SPINE Volume 30, Number 11, pp 1273–1274


# Point of View

Steven R. Garfin, MD* and Andrew S. Mahar, MS†

This study biomechanically assesses motion across functional vertebral segments following partial and complete (unilateral-bilateral) facetectomies that are then altered by an interspinous implant (X-STOP) that attempts to control motion by placing the segment in flexion, restricting extension. Though an interesting study, providing laboratory documentation of the immediate stability offered by the device, there are some biomechanical and clinical concerns to raise. Though the study design appears relatively straight forward and well done, clinical implications cannot necessarily be drawn from this cadaver-based assessment. One of the most important positive components that should not be overlooked is how close this study parallels the data of Abumi *et al*,[1] confirming the importance of the facets in stabilizing the spine.

Although the stepwise analysis is logical, some methodological comments can be made. The first concern is the rationale for the magnitudes and direction of loading. Whereas the moments and axial loads employed in the current study are similar to those used by Abumi *et al*, the authors provide no explanation for these techniques. *In vivo* coupled motions occur that may alter the effect of the implant, limiting or increasing motion. The moments themselves seem physiologic (± 7.5 Nm) for an adult. However, the 700 N axial load represents an axial load of 71.3 kg that may be beyond the typical mass of the head, arm, and trunk. Does this increased load affect what actually occurs? Perhaps what occurs *in vivo* following facetectomy is not as great. The second concern is that the number of cycles used for testing in each direction is not clear. The number of preconditioning cycles could affect the range of motion during the final cycle from which data were combined into single data sets. Although others have reported instability associated with facet removal, separating that data in this study may have been helpful to understand the ability of the X-STOP to stabilize the spine in that particular direction. Finally, a post hoc analysis of each data set indicates a relatively low test power (0.1–4.0). The current sample size (n = 7) does not appear to be adequate to clearly interpret these results and the efficacy of the X-STOP to stabilize the spine. From a methodological viewpoint, the limitations expressed here should be considered when attempting to evaluate the potential utility of this device.

The above comments are designed to fine tune and help the reader assess potential biomechanical concerns of the study. It is unlikely that addressing them would markedly alter the results. However, drawing potential clinically beneficial information from this study is difficult. In the second paragraph, the authors state "Placing the segment in slight flexion increases the space available for the neural elements, relieving the symptoms. . . . " The study, however, does not address how long the "symptoms" or, more appropriately, mechanical alterations related to the device may be relieved. Stenosis is a variant of the normal aging process. The pathoanatomic components of stenosis relate to neural element compression by degenerative discs anteriorly and to thickened lamina, hypertrophic facets, and thickened or redundant ligaments (and/or cysts) posteriorly. The X-STOP purportedly preserves bone and ligaments allowing preservation of some, though limited, motion. This, however, allows the process (motion) that leads to stenosis to continue, suggesting that symptoms have a relatively high likelihood of recurring over time depending on the patient's longevity and activity. Even if the authors argue that the decreased motion lessens the rate of recurrence, what happens to the altered motion mechanics cephalad and caudad to the implanted segment? What correction at adjacent levels is necessary to compensate for the forced flexion and limited extension at the index level? The study does note that "ROM of selected adjacent levels during flexion and extension, however, was affected by the implant." What are the clinical consequences from this? This cavader study does not assess potential adjacent level or same level stenosis occurring when this device is used. Is it significantly different than an *in situ* fusion?

The authors describe the importance of facets, carrying up to 18–25% of the load for each motion segment. The X-STOP, theoretically, "unloads" the facet. Therefore, it must take up some of the load and transmit it to the adjacent spinous processes (normally not heavily weight-bearing structures). What happens to the spinous processes when they become weight bearing and have metal implants tightly inserted between two adjacent ones? In one scenario, perhaps the bone around the implants could erode, leading to loosening at the bone, X-STOP junction, and

From the *Department of Orthopaedic Surgery, USCD Medical Center, San Diego, California; and †Children's Hospital and Health Center, San Diego, California.
The manuscript submitted does not contain information about medical device(s)/drug(s).
No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.
Address correspondence to Steven R. Garfin, MD, the Department of Orthopaedic Surgery, UCSD Medical Center, 200 West Arbor Drive, Mail Code 8894, San Diego, CA 92103-8894; E-mail: sgarfin@ucsd.edu

decrease of the forces in flexion. Loosening of implants is seen in pedicle and long bone screws where a solid fusion does not occur and motion persists between the bone and the implant. Alternatively, there may be increased bone formation at the spinous process (related to Wolff's Law and increase in bone reaction to the load/stress). This could lead to thickening of the spinous processes and the adjacent lamina at the spinous process-lamina junction where the forces are transmitted by the X-STOP. This could potentially lead to thickening and more central stenosis.

Finally, the wings of the device may create some lateral erosion of the bone, or the posterior "maintained" supraspinous ligaments. This may, in the long term (months or more), lead to necrosis of the ligaments or an alteration of the mechanics of the segment and affect the results as presented here.

Making the leap from concept to laboratory to clinical use is challenging. The authors suggest this is the case here when they state ". . . if the X-STOP is used in conjunction with a UTF or BTF. . . . " If they mean in cadavers, that is one thing; in patients, however, they have a ways to go.

## Reference

1. Abumi K, Panjabi MM, Kramer KM, et al. Biomechanical evaluation of lumbar spinal stability after graded facetectomies. *Spine* 1990;15:1142–7.