CLINICAL ARTICLE
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Clinical and Radiological Outcome of an Interspinous Dynamic Stabilization System in Degenerative Lumbar Disease: 24 Cases with Over 24 Months of Follow-up

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Objective: The purpose of this study was to analyze the clinical and radiological outcomes of dynamic stabilization with DIAM implants.
Methods: We evaluated 24 cases in which lumbar decompressive surgery was performed with dynamic stabilization using DIAM and having more than 24 months of follow up. Indications consisted of spinal stenosis with or without a herniated disc and transition level stenosis of the instrumented fusion segment. Operative data, clinical outcome, and plain and flexion/extension radiographs were obtained and compared to preoperative and postoperative data.
Results: The mean age at operation was 56.2 years (range 47–68); the mean follow-up duration was 28.4 months (range 24–37 months). The mean pain and function scores improved significantly from baseline to follow-up, as follows: back pain VAS score from 6.2 to 2.5, leg pain VAS score from 7.2 to 2.4, and Prolo's economic and functional rating score from 5.8 to 8.2. Radiological data demonstrated that the heights of the intervertebral foramen and the posterior disc increased significantly after the procedure. There were no implant-associated complications except for two spinous process fractures which occurred during DIAM insertion, and one case of wound infection. Flexion instability and spondylolisthesis occurred in two cases during the follow-up period.
Conclusion: These mid-term results suggest that DIAM is a safe and effective alternative surgical option in the treatment of degenerative lumbar stenosis without flexion instability. Careful follow-up is needed to watch for the development of flexion instability and spondylolisthesis.

Key Words: Dynamic stabilization • Lumbar vertebra • Degenerative spinal disorder • Instability

INTRODUCTION

There are many different surgical treatments for degenerative lumbar spinal stenosis. One of the most commonly used therapies is a decompressive surgery, which show successful results for pain reduction and neurological improvement. After long-term follow up of decompressive surgeries, however, defects of ligaments, tearing of fibrous annulus, facetectomy or combinations of these complications resulted in spinal instabilities[1)]. As a consequence, lower back pain or lower extremity pain recurred. Lumbar fusion was developed to stabilize decompressed spines, and has been the conventional surgical treatment for chronic low back pain caused by degenerative lumbar spines[4,15)]. Despite the high rate of successful fusions, lumbar fusion surgery has many adverse effects and limitations. Inconsistent clinical results, substantial morbidities and complications as well as accelerated adjacent level degeneration have been reported following lumbar fusion surgery[2)].

As an alternative to fusion, a dynamic stabilization restricting segmental motion would be advantageous in a variety of ways, including allowing for greater physiological function and reducing the inherent disadvantages of rigid instrumentation and fusion. 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"[15)]. The procedure leaves the spinal segment mobile, and its intention

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is to alter the load-bearing pattern of the motion segment and to control any abnormal motion at the segment.

A device for intervertebral assisted motion, or DIAM (Medtronic Sofamor Danek), is one of the most frequently used dynamic stabilization devices. It has an X-shaped silicone core covered by a polyethylene coat and two securing polyethylene cords. The implant is placed between spinous processes and acts as a shock absorber, provides facet distraction, decreases intradiscal pressure, and reduces segmental motion and alignment[12-13,17-18]. It is anchored in place with two laces, one around the spinous process above, and another around the one below, limiting excessive distraction. We evaluated the clinical results and dynamics of 24 patients who underwent decompressive surgery and DIAM implantation.

MATERIALS AND METHODS

1. Patient selection

Twenty-four consecutive patients (16 females, eight males), with a mean age of 56 years (range 47-68), who underwent monosegmental decompression and DIAM implantation, between October 28, 2005, and May 21, 2007, were included this study.

The indication for DIAM stabilization and concomitant decompression was low back pain with claudication due to degenerative spinal canal stenosis confirmed by Magnetic Resonance Imaging (MRI). The patients did not have severe osteoporosis (T score <-3.0), segmental instability (sagittal plane rotation greater than 15 degrees at L3-4, or greater than 20 degrees at L4-5), neither spondylolisthesis (sagittal plane translation greater than 4.5mm or 15% of the anteroposterior diameter of the vertebral body on dynamic radiographs)[6,10]. This study was approved by Institutional Review Board at Yonsei University Hospital (4-2009-0379).

2. Surgical technique

All surgeries were performed as open procedures with a midline incision. After muscle dissection, bilateral partial hemilaminectomy and foraminotomy were performed. Discectomy was performed in seven patients with disc herniation that was compressing nerve roots. Supraspinous ligaments and facet joints were preserved in all patients, whereas interspinous ligaments and ligamentum flavums were partially resected. A space for the DIAM was created between the spinous processes with a Kerrison punch. Then, the distractor was placed and the space was sized. The appropriately-sized DIAM was then folded and deposited. The implant was inserted between the spinous processes. The attached cords were then wrapped around the spinous processes above and below the DIAM implant and tightened (Fig. 1).

3. Preoperative evaluation

All patients were evaluated preoperatively, including documentation of patient history, physical examination, neurological examination, and imaging studies, including anteroposterior and lateral lumbar radiographs in a neutral position and lateral standing dynamic (flexion and extension) views, MRI, computed tomography (CT), and dual-energy X-ray absorptiometry (DEXA) bone densitometry. To evaluate the stabilizing effect of the DIAM, the segmental foraminal height, disc height, and extension-angles were measured at the stabilized segments. The disc heights were measured at the posterior edge of the disc at the stabilized level. The foraminal heights were measured by the distances between the lower margin

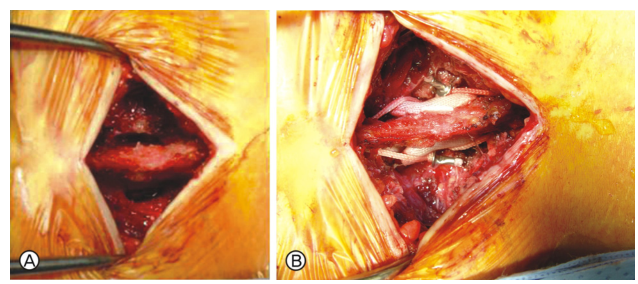

Fig. 1. Photographs showing procedures of DIAM implantation. A: Bilateral hemilaminectomy, discectomy and root decompression are performed. B: DIAM is implanted between spinous processes. The supraspinous ligament is preserved.

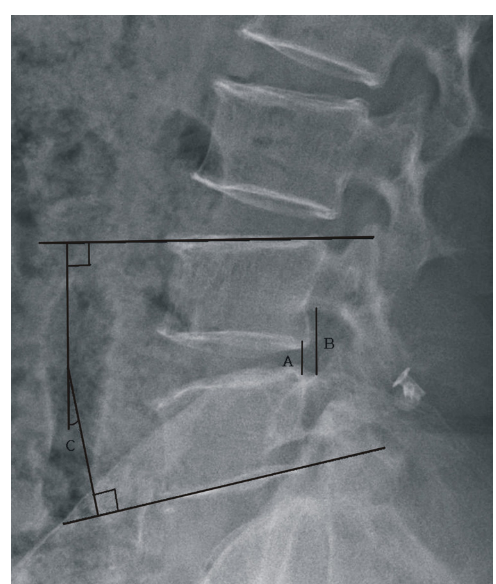

Fig. 2. Lateral standing radiograph obtained after implantation of DIAM at the L4-5 level. A: disc height, B: foraminal height, C: extension angle.

Table 1. Prolo's Economic-Functional Rating System

Economic status		Functional status	
E1	Complete invalid	F1	Total incapacity (or worse than before operation)
E2	No gainful occupation (including ability to do housework or continue retirement activities)	F2	Mild to moderate level of low-back pain and/or sciatica (or pain same as before operation but able to perform all daily tasks of living)
E3	Able to work but not at previous occupation	F3	Low level of pain and able to perform all activities except sports
E4	Working at previous occupation on a part-time or limited status	F4	No pain, but patient has had one or more recurrences of low-back pain or sciatica
E5	Able to work at previous occupation with no restrictions of any kind	F5	Complete recovery, no recurrent episodes of low-back pain, able to perform all previous sports activities

of the upper pedicle and the upper margin of the lower pedicle. The segmental extension-angles were measured on lateral radiographs by Cobb's angle from between the upper endplates of the corresponding segments with the PACS workstation (Centricity 2.0, General Electrics medical systems, Milwaukee, WI, USA) at full-extension (Fig. 2). The patients completed the visual analogue scale (VAS) for axial pain and radiculopathy. Prolo's economic and functional scale (Table 1)[14] were scored by interview.

4. Follow-up evaluation

VAS, Prolo's economic and functional score, pain medication, and complications were evaluated and the data were collected at the time of the patients' final visit. The plain radiographs (anteroposterior and lateral standing), and dynamic radiographs (flexion and extension) were taken at five-days post surgery and at the final follow-up. The foraminal heights, disc heights, and extension-angles were measured on follow-up radiographs. An instability was defined as sagittal plane rotation greater than 15 degrees at L3-4, or greater than 20 degrees at L4-5) or sagittal plane translation greater than 4.5 mm or 15% of the anteroposterior diameter of the vertebral body on dynamic radiographs[6].

RESULTS

The 24 patients in this study underwent DIAM implantation with concomitant decompressive surgery. The mean follow-up duration was 28.7 months (range 24-42 months), and all patients attended follow-ups.

Twelve patients (50%) had only lumbar stenosis, while seven patients (29.2%) had both stenosis and herniated discs requiring discectomy. The remaining five patients (20.8%) had adjacent segment disease after previously performed lumbar fusions. The L4-5 level was treated in 22 patients (91.7%), and the L3-4 level was treated in two patients (8.3%).

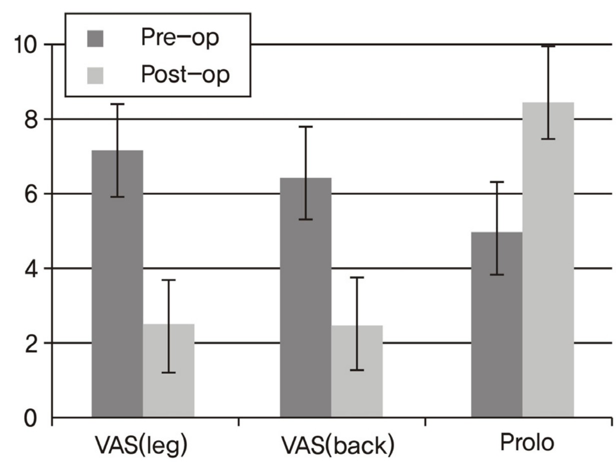

Fig. 3. VAS (leg, back) score decreased significantly in postoperative state, Prolo's scale significantly increased.

The VAS score for leg pain decreased from 7.20 ± 1.21 to 2.41 ± 1.60, and the VAS score for low-back pain decreased from 6.49 ± 1.45 to 2.50 ± 1.54. Prolo's economic and functional score increased from 5.01 ± 1.51 to 8.52 ± 1.41. All results were statistically significant ($p<0.05$) (Fig. 3).

The mean disc height was 9.50 ± 0.81 mm preoperatively, increased to 10.81 ± 1.13 mm postoperatively, and then decreased to 9.89 ± 0.93 mm at the final follow-up. The mean foraminal height was 12.84 ± 1.72 mm preoperatively, increased to 13.32 ± 1.87 mm postoperatively, and then decreased to 13.04 ± 1.78 mm at the final follow-up. The mean extension angle was 18.90° ± 3.56° preoperatively, which significantly decreased to 14.48° ± 3.36° ($P<0.05$) postoperatively and then increased to 16.81° ± 4.14° at the final follow-up (Fig. 4).

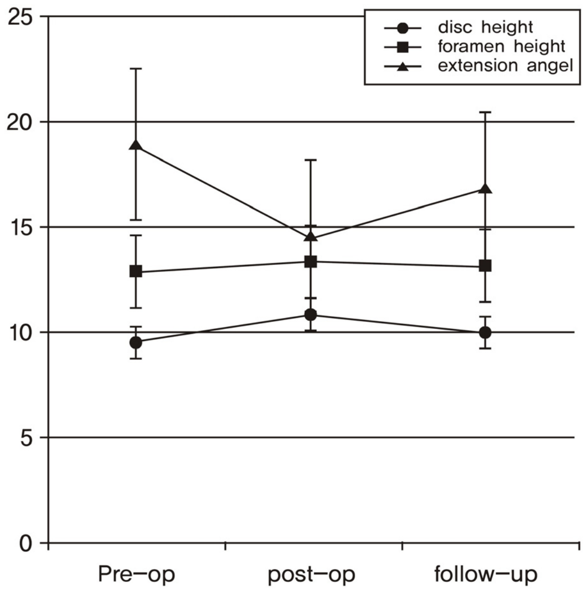

Fig. 4. Post-operative posterior disc height and foramen height increased, whereas extension angle decreased, but changes were not statistically significant.

1. Complications

Flexion instability and spondylolisthesis occurred in two patients during the follow-up period (Fig. 5). Two of the 24 patients showed spinous process fractures on the six-month follow-up CT scan (Fig. 6). All patients were asymptomatic. The implant in one patient needed to be removed due to wound infection.

DISCUSSION

Many dynamic stabilization devices have been introduced to treat lumbar spinal disease[5,17]. The devices can be classified into four categories based on their biomechanical principles[7,15]: 1) interspinous distraction devices; 2) interspinous ligament devices; 3) ligaments across pedicle screws; 4) semi-rigid metallic devices across pedicle screws. All these devices focus on how to preserve the normal dynamics of the spine. Although many biomechanical and clinical studies have been performed to determine the efficacy of these implants, no clear evidence has yet been established.

The DIAM is one of several interspinous distraction devices used, and works by distraction of the spinous process. Minns et al[12] reported that a circular silicone spacer placed between the spinous processes reduces the intradiscal pressure under load at the angles of flexion tested and contributes to the stability of the cadaveric lumbar spine. Phillips et al.[13] performed a biomechanical study with a DIAM, where they simulated surgical interventions (facetectomy and discectomy) at the L4-L5 level of six fresh human lumbar spine specimens, and motions were measured at the operated and adjacent segments. Insertion of the DIAM device after discectomy restored the angular motion to below the level of the intact segment in flexion-extension, reduced the increased motion in lateral bending, but did not reduce the increased axial

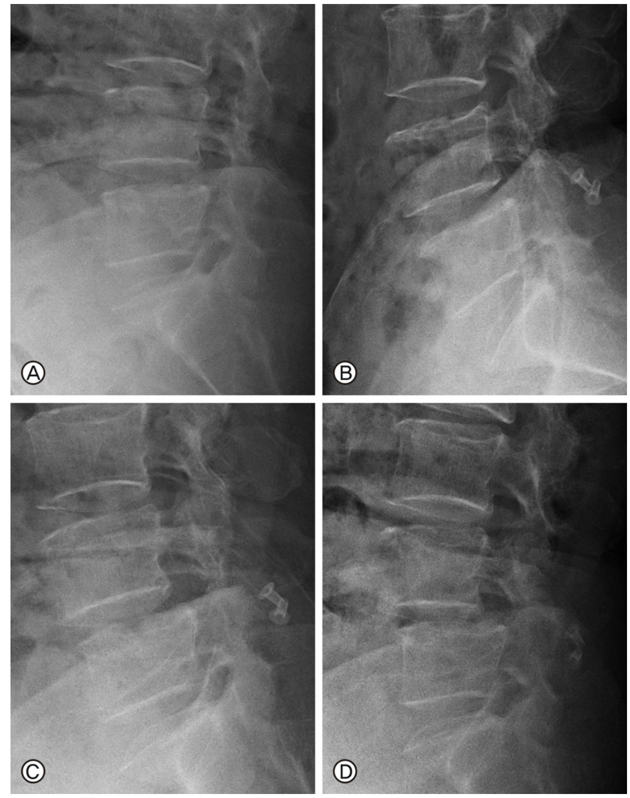

Fig. 5. Lateral radiographs showing increasing flexion instability and spondylolisthesis. A: preoperative radiograph. B: postoperative radiograph one month after surgery, C: six-month follow-up, D: 12-month follow-up.

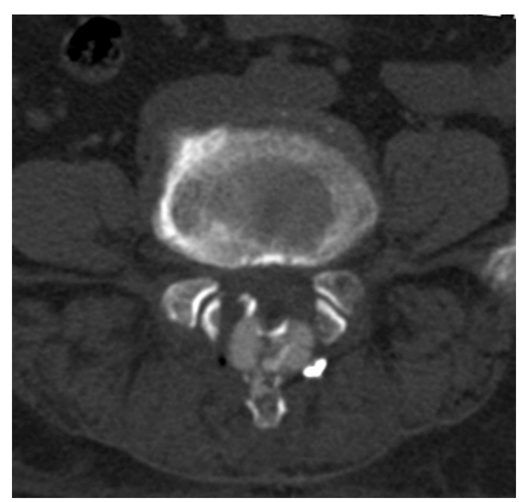

Fig. 6. Computed tomography showing spinous process fracture.

rotation. Bellini et al.[3] performed finite element analysis, simulating DIAM implantation at the L4/5 level. The simulation results suggest that the implant causes a reduction in the range of motion and unloads intradiscal pressure at the instrumented level, especially in extension, relative to the intact condition. Wilke et al.[17] analyzed four different interspinous implants: Colfex, Wallis, DIAM and X-Stop in 24 human lumbar spine specimens. All tested interspinous implants strongly stabilized and reduced the intradiscal pressure in extension, but had almost no effect on flexion, lateral bending or axial rotation. The DIAM did not affect motion of the segments adjacent to the implanted level in any study.

Although biomechanical studies support the efficacy of the DIAM, there are only a few studies evaluating the clinical outcomes of DIAM implantation. Mariottini et al[11] reported a series of 43 patients suffering from lower limb pain, with chronic or acute back pain, treated by microsurgical nerve root decompression and implantation of a DIAM. They showed a satisfying outcome in 97% of cases. Taylor et al.[16] performed a retrospective evaluation in 104 patients who had been implanted with a DIAM. The pain level showed improvement in 88.5% of patients. However, these studies were all retrospective and lack controls. Kim et al.[8] performed a case-control study which included 62 patients who underwent simple lumbar surgery (laminectomy and/or microdiscectomy) in a 24-month period, and 31 of them underwent concomitant implantation of a DIAM (33 devices total). They found no difference in VAS or MacNab outcome scores between the groups treated with or without the DIAM implants.

In our study, VAS scores for back pain and lower extremities pain were decreased significantly following DIAM implantation. Prolo's economic and functional scores were also improved after the surgery. However, the results of this study are limited due to the lack of a control group. It is possible that laminectomy or discectomy alone may improve the symptoms without DIAM implantation.

Disc heights and foraminal heights were increased and extension angles were decreased immediately after surgery, as the DIAM was inserted between the spinous processes as a spacer. It is possible that a DIAM may prevent extension instability, while maintaining disc and foraminal heights, as they were designed to do. However, these changes were not statistically significant as the heights were nearly restored to preoperative values at the final follow-up. It is possible that postoperative pain had transiently reduced extension angles at the immediate postoperative radiographs. At the follow-up study, repetitive compression force might shorten the length of the DIAM. Further studies are needed to confirm DIAM prevent extension instability and preserve disc and foraminal height.

Two patients had flexion instability and spondylolisthesis (anterior translation >4.5 mm at follow-up dynamogram) in our study. DIAM is an interspinous distraction device which is thought to not prevent flexion instability. DIAM should not to be applied to patients who are at risk for flexion instability or spondylolisthesis, for example, who has facet degeneration, adjacent segment fusion, or spondylolysis[9-10]. Osteoporosis is also a contraindication of DIAM implantation because, as shown in this study, spinous process fracture can occur. Those patients did not have osteoporosis, but the procedure for inserting DIAM into two spinous processes incurs some risk of spinous fracture.

In summary, there is no clear evidence of the advantages of DIAM compared to conventional fusion or decompressive surgery. However, biomechanical evidence and the theoretical basis of DIAM support its potency, and compared to conventional fusion surgery, it is safer and less invasive. Further prospective clinical trials are necessary to understand the benefits of DIAM over alternative techniques.

CONCLUSION

The DIAM implantation concomitant with lumbar laminectomy or discectomy significantly improved low-back pain, leg pain, and the functional scale rating compared with the preoperative status in a mean 28 months period. The radiologic findings after the operations showed preservation of disc heights, foraminal heights, and extension angles. However, flexion instability was not alleviated by DIAM. Finally, there were no severe complications associated with DIAM.

Further prospective, controlled long-term studies should be performed in large populations to confirm the efficacy of DIAM and dynamic stabilization.

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