CHAPTER 30

The interspinous ‘U’: a new restabilization device for the lumbar spine

D.L. KAECH, C. FERNANDEZ and D. LOMBARDI-WEBER
Neurosurgical Unit, Kantonsspital, CH 7000 Chur, Switzerland

1. INTRODUCTION

The French orthopedic surgeon Jacques Samani from Lyon originally invented the interspinous ‘U’ in order to protect adjacent levels after spinal surgery implementing rigid spinal instrumentation [1]. An other indication was for the protection of degenerated motion segments following decompressive surgery (e.g., after operation on recurrent disc herniation or following bilateral decompressive fenestrations for central spinal canal and lateral recess stenosis). These indications have immediate attraction for neurosurgeons who like to prevent secondary (i.e., postoperative) instability, or those who like to be able to restabilize moderately unstable motion segments without necessitating extension of a routinely used microsurgical approach.

Sgier [2] presented his preliminary experience with the interspinous ‘U’ in March 2001, and suggested that this interspinous support might be an alternative to pedicle screw fixation. This stimulated the interest of some neurosurgeons from Switzerland, Luxembourg and the Czech Republic, who collectively implanted 131 ‘U’ devices in Switzerland, and 18 in Luxembourg as of August 2001. A preliminary report comparing two dynamic restabilization devices (interspinous ‘U’ and Dynesys) was presented in October 2001 by Matge [3].

The interspinous ‘U’ is inserted after removal of the interspinous ligaments and resection of their bony attachments. At this time the measurement of the required size of the ‘U’ implant is made: 10, 12 or 14 mm. This implant will mainly prevent hyperextension and hyperflexion, but will also restrict some degree of rotation. However, it cannot be used as a substitute for a rigid fusion or three-column reconstruction in cases of marked instability and spinal deformity [4].

Before using these implants one must be aware of the failures reported by the inventor in his series of 106 patients operated between 1994 and 1999. The majority of failures resulted from insufficient decompression of central spinal canal stenosis. In these cases the decompression was insufficient because the bony resection was limited in order to attempt to retain enough laminar and spinous process bone to allow support of the implant. In some cases of attempted implantation at L5–S1 a of the interspinous ‘U’ was observed, due to an insufficient attachment to a too small spinous process of S1 [1].

The indications of interspinous ‘U’ implantation include minor segmental instability in patients requiring surgery for disc herniation and/or for central spinal canal stenosis at L4–L5, L3–L4 and L2–L3, (and only occasionally at L5–S1, if the spinous process of S1 is large enough [1,3]), as well as patients at risk of developing secondary instability after a decompressive spinal operation, as defined by Schönmayer [5]. The interspinous ‘U’ should theoretically prevent the development of the failed back surgery syndrome by restabilizing the intersegmental motion segment and by protecting the posterior spinal facet joints from overloading.

A detailed analysis of preoperative clinical, radiological, and intraoperative findings will confirm or cancel the indication for a restabilization by implantation of the interspinous ‘U’ at the end of a decompressive procedure (e.g., decompressive fenestration) for central canal stenosis, curetage of a herniated disc). There are some similarities of the interspinous
'U' instability workup with that of the evaluation performed prior to intervertebral cage implantation in the lumbar spine [6].

2. THREE PARTS OF INSTABILITY [6]

(1) Clinical instability can be suspected in a patient with mechanically induced low back pain, especially when arising from the forward bended position or under rotational torsion. Ketilainen and Valtosen described the instability catch, the painful catch and the apprehension phenomenon observed in the involuntary guarding against pain seen in cases of acute low back pain induced by forward bending [7]. Some patients have pain at night when they turn in their beds, and some experience pain when they travel by car over an uneven road.

(2) Radiological instability means displacement of more than 4.5 mm on lateral flexion-extension radiographs (i.e., anteroposterior) and/or more than 22 degrees of angular range of motion in the sagittal plane [8,9]. Further signs indicating decreased interssegmental stability include surgical absence of the posterior elements after laminectomy-facetectomy, the presence of intradiscal and/or intra-articular gas/vacuum, and edematous vertebral marrow changes (i.e., type I parietal marrow alteration) [10].

(3) Intraoperative instability can be assessed objectively by placing active traction on the spinous

Figure 1. Testing of 'intraoperative instability' with two clamps allowing traction on the spinous processes of the supra- and infracticent vertebra: (a) the initial distance is 2 cm; (b) under traction the distance is 3 cm; (c) initial position under ra fluoroscopy; (d) under traction the distance between the two clamps increases.
Figure 2. Three probes of differing sizes made for 10, 12 and 14 mm implants. The central probe has mounted the interspinous ‘U’ of 12 mm. Note the wing-clamps having a fenestration for additional tumour to the respective spinous process in order to further securing the implant.

Figure 3. Intraoperative view (head of patient to reader’s left) showing the probe inserting the 12 mm ‘U’ device between the opposed L4 and L5 spinous processes. Note the wing-clamps extending from the central ‘U’ and the internal ridges intended to prevent dislodgement.

processes utilizing clamps. A significant degree of motion induced by mild traction indicates decreased stability, whereas little motion under forced traction indicates a stable motion segment, as in markedly spondylotic patients with extensive osteo-phytic bridges and intersegmental calcifications, who do not need additional restabilization (Figure 1).

In other words, this intraoperative pulling or traction test is useful to confirm that linked vertebrae constituting a motion segment can easily be moved
passively, and can also be utilized to demonstrate rigidity in markedly spondyloitic and stenotic vertebral segments.

Informed consent is obtained before every operation, and the risk of later destabilization requiring a more invasive fusion procedure is explained.

3. SURGICAL TECHNIQUE

The interspinous ligaments together with a thin layer of the bony attachments to the opposing spinous processes must first be removed. The probe for the interspinous 'U' is then gently inserted and should fit reasonably tightly within the interspinous space.
If it is too loose, the next implant of greater size should be chosen. Three sizes are available with superoinferior dimensions of 10, 12, and 14 mm (Figure 2).

In cases of marked arthrosis with osteophytes also around the spinous process, the high speed drill should be used to eliminate unnecessary hypertrophic bone, which may impede a straightforward implantation of the 'U'.

Before insertion under gentle hammering (Figures 3 and 4), the operation table can be tilted back, to avoid an unphysiologic 'forced' kyphosis of a lumbar motion segment.

The wing-clamps of the 'U' are tightened by compression to the upper and lower spinous process (Figure 5). The pliers should allow parallel compression; with a Luor, there is a risk of cutting into the margins of the titanium implant.

The depth of insertion can be verified under lateral fluoroscopy (Figures 6–8) and the surgeon can check with an angled hook, that there is enough free space between the bottom of the 'U' and the thecal sack.

N.B. Problems can be encountered in cases of osteoporosis or in revision cases, where some parts of the spinous process may already be missing before starting the planned decompression. Undercutting decompression with removal of the ligaments flavum and opening of the lateral recess is required in cases of stenosis, but too extensive removal of laminar bone may jeopardize the implantation of the 'U', if it cannot rely on enough supporting bony structures. Total laminectomy is not compatible with the 'U' implant, as it eliminates the bony structures needed for its attachment.

For a straightforward procedure, improved pliers should be developed, that would enable measurement of the spinous process thickness and of the achieved compression on the wing-clamps for fixing the 'U'. Although the wing-clamps of the 'U' can be attached to the spinous processes by a suture passed through the central hole (Figure 2), an additional fixation device may provide more solid and permanent
attachment. Hopefully a modified device will be developed for the L5–S1 level, where the interspinous 'U' cannot be implanted, when the spinous process of S1 is too small.

4. PRELIMINARY RESULTS

18 patients have been operated in Chur, Switzerland, between April and August 2001. The indications were as follows.

(1) Radiologic indicators of instability (minor slip, antero-, retroolisthesis, vacuum appearing on dynamic X-rays) in 8 patients needing surgery for spinal stenosis and in 1 patient for disc herniation.

(2) Increased risk of destabilization/intraoperative hypermobility in 2 patients operated for recurrent disc herniation and in 5 patients for spinal stenosis.

(3) Protection of an adjacent level L4–L5 with annular tear in 1 patient needing a cage fusion for recurrent disc herniation L5–S1 (Figures 9–11).

(4) Protection of stand-alone Steffee ramps in a L4–L5 revision surgery for recurrent disc herniation with stenosis in 1 patient (Figure 12).

Figure 9. Antero-posterior view showing the interspinous 'U' device inserted in order to protect L4–L5 against exaggerated degeneration after VariLift™ cage insertion at L5–S1. The patient was operated for a recurrent disc herniation at L5–S1 and had an annular tear at L4–L5 with posterior bulging of the intervertebral disc.

Figure 10. Lateral follow-up image at 3 months after surgery showing physiologic lumbar lordosis of the lower lumbar spine and at the lumbosacral junction. The implants are in good position.

Figure 11. Ferguson view obtained parallel to the L5–S1 intervertebral disc space showing again the well-placed devices.
This last patient could have been at risk with stand-alone cages. As sufficient parts of the lamina and the intervertebral joints could be preserved in this slim lady, the 'U' was proposed instead of pedicular instrumentation, which would have required a much bigger and traumatizing approach.

N.B. Decompression for stenosis is made through microsurgical interlaminar fenestrations with flavectomy and opening of the lateral recess, and not by the old-fashioned laminectomy, after which the implantation of an interspinous 'U' is no longer possible.

4.1. Complications

One revision for extradural hematoma, including enlargement of the decompressive fenestrations, mainly at the second stenotic level.

Generally speaking, all but 3 patients made a quick postoperative recovery of their walking ability, exception made for 3 ladies over 70 years of age.

4.2. Problems at 6 months follow-up

- One minimal loosening of 2 mm on dynamic X-rays after 3 months, but without local pain or tenderness.
- One patient required local anesthesia of a trigger point at the iliac crest and developed after 4 months some recurrent root pain during work. MRI showed moderate scarring around the L5 root following surgery for recurrent disc herniation.
- One older patient with long lasting and not well improving root pain underwent a CT-guided nerve root injection.
- Two patients had a recurrent low back pain episode, one following body building exercises, one after a fall: radiologic and clinical follow-up will show if the suspected minimal loosening will increase and, in case of daily pain, require revision surgery.

5. CONCLUSIONS

The interspinous 'U' appears to be a minimally invasive stabilization device for patients undergoing microsurgical decompressive procedures, and who have signs of minor instability or risks of a potentially increasing postoperative instability [11].

It is not a substitute for a well-indicated but more invasive 'three-column fusion' procedure in cases of major instability, anterolisthesis, lytic spondylolisthesis, and evident scoliotic deformity [4,6].
It may however be a substitute for elderly patients, who need a spinal decompression, but may not want to undergo 'macroscopic, heavy metal' fusion procedures, and sometimes not even stand-alone cage implantation [11].

As unsatisfied patients may go to another surgeon, it is interesting to acknowledge Marnay's experience of three French patients requiring implant removal for anterior migration with compression of the thecal sac. In one case there was even a dural leak [12].

In cases of bilateral decompressions that include the midline (i.e., 'interlaminectomies') the implant must possibly be secured by an additional fixation to the spinous processes. The company representatives had not heard from a similar complication before. The initial design of this implant has however been improved.

An extension of the indications includes the protection of stand-alone cages, instead of pedicular instrumentation. Biomechanical tests have been initiated with Prof. S. Otahal in Prague, Czech Republic, in August 2001, to investigate the effectiveness of such a combination.

Our patient with stand-alone ramps plus interspinous "U" at L4-L5 is stable after 6 months (Figure 12).

Long-term follow-ups are needed for the neurosurgical community in order to prove the clinical benefit and cost effectiveness of this implant.

REFERENCES