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Dynamic Interspinous Process Technology

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Study Design. A literature review.

Objectives. To evaluate the mechanisms of action and effectiveness of interspinous distraction devices in managing symptomatic lumbar spinal pathology.

Summary of Background Data. Fusion operations have traditionally been used to manage many disorders of the lumbar spine related to deformity, pain, or instability. Concern over the long-term effects of fusion on adjacent segments has led to the development of the concept of dynamic stabilization.

Methods. A Medline search was performed using the key words "interspinous implants," "interspinous devices," and "lumbar dynamic stabilization." The abstracts of each were reviewed. Relevant articles were reviewed in detail and other appropriate references obtained. In addition, when available, nonpublished manufacturer's information was reviewed.

Results. Articles describing the following implants were included in this review: the Minns Device, the Interspinous "U," the Diam, the Wallis Implant, and the X STOP.

Conclusions. These devices continue to be evaluated in clinical trials. Early results suggest a possible role in the management of degenerative disorders of the lumbar spine.

Key words: interspinous, distraction, implant, device, lumbar dynamic stabilization. **Spine 2005;30:S73–S78**

Traditionally, spinal fusion has been the mainstay of surgical approaches to the management of low back pain or lumbar instability. Advances in biomedical technology, including pedicle screw fixation[1] and bone morphogenic proteins,[2] have enabled surgeons to achieve fusion rates between 90% and 100%. However, despite the improvement in radiographic fusion rates, there are some authors who think that there has not been a corresponding improvement in clinical outcomes.[3,4] Furthermore, there is some evidence that fusion may increase the biomechanical stresses imposed on the adjacent segments leading to transitional disease,[5] which may occur at an earlier rate in instrumented fusion cases.[6–8] These issues have led some investigators to explore novel approaches to "stabilize" the lumbar spine.

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One such concept is that of "dynamic stabilization," or "soft stabilization." Dynamic stabilization has been defined as: "a system that would alter favorably the movement and load transmission of a spinal motion segment, without the intention of fusion of the segment."[9] In other words, such a system would restrict motion in the direction or plane that produces pain, or painful motion, but would otherwise allow a full range of motion.

There have been a number of dynamic stabilization devices trialed in lumbar spinal disease, many with differing biomechanical principles. Some examples include the Bronsard's ligament, which loops around the spinous processes;[10,11] the Graf Ligament,[12,13] the Dynesis Spinal System (Zimmer Spine, Warsaw, IN),[14,15] and the FASS system (AO International, Davos, Switzerland),[9] all of which are pedicle screw based. However, this review will focus solely on the interspinous implants used for dynamic stabilization, namely, the Minns device, the Interspinous "U" (Fixano, Péronnas, France), the Diam (Medtronic, Memphis, TN), the Wallis (Spine Next, Bordeaux, France), and the X-Stop (St. Francis Medical Technologies, Concord, CA).

Pathophysiology and Mechanism of Action

Early descriptions of neurogenic claudication secondary to lumbar stenosis have been attributed to Verbiest.[16] This syndrome is manifested by radicular pain, often bilateral, that is exacerbated by standing, walking, and other positions that place the lumbar spine in extension. A flexed posture improves or relieves the symptoms. In severe cases, sensory loss and/or motor deficits are evident. Although several theories have been postulated[17] to explain the occurrence of these symptoms, the precise mechanism remains unclear. It is apparent that the observed pathologic progression begins with degenerative changes within the disc, which eventually lead to loss of disc height. Resultant instability may worsen the spondylosis by inducing facet joint hypertrophy.[18] Furthermore, hypertrophy and buckling of the ligamentum flavum, particularly during extension, contribute to the reduction in size of the thecal sac limiting the space available for the cauda equina. Although there is documentation of improved cross-sectional area with flexion,[19,20] Herno *et al* reported a poor correlation between the degree of radiologic stenosis and the clinical manifestations.[21,22]

The degenerated disc itself has been further examined as a pain source on its own. This has traditionally been attributed to segmental instability that develops with disc degeneration and has been used as an indication for fusion in these patients; however, the concept of a degenerative disc leading to segmental instability has been

challenged by some authors.[9,23] Recent reports suggest that the progressive degeneration of a lumbar disc leads to a reduction in motion, rather than an increase in mobility that would be expected if the process led to instability.[9,24,25] Furthermore, it has been suggested that a degenerated lumbar disc results in altered transmission of forces with a resultant increase in the stress experienced by the anulus. The increased stress is posture dependent and has been postulated to be the cause of "mechanical back pain."[9,23]

Many patients complain of symptoms attributable to both mechanisms and the clinical manifestations of an individual's pain will differ depending on which forces or mechanisms are the most prevalent. Therefore, treatment must be individualized or able to adequately address both mechanisms.

The developers of interspinous implants have attempted to address some of these mechanisms with their devices. In general, these devices are free-floating and act as a spacer placed between the spinous processes at a symptomatic level. Biomechanically, their presence acts to limit extension with no effect on flexion, axial rotation, or lateral bending[26,27] (and product information on the Wallis Implant, Spine Next, Bordeux, France). This is thought to reduce the degree of thecal sac impingement due to buckling of the ligamentum flavum. Furthermore, it is thought that these devices act to "off-load" the facet joints by acting like a "shock-absorber" and dissipate energy forces dorsally.[26,28,29] Cadaveric studies using profilometry have shown that these implants reduce intervertebral disc pressures, particularly in the region of the posterior endplate,[26,30] confirming the data obtained using computer generated models (product information on the Wallis Implant, Spine Next). Therefore, it appears that these implants have several biomechanical effects, which may act to "stabilize" the lumbar spine and have a positive effect on clinical symptomology. Of note, the biomechanical studies published thus far have demonstrated that these devices have no effect on the intradiscal pressures or motion at adjacent segements[26,30] (and product information on the Wallis Implant, Spine Next). Furthermore, when comparing implanted and nonimplanted spines, there was no statistical difference observed in the neural foraminal height, width, or area at adjacent levels,[31] nor was there any change in facet loading pressures above and below the implant.[29] These data support the hypothesis that these implants act locally and have no appreciable effect on the adjacent levels. This is further supported by 2-year clinical follow-up data provided by Zucherman *et al*, in which no changes to lumbar sagittal angulation or coronal curves were noted over this time period.[32] Although further long-term studies are required to thoroughly assess the theoretical risk of segmental kyphosis and possible sagittal imbalance as a result of the use of these implants, the current available data suggest that this may not be an issue.

■ Types of Implants

The concept of an interspinous implant to induce flexion in the lumbar spine was introduced as early as the 1950s with the Knowles device. This was a steel cylindrical implant designed for temporary insertion while the patient healed on their own.[33] There was some difficulty with loosening and migration of the device, which contributed to its disuse.

The Minns device was the first "soft" interspinous spacer to be reported.[26] The implant was fashioned out of silicone into the shape of a dumbbell. They were made in various sizes with the central diameter ranging from 8 to 15 mm. The implants were found to prevent the approximation of the spinous processes when the vertebral bodies were subjected to an axial loading force. The spinous process deflection increased with the increasing diameter of the implant. It was concluded that the implant would "off-load" the facet joints and decrease the intradiscal pressure. However, despite the promising *in vitro* results no further development or clinical application has been published to date.

Two other devices, the Interspinous "U" and the Diam, are undergoing development and clinical trials; therefore, published information is limited. The Interspinous "U" appears to improve clinical symptomatology that is exacerbated in extension.[34]

The Diam (Figure 1) is a silicone interspinous spacer, which is covered by a polyethylene coat. It is secured in place with two ligatures: one placed around the spinous process above and one around the spinal process below. Caserta *et al* published a report of 82 cases that underwent elastic stabilization.[11] Of these cases, 25 were performed in conjunction with instrumented fusion. Initially, they used the Bronsard's ligament but state that they currently prefer the Diam. It is unclear from their report the number of patients receiving the interspinous device, but the authors conclude that the Diam is safe and yields good clinical results. Furthermore, they think that it reduces the mechanical stress on the levels adjacent to the instrumented fusion. Schiavone and Pasquale have reported on 22 patients with segmental degenerative disease who underwent Diam implantation as their sole treatment.[35] After a mean follow-up of 10 months, 16 patients had an excellent and 4 had a good outcome. The authors concluded that Diam implantation is a safe and simple procedure that has good results and does not compromise future surgical options. These proposed indications and the long-term follow-up are currently being further evaluated in randomized prospective trials.

Sénégas began developing an interspinous implant in the mid-1980s. The first report was in 1988[36] with a subsequent report in 1991.[37] This was a "floating system" that was comprised of a titanium spacer placed between the spinous processes and secured with two Dacron "ligaments" that were wrapped around the spinous processes. This system was not initially marketed commercially while waiting for the long-term follow-up of

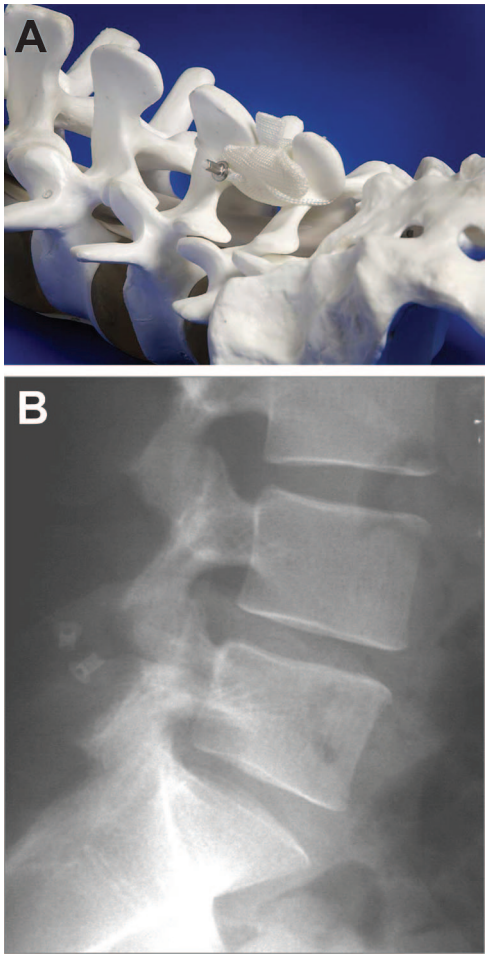

Figure 1. The Diam. **A**, An illustration depicting the implant *in situ*. **B**, Postoperative lateral radiograph. (Images are courtesy of Medtronic.)

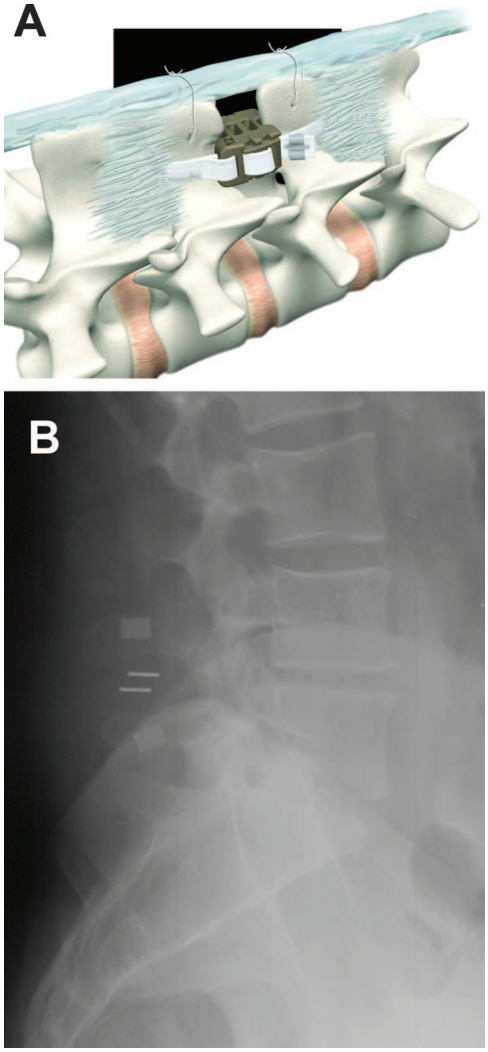

Figure 2. The Wallis implant. **A**, An illustration depicting the implant *in situ*. **B**, Postoperative lateral radiograph. (Images are courtesy of SpineNext and Abbott Laboratories.)

prospective, controlled trials. One reported trial was a comparison of patients undergoing repeat surgery for a recurrent L4–L5 disc herniation.[38] This study was prospective but not randomized. The improvement in leg pain was similar in both groups; however, the patients receiving the interspinous implants displayed a greater improvement in their low back pain and a greater reduction in analgesic requirements. Despite these favorable results, it was thought that the device could be further improved. As a result, a second-generation device was developed and subsequently named the "Wallis Implant" (Figure 2).[28] This newer implant has a slightly different shape and is composed of polyetheretherketone (PEEK) rather than titanium. These properties confer a greater degree of elasticity than the first-generation model. Clinical trials are ongoing with this implant. Currently, Sénégas suggests that the Wallis system is appropriate for the following indications:[28] 1) following discectomy for a large herniated disc in which there is significant loss of disc material, 2) redo discectomy for recurrent herniation, 3) discectomy for herniation of a transitional disc with sacralization of L5, 4) degenerative disc adjacent to a fused segment, and 5) isolated Modic I lesion attributable to chronic low back pain.

Another titanium interspinous implant that is currently undergoing investigation for FDA approval is the X STOP (Figure 3).[27,30,39–41] This device was designed to treat symptomatic lumbar stenosis, in particular those patients suffering from neurogenic claudication who have significant relief when sitting or flexing their lumbar spines, by placing the symptomatic segments in slight flexion and preventing extension.[30] The X STOP consists of an oval titanium spacer that is positioned between the two symptomatic spinous processes. The lateral wing is then attached to prevent the implant from migrating anteriorly or laterally out of position. Initial published reports investigated the biomechanical effects of the implant in cadaveric models. Swanson *et al*[30] examined the changes in intradiscal pressures both at the level of the implant (L3–L4) and at adjacent levels during flexion and extension ranges of motion. They found that, when the spines were in a neutral or extended position, there was a significant decrease in the intradiscal pressure and the pressure at the posterior anulus of the implanted segment. They found no significant changes in the pres-

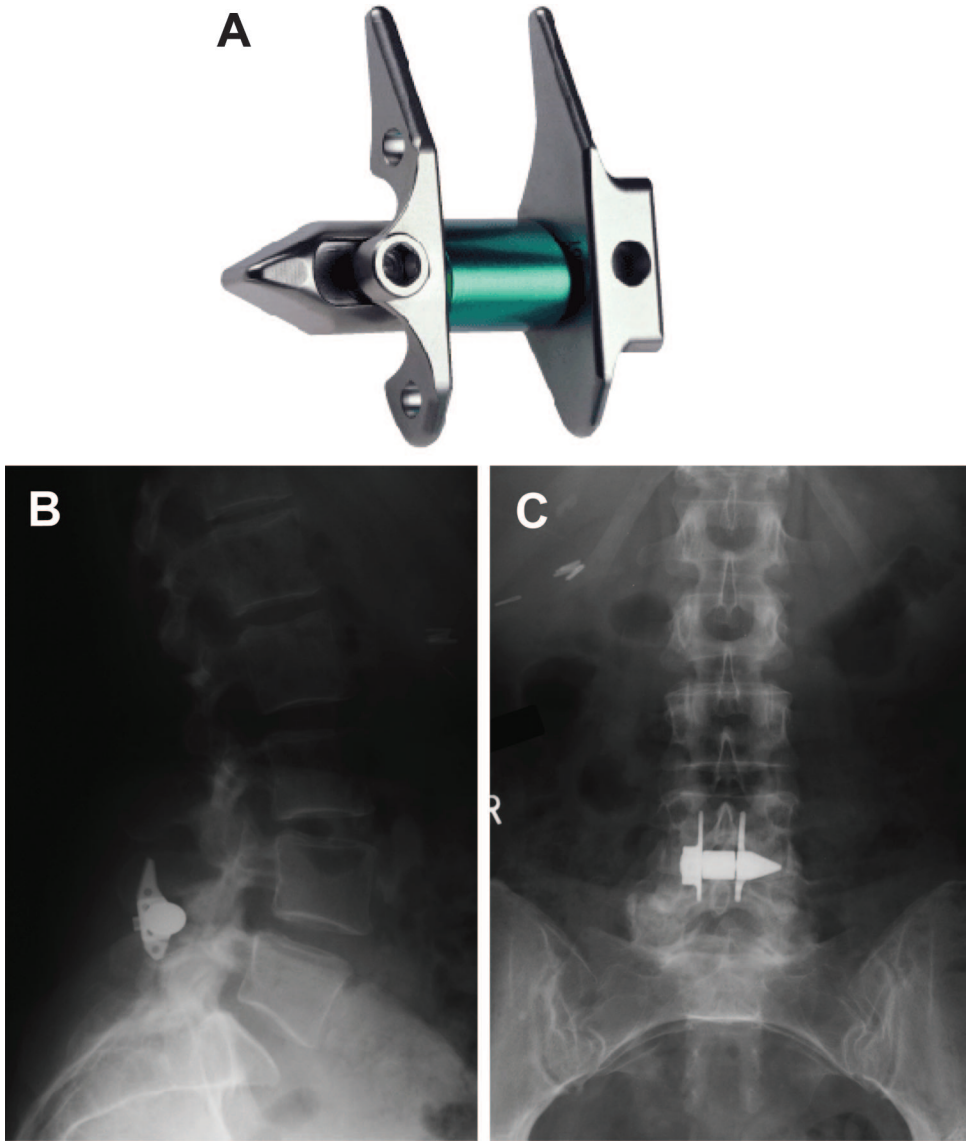

Figure 3. The X Stop. **A**, Illustration of the device. Lateral (**B**) and AP (**C**) postoperative views of implant. (Images are courtesy of St. Francis Medical Technologies.)

sure measurements at adjacent levels. They concluded that the implant would be unlikely to induce any degenerative changes at adjacent levels. Lindsey *et al*[27] explored the resultant changes in kinematics of cadaveric spines (L2–L5) following insertion of the X STOP at L3–L4. They demonstrated that the implant significantly altered the motion during flexion-extension testing. Implantation alone places the spine in approximately 2° of flexion and was found to significantly reduce motion at the implanted level when moving from a flexed to an extended position. However, on the basis of their data, they concluded that there was no effect on axial rotation or lateral bending at the implanted level, nor were there any significant effects observed at the adjacent levels. Encouraged by these *in vitro* studies, the X STOP has been implemented clinically. Of the devices reviewed, this is the only implant that is reported to be inserted under local anesthesia. Zucherman *et al* have published both their 1-year[40] and 2-year[32] results of a prospective, multicenter, randomized trial, in which 191 patients were treated with either the X STOP or nonoperative management.[40] Using the Zurich Claudication Questionnaire and the SF-36, they observed a significantly greater improvement in clinical symptoms in the X STOP group compared with controls at all time points. They concluded that the 59% success rate observed in this study is comparable to the 64% (good to excellent outcomes) reported in a meta-analysis[42] of patients treated with laminectomy. However, a direct comparison between these two methods in a controlled clinical trial has yet to be described. Possible mechanisms to explain this clinical effect may be that the implant prevents extension and reduces intradiscal pressure, as in the cadaveric work discussed above. Furthermore, the X STOP appears to improve the cross-sectional area of the thecal sac as well as the size of the intervertebral foramens.[31,41] As alluded to above, the current primary indication is for patients with symptomatic lumbar stenosis who improve clinically in a flexed position.

■ Conclusion

Because of the anatomic considerations of the S1 spinous process, these implants are not favorable, nor currently recommended, for use at L5–S1. However, there is ongoing research aimed at modifications to overcome these challenges. The concept of dynamic stabilization, compared to fusion, is a particularly attractive one, especially for younger patients who would bear a greater burden on adjacent segments during their prolonged follow-up. In addition, its use does not restrict or eliminate any potential future therapeutic options that are currently being developed, such as arthroplasty. Despite some variation in their proposed indications, interspinous implants share the mechanism of limiting extension of the lumbar spine and, as a result, appear to improve clinical symptoms. Certainly, no meaningful comparison can be made between any of these implants at this time, nor can any comparison between the implants and traditional surgical approaches such as laminectomy and/or fusion; this will require further studies. It may be that these devices will also find an additional roll in conjunction with fusion procedures to "protect" early degenerative discs adjacent to fused segments.[9] Although the use of interspinous implants is still experimental, the early results are promising, and it is likely that future studies will establish a niche for them in the management of lumbar spinal pathology.

■ Key Points

- Dynamic stabilization aims at restricting painful motion while otherwise enabling normal movement.
- Interspinous implants act to distract the spinous processes and restrict extension, having the effect of reducing the posterior anulus pressures and theoretically enlarging the neural foramen.
- There are a number of implants in various stages of development and investigation.
- Further randomized clinical trials will ascertain the optimal use of these devices.

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