Evidence Table

Clinical Area: **Spinal decompression device for lumbar spinal stenosis**

Reference: **Zucherman JF 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; 12:22-31.**
Zucherman JF et al. A multicenter, prospective, randomized trial evaluating the X-Stop interspinous process decompression system for the treatment of neurogenic intermittent claudication: 2-year follow-up results. *Spine* 2005; 30: 1351-1358.

Study Type: Randomized controlled trial.
Study Aim: To evaluate the safety and efficacy of the X-Stop interspinous implant.

Outcomes

- *Primary:* SF-36, Zurich Claudication Questionnaire (ZCQ)
- *Secondary:* Radiography.

Design

- *Number of subjects:* N=200 randomized, n=191 treated (n=100 X-Stop, n=91 non-operative group).
- *Description of study population:* Conducted at 9 centers. X-Stop group: Mean age=69.9 years, 57 males/43 females, mean duration of pain=3.5 years; 76% 1 level, 24% 2 levels: Pre-operative group: Mean age=68.6 years, 52 males/48 females, mean duration of pain=4.7 years; 80% 1 level, 20% 2 levels.
- *Inclusion criteria:* ≥50 years old; leg, buttock or groin pain with or without back pain that is relieved during flexion. Required that patients be able to sit for ≥50 minutes without pain, walk ≥50 feet and have completed ≥6 months of non-operative therapy. Also required stenosis confirmed by CT or MRI scans at 1 or 2 levels.
- *Exclusion criteria:* Fixed motor deficit, cauda equina syndrome, significant lumbar instability, previous lumbar surgery, significant peripheral neuropathy, Cobb angle >25^{o}, spondylolisthesis >grade 1.0 (scale of 1-4), sustained pathologic fractures, severe osteoporosis of the vertebra or hips, obesity, active infection, systemic disease, Paget's disease, metastasis to the vertebrae, steroid use for >1 month within 12 months of study participation.
- *Intervention:* Randomized to either the X-Stop group or a non-operative group. The non-operative group received ≥1 epidural steroid injection and could receive other treatments including NSAIDS, analgesics, physical therapy and certain types of braces (abdominal binders and corsets). Patients in the X-Stop group underwent surgery, and received the X-stop implants at one or two levels. the operative levels were confirmed through fluoroscopy. Patients who did not have significant co-morbidities generally returned home the day of surgery.
- *Source of outcome data*: Self-report instruments; radiographic analysis at each visit.
- *Length of follow-up*: Appeared to be 2 years. Follow-up at 6 weeks, 6 months, 1 year and 2 years.

Validity

- *Blinding?* No.
- *Appropriate randomization procedures?* May not have been appropriate. Used block randomization (blocks of 2) by center. That means, when a patient is randomized to one intervention, the next patient will receive the other intervention. It is possible to choose patients for a particular intervention.
- *Appropriate comparison intervention (placebo or adequate dose of accepted intervention)?* No. The intervention was compared to non-operative treatment, which all participants had already failed (this was an eligibility requirement). In addition, there was no standard protocol for non-operative treatment and it is not clear whether treatment was optimized.
- *Treatment/control groups comparable at baseline?* Appeared similar on reported characteristics.
- *Other than intervention, was care/follow-up similar in each group?* No. Some patients received laminectomy during the follow-up period (6 patients in the X-Stop group and 24 patients in the non-operative group).
- *Adequate compliance with intervention?* Not in control group.
- *Sufficient statistical power?* Not reported.
- *Intention to treat analysis?* No. The 9 control patients who dropped out after randomization were not included. It was not clear whether patients who did not complete the ZCG were included in the analysis—the authors did not report sample sizes in their reporting of the main outcomes. The authors did report that patients who had implants removed, withdrew from the study or went on to laminectomy were considered failures from the time of that event forward..
- *Completeness of follow-up:* 9 patients in the non-operative group withdrew before treatment (mostly because they had hoped to be in the X-Stop group). At the 1 year follow-up, 88% of randomized patients in the X-Stop group and 68% of those in the non-operative group completed the ZCQ. At the 2 year follow-up, data were available on 93 X-Stop patients and 81 non-operative patients (93% and 81% of randomized patients, respectively).
- *Industry funding?* Yes. Industry funds were received and the two primary authors were the inventors of the X-Stop technology.
- **Conclusions regarding validity of methods:**

Threats to validity include:

- Inappropriate comparison group: X-Stop was compared to non-operative therapy. However, to be eligible for the study, all patients had to have failed 6 months of non-operative therapy. Thus, the control group consists of patients who are less likely to respond to the intervention. In addition, the conservative treatment received by the control group was not standardized and may not have been optimal.
- Lack of blinding, expectations about treatment and subjective outcomes-out: 9 patients dropped out of the control group immediately after randomization—the authors mention that this was largely because they had hoped to be randomized to X-Stop. It is likely that other patients who remained in the study also hoped to be randomized to X-Stop and were disappointed with their treatment group. Since the study was blinded and the primary outcomes were self-report, patients expectations could bias outcomes.
- ZCQ as primary outcome: The test-retest reliability and internal consistency of the scale has been validated, but not its ability to evaluate clinical improvement.

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- Incomplete reporting of outcomes and statistics. Many of the outcomes were reported only in figures, exact proportions and p-values were not reported.
- Industry funding: The first two authors were inventors of the X-Stop and stood to benefit financially if the device was found to be effective.
- There was no clear protocol for when a patient was eligible to receive laminectomy. However, patients who received laminectomy were considered treatment failures. It is possible that patients in the X-Stop group were discouraged from undergoing laminectomy and/or patients in the control group were encouraged to get laminectomy, which could bias outcomes.
- Low follow-up rate in the control group, only 68% of patients in the non-operative group completed the ZCQ at 1 year.
- Possibly ineffective randomization, using blocks of 2.

Results

Note on ZCQ: The ZCQ measures three domains: symptoms severity, SS, (7 questions, scored 1-5), physical function. PH, (5 questions, scored 1-4), patient satisfaction, PS (6 questions, scored 1-4, lower is more satisfied). Treatment is considered successful if the patient has an average score of 2.5 on PS, and at least a 0.5 improvement in both SS and PH.

Mean pre-treatment ZCQ scores for the SS and PF domains, patients who received treatment

	X-Stop group n=100	Non-operative group n=91
SS	3.14	3.12
PF	2.48	2.49

Proportion of patients improved at 1 year, according to the ZCQ, completer analysis

	X-Stop group n=88	Non-operative group n=68
SS	≈75%	≈35%
PH	≈75%	≈30%
PS	≈75%	≈50%
Clinical success	≈60%	≈15%

Notes:
- Exact percentages were not reported. Proportions were estimated from figures
- The authors did not specify the criteria for improvement in this analysis. It appears to be the 0.5 point improvement that is part of the overall success measure for the ZCQ.
- P-values were not reported. The authors wrote that the X-Stop group had significantly more improvement.
- Clinical success=significant improvement in SS and PH dimensions and satisfied with care.

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Proportion of patients improved at 2 years, according to the ZCQ, completer analysis

	X-Stop group n=93	Non-operative group n=81	p-value
SS	60.2%	18.5%	<0.001
PH	57.0%	14.8%	<0.001
PS	73.1%	35.9%	<0.001
Clinical success	48.4%	4.9%	Not reported

Mean SF-36 scores at 1 year

	X-Stop group	Non-operative group
Physical function	62.2	42.7
Role physical	57.0	31.9
Bodily pain	56.1	36.9
General health	73.0	64.4
Vitality	53.0	47.4
Social function	79.3	67.3
Role emotional	77.1	58.1
Mental health	66.8	60.4

Notes:

- No significant pre-treatment differences in any domain
- P-values were not reported. The authors wrote that the X-Stop group had significantly better scores at 1 year.

Mean radiographic measurements at 1 year (baseline measurements not provided)

	X-Stop group	Non-operative group	p-value
Spinous process distance (mm)	52.1	51.0	0.336
Anterior disc height (mm)	9.9	9.7	0.776
Posterior disc height (mm)	5.3	5.1	0.626
Treated level angulation (deg)	14.6	16.5	0.099
L1-L5 angulation (deg)	9.9	9.7	0.776
Foraminal height (mm)	23.2	22.5	0.088
Spondylolisthesis (%)	4.1	5.9	0.201
L1-L5 coronal curve (deg)	4.9	5.8	0.267

Note: 2 year radiographic measurements were similar. Thre were no significant between-group differences.

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Adverse effects

	X-Stop n=100	Non-operative n=91
Device related[1]	4	NA
Intraoperative or procedure-related		
Respiratory distress	1	0
Coronary episode, ischemic	1	0
Pulmonary edema	1	0
Wound dehiscence or swelling	2	NA
Hematoma	1	NA
Incisional pain	1	NA
Leg parathesia	0	2
Heart attack	0	1
Injection intolerance	0	1

[1]One each of malpositioned implant, implant dislodgement or migration, spinous process fracture and increased pain at implant level.

Authors' Conclusions

2004: The results of this prospective study indicate that the X-Stop offers a significant improvement over non-operative therapies at 1 year with a success rate comparable to published reports of decompressive laminectomy, but with considerably lower morbidity.
2005: The X-Stop provides a conservative yet effective treatment for patients suffering from lumbar spinal stenosis. In the continuum of treatment options, the X-Stop offers an attractive alternative to both conservative care and decompressive surgery."

Reviewer's Conclusions

The study reported significantly better outcomes in the X-Stop group than the control group at 1 and 2-years, according to self-report data. The validity of the study is threatened factors including a lack of blinding, possible preference for X-Stop on the part of patients, an inappropriate and possibly sub-standard comparison intervention, lack of protocol for undergoing laminectomy during the follow-up period, incomplete reporting of statistical findings and an outcome measure (ZCQ) of questionable validity.

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