

# A Systematic Review of Interspinous Dynamic Stabilization

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**Background:** A systematic literature review of interspinous dynamic stabilization, including DIAM, Wallis, Coflex, and X-STOP, was conducted to assess its safety and efficacy.

**Methods:** The search was done in Korean and English, by using eight domestic databases which included KoreaMed and international databases, such as Ovid Medline, Embase, and the Cochrane Library. A total of 306 articles were identified, but the animal studies, preclinical studies, and studies that reported the same results were excluded. As a result, a total of 286 articles were excluded and the remaining 20 were included in the final assessment. Two assessors independently extracted data from these articles using predetermined selection criteria. Qualities of the articles included were assessed using Scottish Intercollegiate Guidelines Network (SIGN).

**Results:** The complication rate of interspinous dynamic stabilization has been reported to be 0% to 32.3% in 3- to 41-month follow-up studies. The complication rate of combined interspinous dynamic stabilization and decompression treatment (32.3%) was greater than that of decompression alone (6.5%), but no complication that significantly affected treatment results was found. Interspinous dynamic stabilization produced slightly better clinical outcomes than conservative treatments for spinal stenosis. Good outcomes were also obtained in single-group studies. No significant difference in treatment outcomes was found, and the studies compared interspinous dynamic stabilization with decompression or fusion alone.

**Conclusions:** No particular problem was found regarding the safety of the technique. Its clinical outcomes were similar to those of conventional techniques, and no additional clinical advantage could be attributed to interspinous dynamic stabilization. However, few studies have been conducted on the long-term efficacy of interspinous dynamic stabilization. Thus, the authors suggest further clinical studies be conducted to validate the theoretical advantages and clinical efficacy of this technique.

**Keywords:** *Spine, Spinal stenosis, Therapeutics, Review*

Dynamic spinal stabilization is based on the concept of restricting movement of spinal segments rather than pre-

venting the movement. That is, it restricts movements in the directions that may cause pain or instability, but permits other directions and motilities. Dynamic spinal stabilization can achieve spinal stability and prevent diseases of adjacent segments without requiring fusion. Interspinous dynamic stabilization, a type of dynamic spinal stabilization, is a technique that involves the insertions of devices into interspinous processes that distract posterior spinous process and cause local segmental kyphosis.<sup>1)</sup> The inven-

Received March 22, 2015; Accepted March 28, 2015

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Clinics in Orthopedic Surgery • pISSN 2005-291X eISSN 2005-4408

tors of this technique claim that it achieves sagittal balance and segment stability by increasing foraminal height. Bono and Vaccaro<sup>2)</sup> classified devices that are used for interspinous dynamic stabilization as static or dynamic devices. According to this classification, X-STOP (St. Francis Medical Technologies, Alameda, CA, USA), ExtenSure (Nuvasive, San Diego, CA, USA), and Wallis (Abbott Spine, Bordeaux, France) implants are static devices, and Coflex (Paradigm Spine, Wurmlingen, Germany) (interspinous U) and DIAM (Medtronic Sofamor Danek, Memphis, TN, USA) are dynamic devices.

Interspinous dynamic stabilization has theoretical advantages over conventional fusion, because it maintains stability by restricting direction and range of motility, whereas fusion simply prevents spinal segment movement. Good clinical results have been reported in a few studies. However, despite the increasing use of this technique, few review studies have been conducted to assess its safety and efficacy. Accordingly, this study was conducted to assess the safety and efficacy of interspinous dynamic stabilization by systematic literature review of this technique, which included the DIAM, X-STOP, Wallis, and Coflex (interspinous U) devices.

## METHODS

Patients with degenerative lumbar disease, such as spondylosis, disc herniation, foraminal stenosis, posterior facet syndrome, spinal instability, spondylolisthesis, retrolisthesis, spinal stenosis, and neurogenic claudication, were selected as subjects for the systematic literature review. Interspinous dynamic stabilization has been used as a form of intervention for the aforementioned diseases. Decompression, fusion, and dynamic spinal stabilization, such as lumbar laminectomy, discectomy, facetectomy, and foraminal resection, were selected as comparators. Outcomes were classified as safety or efficacy orientated. Postoperative complications such as fracture, allergic reaction, infection, hematoma, neuropathy, incomplete paraplegia, and hip necrosis were included in the safety assessment, and disc herniation, sciatic pain, lumbar pain recurrence, changes in the spinal status (disc height, foraminal height, and sagittal angle alignment), patient subjective improvement scale, physical activities, and amount of analgesics used were included in the efficacy assessment.

### Database Search and Literature Selection

Eight domestic databases that included KoreaMed, and international databases that included Ovid Medline, Embase, CINAHL (Cumulative Index to Nursing and Allied

Health Literature), and the Cochrane Library were subjected to database search. A total of 306 articles written in Korean or English were identified using a strategy that integrated disc herniation, spondylolisthesis, spinal stenosis, neurogenic claudication, dynamic stabilization, soft stabilization, and elastic stabilization. Then, the followings were excluded: (1) non-human and pre-clinical studies, (2) non-original articles, (3) studies that reported only abstracts, and (4) studies that reported the same results.

Articles published after peer review according to the review criteria of each journal were included in the present study. Regarding the study types, articles written in Korean or English were selected, including systematic reviews, clinical controlled trials, observation or comparative studies, pretest-posttest design studies, and case studies. The literature selection criteria included are as follows: (1) studies involving interspinous dynamic stabilization, (2) studies that reported one or more results for appropriate forms of treatment, and (3) studies in which interspinous dynamic stabilization and other treatment methods were compared.

A total of 286 articles were excluded, which included repeatedly searched 184 articles. Thus, the present study was based on the review of 20 articles.

### Quality Assessment

Two assessors independently conducted the literature search, applied article selection criteria, and extracted data. The quality of the literature was assessed using Scottish Intercollegiate Guidelines Network (SIGN). Evidence level and recommendation grade were determined based on the results of the quality assessment.

## RESULTS

Interspinous dynamic stabilization was solely conducted on spinal stenosis patients, aimed at achieving decompression by widening the spinal canal and restricting extension movement of the spinal segment. In some cases, interspinous dynamic stabilization was conducted by decompression rather than fusion, to prevent the instability that occurs after decompression. Thus, in the present study, the results of a systematic literature review of the safety and efficacy of interspinous dynamic stabilization were analyzed for its sole use and its use in combination with other techniques.

### Safety

#### *Treatment by dynamic stabilization alone*

The safety of dynamic stabilization was assessed in two

randomized clinical studies, five other studies, and one case study. The complication rate of the interspinous dynamic stabilization alone was 0% to 11%. In the two randomized clinical studies that compared the complication rates of an X-STOP group and a conservative treatment group,<sup>3,4)</sup> the complication rates of X-STOP group were 4.8% and 11%, respectively, which were slightly higher than 3% and 6.6% found in the conservative treatment group. No complication, such as permanent disability, was observed and the only significant effects on treatment outcome were spinous process fracture, implant displacement, and foreign body reaction to polyethylene.

#### *Combined treatment*

The safeties of combined treatments were assessed in one comparative and observation study and five other studies. The complication rate for combined treatment was 0% to 32.3% in a study that compared the complication rates of a decompression group and a decompression group with DIAM. In this study, the complication rate in the decompression group with DIAM was 32.3%, which was higher than the decompression group (6.5%).<sup>5)</sup> Of the 10 cases with complications, five were directly associated with DIAM. Complications included spinous process fracture, device displacement, and non-infectious serous discharge. However, all resolved spontaneously without antibiotic treatment, and no postoperative clinical outcome difference was observed. Thus, the interspinous dynamic stabilization was assessed to be safe.

#### **Efficacy**

##### *Dynamic stabilization alone*

The efficacy of interspinous dynamic stabilization alone was assessed in three randomized clinical studies and eight other studies.

- Comparative studies with conservative treatment methods
  - Additional surgery rate: In a study that compared an X-STOP group (42 patients) and a conservative treatment group (33 patients), 11.9% (5/42) of patients in the X-STOP group and 12.1% (4/33) of patients in the conservative treatment group required surgery.<sup>4)</sup> In another study, only 6% (6/100) in an X-STOP group and 26.4% (24/91) in the conservative treatment group required surgery.<sup>4)</sup>
  - Radiologic results: In a randomized clinical study that compared the results of postoperative radiography of an X-STOP group and a conservative treatment group, no significant intergroup difference was found in spinous process distance, anterior disc height, posterior disc

height, segment angle, L1–L5 angle, foraminal height, anterior displacement, and L1–L5 sagittal lordosis.<sup>4)</sup>

- Zurich claudication score: Zurich claudication scores of an X-STOP and a conservative treatment group before surgery were 50.4 and 23.1, respectively. Two years after surgery, it was found to be 51.3 and 47.4, which represented a statistically significant difference.<sup>3)</sup> In another study, mean symptom severity scores of an X-STOP group and a conservative treatment group were increased by 45.4% and 7.4%, respectively; and the mean physical activity scores were increased by 44.3% and –0.4%, respectively, which were also significantly different. In addition, as compared with preoperative status, the severity of symptoms in the X-STOP and conservative treatment group were improved by 60.2% and 18.5%, respectively; the physical functions were improved by 57% and 14.8%, respectively; and satisfaction rates were improved by 73.1% and 35.39%, respectively. All of these improvements were shown to be significantly different.<sup>4)</sup>
- Short Form-36 (SF-36) outcomes: The SF-36 physical component summary (PCS) score of an X-STOP group improved from 31.53 before surgery to 41.19 two years after surgery, whereas SF-36 PCS scores of a conservative treatment group were 52.06 before the surgery and 56.29 two years after surgery, which were not significantly different. No significant difference in SF-36 mental component summary (MCS) scores was found between these two groups (before surgery and 2 years after surgery) and normal subjects.<sup>3)</sup> In another clinical study, preoperative SF-36 PCS scores were 28.8 in an X-STOP group and 28.9 in a conservative treatment group. Mean postoperative SF-36 PCS scores at 2 years after surgery, were 38.4 in the X-STOP group and 31.2 in the conservative treatment group, which represented a significant difference in the X-STOP group.<sup>4)</sup> SF-36 MCS scores in these two groups were non-significantly different, with 51.5/54.3 before surgery and 50.6/52.5 at 2 years after surgery.<sup>6)</sup>
- Single-group study
  - Radiologic outcomes: Siddiqui et al.<sup>7)</sup> conducted a 6-month follow-up study on patients with spinal stenosis. A comparison of preoperative and postoperative radiologic examination results showed no significant differences after surgery in the endplate angles, range of motions (ROMs), disc heights, or total lumbar ROMs. The spinal canal area and neuroforaminal area were increased after one- and two-segment surgeries, and significant increase was shown in many segments.<sup>8)</sup> In addition, a comparison of preoperative and postoperative radiologic results of 10 patients with mild stenosis, who under-

went X-STOP surgery, showed the following significant increases: mean spinal canal area, 73.6 mm<sup>2</sup>/90.2 mm<sup>2</sup>; mean foraminal area, 60.3 mm<sup>2</sup>/82.3 mm<sup>2</sup>; interspinous angle, 11.1°/9.05°; posterior disc height, 5.93 mm/7.68 mm; and interspinous process distance, 3.58 mm/9.07 mm.<sup>9)</sup>

- Zurich claudication scores: In a case study of 62 patients with neurogenic claudication caused by spinal stenosis, a good outcome was achieved in 19/62 patients (31.1%).<sup>10)</sup> In a follow-up study on 24 of 40 neurogenic claudication patients, preoperative and postoperative Zurich claudication scores for symptom severity, physical function, and patient satisfaction were 3.37/2.83, 2.45/2.19, and -/2.12, respectively. A significant clinical improvement was shown in 54%, 33%, and 71% of patients for symptom severity, physical function, and patient satisfaction, respectively.<sup>11)</sup> In addition, postoperative satisfaction was measured using the Swiss Spinal Stenosis questionnaire after X-STOP treatment in 10 mild spinal stenosis patients of age ≥ 60 years. The results showed very high patient satisfaction in 50% (5/10) and moderate satisfaction in 20% (2/10).<sup>9)</sup>
- Oswestry Disability Index (ODI) scores: Siddiqui et al.<sup>11)</sup> studied 40 patients with neurogenic claudication, who had treatment failure with more than 6 months of conservative treatment, and 24 patients were followed up. Their ODI scores decreased from 48 before surgery to 37 one year after surgery. Kondrashov et al.<sup>12)</sup> conducted a follow-up study on 18 neurogenic claudication patients over a mean of 51 months. Mean ODI score was improved from 45 before surgery to 15 after surgery. Treatment success was defined as an improvement in ODI score of ≥ 15. The rate of treatment success was 78% (14/18).
- Pain: In a study on 12 patients with lumbar stenosis caused by degenerative spondylolisthesis, who had treatment failure with more than 6 months of conservative treatment, pain was shown to be decreased in 66.7% (8/12) and remained unchanged in 33.3% (4/12) after surgery.<sup>13)</sup>

### Combined treatment

The efficacy of combined interspinous dynamic stabilization and decompression was assessed in two comparative studies and six other studies.

- Comparative study with decompression
  - Radiologic outcomes: a comparative study was conducted on 62 patients with disc herniation and spinal stenosis. Combined DIAM and decompression (laminectomy or

discectomy) was administered to 31 patients, and decompression was administered to the other 31 patients. Postoperative radiologic results were compared. Lordosis was significantly (1.89°) higher in the decompression group than in the decompression group with DIAM, but it was unclear whether the rotational axis was changed due to increased lordosis. No significant difference in disc heights, distances between discs, or spondylolisthesis corrections was found between the two groups.<sup>5)</sup>

- Visual analogue scale (VAS) score and MacNab score: a comparative study showed no difference between the preoperative and postoperative VAS scores of the decompression group with DIAM and the decompression group, and no difference was shown in MacNab results.<sup>5)</sup>
- Comparative study with fusion
  - In a comparative study on 42 spinal stenosis patients, the postoperative radiologic results showed no difference in the disc height and the motion range of the surgery segment, and an increased motion range was observed in the upper adjacent segment (≥ 5°) between the lumbar fusion group with Coflex (18 patients) and the lumbar fusion group (24 patients). For the ODI score, the pain significantly decreased after the surgery from the preoperative status, but there was no significant difference in the pain of the two groups. For the VAS score, the pain significantly decreased after the surgery from the preoperative status, but there was no significant difference in the pain of the two groups.<sup>14)</sup>
  - Study on a single group that received combined treatment
    - Resurgery rate: Taylor et al.<sup>15)</sup> conducted a study on 104 patients who underwent DIAM surgery, with a mean follow-up of 17.7 months. Of these patients, 20 were readmitted. Of these 20 patients, 13 (12.5%) underwent resurgery, and 6 patients underwent resurgery related to DIAM. In another study, discectomy and Wallis placement were simultaneously conducted on 37 patients with a large disc herniation and those with a disc height of ≥ 50%, who underwent 6 to 10 months of conservative treatment. Of these patients, disc herniation recurred among 5 patients, and 2 of these 5 patients underwent resurgery. Symptoms were improved in the remaining 3 patients who did not undergo resurgery.<sup>16)</sup>
    - Radiologic outcomes: Lim et al.<sup>17)</sup> studied 50 patients with spinal stenosis, mild spinal stenosis with anterior displacement, and adjacent segment syndrome after posterior fusion treated using an interspinous U. Postoperative lordosis significantly increased by a mean of 2.9°, and the posterior interbody interval increased by a mean

of 2.35 mm. Motion of the surgical segment decreased from 5.8° before surgery to 3.7° after surgery. In a case study on 20 patients with lumbar stenosis, disc herniation, spinal stenosis with spondylolisthesis, and disc herniation, who underwent interspinous U placement, pre- and postoperative intervertebral heights were compared. Intervertebral height was increased by 0.21 mm (14.7%) 3 days after surgery, and it was increased by a mean of 0.191 mm (6.3%) at the last follow-up visits.<sup>18)</sup>

- ODI: ODIs decreased significantly from 43 before surgery to 12.7 after surgery.<sup>16)</sup>

- Pain severity: Pain VAS decreased significantly from 6.6 before surgery to 1.4 after surgery, and the VAS of lower extremity pain significantly decreased from 8.2 before surgery to 1.5 after surgery.<sup>16)</sup> In another study on 103 patients with lumbar stenosis, degenerative spondylolisthesis, and disc herniation treated by interspinous U placement, pain VAS decreased significantly from 9.08 before surgery to 3.88 after surgery. In addition, the VAS score of lower-extremity pain decreased significantly from 8.81 before surgery to 3.91 after surgery.<sup>19)</sup> In another study, interspinous U was performed on 20 patients, and the pain VAS significantly decreased from 7.9 before surgery to 2.6 after surgery; and VAS for lower-extremity pain decreased significantly from 8.13 before surgery to 2.53 after surgery.<sup>18)</sup> In a case study, patients with degenerative spinal disease underwent DIAM and were followed for a mean of 34.7 months. The proportions of classes 1, 2, and 3 of the Dallas questionnaire were 44%, 53%, and 2.3%, respectively, which showed that 97% of the patients belonged to the first or second groups (class 1, no restriction of physical activities; class 2, returned to past activities; class 3, reduced professional activities; and class 4, non-workable).<sup>20)</sup> In a study on 104 patients treated by DIAM placement, pain assessments showed as follows: improvement in 88.5% (92/104), no change in 9.6% (10/104), and indeterminate in 1.9%. The pain questionnaire was completed by 70 of the 104 patients, and it showed improved status in 46.6% (33/70), aggravation in 10.3% (12/70), and no change in 43.1% (55/70).<sup>15)</sup>

- MacNab score: In a study performed by Lim et al.,<sup>17)</sup> MacNab scores were as follows: excellent in 28%, good in 62%, fair in 8%, and poor in 2%. In another study, patient satisfaction and functional recovery assessment results, according to the modified Macnab classification, were as follows: excellent in 50% (10/20), good in 30% (6/20), fair in 20% (4/20), and poor in 0% (0/20).<sup>18)</sup>

- Activities of daily living (ADL) questionnaire: The results of the ADL questionnaire for 70 respondents among 104 patients showed an increase in 46.2% (32/70), a decrease

in 30.8% (22/70), and no change in 23.1% (16/70).<sup>15)</sup>

## DISCUSSION

Dynamic spinal stabilization is a new treatment concept, which enables the treatment of spinal pain and instability without fusing the involved spinal segment. Instead, the spinal movement is restricted in the direction that causes pain, while permitting mobility in the other directions. Interspinous dynamic stabilization involves different materials and treatment methods that depend on the devices used (DIAM, X-STOP, Wallis, Colflex, or interspinous U). However, these interspinous devices utilize the same principle that distracts the posterior spinal process and maintains kyphosis, and thereby maintaining constant kyphosis between the spinous processes.<sup>1,2)</sup>

Interspinous dynamic stabilization is performed alone on patients with neurogenic claudication caused by spinal stenosis, to decompress the nerve by widening the spinal canal *via* device insertion. It is also performed with decompression to prevent the instability occurring after the decompression and to maintain interspinous distraction. X-STOP is mainly performed alone, whereas DIAM, Wallis, and Colflex (interspinous U) are mainly performed with decompression.

In the present study, the safety of interspinous dynamic stabilization was assessed using 14 articles with respect to spinous fracture, device displacement, and complications of infection. The range of 3- to 41-months of follow-up was used, which showed results in the complication rates of 0% to 32.3%. The complication rate in the patients treated by interspinous dynamic stabilization and decompression (32.3%) was greater than that of the patients treated by decompression alone (6.5%). However, the majority of the complications did not require clinical treatment or significantly affected treatment outcomes; thus, published results show that interspinous dynamic stabilization is a safe technique (Table 1).

In the present study, the efficacy of interspinous dynamic stabilization was assessed using 19 articles with respect to the changes in spinal status, such as disc height and foraminal height, improvement in spinal stenosis, pain severity, and patient-assessed subjective improvement in functional recovery. In three randomized clinical studies, no change in spinal status was found after conservative or interspinous dynamic stabilization treatment in the following patients: the patients with mild lumbar stenosis who had undergone 3 to 6 months of conservative treatment and the patients with neurogenic claudication caused by spondylolisthesis  $\leq$  grade 1.<sup>3,4,6)</sup> However,

**Table 1.** Summary of Cases

Study type	Study	Year	Study target	No. of complications (%)	Type of complication
Comparative observation study	Kim et al. <sup>5)</sup>	2007	DIAM + decompression	10/31 (32.3)	Infection, disc protrusion, subjective lump on back, spinous process fracture, removal of supraspinous ligament
			Decompression	2/31 (6.5)	Infection, disc protrusion
Other study	Taylor et al. <sup>15)</sup>	2007	DIAM alone DIAM + surgery	21/104 (19.2) 6/104 (5.8)	Back pain and lower extremity pain, lumbar meningocele, hematoma, femoral neuropathy, cervicobrachial neuralgia, herniated nucleus pulposus, carpal tunnel syndrome, hallux valgus, dural tear, hip joint necrosis, looseness
Other study	Floman et al. <sup>16)</sup>	2007	Wallis	6/37 (16.2)	Serous discharge
Other study	Lee et al. <sup>19)</sup>	2006	Coflex	1/65 (1.5)	Fracture of spinous process
Other study	Lim et al. <sup>17)</sup>	2004	Coflex	13/50 (26.0)	Posterior displacement of device, fracture of spinous process, wound infection and fluid retention
Other study	Lim et al. <sup>18)</sup>	2004	Coflex	4/20 (20.0)	Posterior displacement of device

Zurich claudication and physical-factor-related quality of life (QoL) scores were significantly higher for the patients treated by interspinous dynamic stabilization. This shows that the interspinous dynamic stabilization was clinically effective in patients who didn't respond to conservative treatment and not required surgical treatment. However, it is clinically difficult to define indications for interspinous dynamic stabilization, in the real situations. In addition, no study has compared interspinous dynamic stabilization with conventional treatment, which is generally performed on patients who had treatment failure by conservative treatment. Accordingly, it is difficult to accept the efficacy of interspinous dynamic stabilization, as reported in the aforementioned studies.

Kim et al.<sup>5)</sup> reported that no significant difference was observed in the spinal status, pain severity, or functional recovery for interspinous dynamic stabilization and decompression or decompression alone. In addition, in a study that compared interspinous dynamic stabilization with posterior lumbar fusion, no differences were observed in the spinal status, disability index, or pain severity.<sup>14)</sup> However, when the operation time and amount of bleeding were considered for posterior lumbar fusion, interspinous dynamic stabilization was found to be clinically useful. But, this study has a number of limitations. For example, indications for fusion were not clearly defined, as disease severity was not described. Furthermore, this study was conducted by using a single-group design on relatively few subjects, and the homogeneity of the two study groups is unclear. In a study where interspinous dynamic stabilization and decompression were performed simultaneously, the combined treatment was found to

have a lower disability index, pain severity, QoL score, and analgesic usage, and it showed improved physical activities of daily life. However, a control group was not used, so the results of this study are inadequate to verify the efficacy of interspinous dynamic stabilization.

Based on our review of the available peer-reviewed articles, we conclude that interspinous dynamic stabilization is probably the safe and meaningful treatment because it regulates rather than prevents spinal movement. However, the technique has its limitations which we summarize as follows: (1) its theoretical background has not been established, (2) its indications and available study results are inconsistent, and (3) the results of long-term follow-ups and randomized clinical studies that compare it with other treatment methods are inadequate. Thus, because various conventional treatment methods are currently available for target diseases, we conclude that more concrete evidence of the safety and efficacy of interspinous dynamic stabilization is required. A well-designed study should be undertaken to provide more concrete evidence of its merits.

### CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

### ACKNOWLEDGEMENTS

This study was supported by grants from the Ministry of Welfare and Family Affairs of Korea.

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