Interspinous spacers for lumbar foraminal stenosis: formal trials are justified

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Abstract

Purpose To determine whether preliminary evidence supports X-STOP implants as an effective treatment for lumbar radiculopathy secondary to foraminal stenosis, and if larger formal trials are warranted.

Methods Participants had a clinical diagnosis of lumbar radiculopathy supported by MRI findings of foraminal stenosis and relevant nerve root compression. Self-reported disability and pain were measured pre-operation, early and late post-operation using the widely used Oswestry Disability Index (ODI) and the bodily pain scale of the Medical Outcomes Study 36-item Short Form Health Survey (SF-36BP). The statistical significance (paired samples *t* test; Wilcoxon signed ranks test), and clinical significance (Cohen's effect size; Standardised response means) of change scores was determined.

Results Fifteen people had X-STOP implants. Data pre-early- and late post-operation were available for ten. Self-reported disability and pain improved substantially by the early post operative measurement. Mean change scores (ODI = 29; SF-36BP = −45), significant at the $p < 0.05$ but not significant at the $p < 0.001$, were very large and effect sizes exceeded notably criteria for large clinical

improvements (>0.80). Improvements were maintained at 2–3 years. Both scales had floor and ceiling effects implying changes may be underestimated. There were no surgical complications.

Conclusions In this small study, X-STOP appeared safe and effective. It is less invasive than other established surgical procedures, but does not jeopardise other options in the event of failure. Large scale clinical trials are justified but floor and ceiling effects suggest that the ODI and SF-36 may not be the best choice of outcome measures for those studies.

Keywords Lumbar radiculopathy · Foraminal stenosis · Interspinous implant · X-STOP · Outcome measures · Oswestry disability index · SF-36 · Ceiling/floor effects

Introduction

It is a poor reflection on spinal surgeons that large numbers of interspinous spacers have been implanted for the treatment of spinal stenosis with little objective evidence to support the efficacy of the procedure. The vast majority of these have been implanted to treat lateral recess (subarticular) stenosis. However, observation suggests that the technique is likely to be more successful in the treatment of the completely distinct but much less common condition of foraminal stenosis. Despite this, there is nothing in the literature which examines the potential efficacy of interspinous implants for the treatment of lumbar nerve root compression as a consequence of foraminal stenosis as distinct from lateral recess stenosis.

It is a common clinical observation that symptoms resulting from spinal nerve root compression often improve significantly following decompression of the affected nerve root [1–4]. The surgical options depend on the nature of the

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compressive lesion. Which procedure is considered most appropriate and whether or not surgery is undertaken will depend on the perceived balance of potential risk and benefit.

We examined the prospective, routinely collected audit data in our people having X-STOP interspinous implants for foraminal stenosis. Our aim was to determine whether our clinical suspicions were supported, formal clinical trials warranted and whether widely used outcome measures might be appropriate.

Methods

Surgery

Sample

People with a clinical diagnosis of lumbar radiculopathy and an MRI demonstrating relevant foraminal nerve root compression were offered treatment with X-STOP implants. Foraminal stenosis was defined as compression of the exiting nerve root in the space defined by pedicle rostrally and caudally, the disc ventrally and the facet joint dorsally. A clinical diagnosis of foraminal stenosis was suspected when a person's pain was relieved by hip and lumbar spine flexion (i.e. adopted the foetal position). If the cause of a person's pain was uncertain a diagnostic dorsal root ganglion block was performed to try and clarify the diagnosis. People were excluded if foraminal compromise was secondary to an isolated far lateral disc protrusion, associated with significant coronal plane deformity, spondylolysis and previous surgery having destroyed relevant spinous processes or, at L5/S1, if the sacral plateau was considered too small to support the implant. The potential risks and benefits of the surgical options available were discussed and all participants gave informed consent to proceeding with surgery.

Procedure

X-STOP implants were inserted under a general anaesthetic, with people in the knee chest position. The device was inserted between the spinous processes, through the interspinous ligament, leaving the supraspinous ligament intact, as described by others [5].

Outcome measures

Since 2001, TG has attempted to collect, routinely, prospective outcome data on all people referred to his spinal neurosurgery service. Currently, this consists of self completed questionnaire booklets at all consultations. These

booklets include the Oswestry Disability Index (ODI; [7] and the Medical Outcomes Study 36-item short form Health Survey (SF36; [8]), two of the most widely used patient-reported outcome measures (PROMs) used in clinical trials of spinal surgery [6].

Oswestry low back pain disability questionnaire [7] This is a self-report measure of the extent to which a person's functional level is restricted by back or leg pain. It has 10 questions (items) concerning different aspects of an individual's life: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. Each item has six response options representing increasing levels of impact or limitation. These are scored either 0–5 or 1–6. Item scores are summed to produce a total score, the Oswestry Disability Index (ODI), ranging from either 0–50 or 10–60. Here, scores were transformed to have a 0–100 range to ease interpretation. High scores indicate greater disability. The ODI has been widely used as an outcome measure in studies of spinal surgery and is considered fit for purpose [6].

Medical outcomes study 36-item short form health survey [8] The SF-36 is a 36-item self-report measure of health status. 35 items are grouped together into scales measuring eight different health aspects (physical function; role limitations due to physical problems; bodily pain, general health perceptions; energy and vitality; role limitations due to emotional problems; social functioning, mental health). Although the eight scales can be further grouped using a specific algorithm to produce two summary scores—physical health and mental health, this algorithm has not proven valid in people undergoing spinal surgery [9]. Therefore, to focus on the key symptom of pain and to avoid statistical issues associated with multiple comparisons, we chose to analyse and report only the 2-item bodily pain subscale, SF-36BP. Both items have six response categories. Responses are scored, summed and transformed to have a range of 0–100. High scores indicate least pain (reverse scoring of ODI).

Analyses

Descriptive statistics were computed for the ODI (Fig. 1) and SF36BP (Fig. 2) at three assessment points: pre-operation, early post-operation (2–4 months), later post-operation (2–3 years, completed by postal survey). For completeness, both parametric (means, standard deviations) and non-parametric (medians, inter-quartile range) descriptive statistics were reported. Also, we computed for both scales the percent of people who had the worst possible score (“floor” effect; ODI = 100; SF36BP = 0), and the percent of people who had the best possible score (“ceiling” effect; ODI = 0; SF-36BP = 100) at each time-point. Only people with data at all three time-points were included.

Fig. 1 Mean scores for the ODI (1) and SF-36 BP (2) pre-, early post- and late post-operatively (blue, maroon, and green respectively)

Fig. 2 **a** Individual-person ODI scores pre-op (1), early post-op (2), and late post-op (3). ODI scores: 0 = least disability; 100 = worst disability. **b** Individual-person SF-36 BP scores pre-op (1), early post-op (2), and late post-op (3) SF-36 scores: 0 = worst pain; 100 = least pain

We examined the magnitude of change between pre and early post-operative measurements, and between early and late post-operative measurements. The statistical significance of changes was determined using parametric (paired samples *t* tests) and non-parametric (Wilcoxon signed rank test) statistical tests. We predicted that even large changes may not be statistically significant ($p < 0.001$), as our sample size was small and statistical significance is sample size dependent.

We also examined the clinical significance of changes in disability and pain because statistical significant changes

are not necessarily clinically meaningful, and non-significant changes can be clinically meaningful. This was achieved by computing two effect sizes (standardised change scores): Cohen's effect size, the mean change score divided by the pre-operative SD (Cohen's ES; [10]); and the standardised response mean, the mean change score divided by the change SD (SRM; [10], [11]). Values for the parametric effect size calculations were interpreted using Cohen's criteria [10] which define widely adopted thresholds for small (0.20), medium (0.50) and large clinical changes (0.80).

For completeness and consistency, non-parametric versions of both effect sizes (Cohen's and SRM) were also reported as recommended by others (median change/interquartile range pre-operation; median change/interquartile range of change). Criteria for their interpretation are less well established.

A large number of analyses are reported because their detail is informative, and there is debate as to whether parametric or non-parametric statistics are more appropriate for rating scale data.

Results

Sample

All 16 people with lumbar radiculopathy secondary to foraminal stenosis who were offered X-STOP implants chose that treatment option. Insertion was not possible in one person as fusion of the posterior elements prevented distraction of the L5/S1 disc space. Implants were implanted successfully in the remaining 15 people. These patients were six women and nine men, aged 37–76 years at operation. Two people had X-STOPS inserted at two levels at the same surgery, whilst the remainder had a single implant. Three X-STOPS were inserted at L3/4, five at L4/5 and ten at L5/S1.

One man was excluded from the analyses as he had two separate surgical episodes. He represented with recurrent radiculopathy secondary to lateral recess stenosis at the level above and underwent a medial facetectomy at that level. However, we did include a female who had two surgical episodes. She represented 6 months after the original procedure with new radiculopathy secondary to foraminal stenosis at a different level and underwent a second X-STOP procedure.

Four people were excluded from the analysis as they did not have data for the three time-points. All completed their first post-operative questionnaire 12–18 months post operatively. We considered this time interval post surgery too long to give a meaningful representation of its direct effect. Thus, there were pre-, early post-, and late post-

Table 1 Disability and pain outcome scores in those with long term follow up (n = 10)

	ODI	SF36-BP
<i>Scale features</i>		
Construct measured	Disability	Pain
No items	10	2
Possible score range	0–100	0–100
High scores indicate	Worst disability	Least pain
<i>Pre-operation assessment</i>		
Observed score range	0–80	0–62
Mean (SD)	46.4 (24.7)	20.2 (19.5)
Median (IQR)	45.9 (39.0)	12.0 (26.0)
Floor effect (worst score)/Ceiling effect (best score)	0/10 %	20/0 %
<i>Early post-operation assessment</i>		
Time of assessment in months: mean (range)	3.3 (2–4)	3.3 (2–4)
Observed score range	0–74	0–100
Mean (SD)	17.4 (22.7)	65.5 (29.2)
Median (IQR)	10.0 (21.0)	72.0 (29.75)
Floor effect (worst score)/Ceiling effect (best score)	0/20 %	10.0/10 %
<i>Change from pre- to post-operation</i>		
Mean change (SD)	29.0 (27.0)	–45.3 (34.3)
Statistical significance		
Paired <i>t</i> test: <i>t</i> value (<i>p</i>)	3.40 (0.008)	–4.17 (<i>p</i> = 0.002)
Wilcoxon-signed ranks: <i>p</i> value	<i>p</i> = 0.012	<i>p</i> = 0.011
Clinical significance		
Cohen's effect size: parametric (non-parametric)	1.18 (0.69)	–2.32 (–1.90)
Standardised response mean (SRM): para (non-para)	1.08 (0.86)	–1.32 (–1.01)
<i>Late post-operation assessment</i>		
Time of assessment in months: mean (range)	30 (22–36)	30 (22–36)
Observed score range	0–58	0–100
Mean (SD)	15.4 (20.2)	67.2 (33.8)
Median (IQR)	6.0 (26.0)	77.0 (61.5)
Floor effect (worst score)/Ceiling effect (best score)	0/20 %	10.0/30 %
<i>Change between early and late post operation</i>		
Mean change (SD)	2.0 (16.4)	–1.7 (22.1)
Statistical significance		
Paired <i>t</i> test: <i>t</i> value (<i>p</i>)	0.385 (<i>p</i> = 0.709)	–0.243 (<i>p</i> = 0.814)
Wilcoxon-signed ranks: <i>p</i> value	<i>p</i> = 0.798	<i>p</i> = 0.888
Clinical significance		
Cohen's effect size: parametric (non-parametric)	0.09 (–*)	–0.06 (–*)
Standardised response mean (SRM): para (non-para)	0.12 (–*)	–0.08 (–*)

* Values could not be computed as the median change was zero

operative data for 10 people. We performed two main change analyses: pre-op to early post op; and early post op to late post-op (Table 1).

Impact on self-reported disability and pain

Table 1 shows the disability and pain outcome measurements for the 10 people. Reported are: descriptive statistics for the pre-operation, early and late post-operation assessments; change scores from pre-to-early post

operation and from early-to-late post operation; statistical and clinical indicators of change at these two time-points.

The pre-operation ODI mean score (46.4) was near the mid-point of the scale range implying moderate disability, on the average. The early post-operation mean score was low (17.4) implying less disability. The average change score (29.0) was large: 29 % of the possible scale range (0–100) and 36 % of the observed score range (0–80). This change in disability score was not statistically significant at the $p < 0.001$ level, but significant at lower levels using

both parametric and non-parametric statistical tests. However, both effect sizes were large (Cohen's $ES = 1.18$; $SRM = 1.08$), exceeding substantially the threshold for a large clinical improvement in disability (0.80; 7). ODI changes from early to late post-operative periods were very small (mean 2.0) and non-significant statistically and clinically. These findings imply that the X-STOP procedure was associated with substantial patient-perceived improvements in disability that appeared to persist.

The results for the SF-36BP scale were similar. Pre-operation SF-36BP mean score was low (20.2) implying substantial pain before surgery, on the average. The post-operation mean score was much higher (65.5) implying notably less pain. The average change score (-45.3) was almost 50 % of the possible scale range (0–100), and 73 % of the observed pre-operation score range (0–62). This implied a marked reduction in pain. This change in pain score was not statistically significant at the $p < 0.001$ level, but significant at lower levels. Clinically, however, the improvements in SF-36BP scores were very notable as both effect sizes (Cohen's $ES = -2.32$; $SRM = -1.32$) exceeded comfortably the recognised threshold for a large clinical change. The SF-36BP late post-operation mean score was very similar to the early post-operation mean score (mean change = -1.73) implying that improvements in self-reported pain persisted.

Excluded data

Our hypothesis was that for any improvement to be attributable to the surgical intervention there should be an early post operative improvement which was sustained at the late follow-up. This required three data points for each patient, pre-op, early post -op and late post op. The four people who had their “early” post operative measurements 12–18 months post surgery did not fulfil this requirement and were, therefore, excluded. However, these patients had improved average disability scores (mean ODI change = $+10$ pts, range -2 to $+26$) and improved average pain scores (mean SF-36BP = -30.3 pts, range 0 to -78 pts). Three of these four people also had “late” post operative measurements 29–36 months post surgery. Further improvements were observed in average disability scores (mean ODI change = $+20$ pts, range 0 to $+56$) and pain scores (mean SF-36BP change = -34.3 pts, range -9 to -78 pts). These findings are completely consistent with those 10 patients in whom we had an early and late post-operative follow-up rather than delayed measurements.

The female who had two procedures 6 months apart only had the second procedure included. She did improve after the first procedure, but subsequently developed symptoms from nerve root compression at an adjacent level. At her late post op follow, her symptoms had

improved implying longer term benefits from both procedures. We took the view that she could only be included once because she only has a single late post-operative measurement for the independent two procedures.

Discussion

The aim of this study was to gain a preliminary understanding of the effectiveness of X-STOP implants as a treatment for lumbo-sacral radiculopathy caused by foraminal stenosis. Our results, albeit from a small study of consecutive patients at a single site, are very encouraging. They imply foraminal stenosis is associated with notable pain and moderate disability that improves substantially with surgery and that these improvements appear to persist. These results have implications for spinal surgery. In addition, this study provides useful information about the ODI and SF-36 as outcome measures for future clinical trials.

The principle of decompressing a nerve root to alleviate symptoms caused by compression seems reasonable. Evidence from controlled trials supports this principle [2–4]. However, the surgical technique employed to achieve decompression depends on the anatomical nature of the compressive lesion. The balance of potential risk and benefit from a particular operation depends on the size of the likely treatment effect of the proposed operation and the potential complications. More complex operations are associated with an increased risk of complications. Therefore, unless there is a significant difference in benefit more simple surgical solutions should be preferred to more complex ones.

The X-STOP interspinous implant has been available in Europe since June 2002. The underlying principle is that distraction between the spinous processes of adjacent lumbar vertebrae increases the cross sectional area of the spinal canal and the exit foramina, thus providing indirect decompression of nerve roots. Application of this principle has been used to treat neurogenic claudication secondary to lumbar canal (lateral recess) stenosis. Early results were encouraging suggesting it is as effective as conservative management [5]. Unfortunately, subsequent reports of effectiveness have been less encouraging [12, 13] and demonstrated disappointing failure rates [12, 14, 15]. In contrast, direct surgical decompression in lateral recess stenosis has been shown to be far more effective than conservative management [3]. Together, these studies imply that managing lumbar canal (lateral recess) stenosis is complex and that a thorough evaluation of the role of interspinous implants is required to guide surgical practice and maximize patient care.

Foraminal stenosis is a separate diagnostic entity, although it may co-exist with lateral recess stenosis. It is

much less common, probably under-diagnosed and there is comparatively little in the literature describing its management. However, the aim of surgery is clear: safe and achieve adequate decompression of the nerve root that results in maximal and persistent resolution of symptoms that persists and minimal compromise of the structural integrity and function of the spinal column.

Direct decompression is probably the most common surgical treatment performed for foraminal stenosis. It has been studied with and without instrumented postero-lateral fusion [16]. The rationale for fusion was to prevent further collapse of the disc space and consequent foraminal restenosis. There was no significant difference in outcomes. The SF-36BP scale mean change score was 16 points at 2 years and 21 points at 5 years. Interestingly, 5 years post surgery, disc height was maintained in both groups. This implies that the decision for fusion is not random, and needs to be tailored to the individuals undergoing surgery.

In our practice, adjunctive fusion is advocated when decompression results in so much facet joint destruction that some form of stabilisation appears required. Fusion is typically postero-lateral, with or without transforaminal interbody fusion. The theoretical advantage of interbody fusion is that it restores disc height and, therefore, addresses cranio-caudal foraminal compression. Again, these decisions are bespoke to the individuals undergoing surgery. Bespoke surgical decisions make clinical trials of direct decompression difficult as they undermine the potential to achieve comparable groups, and affect the interpretation of statistical comparisons between groups.

Other techniques have been described with the objective of achieving satisfactory nerve root compression with minimal disruption to the structural integrity of the spinal column. A combined lateral and medial facetectomy and a foraminotomy performed via a trans-laminar fenestration have both been described [17, 18]. However, there has been no objective assessment of the clinical outcome from these operations. Postero-lateral percutaneous endoscopic lumbar foraminotomy has been described as a technique to treat lumbar foraminal stenosis [19, 20]. However, despite several publications describing the technique, its efficacy has not been proven in controlled clinical trials [21].

Implantation of interspinous distraction devices has been proposed as a simple way to achieve indirect decompression of lumbo-sacral nerve roots. It is relatively straightforward, minimally destructive, and can be performed as a day-case under local or general anaesthesia. Indirect decompression is an attractive proposition as the incidence of durotomy and nerve root damage is expected to be lower than with direct nerve root exposure.

Empirical observation suggests that interspinous distraction should increase both cranio-caudal and dorso-ventral diameters of the exit foramen. This has been

confirmed by Positional MRI studies which have shown that X-STOP interspinous implants increase foraminal area by 20–34 % [22]. Moreover, as the surgical treatment of foraminal stenosis is more difficult than lateral recess stenosis, the potential benefit of a more simple surgical procedure to treat the condition would be greater.

However, it goes without saying that formal clinical trials and observational studies are required to determine if theoretical benefits translate into effective and safe treatments for people. So, in the era of evidence-based medicine, it is perhaps surprising that large numbers of interspinous implants have been implanted and that there are few published reports assessing their effectiveness and no controlled comparisons with pre-existing treatments proven to be effective. At the same time, there are significant differences in the anatomy of nerve root compression in the subarticular zone and exit foramen and their surgical management is different. Despite this, there do not appear to be publications investigating the effectiveness of interspinous implants which distinguish between the two diagnostic entities.

Our aim was to begin to establish a literature assessing the effectiveness of interspinous implants for foraminal stenosis. The study has limitations: it is small and from a single surgeon. Nevertheless, it provides useful evidence, albeit preliminary, to support the use of X-STOP implants in the treatment of symptomatic lumbar foraminal stenosis. We suggest that there is sufficient evidence to justify a more detailed investigation.

The study sample was small. One reason is that foraminal stenosis is an uncommon, although probably under-diagnosed, cause of lumbar radiculopathy. Another reason for the small sample was incomplete data. A total of 15 people had X-STOP implants. The “early” post operative assessment of four people was not until 12–18 months post surgery; too late for us to be sure that any change was a consequence of the surgery. The data completeness issues of this unfunded study highlight the difficulties of collecting audit and outcome data in routine clinical practice without investment in the administration infrastructure. Whilst, the incomplete data could undermine the generalisability of our findings, it's notable that the pre-op and change indicators for the subsample of excluded data are similar to those for the whole sample.

This study demonstrates and highlights the value of incorporating indicators of clinical meaningfulness routinely into clinical studies. Typically, studies rely on statistical significance testing to determine effectiveness. Here, the results were significant at the $p < 0.05$ level, but not at the more convincing $p < 0.001$ level despite absent power calculations. Yet, the magnitude of change, whether considered as raw scale score changes or effect sizes, is substantial and cannot be ignored.

Even though the number of people studied was small, this study provides useful insights about the performance of the ODI and SF-36BP as outcome measures that are irrespective of evidence for their reliability and validity. For example, the ODI had a ceiling effect of 20 % at both post-operation time-points. Ceiling effects represent subgroups of people in whom the scale limits our evaluation of the extent of change they have experienced with surgery. In essence, the ceiling effects here imply that changes in disability associated with surgery could be an underestimation of the true change.

Likewise, the SF-36 also had ceiling effects post-operatively—these were 10 % (early) and 30 % (late)—implying the impact of surgery on pain may be underestimated. In addition, the pre-operative SF-36BP has a 20 % floor effect. A floor effects on the SF-36BP represent a subgroup of people who could have more pain than the scale can measure. As such, the scale has the potential to underestimate change in pain associated with surgery. Scales with few items are particularly susceptible to floor and ceiling effects.

These relatively simple findings, which require a thorough tabulation of the results, are important for those considering or planning larger clinical trials of surgical treatments for lumbar nerve root compression that might be used to guide evidence-based surgical practice. They suggest that other rating scales might be better candidates as outcome measures in larger more definitive clinical trials of interspinous implants, or indeed any surgery of lumbar nerve root compression. Certainly, other scales should be considered and tested, and including pre and post-operative imaging would also be valuable. As such, the findings of this study contribute towards both evidence-based measurement and evidence-based medicine.

Conflict of interest None.

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