

SPINAL NEWS

International

September 2014

This educational supplement has been sponsored by Aurora Spine

The ZIP ULTRA™ is “a game changer” for spinal surgery

Interspinous process fixation devices are increasingly being used as minimally invasive alternatives for the management of spinal stenosis and for pedicle screw constructs in patients undergoing decompression and fusion. *Spinal News International* reviews the use of the ZIP ULTRA™, which is the first interspinous process fixation device to use ziplock technology.

SPORT (Spine patient outcomes research trial) has shown that spinal surgery is an effective treatment for spinal conditions that are resistant to conservative care—it found that surgery was associated with significantly better outcomes at four years than non-operative care in patients with intervertebral disc herniation, degenerative spondylolisthesis, or spinal stenosis.¹

However, traditional open surgical approaches are associated with wide muscle dissection and a long operative time—both of which increase the risk of complications and may lengthen the recovery period. Therefore, minimally invasive approaches have been developed to reduce these risks.

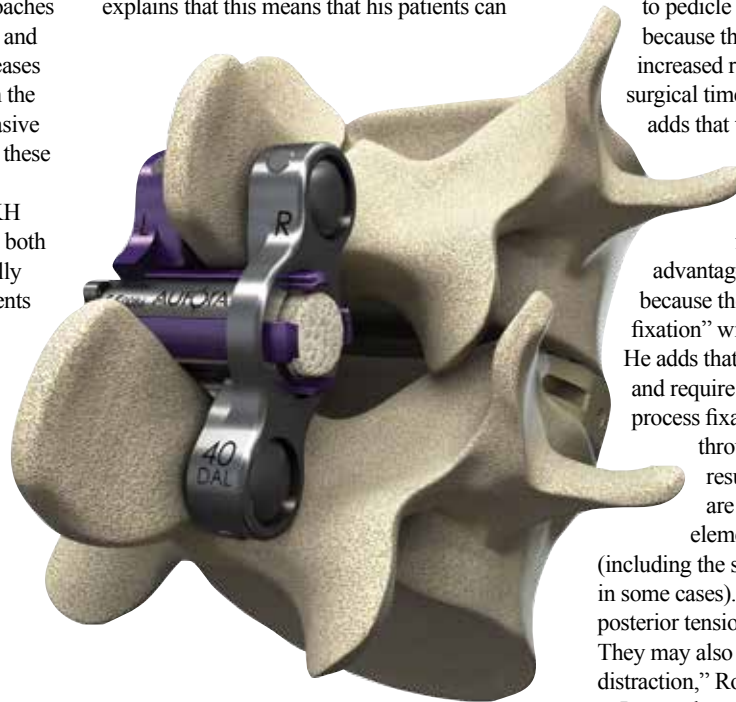
Michael Pfeiffer (Spine Clinic of the KKH Lörrach, Lörrach, Germany) considers that both patients and surgeons benefit from minimally invasive surgery. He says that suitable patients experience “less tissue damage, faster recovery, a better cosmetic result, and the positive attitude from the knowledge of having access to the forefront of technology with minimally invasive surgery.” The surgeon benefits from receiving high patient satisfaction and developing a more reliable patient-surgeon relationship in the long run.

Interspinous process fixation devices

Interspinous process fixation devices, or interspinous fusion devices as they are also known, are one example of an emerging minimally invasive technique. They were originally developed as minimally invasive standalone non-fusion spacers for the management of spinal stenosis. In the white paper “Interspinous process fixation: safe and effective fusion alternative”,² Joseph A Sclafani (Spine Institute of San Diego, San Diego, USA) and others report that the aim with the devices was to “create a localised kyphosis, which indirectly decompressed a stenotic segment while increasing

the structural diameter of the neural foramina.”

Steward Eidelson (South Palm Orthospine Institute, Boca Raton, USA) believes the devices, when appropriately indicated, are a good option for active seniors (eg. aged 55 or older) with moderate spinal stenosis because they enable the postoperative recovery time to be “dramatically less” than with traditional approaches. He explains that this means that his patients can



quickly get back to the activities that they enjoy (such as golf).

Furthermore, Eidelson says that because the devices are smaller and require a smaller incision, they may reduce the risk of wound infection—noting that while the rate of wound infection is 3–5% with standard procedures, he has never observed this type of complication with the 500 devices he has implanted over the last five to six years.

Sclafani *et al* comment that newer devices, such as the ZIP ULTRA™ (Aurora Spine), are now also being used in conjunction with anterior column reconstruction procedures as an alternative to pedicle screw fixation for patients requiring decompression and fusion.

Scott Robertson (Midwest Neurosurgery, Oklahoma City, USA) explains that alternatives to pedicle screw constructs are needed because they are associated with “an increased risk of nerve damage, longer surgical time, and greater tissue damage”. He adds that they may also lead to adjacent segment disease.

Therefore, according to Robertson, interspinous process fixation devices may provide advantages over pedicle screw constructs because they offer a “fast and reliable fixation” with “very few complications”. He adds that they are “very simple” to apply and require less surgical time. “Interspinous process fixation devices may be applied through a midline incision, which may result in less tissue damage. They are attached to the posterior bony elements of the thoracolumbar spine (including the spinous processes and lamina in some cases). Most of these devices act as a posterior tension band reducing spinal motion. They may also provide some compression or distraction,” Robertson explains.

In a study, published in the *Journal of Korean Neurosurgical Society*,³ Ho Jung Kim (Department of Neurosurgery, Hanyang University College of Medicine, Seoul Hospital, Seoul, South Korea) and others evaluated the potential advantages of interspinous process fixation devices for the management of lumbar spine disease.

The investigators compared radiological and clinical outcomes of 40 patients who underwent one-level posterior lumbar interbody fusion

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(PLIF) with an interspinous process fixation device for the management of degenerative lumbar spine disease with those of 36 patients who underwent PLIF with a pedicle screw construct (the control group).

They found that the mean operative time was significantly less in the interspinous process fixation device group compared with the control group (135.8 minutes vs. 170.8 minutes, respectively; $p=0.03$) and so was the estimated blood loss (478.8ml vs. 1130.9ml, respectively; $p=0.001$).

In terms of postoperative outcomes, Kim *et al* note that the Visual Analogue Scale (VAS) score improved significantly in both groups after the surgery. However, they add that the VAS score was significantly improved at the immediate follow-up point in the interspinous process fixation device group compared with the control group: 4.6 ± 3.7 vs. 7 ± 3.5 , respectively ($p<0.05$). Furthermore, the percentage of patients

techniques that will be able to span several spinal segments in a minimally invasive way.”

Michael Pfeiffer believes that interspinous fusion, in a reliable fashion, “helps to save precious time resources intra- and post-operatively”. He also comments that the risks of implant related nerve lesions may be reduced and that revisions and extensions of the stabilisation, if necessary, could be made easier later on.

ZIP ULTRA™

The ZIP ULTRA™ is a new interspinous process fixation device that received the CE mark and FDA approval in August and December 2013, respectively, and is indicated for plate fixation/attachment to the spinous process for supplemental fusion in patients with degenerative disc disease, spondylolisthesis, trauma, and/or tumour.

Steward Eidelson believes that it is the most “technologically advanced” of all the interspinous process fixation devices available because of its

application and use—though innovative and disruptive in the spinal world—still follows the long-standing recommendations and indications for spinal fusion that are standard in the field. It just allows the procedure to take place with minimal disruption of the spinal anatomy, meaning minimal blood loss, shorter surgical times and shorter hospital stays.”

Armstrong adds that the device is placed well away from the nerves and the neural foramina, which he explains is safer in his opinion because it means implanting the ZIP ULTRA™ requires “much, much less fluoroscopy (ie. reduced radiation exposure) time” than with open procedures. Reduced radiation exposure has obvious benefits for both the spinal surgeon and the patient.

While minimally invasive procedures may reduce the risk of complications, they can only be considered as good alternatives to open procedures if they achieve similar results. In his experience, Armstrong says that the ZIP ULTRA™ had produced “very good results”. He adds: “We have excellent fusion rates and overall success rates. Our patients are pleased with the operation, the technique and the results as well.”

Furthermore, Armstrong says patients that are able to easily understand the design and function of the ZIP ULTRA™ device and its role in spinal fusion. He explains that this is a benefit of the device because good patient education is an important part of the preoperative preparation.

“As a fellowship-trained board certified spinal neurosurgeon, with 20 years of spinal surgery experience I find the ZIP ULTRA™ device to be a giant technological leap forward in spinal surgery and an important advancement in the field. I feel it will improve the outcome and level of satisfaction for many of my fusion patients,” Armstrong summarises.

References

1. Tosteson *et al.* *Spine* (Phila PA) 1976; 2011; 36: 2061–68
2. Sclafani *et al.* <http://bit.ly/1nzPMjo>
3. Kim *et al.* *J Korean Neurosurg Soc* 2012; 52: 359–64

“The ZIP ULTRA™’s well-thought-out design makes its use easy and intuitive for the surgeon. There is virtually no learning curve.”

with adjacent segment disease was significantly decreased in the device group (12.5% vs. 36.1% for the pedicle screw fixation group; $p=0.029$).

The authors also report that the rate of bone fusion was high in both groups (92.5% for the interspinous process fixation device group and 91.6% for the control group). They comment that there were three cases of deep infection, two cases of cerebral spinal fluid leakage, and one case of postoperative epidural haematoma requiring re-operation in the control group but add that there were no such cases of major surgery related complications in the interspinous process fixation device group. “The interspinous fusion [ie. interspinous process fixation] with PLIF may be an alternative technique if commanded under selected cases,” Kim *et al* conclude.

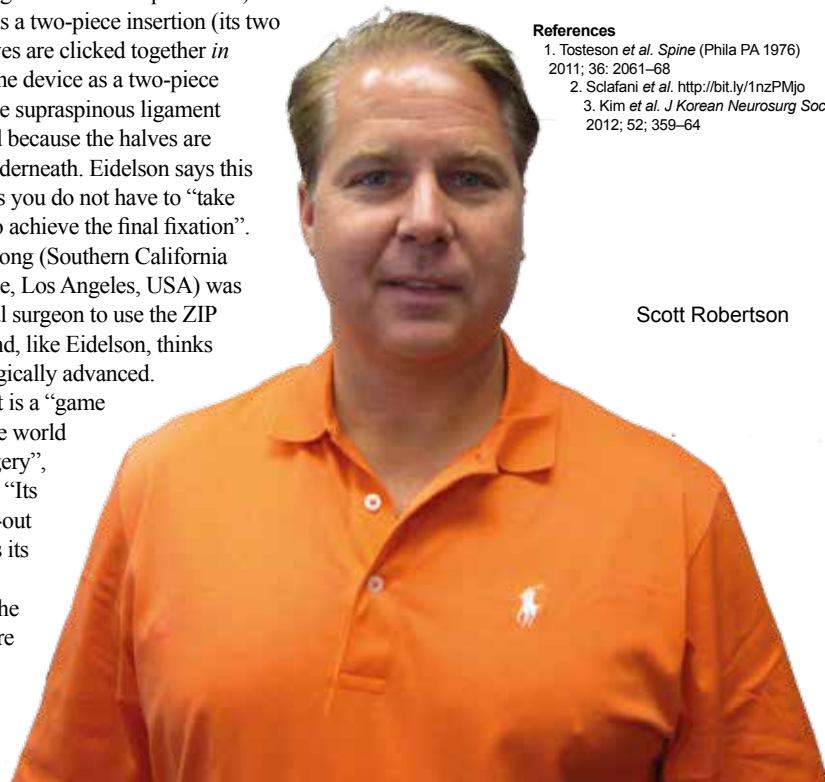
Examining the data from Kim *et al*’s study and other data for interspinous process fixation devices, Sclafani *et al* comment that these devices “provide immediate rigid fixation of destabilised motion segments”. They add that they do not “violate adjacent facet joints”, which means the risk of adjacent segment degeneration may be decreased, and state: “The interspinous process fixation adjunct to interbody fusion is a valuable alternative technique for patients requiring single-level lumbar interbody fusion.”

Scott Robertson believes that interspinous process fixation devices will become a “very important spinal device in the future” and thinks their indication for use has increased as surgeons have become more aware of their benefits. He adds: “I think we will see more companies developing smaller devices with better insertion

“very ingenious” ziplock technology (it is the first device to use such technology). This technology enables the device to work in a similar way to a cable tie, which means you can compress the fusion implant but also lock and stop it from opening. It does not require a locking screw of any kind.

Another feature of the Zip is that it can be used as a one-piece insertion (its two implant halves are clicked together before implantation) or it can be used as a two-piece insertion (its two implants halves are clicked together *in situ*). Using the device as a two-piece means that the supraspinous ligament can be spared because the halves are connected underneath. Eidelson says this feature means you do not have to “take many steps to achieve the final fixation”.

Ian Armstrong (Southern California Spine Institute, Los Angeles, USA) was the first spinal surgeon to use the ZIP ULTRA™ and, like Eidelson, thinks it is technologically advanced. He believes it is a “game changer in the world of spinal surgery”, commenting: “Its well-thought-out design makes its use easy and intuitive for the surgeon. There is virtually no learning curve, and



Scott Robertson