Biomechanical effects of interspinous process devices using a hybrid testing protocol

Paul M. Arnold, MD, and Elizabeth A. Friis, PhD

Department of Neurosurgery, University of Kansas Medical Center, Kansas City; and Department of Mechanical Engineering, University of Kansas, Lawrence, Kansas

The use of lumbar interspinous process (ISP) devices for the treatment of symptomatic lumbar stenosis has dramatically increased in the past decade, very likely because of the increased number of elderly patients in the population. Such patients tend to have several comorbidities, which increase the risk of lumbar laminectomy; thus, a less invasive surgical procedure was required to manage this common problem. Interspinous process devices are appealing because they can often be inserted with less risk than a standard laminectomy.

In 2005, the FDA approved the use of ISP devices for the treatment of neurogenic claudication. Currently, several devices are on the market in Europe and the United States, and the most frequently used device is the X-Stop (Medtronic Inc.). The goal of an ISP device is to prevent extension and functionally increase the area of the spinal canal and neuroforamina at the level at which the device is placed. The procedure often takes less than 30 minutes, and minimal dissection of the posterior elements is required.

Knowledge of the biomechanics of these devices is useful to the practicing surgeon. Several in vitro and in vivo studies have assessed range of motion (ROM), intradiscal pressure (IDP), facet loading, and effects on adjacent segments. The study by Erbulut et al. is a finite-element (FE) analysis in which the authors looked at several biomechanical effects of an X-Stop–like device on the implanted and adjacent lumbar segments. The authors used a hybrid testing model that applied the moment levels necessary to achieve displacements identical to those of the intact specimen. While this approach may better represent the in vivo mechanics of motion, this particular test protocol has been studied infrequently.

The authors found that the device tested would be predicted to decrease ROM, facet load, and IDP at the index level, although this was only tested in extension. Notably, they found that the facet load at the index level would be nearly 0 in extension in the implanted condition. They also noted that both IDP and facet loads would increase at the adjacent levels.

These study findings are helpful for surgeons contemplating the use of ISP devices in patients with lumbar stenosis. The findings are similar to those in several other studies, with a notable exception: previous studies predicted that IDP at the adjacent levels would decrease after the ISP device was placed, but in fact it increased in the FE model. The reason for this difference from cadaveric studies was thought to be a result of the hybrid loading applied. The current study also showed maximum stresses at the site of implantation and compared these locations to spinous process fractures that have been associated with ISP device placement.

There are several flaws in the design of the current study that must be taken into consideration. The FE model developed by the authors used data from a healthy 35-year-old male, not a 70-year-old patient who would be more likely to receive the device. Though tissue property data from other FE studies were used, the spinous processes (where most of the stress is transferred after instrumentation) were probably more robust in the younger patient. It was not stated what age range the material properties represented, and viscoelastic properties were not simulated. Validation of the model was done through comparison of motion data from previous studies, which is not necessarily valid for a different geometric specimen. In addition, no validation or comparison was made for IDPs in the model, yet those parameters were measured and compared between conditions. While the study pointed out some limitations of cadaveric mechanical testing, it does not fully explore the many limitations of FE analysis. Moreover, implantation of the device was only simulated at 1 level, L3–4. It is not clear why this level was chosen despite the fact that...
L4–5 is the more commonly implanted level. Other levels and implant designs could have been incorporated into their analysis. The authors discussed extensively how the hybrid loading approach influenced study results, yet no direct comparisons were made in their model. Comparison of a fixed moment versus hybrid loading technique could have yielded interesting comparisons to reinforce the authors’ position.

The device tested was purported to resemble X-Stop. However, the rendering accompanying the paper has several design features that differ from the X-Stop, including the ability to have some effect on lateral bending and rotation. There was no explanation for why this particular device alone was studied. In addition, the authors chose only to test extension in their ROM analysis, whereas other FE studies routinely test flexion, lateral bending, and axial rotation, even though, as the authors note, the ISP device has little if any effect on those parameters.

Biomechanical testing and FE analysis play valuable roles in the assessment and creation of spinal implants and devices. To a certain extent, they can often model and predict in the laboratory how hardware will perform in humans, without the need for more elaborate or invasive investigation. However, when evaluating data, and perhaps when extrapolating the findings, close attention must be paid to the design and methodology of each individual study.

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References


Response

Deniz U. Erbulut, PhD, MD Iman Zafarparandeh, MSc and Ali F. Ozer, MD

Departments of *Mechanical Engineering and ‡Neurosurgery, Koc University, Istanbul, Turkey

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The goal of our study was to investigate the effect of an ISP device on the biomechanical behavior of treated and adjacent segments of the lumbar spine. An FE method was used in our study because it can help to understand internal biomechanical parameters, such as stresses and strains.6 A hybrid, rather than a flexible, protocol was selected to better understand the behavior of adjacent segments. Compared to a flexible protocol, the hybrid protocol is more anatomically relevant, especially when the response of adjacent levels is of interest.2

In our study we focused on the design concept of the ISP devices, which are mainly designed to prevent motion in extension. Therefore, we did not compare different ISP devices. We used a design similar to X-Stop, as that device has been documented most extensively in the literature.3 In the design of the device, the lateral wings were also modeled to simulate the effect of the device in lateral bending. The device was implanted at the L3–4 segment to study both caudal and cranial segment behavior. The intact and implanted models were loaded in all 3 main directions with the corresponding hybrid load.

In general, FE models are constructed from the CT data for a healthy human spine, which places patient-specific FE modeling out of the scope of this paper. In our study,