

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.

Keywords: 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.[\[11,15,18,21\]](#) 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.[\[2,3,7,9,10,11,12,20,26\]](#) A recent comparison of product information revealed incongruous statements regarding Grade 1 spondylolisthesis as an indication or contraindication.[\[1\]](#) Concerns have been raised about the use of other interspinous devices in the setting of Grade 1 spondylolisthesis as well.[\[15\]](#) 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 spondylosis. 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, spondylosis, and/or spondylolisthesis. Decompression of the thecal sac and nerve roots was performed via foraminotomies, laminectomies, and/or discectomies. Removal of the device(s) was followed by instrumentation with arthrodesis using local bone graft, demineralized bone matrix, and/or crushed cancellous allograft. Mean operative time was 3.5 h (range 2 h 12 min to 4 h 30 min). Findings during surgery included dystrophic muscle, significant scar tissue (some adherent to the dura), significant stenosis, and hypertrophied ligament. In some cases, the device barely had purchase on the spinous processes. There were no intraoperative complications during device removal. One patient experienced a small area of skin breakdown without drainage that was treated with oral antibiotics. Another patient developed a postoperative hematoma at the surgery site, which was treated successfully with irrigation, debridement, and evacuation. At follow-up, all patients reported symptom improvement, with some patients reporting complete resolution of preoperative pain. The patient who could not walk prior to device removal due to pain could now walk without her walker. Follow-up imaging revealed stable alignment and intact instrumentation.

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.*[3] 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).[6,12,14,16,17,18,19,28] 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. [2,3,4,9,20,26]

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.[6,14,16,17,18,19,28]

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.[8] The 2008 study by Verhoof *et al.*[26] 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.*[6] and Puzzilli *et al.*[20] endorsed the recommendation that even Grade 1 spondylolisthesis should be considered a contraindication for X-STOP placement. Puzzilli *et al.*[20] 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.*[6] 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.[4] 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.[15] 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.[13,24] 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.[22] Wiseman *et al.* found that the X-STOP decreased pressure across the facet joints.[27] As noted by Bono *et al.*[5] and Kabir *et al.*,[14] 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.[23] 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.

Footnotes

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REFERENCES

1. Anderson JT, Sullivan TB, Ahn UM, Ahn NU. Analysis of Internet information on the controversial X-Stop device. *Spine J*. 2014;14:2412–9. [PubMed: 24509178]
2. Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: Application of the X-STOP device in patients with lumbar degenerative spondylolisthesis. *J Neurosurg Spine*. 2006;4:463–71. [PubMed: 16776357]
3. Barbagallo GM, Olindo G, Corbino L, Albanese V. Analysis of complications in patients treated with the X-Stop Interspinous Process Decompression System: Proposal for a novel anatomic scoring system for patient selection and review of the literature. *Neurosurgery*. 2009;65:111–9. [PubMed: 19574832]
4. Barbagallo GM, Corbino LA, Olindo G, Foti P, Albanese V, Signorelli F. The “sandwich phenomenon”: A rare complication in adjacent, double-level X-stop surgery: Report of three cases and review of the literature. *Spine (Phila Pa 1976)* 2010;35:E96–100. [PubMed: 20075767]
5. Bono CM, Vaccaro AR. Interspinous process devices in the lumbar spine. *J Spinal Disord Tech*. 2007;20:255–61. [PubMed: 17473649]
6. Bowers C, Amini A, Dailey AT, Schmidt MH. Dynamic interspinous process stabilization: Review of complications associated with the X-Stop device. *Neurosurg Focus*. 2010;28:E8. [PubMed: 20568923]
7. Brodke DS, Annis P, Lawrence BD, Woodbury AM, Daubs MD. Reoperation and revision rates of 3 surgical treatment methods for lumbar stenosis associated with degenerative scoliosis and spondylolisthesis. *Spine (Phila Pa 1976)* 2013;38:2287–94. [PubMed: 24150428]
8. Epstein NE. A review of interspinous fusion devices: High complication, reoperation rates, and costs with poor outcomes. *Surg Neurol Int*. 2012;3:7. [PMCID: PMC3280001] [PubMed: 22347676]
9. Epstein NE. How often is minimally invasive minimally effective: What are the complication rates for minimally invasive surgery? *Surg Neurol*. 2008;70:386–8. [PubMed: 18207510]
10. Epstein NE. X-Stop: Foot drop. *Spine J*. 2009;9:e6–9. [PubMed: 18809360]
11. Gazzeri R, Galarza M, Alfieri A. Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: Past, present, and future. *Biomed Res Int* 2014. 2014 975052. [PMCID: PMC4005216]
12. Hsieh PC. Efficacy of surgical treatment for lumbar stenosis with the X-STOP: An issue in need of closer inspection. *World Neurosurg*. 2013;80:74–7. [PubMed: 22634461]
13. Hutton WC, Stott JR, Cyron BM. Is Spondylolysis a Fatigue Fracture? *Spine (Phila Pa 1976)* 1977;2:202–9.
14. Kabir SM, Gupta SR, Casey AT. Lumbar interspinous spacers: A systematic review of clinical and biomechanical evidence. *Spine (Phila Pa 1976)* 2010;35:E1499–506. [PubMed: 21102279]
15. Kim DH, Shanti N, Tantorski ME, Shaw JD, Li L, Martha JF, et al. Association between degenerative spondylolisthesis and spinous process fracture after interspinous process spacer surgery. *Spine J*. 2012;12:466–72. [PubMed: 22622239]
16. Kondrashov DG, Hannibal M, Hsu KY, Zucherman JF. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: A 4-year follow-up study. *J Spinal Disord Tech*. 2006;19:323–7. [PubMed: 16826002]
17. Moojen WA, Arts MP, Bartels RH, Jacobs WC, Peul WC. Effectiveness of interspinous implant surgery

- in patients with intermittent neurogenic claudication: A systematic review and meta-analysis. *Eur Spine J.* 2011;20:1596–606. [PMCID: PMC3175877] [PubMed: 21667130]
18. Nandakumar A, Clark NA, Smith FW, Wardlaw D. Two-year results of X-stop interspinous implant for the treatment of lumbar spinal stenosis: A prospective study. *J Spinal Disord Tech.* 2013;26:1–7. [PubMed: 23348569]
19. Patel VV, Whang PG, Haley TR, Bradley WD, Nunley PD, Miller LE, et al. Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis. *BMC Musculoskelet Disord.* 2014;15:221. [PMCID: PMC4109165] [PubMed: 24996648]
20. Puzzilli F, Gazeri R, Galarza M, Neroni M, Panagiotopoulos K, Bolognini A, et al. Interspinous spacer decompression (X-STOP) for lumbar spinal stenosis and degenerative disk disease: A multicenter study with a minimum 3-year follow-up. *Clin Neurol Neurosurg.* 2014;124:166–74. [PubMed: 25064150]
21. Strömqvist BH, Berg S, Gerdhem P, Johnsson R, Möller A, Sahlstrand T, et al. X-stop versus decompressive surgery for lumbar neurogenic intermittent claudication: Randomized controlled trial with 2-year follow-up. *Spine (Phila Pa 1976)* 2013;38:1436–42. [PubMed: 23403549]
22. Talwar V, Lindsey DP, Fredrick A, Hsu KY, Zucherman JF, Yerby SA. Insertion loads of the X STOP interspinous process distraction system designed to treat neurogenic intermittent claudication. *Eur Spine J.* 2006;15:908–12. [PMCID: PMC3489454] [PubMed: 15926059]
23. Toyone T, Ozawa T, Kamikawa K, Watanabe A, Matsuki K, Yamashita T, et al. Facet joint orientation difference between cephalad and caudad portions: A possible cause of degenerative spondylolisthesis. *Spine (Phila Pa 1976)* 2009;34:2259–62. [PubMed: 19934805]
24. Troup JD. Mechanical factors in spondylolisthesis and spondylolysis. *Clin Orthop Relat Res.* 1976;117:59–67. [PubMed: 1277687]
25. Tuschel A, Chavanne A, Eder C, Meissl M, Becker P, Ogon M. Implant survival analysis and failure modes of the X-Stop interspinous distraction device. *Spine (Phila Pa 1976)* 2013;38:1826–31. [PubMed: 21311406]
26. Verhoof OJ, Bron JL, Wapstra FH, van Royen BJ. High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. *Eur Spine J.* 2008;17:188–92. [PMCID: PMC2226191] [PubMed: 17846801]
27. Wiseman CM, Lindsey DP, Fredrick AD, Yerby SA. The effect of an interspinous process implant on facet loading during extension. *Spine (Phila Pa 1976)* 2005;30:903–7. [PubMed: 15834334]
28. Wu AM, Zhou Y, Li QL, Wu XL, Jin YL, Luo P, et al. Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: A systematic review and meta-analysis. *PLoS One.* 2014;9:e97142. [PMCID: PMC4014612] [PubMed: 24809680]
29. Zucherman JF, Hsu KY, Hartjen CA, Mehlic TF, Implicito DA, Martin MJ, et al. A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X-STOP interspinous implant: 1-year results. *Eur Spine J.* 2004;13:22–31. [PMCID: PMC3468027] [PubMed: 14685830]
30. Zucherman JF, Telles CJ. Commentary: Interspinous devices, spondylolisthesis, and spinous process-related complications. *Spine J.* 2012;12:473–5. [PubMed: 22857646]
31. Zucherman JF, Hsu KY, Hartjen CA, Mehlic TF, Implicito DA, Martin MJ, et al. A multicenter, prospective, randomized trial evaluating the X-STOP interspinous process decompression system for the

treatment of neurogenic intermittent claudication: Two-year follow-up results. *Spine (Phila Pa 1976)* 2005;30:1351–8. [PubMed: 15959362]

Figures and Tables

Figure 1



Neutral lateral X-rays show interspinous process devices at L4-5 and L5-S1, with minimal spondylolisthesis

Figure 2



Extension films show exaggeration of the spondylolisthesis

Table 1

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age at implant/age at presentation	51 (Aspen®)/52	83 (Aspen®)/84	60 (X-STOP®)/62	60 (X-STOP®)/63	65 (X-STOP®)/73	59 (X-STOP®)/62
Time since implant	3 months	11 months	21 months	36 months	96 months	48 months
Levels treated	1: L5-S1	1: L4-5	2: L3-4, L4-5	2: L3-4, L4-5	2: L3-4, L4-5	2: L4-5, L5-S1
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	6 months: Strength intact, X-rays satisfactory

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

Summary of patient characteristics

Table 2

Study, year	Study design	# with G1S receiving device	Results	Original authors' conclusions
FDA approval study (same patient population)				
Zucherman <i>et al.</i> , 2005 ^[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 <i>et al.</i> , 2006 ^[16]	RCT	6	Clinical success in 5/6 with G1S compared to 9/12 without G1S	Effect of G1S not specifically addressed
Bowers <i>et al.</i> , 2010 ^[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 <i>et al.</i> , 2012 ^[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 <i>et al.</i> , 2013 ^[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 <i>et al.</i> , 2013 ^[21]	RCT	10	Outcomes similar in patients with and without G1S	Effect of G1S not specifically addressed
Tuschel <i>et al.</i> , 2013 ^[25]	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 <i>et al.</i> , 2014 ^[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

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

Studies on Spondylolisthesis and X-STOP Placement with Controls

Table 3

Study, year	Study design	# with G1S receiving device	Results	Original authors' conclusions
FDA approval study (same patient population as above)				
Anderson <i>et al.</i> , 2006 ^[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 <i>et al.</i> , 2008 ^[26]	Retrospective cohort	9	67% (6/9) required reoperation	G1S is a contraindication for X-STOP placement in LSS patients
Barbagallo <i>et al.</i> , 2009 ^[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 ^[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 <i>et al.</i> , 2010 ^[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 <i>et al.</i> , 2014 ^[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

FDA: Food and drug administration, RCT: Randomized controlled trial, NIC: Neurogenic intermittent claudication, ESI: Epidural steroid injections, LSS: Lumbar spinal stenosis, G1S: Grade I spondylolisthesis, SP: Spinous process

Studies on spondylolisthesis and X-STOP placement without controls

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