A randomized controlled trial of the X-Stop interspinous distractor device versus laminectomy for lumbar spinal stenosis with 2-year quality-of-life and cost-effectiveness outcomes

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Objective Lumbar spinal stenosis (LSS) is a common and debilitating condition that is increasing in prevalence in the population. Surgical decompression is often standard treatment when conservative measures have failed. Interspinous distraction devices (IDDs) have been proposed as a safe alternative; however, the associated cost and early reports of high failure rates have brought their use into question. The primary objective of this study was to determine the cost-effectiveness and long-term quality-of-life (QOL) outcomes after treatment of LSS with the X-Stop IDD compared with surgical decompression by laminectomy.

Methods A multicenter, open-label randomized controlled trial of 47 patients with LSS was conducted; 21 patients underwent insertion of the X-Stop device and 26 underwent laminectomy. The primary outcomes were monetary cost and QOL measured using the EQ-5D questionnaire administered at 6-, 12-, and 24-month time points.

Results The mean monetary cost for the laminectomy group was £2712 ($3316 [USD]), and the mean cost for the X-Stop group was £5148 ($6295)- £1799 ($2199) procedural cost, plus £2605 ($3185) additional cost per device). With intention-to-treat analysis, the mean quality-adjusted life-year (QALY) gain for the laminectomy group was 0.92, and for the X-Stop group it was 0.81. The incremental cost-effectiveness ratio was –£22,145 (–$27,201). The revision rate for the X-Stop group was 19%. Five patients crossed over to the laminectomy arm after being in the X-Stop group.

Conclusions Laminectomy was more cost-effective than the X-Stop for the treatment of LSS, primarily due to device cost. The X-Stop device led to an improvement in QOL, but it was less than that in the laminectomy group. The use of the X-Stop IDD should be reserved for cases in which a less-invasive procedure is required. There is no justification for its regular use as an alternative to decompressive surgery.

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Keywords lumbar spinal stenosis; interspinous distraction; quality of life; cost

Abbreviations CELAX = Cost-Effectiveness and Quality of Life After Laminectomy or X-Stop; ICER = incremental cost-effectiveness ratio; IDD = interspinous distractor device; LSS = lumbar spinal stenosis; NICE = National Institute for Health and Care Excellence; ODI = Oswestry Disability Index; PROM = patient-reported outcome measure; QALY = quality-adjusted life-year; QBPDS = Quebec Back Pain Disability Scale; QOL = quality of life; UK = United Kingdom; ZCQ = Zurich Claudication Questionnaire.

L UMBAR spinal stenosis (LSS) is the most common degenerative condition of the lumbar spine. It causes symptoms of neurogenic claudication and is the most frequent cause of back and leg pain in the aging population. The condition mainly affects individuals older than 50 years, impairing quality of life (QOL) and consuming large amounts of healthcare resources.[1]

LSS is the most common indication for spine surgery. Decompressive lumbar laminectomy is conventionally considered as the first-line surgical option for LSS. However, due to the morbidity associated with this invasive surgical treatment and a higher complication rate in the elderly population, laminectomy is not universally accepted as the optimal treatment.[2–4] Interspinous distractor devices (IDDs) have been used in the management of lumbar spinal stenosis (LSS) for over a decade.[5–7] Their use is controversial due to mixed reports on their success rates, cost, and high failure rates.[8,9] The X-Stop Interspinous Process Decompression System (Medtronic Spine LLC) (Fig. 1) was the first IDD to be approved by the US FDA for the treatment of LSS. This device is intended to provide relief of the symptoms of neurogenic claudication from LSS while being minimally invasive. The procedure time for insertion is short, with potentially fewer complications, and the device can be removed if necessary. X-Stop use became increasingly popular in the management of LSS.[7] Safety of the device was confirmed by the FDA in the US and by the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK), and its clinical efficacy was found to be similar to that of laminectomy, with a reported 70% success rate for improvement in symptoms.[10,11] However, questions have arisen regarding its cost-effectiveness; we are not aware of any data for the cost-effectiveness of IDDs in the UK, and the long-term impact on QOL needs to be determined.[4] The objective of this study was to determine whether the device is cost-effective when compared with the standard treatment of laminectomy and how it influences QOL.
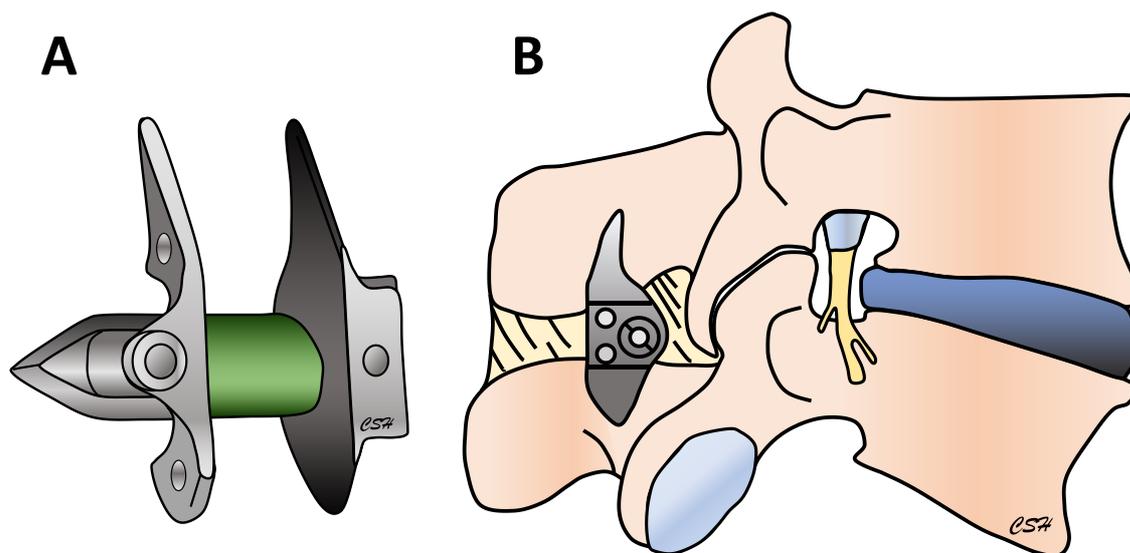

Fig. 1. Schematic diagram of the X-Stop implant. **A:** The X-Stop is a titanium/polyether ether ketone (PEEK) IDD. **B:** The X-Stop interspinous device is inserted between the spinous processes of the affected spinal segments. It limits extension and results in distraction of the neural foramina.[11]

Image from Richards et al (2005).{Richards et al., 2005, #47753}

Methods

The Cost-Effectiveness and Quality of Life After Laminectomy or X-Stop (CELAX) trial was an open-label randomized controlled trial conducted in three centers in the UK. Registration was obtained with the National Institute for Health Research (NIHR UK; clinical trial registration no. ISRCTN88702314, www.isrctn.com). The hypothesis was that there was no important clinical difference in cost-effectiveness between laminectomy and X-Stop in the treatment of patients with LSS. Ethics approval for the study was granted by The Charing Cross Research Ethics Committee, and ethical approval was obtained for each of the participating centers.

The CELAX trial consisted of two comparative surgical arms: the laminectomy group and the X-Stop group. Written consent was sought from patients before entering the trial. The duration of clinical follow-up was 2 years. Patients were screened for symptoms of LSS when referred to the neurosurgical outpatient department at the participating centers. MRI was performed in patients who reported symptoms of neurogenic claudication as routine standard of care. The recruitment period was between 2010 and 2014. Patients with LSS who met the eligibility criteria were invited to participate in the trial. The inclusion and exclusion criteria are shown in Table 1.

TABLE 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age ≥18 yrs	Fixed motor deficit
BMI <35 kg/m^2	Skeletal immaturity
Claudication leg pain w/ or w/o back pain of greater than 6 months duration	Previous lumbar spinal surgery
Completed ≥ 6 months of conservative treatment w/o obtaining adequate symptomatic relief	Peripheral vascular cause of claudication leg pain
Degenerative changes at 1 or 2 adjacent levels between L1 & S1 confirmed by MRI causing canal reduction of > two-thirds of the spinal canal calibre	Obvious signs of psychological or workers' compensation or litigation claims elements to their condition
Physically & mentally willing & able to comply w/ postop scheduled clinical & radiographic evaluation	Unwilling or unable to give consent or adhere to the follow-up program
	Active infection or metastatic disease
	Nondegenerative spondylolisthesis
	Degenerative spondylolisthesis: Meyerding grade ≥ 2
	Known allergy to implant materials
	Diagnosis of osteoporosis, rheumatoid arthritis, or achondroplasia
	Cauda equina syndrome
	Acute disc extrusion or sequestered fragments
	Pregnancy

The laminectomy operation was performed according to the standard practice of each surgeon and was not dictated by inclusion in the trial—all were simple 1- or 2-level laminectomies with bilateral muscle strip and no instrumentation or laminoplasty. The X-Stop insertion procedure was to be performed according to the manufacturer's instructions. Correct positioning and adequate spacing were confirmed by radiography, and postoperative CT and/or MRI was performed at the discretion of the operating surgeon. This trial was conducted in accordance with CONSORT guidelines.[12] The CONSORT flow diagram demonstrating stages of enrollment, allocation, follow-up, and analysis is shown in Fig. 2.

CONSORT 2010 Flow Diagram

Enrollment

Assessed for eligibility (n=300)

Excluded (n= 251)
- Not meeting inclusion criteria (n=244)
- Declined to participate (n= 7)

Randomized (n= 49)

Allocation

Allocated to laminectomy (n= 27)
- Received allocated intervention (n= 26)
- Did not receive allocated intervention (sought the X-Stop® device privately) (n= 1)

Allocated to X-Stop® (n= 22)
- Received allocated intervention (n= 21)
- Did not receive allocated intervention (device not available on day of surgery) (n= 1)

Follow-Up

Lost to follow-up (1 death unrelated to the study) (n= 1)

Lost to follow-up (death unrelated to the study) (n= 2)

Analysis

Analysed (n= 26)
- Excluded from analysis (1 withdrawal was not included) (n= 1)

Analysed (n= 21)
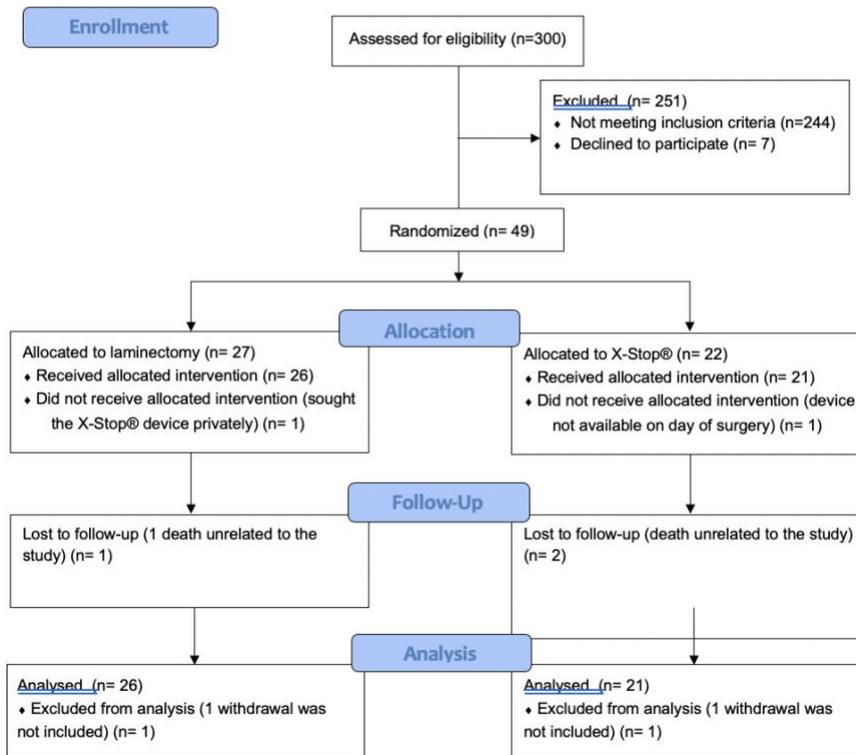- Excluded from analysis (1 withdrawal was not included) (n= 1)

Fig. 2. Consort flow diagram demonstrating stages of enrollment, allocation, follow-up, and analysis. Figure is available in color online only.

The primary outcome measures were cost and QOL. Analysis was performed using intention-to-treat as well as-treated principles. Figure 3 depicts the trial flowchart.
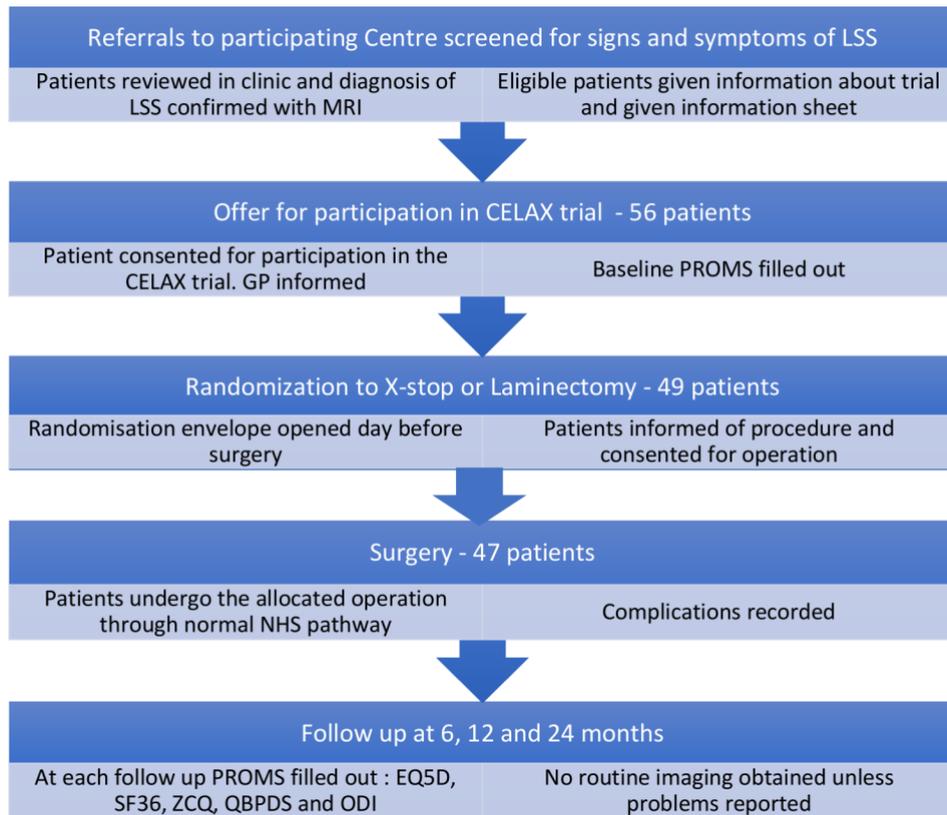
Referrals to participating Centre screened for signs and symptoms of LSS

| Patients reviewed in clinic and diagnosis of LSS confirmed with MRI | Eligible patients given information about trial and given information sheet |

↓

Offer for participation in CELAX trial - 56 patients

| Patient consented for participation in the CELAX trial. GP informed | Baseline PROMS filled out |

↓

Randomization to X-stop or Laminectomy - 49 patients

| Randomisation envelope opened day before surgery | Patients informed of procedure and consented for operation |

↓

Surgery - 47 patients

| Patients undergo the allocated operation through normal NHS pathway | Complications recorded |

↓

Follow up at 6, 12 and 24 months

| At each follow up PROMS filled out : EQ5D, SF36, ZCQ, QBPDS and ODI | No routine imaging obtained unless problems reported |

Figure 3. Trial flow chart

Cost was measured per patient episode, and details were provided by the finance department of each center. In the National Health Service in England, hospitals are reimbursed for procedures using national tariffs based on Healthcare Resource Groups codes. These tariffs for reimbursements often differ significantly from the true hospital costs. Since these charges and fees do not reflect the real cost, it was decided to use the price for operating room time per minute and the price per day of admission to estimate the cost per patient. Treatment costs at each of the participating centers were as follows (operating time costs and admission costs, respectively): center 1, £17.98/min and £188.16/day ($230 [USD]); center 2, £16.79/min ($20.5) and £175.61/day ($214); and center 3, £14.99/min ($18.3) and £156.80/day ($192). The prices obtained were for 2010 with the adjusted marketing force factor, which varies for different centers. An additional 2% per year inflation was used. The currency conversion of British pound sterling to US dollar was 1:1.22.

QOL was measured using the EQ-5D (UK, time trade-off tariff). This was then used to calculate quality-adjusted life-years (QALYs) by taking measurements at baseline and then postoperatively at 6 months, 1 year, and 2 years.[13,14] The area-under-the-curve method was used to calculate QALYs. This was done by plotting the QOL utility index over the four study time points. The change in QALYs and the cost per QALY were calculated for each patient over the study period based on the EQ-5D response at 2 years. The cost-effectiveness ratio was then calculated by comparing the mean cost per QALY of the two operations. The SF-36 was also used at the same time points (baseline, 6, 12, and 24 months) for sensitivity analysis. Secondary outcome measures were disease-specific patient-reported outcome measures (PROMs). These were the Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and Quebec Back Pain Disability Scale (QBPDS).[15–19] These PROMs

were chosen in concordance with the instruments recommended by the NICE guidelines to measure outcomes in LSS (ODI and ZCQ) and based on published health economic studies where QALYs are calculated (EQ-5D and SF-36).[19] The other secondary outcome measures were complication rates and length of hospital stay.

Sample size calculation was based on a study by Katz et al.[20] This was based on a type I error estimate of 0.05 and type II estimate of 0.2. We estimated a standard deviation of 33% across measurement scales, and the study was powered to detect a difference between groups of 20%. Using these estimates, a sample size of 50 patients (25 per arm) was required, which included an attrition rate of 10%. An open-label randomized design was used with a 1:1 treatment allocation. A computer random number generator was used with a block size of 10. Two authors (A.B. and B.N.) were responsible for randomization allocation sequence, patient enrollment, and assigning interventions. Significant variation between the baseline scores of the two groups was checked using the two-sample Wilcoxon rank-sum (Mann-Whitney) test set at $p < 0.05$. The paired Wilcoxon signed-rank test was used to analyze the difference in response at the various time points. All analyses were performed using Stata (version 16.0, StataCorp) and Microsoft Excel for Macintosh.

Results

Between 2010 and 2014, 56 patients who met inclusion criteria for the CELAX trial accepted an invitation to participate. Forty-nine patients were randomized, and, of these, 7 were managed conservatively. One laminectomy patient was lost to follow-up, and an X-Stop patient withdrew after 6 months. Of the 47 included patients, 27 were randomized to lumbar laminectomy and 22 were randomized to X-Stop insertion; of these patients, 26 underwent a laminectomy and 21 had an insertion of X-Stop device. During the study period, 3 patients died of causes unrelated to their LSS diagnosis or treatment. Recruitment was stopped when the 4-year study period was completed. Follow-up continued for 2 years after the last patient was recruited.

The mean patient age was 69 years (range 47–86 years). Eighteen patients were female, and 29 were male. Patient demographics and baseline characteristics of their clinical condition are shown in Table 2. Leg symptoms were present in 79% of patients, and 75% had back pain. Grade 1 spondylolisthesis was present in 6 patients (5 in the X-Stop group and 1 in the laminectomy group). No statistically significant intergroup differences were identified for patient symptoms, comorbidities, or number of levels treated.

TABLE 2. Demographic and baseline surgical characteristics of trial patients by treatment group

	Laminectomy Group (n = 26)	X-Stop Group (n = 21)
Mean age, yrs (range)	69 (51–84)	70 (47–86)
Male/female	17:9	12:9
Comorbidities	9 nil, 9 minor, 9 serious	7 nil, 5 minor, 10 serious
Hypertension	8 (31)	5 (24)
Respiratory disease	2 (8)	2 (10)
Diabetes	3 (12)	2 (10)
BMI >30	1 (4)	2 (10)
Cardiovascular disease	8 (31)	7 (33)
Smoker	2 (8)	1 (5)
Musculoskeletal disease	2 (8)	10 (48)
Unemployed/retired	23	19
Employed	3	3

No. of operated levels		
1	16	15
2	8	6
3	2	0
Level operated		
L2–3	2	1
L3–4	13	11
L4–5	20	14
L5–S1	0	1
Spondylolisthesis grade 1	1	5

Primary Outcomes

Both groups showed an overall improvement in mean QOL (as measured by the EQ-5D) at 6 months when compared with the preoperative baseline, but at 12 and 24 months the improvement only remained significant for the laminectomy group. For the X-Stop group, the mean increase from preoperative EQ-5D score after 6 months was 0.25 ($p < 0.01$), at 12 months was 0.21, and at 24 months was 0.25 (neither of which reached significance). For the laminectomy group the mean increase from preoperative EQ-5D score after 6 months was 0.18 ($p < 0.05$), at 12 months was 0.24 ($p < 0.01$), and at 24 months was 0.29 ($p < 0.001$). Table 3 shows a summary of the results of the intention-to-treat analysis with the mean scores for all questionnaires, including the secondary outcome measures (QOL and disease specific), for all study time points (baseline, 6, 12, and 24 months). Figure 4 displays box-and-whisker plots representing the mean EQ-5D scores for the two surgical arms.

TABLE 3. Intention to treat primary (QOL) and secondary (disease-specific) outcomes

|	Preop		6 Mos Postop		12 Mos Postop		24 Mos Postop	
	Laminectomy	X-Stop	Laminectomy	X-Stop	Laminectomy	X-Stop	Laminectomy	X-Stop
QOL								
EQ-5D	0.29	0.20	0.47*	0.45**	0.53**	0.41	0.58***	0.45
SF-36								
Bodily pain	30	25	42	43	44	51	44	50
Physical function	27	21	42	42	42	48	39	43
Disease specific								
ZCQ								
Symptom severity	70	73	57	57	57	52	56**	58
Physical function	61	67	49	55	50	46	57	49**
Satisfaction	NA	NA	55	57	59	47	60	53
ODI	45	49	37	37*	42	31*	44	38
QBPDS	58	64	45	50	55	45	59	41*
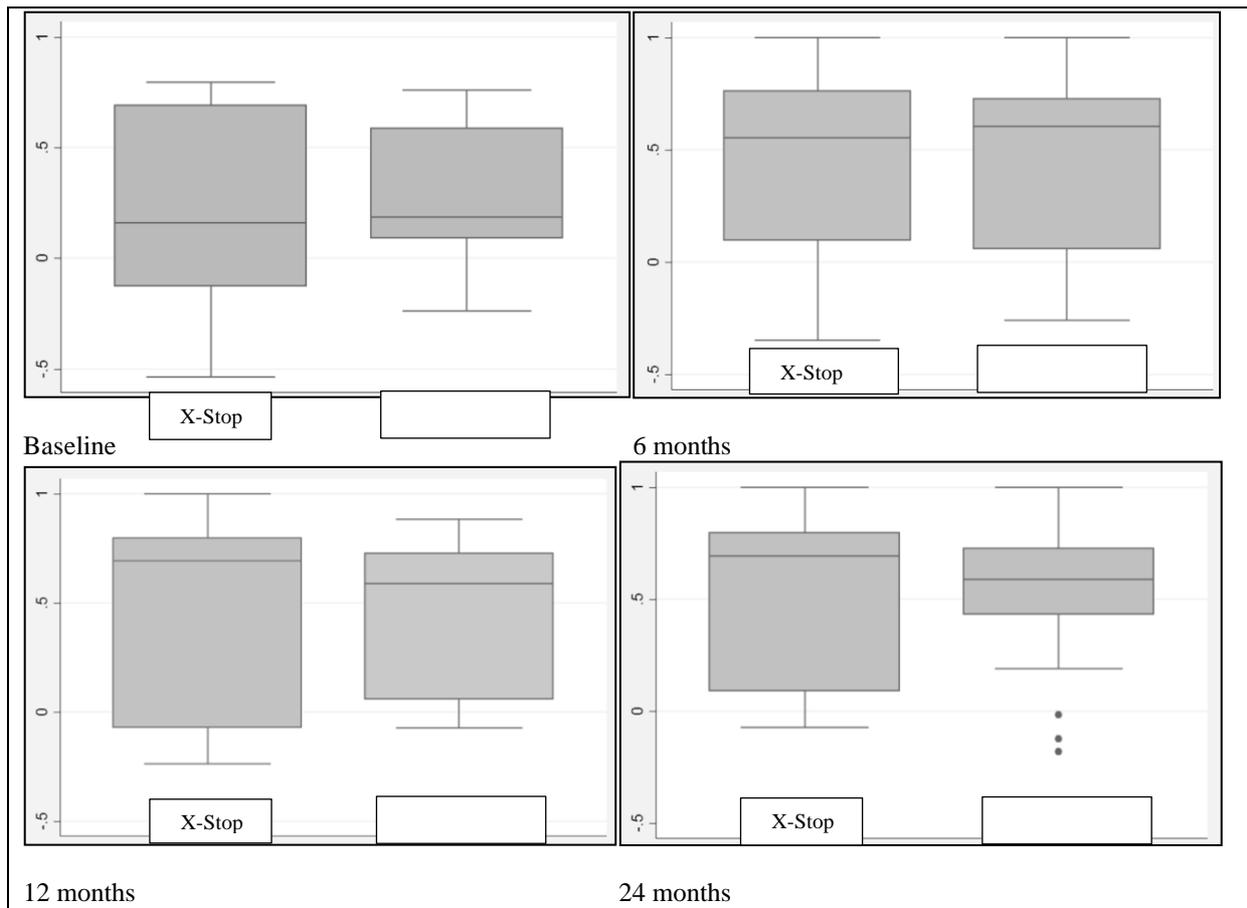
Fig. 4. Comparison of EQ-5D scores between the laminectomy and X-Stop groups at baseline, 6 months, 12 months, and 24 months. The y-axis represents the EQ-5D score which ranges between −0.594 (worst health) and 1 (full health). Horizontal line represents the mean, the box represents the standard deviation and the whiskers represent the range with outliers.

There were 5 patients in the X-stop group who crossed over into the laminectomy group. An as-treated analysis was conducted at a 2-year time point to assess the outcome compared with intention-to-treat by allocating the 5 crossover patients to the laminectomy group. This analysis showed a statistically significant improvement in the primary outcome measure (EQ-5D at 2 years) for both groups compared with their preoperative scores. At 2 years, using EQ-5D QOL scores, there were 7 (33%) X-Stop patients whose condition deteriorated and 14 (67%) whose condition improved, compared with 5 (19.2%) laminectomy patients whose condition deteriorated and 20 (76.9%) who experienced improvement.

QALYs were calculated using the area-under-the-curve method (AUC).[21] Figure 5 shows the mean QALY calculated using the EQ-5D time trade-off scores for each time point for both groups. The average QALY was 0.81 for the X-Stop group and 0.92 for the laminectomy group. The QALYs of the two groups did not show any significant difference (p = 0.77, CI −0.349 to 0.078).
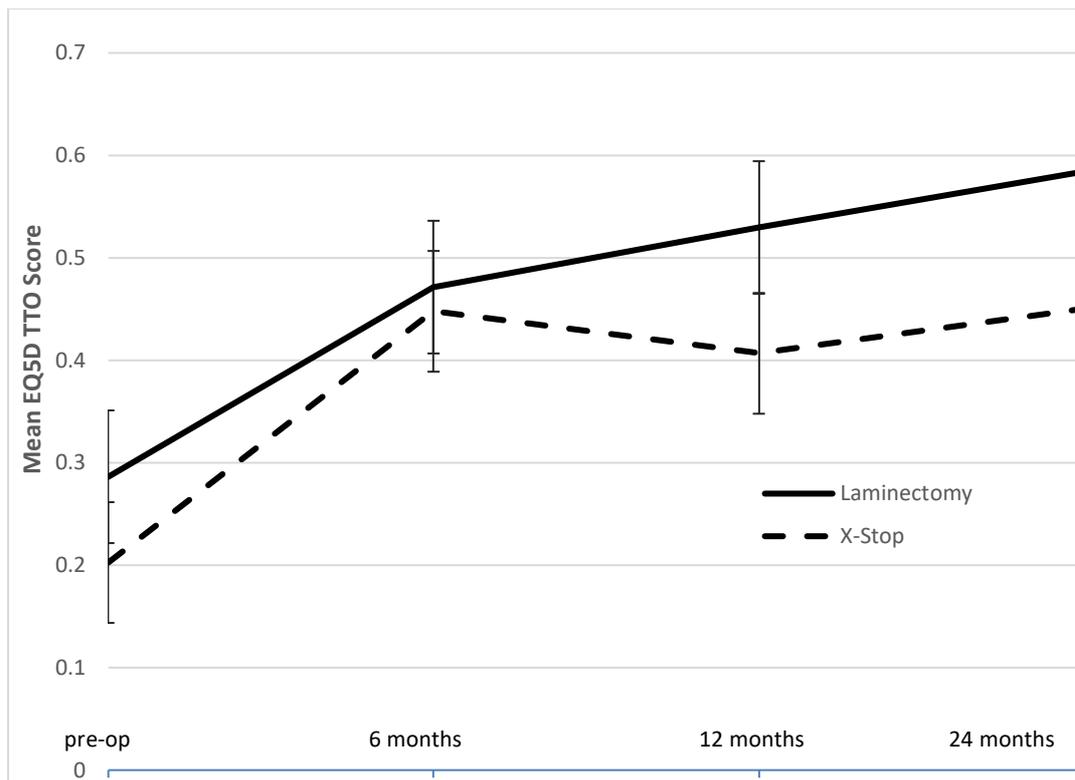
Fig. 5. Mean EQ-5D time trade-off (TTO) scores over the different study time points. QALYs were calculated using the area under the curve method. Figure is available in color online only.

Further details of the primary outcomes measures, including comparative EQ-5D subcomponent scores, preoperative EQ-5D scores, and intention-to-treat and as-treated analyses, QALY scores, and cost results are included in the Supplementary Materials (Supplementary Figs. 1–3 and Supplementary Tables 1–3).

Secondary Outcomes

The results of the secondary outcome measures, SF-36, ZCQ, ODI, and QBPDS, are displayed in Table 3. For the SF-36 questionnaire, the laminectomy group showed improvement in 5 of 8 domains, whereas the X-Stop group showed improvement in 7 of 8 domains. Using intention-to-treat analysis, this was statistically significant for the social functioning domain for the X-Stop group (Supplementary Table 4). Bodily pain and physical function domains did not show statistically significant improvement in either group. Overall, the results of the disease-specific questionnaires were similar between the two groups. The X-Stop group reached statistically significant improvement for the ZCQ physical function scale and QBPDS at 24 months. The laminectomy group reached statistically significant improvement for the ZCQ symptom severity score at 24 months.

The mean operative time for the laminectomy group was 122 minutes (SD 3 minutes, 95% CI 105–137 minutes), and for the X-Stop group it was 66 minutes (SD 21 minutes, 95% CI 56–75 minutes). The operative time was significantly longer for the laminectomy group (T score = 6, unpaired Student t-test). Sixteen of the 21 X-Stop operations were conducted by an independent attending or consultant surgeon, and 5 were performed by neurosurgeons in training under supervision. Eight laminectomies were performed by a consultant and 18 by neurosurgeons in training under supervision. There were 16 1-level laminectomies and 8 2-

level laminectomies. Two patients were considered as having undergone a 3-level laminectomy, as the operating surgeon also performed a partial laminectomy of an adjacent moderately stenotic level. In the X-Stop group, there were 15 1-level and 6 2-level procedures. There was no statistically significant difference in EQ-5D scores or number of levels operated on for either group. All laminectomies were bilateral with bilateral muscle stripping.

The average hospital length of stay was 4.2 days for the X-Stop group (range 1–20 days) and 4.3 days for laminectomy (range 1–15 days). The distribution of length of stay did not show any significant difference between the groups. There was a single complication in each group that resulted in a prolonged length of stay. No significant difference was found for the length of stay between groups (p = 0.404, Fisher's exact test). The total complication rate for the study was 15%. The laminectomy group had 5 (19%) complications, and there were 2 (10%) in the X-Stop group. In the laminectomy group, there were 4 intraoperative dural tears. Three resolved without additional treatment, and the fourth required a return to the operating room for repair. One patient had a postoperative myocardial infarction within 30 days of the operation. In the X-Stop group, there was 1 case of worsening back pain immediately postoperatively that required IDD removal and laminectomy after 6 months and 1 intraoperative fracture of the spinous process that required intraoperative IDD removal. Both of these were coded as complications. The former complication was also coded as a reoperation, but the latter was not, as it occurred in the same anesthesia session. An additional 3 IDD patients went on to have X-Stop removal and laminectomy at the same level; all procedures were performed to treat persistent symptoms during a second operation on a separate date (1 after 8 months and 2 after 12 months). These are treatment failures and were not coded as complications.

Further details of the secondary outcome measures, including comparative mean subgroup SF-36 scores (and intention-to-treat and as-treated analyses), multivariate analysis of potential predictors of outcome, and sensitivity analysis are included in the Supplementary Materials (Supplementary Tables 7–10).

The incremental cost of the X-Stop was £2437 ($2980), and the incremental QALY was −0.11. These values were used as the basis to calculate the incremental cost-effectiveness ratio (ICER)[11,22]: ICER = (total cost of X-Stop − total cost of laminectomy)/(QALY X-Stop − QALY laminectomy) = (£5148 − £2712)/(0.81 − 0.92) = −£22,145 (−$27,078).

The X-Stop had a lower gain in QALY and cost more than a laminectomy on average. This results in a negative ICER (QALY loss for increased cost). If the device cost is subtracted from the equation, the incremental cost would be less for the X-Stop. It would be −£912.8 (−$1116), and the ICER would change to £8298 ($10,138).

If the reoperation cost for removal of four X-Stop devices and decompression are included, then the average additional cost for the subsequent surgery and admission would be £3147.35 ($3848), which raises the X-Stop average cost from £5148 ($6417) to £5747 ($7027). There was a single reoperation in the laminectomy group (dural tear repair) that resulted in an additional cost of £3442.71 ($4209) consisting of £1511 ($1848) for additional operating room time and £1931.71 ($2361) for the admission. This results in an increased average laminectomy cost from £2712 ($3315) to £2844 ($3477).

Discussion

This study concerns a prospective randomized controlled trial of the X-Stop IDD versus laminectomy for LSS. It is a pragmatic trial and hence compares the most common treatment for LSS (standard bilateral laminectomy) as performed in 3 UK centers as opposed to advanced or minimally invasive techniques that some authors will argue are the gold standard. This trial sought to address cost and QOL as opposed to biomechanical or imaging-based outcomes.

In recent years, there has been increased interest in the economic evaluation of healthcare. The value of looking at both the clinical effect of treatment and its economic impact and financial feasibility is increasingly recognized. The economic importance of LSS is increasing in relevance due to increasing life expectancy and disease prevalence. This is the first randomized controlled trial in the UK investigating QOL and cost of an IDD. The results of this study have important implications for the use of healthcare resources and decisions regarding the use of IDDs. The average cost for a laminectomy was £2712 ($3316) and that for X-Stop insertion was £5148 ($6295). Unsurprisingly, a significant element of the excess cost was the device itself. Cost reduction and mitigation is an important element of healthcare. If the X-Stop device cost were to be removed, it would cost less than a laminectomy, with the cost savings being mainly due to shorter operating times. The length of stay was similar between the two groups, and therefore the expected cost savings in hospital admission for the X-stop group were not observed. This may be due to various factors; lack of a standardized discharge protocol between the different centers, the novelty of the X-Stop insertion procedure, and the age and comorbidities of LSS patients means that safe and independent ambulation takes longer to achieve.

Our results suggest that a lumbar laminectomy is more cost-effective than X-Stop insertion for treatment of LSS. The primary reason for this is the additional device cost rather than clinical efficacy. The intention-to-treat and as-treated analyses both found that patients treated with the X-Stop had improved outcomes in all PROMs but to a lesser degree than those treated with a laminectomy (Fig. 4). If the reoperation costs are included, then the X-Stop cost-effectiveness is reduced and the ICER becomes negative (−£22,145 [−$27,202]). This can mean that either the new treatment is cheaper (as was the case here) or it had a less effective health outcome. It should be noted that the cost of operating room time in the UK is similar to that in other European countries (around €12/min).[22]

In this study, both groups improved and maintained improvement with surgery for the duration of follow-up (2 years). The overall complication rate was 14.9%, which is similar to that reported in other studies such as the SPORT (12%).[3] However, the complication rate following laminectomy was higher, at 19.2% (5/26 patients). The 5 complications included 4 dural tears, one of which required reoperation for repair. The remaining 3 dural tears resulted in a longer stay in the hospital but no long-term morbidity. The other complication was a myocardial infarct that occurred immediately postoperatively. All complications occurred in cases performed by neurosurgeons in training under supervision. It should be noted that the reporting of complications varies between studies, as some authors do not include intraoperative dural tears that do not require repair as complications.

This study adds to the existing literature that compares the X-Stop device with conventional surgery. Three RCTs have investigated the use of the X-Stop versus standard decompression.[8,9,22] In these studies, the X-Stop reoperation rates were 26%, 29%, and 25%. All found a similar primary clinical outcome between the two groups, but, due to the high reoperation rate in the X-Stop group, the procedure was less cost-effective. We also found a

similar result with a reoperation rate of 19% within the 2-year study period that reduced the ICER for the X-Stop group and made laminectomy more cost-effective. In 2010, Azzazi et al. compared the X-Stop device with surgical decompression and fusion.[23] In that study, the authors showed that the X-Stop device had better clinical outcomes and lower complication rates than fusion. Other retrospective comparative studies have compared other types of IDDs with laminectomies, and, similar to the findings in our study, have shown them to be more costly and with a higher reoperation rate.[24]

The study was limited by small numbers and challenging recruitment. A large number of assessed patients did not meet the inclusion criteria or declined to participate. There is a wide variation in the funding and organization of different healthcare systems and so applicability of the cost-effectiveness findings to non-UK systems needs to be made with caution.

We found that, on the basis of cost and QOL outcomes, the X-Stop should not be used as an alternative to conventional lumbar decompression. However, the X-Stop procedure does have the advantage of a shorter operating time and may be performed under local anesthesia. Therefore, there remains a limited a role for the X-Stop as a treatment option in patients who are medically unfit for conventional surgery under general anesthesia.

Conclusions

Treatment of LSS with an X-Stop IDD had a higher cost (primarily device-related) and a lower improvement in QOL measures at 24 months compared with laminectomy. The complication rate was lower for X-Stop than for a laminectomy, but the reoperation rate was higher. IDD devices like the X-Stop are inferior to standard laminectomy but may still be appropriate in patients with severe comorbidities in whom an invasive operation or general anesthesia would be contraindicated.

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