Washington. He is a consultant for Merit Medical and a faculty member for the company's training program, Think Spine.

References

1. Zhang L, Liu Z, Wang J, et al. Unipedicular versus bipedicular percutaneous vertebroplasty for osteoporotic vertebral compression fractures: a prospective randomized study. **BMC Musculoskelet Disord**. 2015;16:145.
2. Steinmann J, Tingey CT, Cruz G, Dai Q. Biomechanical comparison of unipedicular versus bipedicular kyphoplasty. **Spine (Phila Pa 1976)**. 2005;30(2):201-205.
3. Dalton BE, Kohm AC, Miller LE, Block JE, Poser RD. Radiofrequency-targeted vertebral augmentation versus traditional balloon kyphoplasty: radiographic and morphologic outcomes of an ex vivo biomechanical pilot study. **Clin Interv Aging**. 2012;7:525-531.
4. Meng B, Qian M, Xia SX, Yang HL, Luo ZP. Biomechanical characteristics of cement/gelatin mixture for prevention of cement leakage in vertebral augmentation. **Eur Spine J**. 2013;22(10):2249-2255.
5. Baroud G, Falk R, Crookshank M, Sponagel S, Steffen T. Experimental and theoretical investigation of directional permeability of human vertebral cancellous bone for cement infiltration. **J Biomech**. 2004;37(2):189-196.

6. Nieuwenhuijse MJ, Van Erkel AR, Dijkstra PS. Cement leakage in percutaneous vertebroplasty for osteoporotic vertebral compression fractures: Identification of risk factors. **Spine J.** 2011;11:839-848.
7. Anselmetti GC, Zoarski G, Manca A, et al. Percutaneous vertebroplasty and bone cement leakage: clinical experience with a new high-viscosity bone cement and delivery system for vertebral augmentation in benign and malignant compression fractures. **Cardiovasc Intervent Radiol.** 2008;31(5):937-947.
8. Boger A, Wheeler KD, Schenk B, Heini PF. Clinical investigations of polymethylmethacrylate cement viscosity during vertebroplasty and related in vitro measurements. **Eur Spine J.** 2009;18(9):1272-1278.
9. Baroud G, Böhner M, Heini P, Steffen T. Injection biomechanics of bone cements used in vertebroplasty. **Biomed Mater Eng.** 2004;14(4):487-504.
10. Gisep A, Boger A. Injection biomechanics of in vitro simulated vertebroplasty — correlation of injection force and cement viscosity. **Biomed Mater Eng.** 2009;19(6):415-420.