Original Article

Grade 1 spondylolisthesis and interspinous device placement: removal in six patients and analysis of current data

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Abstract

Background: In the treatment of patients with Grade 1 spondylolisthesis, the use of interspinous devices has been controversial for nearly a decade. Several authors have suggested that Grade 1 spondylolisthesis be considered a contraindication for interspinous device placement.

Methods: We removed interspinous devices in six symptomatic Grade 1 spondylolisthesis patients and analyzed pertinent literature.

Results: All six patients reported an improvement in symptoms following device removal and subsequent instrumented fusion. One patient who had not been able to walk due to pain regained the ability to walk. Several articles were identified related to spondylolisthesis and interspinous devices.

Conclusions: Regarding patients receiving interspinous devices for symptomatic lumbar spinal stenosis, several high-quality studies have failed to demonstrate a statistical difference in outcomes between patients with or without Grade 1 spondylolisthesis. Nevertheless, surgeons should have a high degree of suspicion when considering use of interspinous devices in this patient population.

Key Words: Interspinous process device, interspinous process spacer, lumbar spinal stenosis, neurogenic intermittent claudication, spondylolisthesis, X-STOP®

INTRODUCTION

In recent years, interspinous devices such as interspinous process spacers (IPSs) have been shown to be effective in reducing symptoms of lumbar spinal stenosis (LSS) by providing constant distraction of spinous processes. Although decompressive laminectomy has been considered the gold standard for treating LSS, IPSs may alleviate symptoms by creating a local environment of spinal flexion via a minimally invasive surgical approach. The relationship between spinal decompression and IPSs has been evaluated recently in a meta-analysis and high-quality studies.[11,13,14,21] One such device, the X-STOP® Interspinous Process Decompression (IPD®) System (Medtronic, Inc., Minneapolis, MN) has been studied extensively since its approval by the Food and Drug Administration (FDA) in November 2005.[29] Research on the X-STOP has not been without controversy, however. One particular point of contention among researchers has been the relationship between spondylolisthesis and X-STOP placement, specifically whether Grade 1 degenerative spondylolisthesis should be considered a contraindication.[2,3,7,9,12,20,26] A recent comparison of product information revealed incongruous statements
regarding Grade 1 spondylolisthesis as an indication or contraindication. Concerns have been raised about the use of other interspinous devices in the setting of Grade 1 spondylolisthesis as well. The majority of published studies regarding interspinous devices have small patient numbers and short-term follow-up, so information about complications and possible contraindications is lacking.

We present a series of six patients who had Grade 1 spondylolisthesis at the time of interspinous device placement and continued to have symptoms of neurogenic intermittent claudication (NIC) after surgery, necessitating device removal and instrumented lumbar fusion.

**METHODS**

After approval by our institutional review board, we used two methods to analyze the relationship between Grade 1 spondylolisthesis and interspinous device placement. First, we retrospectively reviewed the medical records of six patients who underwent interspinous device removal at our institution. Second, we conducted a literature search in PubMed to find articles written in English that contained data, conclusions, or commentary regarding the use of interspinous devices in the setting of spondylolisthesis. There were more than 200 articles found using the search criteria (“X-STOP device”), (“X-STOP and spondylolisthesis”), and (“interspinous spacer” and spondylolisthesis). All articles were screened for potential relevance to the research question. Information from pertinent studies was collected and analyzed, including study design, number of patients with Grade 1 spondylolisthesis, results, and the authors’ conclusions. No formal appraisal of collected studies was conducted.

**RESULTS**

Our series included six patients, all women, who were treated at our institution between 2009 and 2013. Mean age at time of interspinous device placement was 63 years (range 51-83 years), and mean time elapsed since interspinous device placement was 35.8 months (range 3-96 months). Mean age at presentation to our clinic was 66 years (range 52-84 years), and mean overall duration of symptoms was 6.3 years (range 2-13 years). Mean follow-up after device removal was 9.2 months (range 4-12 months).

Four patients had received X-STOP devices for symptoms of NIC due to LSS. The other two patients had received the Aspen device (Lanx, Inc., Broomfield, CO) for the same symptoms following microdecompression with stabilization. All four X-STOP patients had the X-STOP device implanted at two levels (three at L3-4/L4-5, one at L4-5/L5-S1), and the two Aspen patients had the Aspen device implanted at only one level (L4-5 or L5-S1) [Figure 1]. The indications for initial device placement included intractable or progressive low back pain; chronic hip, buttock, and/or leg pain; and lumbar stenosis; as well as Grade 1 lumbar spondylolisthesis, radiculopathy, and/or spondylolisthesis. After interspinous device placement, all patients reported improvement in symptoms for 2 weeks to 2 months, but then all patients reported a return of symptoms, including back and leg pain and weakness or numbness in one or both legs; in some cases, these symptoms progressively worsened. Upon presentation, motor and sensory function was normal in all patients; reflexes were normal in five patients and diminished in one patient. Imaging revealed lumbar stenosis and spondylolisthesis [Figure 2]. Patients complained of low back pain radiating into buttocks and legs and limited range of motion of the back [Table 1].

Removal of the interspinous devices was performed because of persistent radicular lower back, buttock, and leg pain with movement on flexion-extension films, as well as lumbar stenosis, spondylolysis, and/or spondylolisthesis. Decompression of the thecal sac and nerve roots was performed via foraminotomies, laminectomies, and/or

![Figure 1: Neutral lateral X-rays show interspinous process devices at L4-5 and L5-S1, with minimal spondylolisthesis](image1)

![Figure 2: Extension films show exaggeration of the spondylolisthesis](image2)
Table 1: Summary of patient characteristics

| Patient 1 | Patient 2 | Patient 3 | Patient 4 | Patient 5 | Patient 6 |
|-----------|-----------|-----------|-----------|-----------|-----------|
| Age at implant/age at presentation | 51 (Aspen\(^\text{®}\))/52 | 83 (Aspen\(^\text{®}\))/64 | 60 (X-STOP\(^\text{®}\))/62 | 60 (X-STOP\(^\text{®}\))/63 | 65 (X-STOP\(^\text{®}\))/73 |
| Time since implant | 3 months | 11 months | 21 months | 36 months | 96 months |
| Levels treated | 1: L3-S1 | 1: L4-S | 2: L3-4, L4-5 | 2: L3-4, L4-5 | 2: L3-4, L4-5 |
| Postoperative course after initial improvement | LBP, pain radiating BLE to calves; numbness LLE Radiating back pain; weakness BLE | Numbness/weakness BLE, LBP unresponsive to ESI & PT | Pain radiating BLE | Back/leg pain progressively worsened | Back/leg pain returned, unresponsive to ESI |
| Follow-up | 12 months: L3-4 G1S in flexion, less in extension; persistent hyperlordosis; occasional mild pain; patient very pleased | 10 months: LBP and BLE pain unresponsive to ESI; continuing medical therapy | 11 months: Strength intact, ESI relieved residual LBP | 12 months: Strength intact, X-rays satisfactory | 4 months: Stable alignment, intact instrumentation; patient very pleased |

BLE: Bilateral lower extremity, ESI: Epidural steroid injections, G1S: Grade 1 spondylolisthesis, LBP: Low back pain, LLE: Left lower extremity, PT: Physical therapy

Discussion

The relationship between spondylolisthesis and interspinous devices has been controversial for nearly a decade. Despite the number of interspinous devices currently available for use, there is a paucity of published results regarding their safety and efficacy in patients with LSS, let alone in patients with concomitant spondylolisthesis. Of the studies that have been published, the vast majority have involved the X-STOP device.

In 2005, the FDA approved the X-STOP for the treatment of NIC due to LSS.\(^{[25]}\) The approval applied to patients with Grade 1 spondylolisthesis, and spondylolisthesis above Grade 1 was considered a contraindication for X-STOP placement. Soon after, Anderson et al. reported promising outcomes following X-STOP placement in patients with Grade 1 spondylolisthesis.\(^{[2]}\) However, several reports were subsequently published that cautioned against the use of the X-STOP in this patient population. Barbagallo et al.\(^{[1]}\) and Zucherman and Telles\(^{[30]}\) reported that developing proper technique for X-STOP placement is more difficult in patients with spondylolisthesis, and described important technical nuances that should be considered before and during X-STOP placement in these patients.

We sought to determine whether or not Grade 1 spondylolisthesis should be considered a contraindication for X-STOP placement. In our study, we report six cases of X-STOP device removal—all in patients who had Grade 1 spondylolisthesis at the time of device placement. The results of our study, in addition to the results of several other studies summarized in Tables 2 and 3, indicate that any degree of spondylolisthesis should be considered a contraindication for X-STOP placement.

Generating conclusions based on case reports and small studies is difficult due to the lack of control groups, especially when technique and experience vary between surgeons and institutions. Table 2 summarizes studies in which data were reported for both a “treatment group” (patients with spondylolisthesis who received the X-STOP) and a “control group” (patients without spondylolisthesis who received the X-STOP).\(^{[6,12,14,16-19,28]}\) These studies reported results in a manner that allowed for comparison between outcomes of X-STOP patients with and without Grade 1 spondylolisthesis. Table 3 summarizes case reports and studies in which data were not reported for both treatment and control groups.\(^{[2,4,5,20,26]}\)

The studies summarized in Table 2 were high-quality randomized controlled trials or cohort studies that reviewed the outcomes of patients with and without spondylolisthesis who had the X-STOP implanted, which allowed for a direct comparison of outcomes between these two groups. Seven of these studies, involving...
five different patient populations, demonstrated no significant difference in clinical outcomes in patients with Grade 1 spondylolisthesis who underwent X-STOP placement.\textsuperscript{[6,14,16,19,28]}

### Table 2: Studies on Spondylolisthesis and X-STOP Placement with Controls

| Study, year          | Study design       | # with G1S receiving device | Results                                                                 | Original authors’ conclusions              |
|----------------------|--------------------|-----------------------------|-------------------------------------------------------------------------|--------------------------------------------|
| **FDA approval study** (same patient population) |                    |                             |                                                                         |                                            |
| Zucherman et al., 2005\textsuperscript{[31]} | RCT                | 34                          | Clinical success in 55.9\% (19/34) with G1S, compared with 44.1\% (26/59) without G1S | Presence of G1S not predictive of outcomes |
| Kondrashov et al., 2006\textsuperscript{[16]} | RCT                | 6                           | Clinical success in 5/6 with G1S compared to 9/12 without G1S          | Effect of G1S not specifically addressed   |
| Bowers et al., 2010\textsuperscript{[6]}     | Retrospective cohort | 5                           | 80\% (4/5) with G1S required reoperation compared with 87.5\% (7/8) without G1S | 80\% (4/5) with G1S required additional surgery |
| Kim et al., 2012\textsuperscript{[15]}       | Prospective observational cohort | 20                          | 55\% (11/20) with G1S experienced SP fracture within 6 months; trend toward poorer 1-year outcomes in patients with SP fractures | G1S strongly associated with SP fracture after IPS placement |
| Nandakumar et al., 2013\textsuperscript{[18]} | Prospective observational cohort | 15                          | Clinical success in 67\% (10/15) at 1 year and 60\% (6/10) at 2 years in patients with LSS with G1S, compared to 67\% (14/22) at 1 year and 52\% (11/21) at 2 years in patients with LSS alone | Effect of G1S not specifically addressed |
| Stromqvist et al., 2013\textsuperscript{[21]} | RCT                | 10                          | Outcomes similar in patients with and without G1S                        | Effect of G1S not specifically addressed   |
| Tuschel et al., 2013\textsuperscript{[29]}   | Retrospective cohort | 46 total enrolled; # with G1S not specified | Presence of G1S did not significantly increase risk for re-intervention. | Effect of G1S not specifically addressed   |
| Patel et al., 2014\textsuperscript{[19]}     | RCT                | 36                          | By 2 years, 23.5\% of patients with G1S required reoperation             | Long-term clinical outcomes similar in patients with and without pre-existing G1S |

**Note:** FDA: Food and drug administration, G1S: Grade 1 spondylolisthesis, IPS: Interspinous process spacer, LSS: Lumbar spinal stenosis, RCT: Randomized controlled trial, SP: Spinous process

### Table 3: Studies on spondylolisthesis and X-STOP placement without controls

| Study, year          | Study design       | # with G1S receiving device | Results                                                                 | Original authors’ conclusions              |
|----------------------|--------------------|-----------------------------|-------------------------------------------------------------------------|--------------------------------------------|
| Anderson et al., 2006\textsuperscript{[2]} | RCT                | 42                          | Clinical success in 63.4\% of X-STOP patients at 2 years              | For NIC secondary to G1S, X-STOP placement resulted in significantly greater improvement in pain and satisfaction compared to ESI |
| Verhoof et al., 2008\textsuperscript{[26]}  | Retrospective cohort | 9                           | 67\% (6/9) required reoperation                                        | G1S is a contraindication for X-STOP placement in LSS patients |
| Barbagallo et al., 2009\textsuperscript{[3]} | Retrospective cohort | 2                           | Complications in 8/92 X-STOP patients, 2 of whom had G1S              | Evaluate interspinous height, especially in elderly patients or those with G1S |
| Epstein, 2009\textsuperscript{[10]}        | Case report        | 1                           | Bilateral foot drop in elderly male following placement, resolved after spinal decompression | Give careful consideration to using the X-STOP device in patients (particularly older patients) who have severe LSS with degenerative spondylolisthesis |
| Barbagallo et al., 2010\textsuperscript{[4]} | Case report        | 1                           | Complications in 3 patients, 1 of whom had G1S (SP fracture; revision surgery) | L4 spondylolisthesis may have determined a more posterior position of the X-STOP causing increased stress and fatigue fracture of the middle portion of L4 SP |
| Puzzilli et al., 2014\textsuperscript{[20]}  | RCT                | 16                          | Significant pain improvement in 87.5\% at 6 months; at 3 years, 31.3\% (5/16) had undergone reoperation for worsening neurological status | X-STOP should not be used in patients with spondylolisthesis suitable for instrumentation with pedicle screws |

**Note:** FDA: Food and drug administration, RCT: Randomized controlled trial, NIC: Neurogenic intermittent claudication, ESI: Epidural steroid injections, LSS: Lumbar spinal stenosis, G1S: Grade 1 spondylolisthesis, SP: Spinous process
Nevertheless, many surgeons have noted a disproportionate amount of complications requiring reoperation in patients with Grade 1 spondylolisthesis who have had the X-STOP implanted at a single or double level. The 2008 study by Verhoof et al. is the most frequently cited study recommending that any degree of spondylolisthesis be considered a contraindication for X-STOP placement. The authors reviewed the medical records of nine patients with Grade 1 spondylolisthesis and found that reoperation was required in 67% of patients. Bowers et al. and Puzzilli et al. endorsed the recommendation that even Grade 1 spondylolisthesis should be considered a contraindication for X-STOP placement. Puzzilli et al. reported that in five cases of spondylolisthesis at 3 years follow-up, the X-STOP had to be removed and followed by decompression with instrumented fusion. The authors concurred that the X-STOP should not be used in patients with spondylolisthesis suitable for instrumentation with pedicle screws. While this information is valuable, the authors did not report how many X-STOP patients without spondylolisthesis required reoperation, thus making a direct comparison difficult. Although Bowers et al. found lower reoperation rates in four of five patients with concurrent spondylolisthesis (80%) than in seven of eight patients without concurrent spondylolisthesis (87%), the authors concluded that X-STOP should not be used in patients with concurrent spondylolisthesis. In addition, Barbagallo et al. reported on the complications seen in patients who had undergone adjacent double-level X-STOP surgery. In our study, all four of our X-STOP removal cases had the device implanted at two adjacent levels.

Kim et al. reported a 52% rate of spinous process fractures in patients with Grade 1 spondylolisthesis compared with none in patients without spondylolisthesis. The authors proposed two possible mechanisms for this high fracture rate. First, spondylolisthesis changes the contact point with the cephalad vertebrae, and this contact point may be a weaker part of the spinous process. Alternatively, interspinous spacers may cause the spinous processes to bear more weight through distraction of the posterior column. Early mechanical studies showed that patients with spondylolisthesis may have lower bone fatigue strength. Talwar et al. found that the force on the spinous process required to insert the X-STOP was below the average static failure forces; however, after insertion, there was still a residual higher state of stress on the spinous processes of patients with lower bone fatigue strength (i.e., patients with spondylolisthesis) that could lead to pain from gradual fatigue crack formation. Wiseman et al. found that the X-STOP decreased pressure across the facet joints. As noted by Bono et al. and Kabir et al., this decreased pressure might over time decrease the pain originating from these joints. Toyone et al. reported that patients with spondylolisthesis (including Grade 1) had a significantly different lumbar facet angle than patients without spondylolisthesis. It is possible that this change in facet orientation influences the ability of the device to decrease pressure and therefore to decrease pain over time.

In conclusion, we report six patients who required interspinous device removal and subsequent surgical decompression, all of whom had Grade 1 spondylolisthesis at the time of device placement. Review of the literature revealed several high-quality studies that found no statistically significant difference in outcomes between patients with or without Grade 1 spondylolisthesis receiving the X-STOP implant. However, surgeons should have a high degree of suspicion of potential complications in patients with Grade 1 spondylolisthesis who received an interspinous device, as many technical aspects may not have been considered before and during placement.

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