Editorial

A novel strategy of non-fusion instrumentation with coflex interlaminar stabilization after decompression for lumbar spinal stenosis

Hiroshi Nomura

Department of Orthopaedic Surgery, Hiroshima Red Cross Hospital & Atomic-Bomb Survivors Hospital, Hiroshima, Japan

Correspondence to: Hiroshi Nomura. Department of Orthopaedic Surgery, Hiroshima Red Cross Hospital & Atomic-Bomb Survivors Hospital, Hiroshima, Japan. Email: hiroshi20052002@yahoo.co.jp.

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Lumbar spinal stenosis (LSS) is a pathological condition in which degenerative changes in the lumbar spine lead to spinal canal narrowing and compression of the dural tube and spinal nerve roots. Most patients with LSS have accompanying lumbar spondylosis with or without spondylolisthesis based on the aging process, and some experience regional low back pain due to spinal instability. Surgical treatment is indicated for patients with LSS who do not respond to conservative therapy. Conventional treatments are decompression alone and decompression plus spinal fusion using a pedicle screw and rod system with bone graft materials or a combination of anterior and posterior fusion. In terms of decompressive procedure, insufficient decompression can cause recurrence of stenosis after surgery; however, too much removal of the posterior elements and excessive facetectomy can cause postoperative spinal instability of the operated level. Iatrogenic fracture of the pars interarticularis due to massive laminectomy during surgery may result in isthmic spondylolisthesis. To avoid postoperative instability or to reduce regional low back pain due to degenerative spinal instability, additional spinal fusion is a promising strategy. Between 2002 and 2007 in the United States, 4,699 (79.4%) of 5,915 patients with stenosis plus spondylolisthesis were treated with decompression plus spinal fusion, whereas 19,699 (78.6%) of 25,060 patients with stenosis alone were treated with decompression alone (1). Whether additional spinal fusion is essential for LSS with low-grade spondylolisthesis remains controversial, but there is no doubt that spinal fusion is the gold standard operation for LSS.

However, spinal fusion is associated with more complications than decompression alone, such as deep infection, implant fracture, bleeding, pseudarthrosis, or occasionally mortal neurovascular injury (1). Additionally, one of the most important complications is adjacent segment disease (ASD) due to abnormal loading and increased mobility in adjacent segments after spinal fusion. For example, Ghiselli *et al*. (2) reported that the rates of symptomatic ASD requiring surgery at adjacent segments were 16.5% at 5 years and 36.1% at 10 years after the index fusion. From the viewpoint of ASD, decompression alone with the preservation of the motion segment is reasonable. However, around 10–25% of the patients with decompression alone are also required to undergo a second surgery depending on the progression of the spinal degeneration due to the aging process, e.g., recurrence of the stenosis or low back pain due to spinal instability of the operated level (3-5). In fact, Postacchini (5) reported that bone regrowth of the previously resected posterior vertebral elements in patients with degenerative spondylolisthesis was more severe when no fusion was performed. Thus, choosing between decompression alone and decompression plus spinal fusion to acquire long-term successful outcome is a dilemma.

Regarding this issue, Auerbach's group (6) proposed a new spinal fusion option using the novel spinal implant Coflex Interlaminar Stabilization (ILS) (Paradigm Spine), which was approved by the Food and Drug Administration, with 2-year results from prospective and randomized study published in *Spine* in 2013. The Coflex ILS is a U-shaped titanium device implanted in the interlaminar space with the "U" placed within millimeters of the dura

after laminectomy. This has superior and inferior wings that are crimped against the spinous process to provide stability. Implantation is done by simply placing the device into the interlaminar space between the superior and inferior spinous processes after bilateral segmental laminectomy. Functionally, the device acts as a third joint and offloads the facet joints, providing neutral stabilization while maintaining normal spinal kinematics. Furthermore, it allows for compression in extension while permitting normal flexion, allowing maintenance of sagittal balance and lordosis as well as rotational and translational motion as opposed to fusion. Additionally, the mechanical offloading of the facets aids in the relief of back pain and maintenance of foraminal height over time. Hence, this implant appears ideal in overcoming time-dependent degenerative changes after laminectomy; however, further long-term safeguard examination is needed.

In 2016, Bae *et al*. (7) reported on a long-term 36-month follow-up analysis of the Coflex ILS after decompression, examined under a Food and Drug Administration investigational device exemption clinical trial, published in *Neurosurgery*. They compared decompression and Coflex ILS with decompression and posterolateral fusion with autologous bone graft applied to patients with moderate to severe LSS with back and leg pain with or without low-grade spondylolisthesis. This large-scale trial was a prospective, randomized investigational device exemption study conducted at 21 clinical sites in the United States. The clinical outcomes measured included the Oswestry Disability Index (ODI), Short-Form 12, Zurich Claudication Questionnaire, and visual analogue scale back and leg pain assessments. Radiographic outcome measures were collected at baseline and 36 months to compare dynamic stabilization with ILS with static stabilization of fusion for quantitative motion analysis as well as measurement of foraminal height in the ILS group.

According to the results, substantial and comparable improvements were observed in both groups for patient-reported outcomes, but the ILS group had a higher percentage of clinically significant improvement in the ODI compared with the fusion group. The radiographic examination showed that the range of motion at both operated and adjacent levels were maintained in the patients treated with the ILS, although the range of motion at the level superior to the fusion was significantly increased in the fusion group, implicating the possibility of ASD. The mean change from preoperative to month 36 was minimal in the foraminal height of the ILS group. Therefore, the authors concluded that Coflex ILS is durable and effective at improving overall composite clinical success without altering normal spinal kinematic motion at the operated level of decompression or at the adjacent levels.

The authors mentioned specific representative non-operative site adverse events with Coflex ILS: new or worsening pain, 40%; deep infection, 0.9%; wound problems, 13%; component loosening, 1.9%; component migration, 1.4%; component breakage, 1.4%; fracture of the spinous process or pars interarticularis, 5.1%; musculoskeletal and neurological events, 64.2% and 26.0%, respectively. The indications for reoperations in the ILS group are the following: persistent pain, 7.4%; wound problems, 3.3%; component loosening, 1.4%; fracture of the spinous process or pars interarticularis, 1.9%. Because each individual incidence of adverse events was closely similar to that in the fusion group, the authors emphasized that Coflex ILS is a safe implantation device for fusion, similar to conventional fusion implant. To prevent fracture of the spinous process, the remaining size and fragility of both the superior and inferior spinous processes after laminectomy should be considerable in each case before implanting the ILS.

Since the early 1990s, posterior dynamic stabilization of the lumbar spine using Graf ligamentoplasty system (Sem Co.) has been utilized in the treatment of degenerative lumbar disorders, the main concept of which is similar to that of the ILS (8-10). The Graf artificial ligament system is composed of titanium pedicle screws and looped braided polyester bands connected to the pedicle screws under applied compressive force between the screws to stabilize the operative segment in lordosis. Although Kanayama *et al*. (8) reported that the long-term outcome of Graf ligamentoplasty was rather satisfactory, several clinicians reported negative clinical outcomes of the Graf system involving high incidence of ASD, and they stated that the outcome was apparently less promising than that of posterolateral fusion (9,10).

Similarly, in 1994, dynamic stabilization *in situ* through the Dynesys system (Zimmer Spine), which consists of titanium alloy screws connected by an elastic synthetic compound (polycarbonate-urethane spacers and polyester cords), has been introduced as a motion-preserving device in an attempt to overcome the disadvantages of fusion and provide sufficient stability to restore normal segmental kinematics, prevent instability, and avoid adjacent segmental degeneration (11,12). According to Schaeren *et al*. (11), dynamic stabilization through the Dynesys pedicle screw

system in addition to decompressive laminectomy was applied for patients with LSS plus degenerative spondylosis, leading to excellent clinical and radiologic results; however, some degeneration at the adjacent levels was noted in 47% of the patients 4 years after the operations, implicating that the degenerative disease was progressive and that degeneration at adjacent motion segments remained a problem. Furthermore, the recent comparative study of the Dynesys dynamic stabilization with the traditional fusion technique showed that Dynesys has less promising long-term outcomes than fusion (13).

Correspondingly, at the beginning of the 21st century, the segmental spinal correction system (SSCS) (ulrich Gmbh & Co.) has been introduced as one of the dynamic non-fusion pedicle screw-rod systems used for stabilization of the lumbar spine, with several positive clinical results (14). For example, Morishita *et al*. (14) reported on the kinematic evaluation of the adjacent segment after lumbar instrumented surgery using dynamic non-fusion stabilization. Their results were compared with those that used rigid fusion, and they showed that the SSCS preserved 14% of kinematic operations at the instrumented segment at around 36 months after implantation, which may prevent the incidence of ASD. Although it is debatable if the 14% preservation of the kinematic motion at the operated level after implantation of the SSCS is adequate for long-term prevention of ASD, this is likely one of the most promising screw-rod dynamic stabilization systems thus far.

As for another unique challenge of the interspinous implantation similar to the ILS, the X-STOP interspinous process distraction system (Medtronic) has been attempted in Europe since 2002 principally for patients with LSS whose symptoms are exacerbated in extension and relieved in flexion of the lumbar spine (15). In the operative method, the X-STOP implant is only inserted between the spinous processes without decompressive procedure. The patient is under a local or general anesthetic in the knee-to-chest position, providing indirect decompression of nerve roots with distraction between the spinous processes of adjacent lumbar vertebrae. Thus, the main benefit of the X-STOP implant is that it is less invasive than other surgical procedures. Unfortunately, subsequent reports of effectiveness have been less promising and revealed unsatisfactory failure rates (16). A recent small study of the X-STOP implant focusing on lumbar foraminal stenosis, but not cauda equina claudication, showed acceptable clinical results (17). The patient number of all trials described above was relatively small, usually fewer than a hundred. Compared to those trials, the size of the ILS trial of Bae *et al*.'s (7) is much larger (n=322; ILS group, 215; fusion group, 107). They also evaluated the ILS study using different objective methods, which were all considerable assessments (7).

As mentioned above, the ability of the ILS to provide relief of painful symptoms while maintaining segmental motion at both operated and adjacent levels is remarkable (7). In addition, the ILS maintains segmental stabilization without increasing angular and translational motion at the adjacent segments, thus maintaining the kinematics of the adjacent level. Bae *et al*. (7) listed several limitations of the study, including the lack of comparison with decompression alone, and recommended further study to compare decompression with ILS stabilization with decompression alone to determine the appropriateness of ILS, particularly in patients without spondylolisthesis. The clinical outcome after decompression and ILS stabilization is possibly superior to that after compression treated by conventional laminectomy associated with extensive detachment of the multifidus muscle from the spinous process bilaterally and wide facetectomy. Currently, various minimally invasive laminectomies without spinal fusion have been developed to treat LSS, such as bilateral decompression via a unilateral approach using a microendoscope and a tubular retractor, lumbar muscle-preserving interlaminar decompression, and lumbar spinous process-splitting laminectomy (18). In any minimally invasive technique, the posterior supporting structures and paravertebral muscles can be strictly preserved as much as possible during the decompressive procedure. Interestingly, a recent report revealed that there is little value in adding fusion to decompression surgery compared with decompression only, even with standard laminectomy (19). If the long-term outcome of decompression plus ILS is almost the same as that of decompression alone, the latter would be more favorable because it has no graft-related complication, as described above. Further comparative studies of ILS stabilization to decompression alone, especially performed using a minimally invasive technique, are interesting.

The ILS study reported by Bae *et al*. (7) targeted patients with degenerative spondylolisthesis up to Meyerding grade I who were evaluated in sagittal plane translation on flexion-extension radiographs; however, they did not evaluate the scoliotic degeneration in the coronal plane. Considering that the mean change from preoperative to month 36 was only –0.30 mm in foraminal height after the ILS implant, the ILS might be also useful for the treatment

of degenerative scoliosis associated with foraminal stenosis. Cho *et al*. (20) previously reported that the complication rate after posterior fusion and instrumentation for degenerative lumbar scoliosis was 68%, consisting of 30% early perioperative complications, including one case of mortality by pulmonary embolism, and 38% of late complications. In addition, they showed that ASD was associated with 32% of the patients. In contrast, dynamic stabilization using the Dynesys system, in addition to decompression, was reported to be a safe procedure in elderly patients with degenerative lumbar scoliosis and leads to significant improvement of clinical outcome (12). Because non-fusion stabilization is less invasive than instrumented fusion, it has reduced intra- and post-operative risk factors, making it beneficial for elderly patients. Therefore, the ILS has applications for various types of degenerative lumbar disorders as it may be sufficient beneficial for long-term outcomes. A further report on the ILS is appreciated.

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Footnote

Conflicts of Interest: The author has no conflicts of interest to declare.

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