Spine

SPINE Volume 36, Number 5, pp E345–E356

HEALTH SERVICES RESEARCH

Cost-effectiveness of the X-STOP® Interspinous Spacer for Lumbar Spinal Stenosis

A Comparison with Conservative Care and Laminectomy

Grant Skidmore, MD,* Stacey J. Ackerman, PhD,† Christopher Bergin, MD,‡ Dan Ross, MBA,† Jesse Butler, MD,‡ Manish Suthar, MD,§ and Joshua Rittenberg, MD¶

Study Design. Economic evaluation from the societal perspective, using data from various sources, including a multicenter, randomized clinical trial.

Objective. To evaluate the relative cost-effectiveness of interspinous process decompression using the X-STOP® Interspinous Spacer (Medtronic, Inc, Sunnyvale, CA) compared with both conservative care (CC) and laminectomy (LAMI) for patients moderately impaired by lumbar spinal stenosis.

Summary of Background Data. Placement of the X-STOP spacer is a minimally invasive surgical treatment for patients experiencing symptoms of lumbar spinal stenosis. The cost-effectiveness of the X-STOP spacer in the United States has not been evaluated.

Methods. A cost-effectiveness analysis was conducted using clinical, quality-of-life, and economic data from a total of 131 moderately impaired lumbar spinal stenosis patients (aged 50 years or older) randomly assigned to the X-STOP device (n = 69) or CC (n = 62) and followed up for 2 years. Data for LAMI are from patients who failed CC during the clinical trial and underwent LAMI, Medicare claims data, and published literature. An economic model comparing the X-STOP spacer with CC and LAMI was developed, and the incremental cost-effectiveness ratios were calculated in 2009 US dollars and reported. The primary clinical outcome measure was determined using the Zurich Claudication Questionnaire. The 36-Item Short-Form was used to calculate quality-adjusted life-years. Costs included first- and second-line treatment costs, follow-up costs, and adverse event–related treatment costs.

Results. For patients treated with the X-STOP spacer in the outpatient setting, the X-STOP spacer was cost-effective when compared with CC (the incremental cost-effectiveness ratio relative to CC was $17,894 per quality-adjusted life-year) and the X-STOP spacer was dominant when compared with LAMI (*i.e.*, the X-STOP spacer both was less expensive and provided better quality of life than LAMI).

Conclusion. In lumbar spinal stenosis patients with moderately impaired physical functioning, the clinical and quality-of-life benefits of the X-STOP spacer yielded favorable cost-effectiveness ratios. Placement of the X-STOP spacer performed in the outpatient setting compared with LAMI was more cost-effective than treatments such as hip replacement surgery ($2004 per quality-adjusted life-year). These results support the use of interspinous process devices to treat patients experiencing symptoms of lumbar spinal stenosis.

Key words: X-STOP, interspinous process decompression, lumbar spinal stenosis, cost-effectiveness, epidural injection, laminectomy.

Spine 2011;36:E345–E356

Lumbar spinal stenosis is defined as a narrowing of the spinal canal and peripheral neural pathways, resulting in compression of neural elements. Treatment initially consists of conservative care (CC), with nonsteroidal anti-inflammatory medication, oral steroids, analgesics, epidural steroid injections, physical therapy, and spinal manipulation. Spinal decompression with laminectomy (LAMI), with or without fusion, is the standard surgical procedure for patients failing CC. Surgical success rates vary widely in the clinical literature because of variations in the definition of treatment success, patient sample, and clinical endpoint measures. In addition, LAMI complication and reoperation rates are substantial, with intraoperative complication rates ranging from 9% to 12%,[1–3] postoperative complication rates ranging from 12% to 29%[1–2,4–6] depending on age and comorbidity status,[7] and reoperation rates ranging from 6% at 2-year follow-up to 23% at 7- to 10-year follow-up.[1,7–10]

Interspinous process decompression has been developed as a minimally invasive surgical treatment for patients experiencing symptoms of lumbar spinal stenosis. The clinical effectiveness

From the *Neurosurgical Specialists, Inc, Norfolk, VA; †Covance, Inc, San Diego, CA; ‡Illinois Bone and Joint Institute Ltd, Chicago, IL; §Pain Prevention and Rehabilitation Center, St. Louis, MO; and ¶Spine and Sports Rehabilitation Center, Chicago, IL.

Acknowledgment date: April 29, 2008. First revision date: October 31, 2008. Second revision date: March 12, 2010. Third revision date: May 26, 2010. Fourth revision date: July 2, 2010. Acceptance date: July 6, 2010.

The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

Corporate/industry funds were received in support of this work. One or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript: for example, honoraria, gifts, consultancies, royalties, stocks, stock options, and decision-making position.

Supported by Medtronic, Inc (formerly Kyphon, Inc), Sunnyvale, CA.

Data from the X-STOP interspinous spacer clinical trial were made available for this study. The X-STOP interspinous spacer clinical trial was conducted after the institutional review board approval at the participating institutions.

Address correspondence and reprint requests to Grant Skidmore, MD, Neurosurgical Specialists, Inc, 580 E Main St, Ste 200, Norfolk, VA 23510; E-mail: grant.skidmore@yahoo.com

DOI: 10.1097/BRS.0b013e3181f2ed2f

(treatment success rate) of the X-STOP® Interspinous Spacer (Medtronic, Inc, Sunnyvale, CA) has been demonstrated in a prospective, randomized clinical trial to be superior to continued CC.[11] In addition, the X-STOP device has demonstrated superior efficacy compared with CC in improving the quality of life (as measured by the 36-Item Short Form Health Survey [SF-36]) in patients with lumbar spinal stenosis.[12] After at least 6 months of CC, this procedure can be a logical next step for the treatment of lumbar spinal stenosis symptoms. However, the economic aspects of the X-STOP spacer in the United States have not been explored.

This study evaluates the cost-effectiveness of the X-STOP spacer relative to continued CC or LAMI in lumbar spinal stenosis patients with moderately impaired physical functioning, using the analysis methodology termed "societal perspective" analysis.[13] Cost-effectiveness analysis compares two or more alternative health interventions in terms of their costs and benefits (or improvement in patient quality-of-life) to evaluate whether the added benefits outweigh the incremental costs.[14] Our analyses are primarily based on data collected during a multicenter, prospective, randomized clinical trial of the X-STOP spacer, supplemented with published data on LAMI. The X-STOP spacer is designed to create and maintain distraction of the spinous processes at the treatment level, while enabling lumbar extension at other levels. The X-STOP interspinous spacer is approved by the US Food and Drug Administration for treating patients aged 50 years or older with symptoms of neurogenic intermittent claudication and a confirmed diagnosis of lumbar spinal stenosis in patients who experience moderate physical impairment with relief in flexion. The X-STOP spacer is indicated for patients who have undergone at least 6 months of CC and may be implanted at one or two lumbar levels when treatment is indicated at no more than two levels.[15]

MATERIALS AND METHODS

This study incorporates clinical, quality-of-life, and economic data collected during a randomized trial comparing the X-STOP device with CC. Conducted between May 2000 and July 2003, the trial involved nine US sites and included 191 patients with mild to severe lumbar spinal stenosis.[11] During the clinical trial, *CC* was defined as at least one epidural steroid injection, supplemented by nonsteroidal anti-inflammatory medication, oral steroids, analgesics, physical therapy, and spinal manipulation therapies, as appropriate.[11] Patients were eligible to participate in the clinical trial if they were at least 50 years of age, had neurogenic intermittent claudication, secondary to imaging-confirmed lumbar spinal stenosis at 1 or 2 levels, had pain relief in flexion, were able to sit 50 minutes without pain, were able to walk 50 ft or more, and had undergone at least 6 months of CC. Of note, the present cost-effectiveness analysis incorporates only those data from X-STOP spacer clinical trial patients in the indicated population (N = 131; X-STOP: n = 69, CC: n = 62), that is, moderately impaired lumbar spinal stenosis patients who scored greater than 2 in the physical function domain of the Zurich Claudication Questionnaire (ZCQ).[15] Key exclusion criteria for the X-STOP spacer trial included, but were not limited to, those patients who had undergone prior lumbar spinal surgery, had more than two affected levels, had cauda equine syndrome, had other defined neurologic deficits or significant instability of the spine, had significant scoliosis of the spine (Cobb angle greater than 25°), had spondylolisthesis greater than grade 1 at affected levels, and had severe osteoporosis. The clinical trial demonstrated that patients who received the X-STOP spacer had significantly better outcomes in each domain of the ZCQ (specifically, physical function, symptom severity, and patient satisfaction) relative to CC patients.[11] Clinical, adverse-event, and quality-of-life data from the X-STOP spacer clinical trial were made available for this cost-effectiveness analysis.

Of note, the present cost-effectiveness analysis incorporates only those data from the X-STOP spacer–clinical trial patients diagnosed with moderate-to-severe lumbar spinal stenosis (N = 131; X-STOP: n = 69, CC: n = 62).[15] Among these patients, the mean age was 69.8 years (70.2% were 65 years or older), 72.3% had one affected level, 27.7% had two affected levels, and the mean baseline ZCQ physical function score was 2.68. *Treatment success*, defined for this cost-effectiveness study as meeting all the three ZCQ criteria,[11,15] was significantly higher in patients receiving the X-STOP spacer than in those undergoing CC (55.1% *vs.* 4.8%, $P < 0.001$)[15]; the incidence of X-STOP device-related adverse events (*i.e.*, device migration, dislodgement, or removal) was 2.9%.[15]

Comparison of the X-STOP spacer with LAMI was not an objective of the randomized trial comparing the X-STOP spacer with CC. Data for LAMI come from multiple sources, including health insurance claims data and the published literature. Specifically, data on the clinical effectiveness of LAMI come from the published literature. Adverse event rates for LAMI come from MedPAR and MedStat Market Scan claims databases, while associated LAMI adverse event–related costs come from MedPAR. Utility values for LAMI treatment–related adverse events come from the clinical panel using the X-STOP spacer clinical trial data as reference points. First- and second-line LAMI treatment costs come from MedPAR. LAMI follow-up costs come from a number of sources, including MedPAR, RedBook, Medicare Outpatient Prospective Payment System, and Medicare Physician Fee Schedule. LAMI quality-adjusted life-years (QALYs) come from SF-36 data for CC patients who proceeded to LAMI during the X-STOP spacer clinical trial.

Analysis Method

Cost-utility analysis is a type of cost-effectiveness analysis in which outcomes are adjusted for quality of life, often using QALYs gained. The quality adjustment comes from utilities, numbers that reflect an individual's preference for particular health outcomes.[16] In this study, we developed an incremental cost-effectiveness analysis to evaluate the 2-year clinical, economic, and quality-of-life outcomes associated with the three lumbar spinal stenosis treatment strategies: CC, the X-STOP device, and LAMI. A multispecialty clinical panel of five physicians (two neurosurgeons, one orthopedic surgeon, and two physiatrists) provided the clinical framework for the economic

model and made final decisions on parameters. This research was performed according to guidelines established to minimize conflict of interest in pharmacoeconomic studies.[17,18] The authors independently framed the cost-effectiveness analysis, including the perspective to adopt, settings of care to evaluate, costs to measure, outcomes to assess, and assumptions to make. The sponsor was invited to review the draft manuscript for accuracy of describing the X-STOP interspinous spacer, clinical trial data, and device cost. All final editorial decisions were made by the coauthors.

The incremental cost-effectiveness ratio is calculated as the difference in *costs incurred* divided by the difference in *QALYs accrued* between the two treatments being compared. The term *dominant* is used to reflect instances in which one intervention is both less expensive and more effective (*i.e.*, offers better quality of life) than the alternative intervention. The present societal perspective-type analysis considers all relevant costs and benefits, regardless of where incurred or accrued (patient, physician, or payer). Direct medical costs include first- and second-line treatments, follow-up, and adverse events. All results are expressed in 2009 US dollars. Sensitivity analyses assessed the external validity and generalizibility of our estimates.[19] A 2-year time horizon was selected because the published follow-up data on the X-STOP device were limited to 2 years. Sensitivity analysis was performed to address this limitation. Costs and health effects are not discounted, given the 2-year time frame. Parameter estimates derived from the X-STOP spacer clinical trial, a comprehensive literature review, Medicare claims data, and the opinions of the clinical panel are provided in Table 1.

Assumptions

Several assumptions were made to construct this cost-effectiveness model: (1) This analysis applies only to moderately impaired lumbar spinal stenosis patients, aged 50 years or older with one or two affected levels, who have failed at least 6 months of CC and are candidates for the X-STOP spacer, continued CC, or LAMI; (2) in the base case analysis, we assumed that the X-STOP procedure is performed in the outpatient setting; (3) only those patients who are classified as clinical failures undergo additional treatment, as depicted in Table 1; (4) the sequelae of treatment-related adverse events are treated the same, irrespective of the first-line treatment; (5) treatment success and reoperation rates among patients undergoing LAMI without fusion *versus* those undergoing LAMI with fusion are similar[8,20]; (6) LAMI patients undergoing reoperation after first-line treatment failure have an increased probability of undergoing LAMI with fusion; (7) the quality-of-life effect of LAMI does not change after 1-year postoperation; (8) this analysis does not apply to workman's compensation patients because we excluded five patients who were receiving workman's compensation (three X-STOP spacer, two CC).

Utility Values

This cost-utility analysis is based on the idea that diminishing health results in diminished quality of life. This is accomplished by applying different utility weights to life expectancy according to the level of health experienced over time. Utility weights reflect the preference for a particular health outcome and range from 0 ("death") to 1 ("full health"). QALYs were calculated from the utility values by estimating the area under the curve mapped out by the utility values over time. Utility values were derived from three sources: (1) for X-STOP spacer and CC, SF-36 data (Medical Outcomes Study 36-item Short Form Health Survey) from the X-STOP spacer clinical trial at baseline, 6 weeks, 6 months, 1 year, and 2 years; (2) for LAMI, SF-36 data at baseline and 1 year from CC patients who proceeded to LAMI during the X-STOP spacer clinical trial (n = 21); and (3) for treatment-related adverse events, estimates from the clinical panel using the trial data as reference points. Because the SF-36 assessment asks about the previous 4 weeks, the 6-week SF-36 assessment in the X-STOP spacer clinical trial did not address the time from baseline through week 2. Therefore, disutilities associated with treatment-related adverse events were assumed to occur at time zero and were applied for a 2-week duration to the percentage of each adverse event that occurred intraoperatively or within 2 weeks after surgery (Table 2).

SF-36 scores for the X-STOP device, CC, and LAMI were transformed to utilities on the basis of equations from Nichol et al.[21] Before eliciting utility estimates from the panel for treatment-related adverse events, we transformed the reference utilities (for X-STOP spacer and CC, success and failure; and for deep wound infection, dural tear, chronic back pain [symptoms of spinal stenosis not improved], and degenerative spondylolisthesis and spinal stenosis free of symptoms[22]) to rating scale values using a power curve transformation[23] and placed the values on a rating scale ranging from 0 ("death") to 1 ("full health"). The panelists ranked the treatment-related adverse events on the rating scale by indicating a patient's likely preference for each event. Panelists' values were transformed back into utilities for use in the cost-effectiveness model (Table 2).

Medical Resource Utilization and Costs

Costs are assessed from the societal perspective. Indirect costs of lost productivity and intangible costs of pain and suffering related to treatment morbidity are not estimated directly but instead are implicitly incorporated in the utility values. To estimate 2-year direct medical costs, panelists enumerated medical resource utilization associated with the three therapeutic alternatives and their potential sequelae. A physician and a billing administrator experienced in medical reimbursement assigned procedure and diagnosis codes to hospitalizations, physician office visits, radiographic imaging studies, laboratory tests, and professional services. After identifying codes for resource use, we derived cost estimates from 2006 national Medicare reimbursement schedules and inflated these costs to 2009 US dollars, using the medical care component of the consumer price index.[24] Tables 2 and 3 list adverse event–related and treatment-related costs, respectively.

Medicare payments (national averages) were used as a proxy for cost, a well-established methodologic approach for such economic analyses.[25] Professional services associated

TABLE 1. Base Case Values Used in the Model

	Treatment Choice			
	CC	X-STOP Spacer	LAMI	Source
First-line treatment success rate*	4.8%	55.1%	47.4%	XCT, 20, 35, 36
Patient utility†				
Baseline	0.61	0.62	0.59	XCT, CP
2 wk	0.60	0.65	0.53	
6 wk	0.62	0.78	0.60	
6 mo	0.62	0.77	0.62	
1 yr	0.65	0.79	0.67	
2 yr	0.65	0.76	0.67	
No. of affected levels‡				
1	72.3%	72.3%	72.3%	XCT
2	27.7%	27.7%	27.7%	
Second-line treatments§				
CC	27.0%	54.8%	61.8%	XCT, CP
X-STOP Spacer	20.4%	0%	0%	XCT, CP
LAMI ||	37.3%	12.9%	12.2%	XCT, 1, 35
No second-line treatment#	15.3%	32.3%	26.0%	XCT, CP, 35
First-line LAMI				
With fusion	-	-	22.8%	26
Without fusion	-	-	77.2%	26
Average no. of epidural steroid injections	2.4	0.3	0.4	XCT
Anesthesia				
Local; conscious IV sedation	-	98.6%	-	XCT, CP
General anesthetic	-	1.4%	100%	

**Treatment success defined as meeting all three Zurich Claudication Questionnaire criteria.[11] Treatment failures (calculated as 1 −the treatment success rate) go on to second-line treatment according to the second-line treatment distribution provided earlier.*

†Utility weights reflect the preference for a particular health outcome and range from 0 ("death") to 1 ("full health"). Utility values were derived from three sources: (1) For X-STOP spacer and CC, SF-36 data (Medical Outcomes Study 36-item Short Form Health Survey) from the X-STOP spacer clinical trial at baseline, 6 wk, 6 mo, 1 yr, and 2 yr; (2) For LAMI, SF-36 data at baseline and 1 yr from CC patients who proceeded to LAMI during the X-STOP spacer clinical trial (n = 21); and (3) For treatment-related adverse events, estimates from the clinical panel using the trial data as reference points, which were applied for only the duration of the event. The LAMI utility value for 6 mo was estimated by linear interpolation. Per the clinical panel, the quality-of-life effect of LAMI does not change after 1 yr postoperation; therefore, the LAMI utility at 2 yr was assumed to be the same as at 1 yr.

‡No. of affected levels in the CC and LAMI groups is based on data from the X-STOP spacer group in the clinical trial.

§Second-line treatments were assumed to occur at 3 mo.

\|\|Among all patients initially treated with CC, X-STOP spacer, and LAMI, 35.5% (22/62), 5.8% (4/69), and 6.4% (10/157) underwent LAMI as subsequent therapy.[1,15] Among LAMI as first-line treatment or CC patients proceeding to LAMI as second-line treatment, 22.8% undergo LAMI with fusion.[26] Among patients failing X-STOP spacer or LAMI as first-line treatment and proceeding to LAMI as second-line treatment, 75% undergo LAMI with fusion (clinical panel).

#Patients who met two of the three ZCQ criteria are considered clinical successes and do not undergo additional therapy, per the clinical panel.

CC indicates continued conservative care; CP, clinical panel, IV, intravenous; LAMI, laminectomy; XCT, X-STOP spacer clinical trial.

with hospitalizations and outpatient visits were assigned current procedural terminology codes. The corresponding unit costs for physician services are based on Medicare Physician Fee Schedule. We calculated hospitalization costs as the amount Medicare pays on the basis of assignment to a diagnosis related group. Inpatient facility service costs (Diagnosis Related Group payments) are based on Medicare Provider Analysis and Review Data[26] (representing 100% of Medicare inpatient stays) and outpatient facility service costs (Ambulatory Payment Classification [APC] payments) are based on Medicare

TABLE 2. Adverse Event Probabilities, Costs, and Utility Values for First-Line Treatments

Adverse Event	Probability, %	Percent Occurring Perioperatively,* %	Cost† (2009 US $)	Utility‡
Laminectomy§				
Cardiac arrest	0.78	90	17,054	0.04
Cardiac disturbances	0.02	90	26,016	0.55
Cardiac dysrrhythmia	5.49	90	12,244	0.49
Cauda equine syndrome	0.22¶	100	12,270	0.58
Cerebral infarction	0.18	90	14,046	0.30
Cerebrospinal fistula	0.03	100	14,067	0.65
Coronary episode, ischemic	0.03	90	24,850	0.55
Deep infection	0.81	0	25,841	0.50
Deep venous thrombosis	0.42	10	18,358	0.68
Dural sac tear	4.55	100	12,954	0.66
Gastro-intestinal hemorrhage	0.17	0	19,180	0.60
Hematoma	0.86	90	15,927	0.90
Instrument failure	0.83	0	23,261	0.57
Leg parasthesia	0.28	90	||	0.88
Malignant arrhythmia	0.88	90	12,244	0.43
Myocardial infarction	0.07	90	15,165	0.41
Nerve damage	0.50	100	1,004	0.63
Pulmonary edema	0.02	90	19,637	0.59
Pulmonary embolism	0.18	10	18,695	0.38
Pyelonephritis	0.13	90	21,786	0.63
Respiratory distress	0.10	90	17,947	0.60
Severe pain (lumbago)	0.60	0	10,092	0.68
Urinary tract infection (severe)	2.80	50	14,868	0.68
Wound dehiscence	0.20	0	21,606	0.78
Wound swelling	0.20	50	||	0.90
X-STOP Spacer#				
Coronary episode, ischemic	1.4	90	24,850	0.55
X-STOP device migration/dislodgement	1.4	100	9,191	0.54
X-STOP device removal	1.4	**	**	**
Hematoma	1.4	90	15,927	0.90
Incisional pain (postoperative)	1.4	100	||	0.91
Increased back pain (postoperative)	1.4	100	||	0.89
Pain (moderate), stenosis	25.8	**	**	**
Pulmonary edema	1.4	90	19,637	0.59
Respiratory distress	1.4	90	17,947	0.60
Wound dehiscence	1.4	0	21,606	0.78
Wound swelling	1.4	50	||	0.90

(*Continues*)

TABLE 2. (Continued)				
Conservative care#				
Epidural Injection intolerance	1.6	100	||	0.88
Epidural Injection reaction	3.2	100	||	0.88
Increased back pain	1.6	0	||	0.89
Myocardial infarction	1.6	90	15,165	0.41
Pain/progressive to neurological deficit	1.6	**	**	**
Pain (moderate), stenosis	60.5	**	**	**

*Percentage of adverse events occurring intraoperatively or within 2 wk postoperatively, per the clinical panel.
†Costs based on MedPAR 2006 inpatient claims analysis inflated to 2009 US dollars.
‡Utilities elicited from clinical panel. Because the SF-36 assessment asks about the previous 4 wk, the 6-wk SF-36 assessment in the X-STOP spacer clinical trial did not address the time from baseline through week 2. Therefore, disutilities associated with treatment-related adverse events were assumed to occur at time zero and were applied for a 2-week duration to the percentage of each adverse event that occurred intraoperatively or within 2 wk postoperatively.
§Adverse event probabilities for laminectomy calculated using Medical Provider Analysis and Review[26] (Department of Health and Human Services, Washington, DC, 2006) and MedStat MarketScan (MedStat, Ann Arbor, MI, 2006) claims databases.
¶ This rate was assumed to be 25% of the rate of hematoma, per the clinical panel.
||Clinical panel indicated that certain adverse events do not result in additional treatment-related costs.
#Adverse event probabilities from the X-STOP spacer clinical trial were further informed by the clinical panel, particularly for less frequent adverse events.
**Incorporated under second-line treatment.

Outpatient Prospective Payment System. X-STOP device cost is based on the 2009 Medicare Outpatient Prospective Payment System ($5720 for 1-level and $8580 for 2-level based on APC 0052). Laboratory test costs are from the Clinical Laboratory Information Act fee schedule. Drug costs are estimated from the *Drug Topics Red Book*.[27]

Sensitivity Analyses

Sensitivity analyses were performed to determine the consequences of making alternative assumptions, for instance, about the definition of treatment success, the durability of the X-STOP spacer treatment success rate, the X-STOP device placement setting of care, the number of affected levels, patient age (elderly *vs.* nonelderly), and the number of QALYs. The generalizibility of the results was assessed using one-way sensitivity analyses and several other analyses, in which multiple parameters were varied simultaneously over plausible ranges.[16]

RESULTS

Table 4 reports the 2-year costs, utilities (expressed in QALYs), and cost-effectiveness ratios for moderately impaired lumbar spinal stenosis patients.

TABLE 3. Treatment Costs by No. of Affected Levels (Excludes Adverse Events)			
	Cost (2009 US Dollars)		
	1 Level	2 Levels	Source
First- or Second-Line Treatment			
X-STOP Spacer (Outpatient)	$7568	$11,048	*,†, ‡, §
Epidural steroid injections¶	$495||	$909	*, §
LAMI without fusion	$7348#	$7348#	†, §, 26
LAMI with fusion	$22,903#	$22,903#	†, §, 26
Follow-Up Care			
X-STOP Spacer	$2921	$2921	*, §, 26–27
CC	$1219	$1484	*, §, ‡, 26–27
LAMI	$4602	$4602	*, §, 26–27

*Medicare Outpatient Prospective Payment System – Final Rule; 2006, inflated to 2009 US dollars.
†Medicare Clinical Lab Fee Schedule – Final Rule; 2006, inflated to 2009 US dollars.
‡Medicare Outpatient Prospective Payment System for APC 0052 (payment of $5720 for 1 level and $8580 for 2-levels); 2009.
§Medicare Physician Fee Schedule—Final Rule; 2006, inflated to 2009 US dollars.
¶ All CC patients received at least one epidural steroid injection.
||Cost per injection.
#MedPAR claims data for LAMI do not distinguish between 1 and 2 treated levels.
APC indicates Ambulatory Payment Classification; CC, continued conservative care; LAMI, laminectomy.

TABLE 4. Cost-effectiveness of X-STOP Interspinous Spacer Compared with Continued Conservative Care and Laminectomy (2009 US Dollars)

Treatment Choice	Total Costs*	Total Utilities (QALY)†		Incremental Cost	Incremental Utilities (QALY)	Incremental Cost per QALY Gained‡
CC	$9,938	1.28	[GRAPHIC]	$4714	0.26	$17,894
X-STOP® Spacer	$14,652	1.54				
LAMI	$17,892	1.30	[GRAPHIC]	($3241)	0.24	Dominant§

*Total costs rounded to the nearest dollar.
†Total utilities rounded to two decimal places.
‡Treatments are generally considered cost-effective when their ICERs are less than $50,000 per QALY.[30–31]
§Dominance occurs when the X-STOP spacer is both less expensive and yields greater QALYs.
CC indicates continued conservative care; ICER, incremental cost-effectiveness ratio; LAMI, laminectomy; QALY, quality-adjusted life-year.

X-STOP Spacer *Versus* CC

When performed on an outpatient basis, the X-STOP spacer was determined to be a cost-effective therapy compared with CC. The 2-year costs for patients undergoing X-STOP device placement were $14,652 *versus* $9938 for CC. The X-STOP spacer resulted in a 2-year utility value of 1.54 QALYs *versus* 1.28 for CC. This yielded an incremental cost-effectiveness ratio of $17,894 per QALY for the X-STOP spacer compared with CC (incremental cost of $4714 divided by incremental QALYs of 0.26).

X-STOP Spacer *Versus* LAMI

When performed on an outpatient basis, the X-STOP device is "dominant" compared with LAMI; that is, X-STOP device placement is less costly and yields better quality of life than LAMI. The 2-year costs of the X-STOP spacer were $14,652 compared with $17,892 for LAMI. The 2-year utility values were 1.54 QALYs for the X-STOP spacer and 1.30 QALYs for LAMI.

Sensitivity Analyses

Sensitivity analysis was used to test the robustness of the results and to determine which variables have a substantial effect on the results. The results generated by the cost-effectiveness model are considered robust because the cost-effectiveness ratios fall within a narrow range when key model assumptions and parameters are varied. In the analyses comparing the X-STOP device with CC, the results were most sensitive to the X-STOP device placement setting of care, the number of QALYs for CC, and the SF-36 transformation algorithm (Table 5).

TABLE 5. Sensitivity Analysis for X-STOP Spacer Compared with Continued Conservative Care and Laminectomy (2009 US Dollars)

	Incremental Cost Per QALY Gained*	
Description	X-STOP Spacer *vs.* CC	X-STOP Spacer *vs.* LAMI
Base case analysis	$17,894	Dominant†
Definition of success		
Overall treatment success‡	$19,108	Dominant†
Tuli *et al.* definition of treatment success§	$17,894	Dominant†
LAMI reoperation rate		
2% LAMI reoperation rate	Not applicable	Dominant†
8% LAMI reoperation rate	Not applicable	Dominant†
Durability of X-STOP Spacer treatment success¶		
Decreased X-STOP Spacer success by 15%	$22,838	Dominant†
X-STOP Spacer setting of care		

(*Continues*)

TABLE 5. (Continued)		
100% inpatient	$28,336	$715
80% inpatient/20% outpatient	$26,247	Dominant†
Patient age‖		
Nonelderly (<65)	$14,798	Dominant†
Elderly (≥65)	$18,371	Dominant†
No. of QALYs		
Increase CC and LAMI by 15%	$64,886	Dominant†
SF-36 transformation algorithm#		
Schmueli	$20,069	Dominant†
Fryback	$30,800	Dominant†
No. of affected levels		
1 level	$14,974	Dominant†
2 levels	$25,516	Dominant†
Percent of laminectomies without fusion		
100% LAMI without fusion (first-line)	$22,680	$1326
Exclude treatment-related adverse events	$15,961	Dominant†
Medicare physician payment		
Decreased by 50%	$13,711	Dominant†
Increased by 50%	$22,078	Dominant†
X-STOP Spacer APC payment		
Decreased by 20%	$13,367	Dominant†
Increased by 20%	$22,421	Dominant†

**Treatments are generally considered cost-effective when their ICERs are less than $50,000 per QALY.[30–31]*

†Dominance occurs when the X-STOP spacer both is less expensive and yields greater QALYs.

‡Overall Treatment Success ("composite endpoint") was defined as meeting all three ZCQ criteria with no additional surgery for lumbar spinal stenosis and, for X-STOP® spacer patients, also required that distraction of the spinous processes was maintained, there was no dislodgement of the implant, and there was absence of implant-related complications.[11,15] For this sensitivity analysis, the overall treatment success rate was 52.2% for the X-STOP® spacer, 4.8% for CC, and 46.57% for LAMI.[15, 35]

§Tuli et al recommended that treatment success be defined as achieving at least two of the three ZCQ criteria. The resulting ICERs are the same as those in the base case analysis because, in the base case analysis, patients who meet at least two of the three ZCQ criteria are considered clinical successes and would not undergo additional therapy or incur those costs, per the clinical panel.

¶Long-term X-STOP spacer treatment success data are not yet available. The X-STOP spacer treatment success rate was decreased by 15% (from 55.1% to 46.8%) for this sensitivity analysis, per the clinical panel.

‖Conducted by applying age group-specific treatment success rate for CC and X-STOP spacer from the X-STOP spacer clinical trial, and adverse event rates from Medical Provider Analysis and Review[26] (Department of Health and Human Services, Washington, DC, 2006) and Medstat Marketscan (The Medstat Group, Ann Arbor, MI, 2006). Note: Age group-specific LAMI success rates were not available; therefore, overall LAMI success rates were used.[20, 35–36]

#SF-36 transformation algorithms transform SF-36 scores into utility values. For the base case analysis, we selected the Nichol[21] algorithm, which is sensitive to changes in physical symptoms such as those experienced by patients with lumbar spinal stenosis. The Fryback[38] algorithm has a narrow theoretical utility value range from 0.59 to 0.84[39] on a scale of 0 to 1. The Schmueli[40] algorithm's source of original SF-36 data, as well as the validation sample, is from Israeli subjects.[38]

APC indicates Ambulatory Surgical Classification; CC, continued conservative care; ICER, Incremental Cost-Effectiveness Ratio; LAMI, Laminectomy; SF-36, Medical Outcomes Study 36-item Short Form Health Survey; QALY, quality-adjusted life-year; ZCQ, Zurich Claudication Questionnaire.

In the majority of the sensitivity analyses comparing the X-STOP spacer with LAMI, the X-STOP spacer remained dominant. For example, in lumbar spinal stenosis patients with either one or two affected levels, as well as in nonelderly or elderly patients, X-STOP device placement performed on an outpatient basis both is less expensive and offers improved quality of life ("dominant") relative to LAMI. When X-STOP device placement is performed on an inpatient basis, the cost-effectiveness relative to both CC and LAMI remains favorable.

DISCUSSION

To the best of our knowledge, this study is the first to evaluate the cost-effectiveness of the X-STOP spacer compared to both CC and LAMI in treating lumbar spinal stenosis in the United States. This study demonstrates that the X-STOP

spacer is a cost-effective treatment alternative to continued CC and LAMI in moderately impaired lumbar spinal stenosis patients. The favorable cost-effectiveness ratios appear to be due, in part, to the high treatment failure rate in the treatment group that continued to receive CC, the incidence of adverse events associated with LAMI, and the quality-of-life improvements associated with X-STOP spacer treatment. Hsu and colleagues[12] previously reported significant improvements in nearly all SF-36 domains in patients treated with X-STOP relative to CC over 2 years.

Many complications described with LAMI (Table 2) prolong hospitalization; most of these are avoided in X-STOP spacer surgery. The low-risk, high-benefit nature of the X-STOP spacer procedure may suit both older, sicker patients unable to undergo LAMI and younger, active patients who want the better clinical results than what CC offers, but not the higher risk and longer recovery associated with LAMI.

Burnett *et al.*[28] recently evaluated the cost-effectiveness of X-STOP compared to LAMI by attempting to systematically combine data from numerous studies with different patient populations, methodologies, and outcomes measures. In addition to the caveats discussed in the accompanying Editorial,[29] upon our critical review of this article we identified five limitations that could have substantially influenced the results, specifically, (1) inclusion of papers from disparate patient populations, (2) use of untransformed SF-36 scores rather than utilities to inform QALYs, (3) inconsistent definitions of treatment failure, (4) lack of consideration about the frequency and costs associated with spinal fusion, and (5) outdated X-STOP payment mechanisms and amounts. In light of these limitations, we question the validity of their central finding that LAMI is more effective and less costly than the X-STOP spacer.

The National Institute for Health and Clinical Excellence describes £20,000 to £30,000 per QALY (or approximately $40,000–$60,000 per QALY) as its threshold range for cost-effectiveness to inform budget allocation in the United Kingdom.[30] That said, to the best of our knowledge, no definitive cost-effectiveness threshold has been defined in the United States, although a rule of thumb is that treatments are generally considered cost-effective when their incremental cost-effectiveness ratios are less than $50,000 per QALY.[31*] As a point of reference, cost-effectiveness ratios for other common orthopedic interventions range from approximately $2238 to $56,644 per QALY gained (Figure 1).[32–34]

The cost-effectiveness of the X-STOP spacer compares favorably with that of other common orthopedic procedures. X-STOP device placement performed in the outpatient setting compared with CC ($17,894 per QALY) is more cost-effective than cervical discectomy and fusion with autograft *versus*

**Laupacis indicated that nominal figures should be adjusted periodically to maintain constant value in real terms. Therefore, $20,000 per QALY in 1990 Canadian dollars (as per Laupacis, 1992) was converted to approximately $47,000 per QALY in 2009 US dollars, using US Department of Labor Bureau of Labor Statistics Consumer Price Index—All Urban Consumers US Medical Care.*

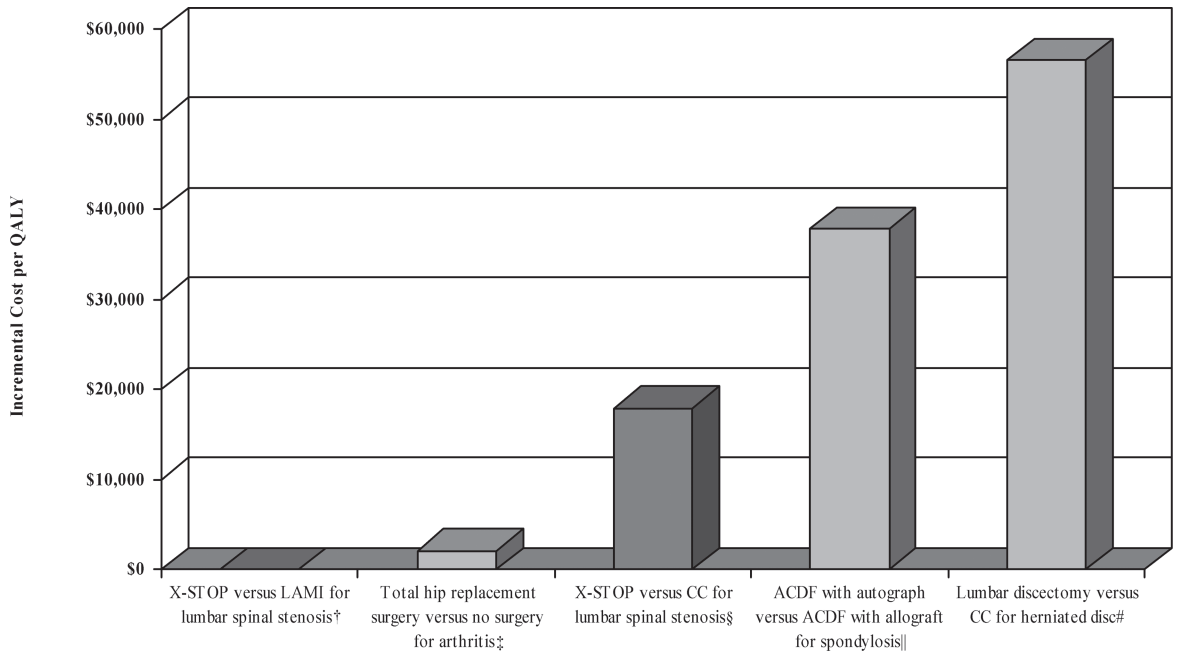

Figure 1. Relative cost-effectiveness of orthopedic procedures expressed as incremental cost per QALY gained (2009 US $). *Treatments are generally considered cost-effective when their ICERs are less than $50,000 per QALY.[30,31] †X-STOP device placement performed in the outpatient setting *versus* LAMI for treatment of moderately impaired lumbar spinal stenosis patients. The X-STOP spacer is dominant compared with LAMI (*i.e.*, the X-STOP spacer is less expensive and provides better quality of life than LAMI). ‡Total hip replacement surgery *versus* no total hip replacement surgery in men (60-69 years of age) with arthritis.[33] §X-STOP device placement performed in the outpatient setting *versus* CC for treatment of moderately impaired lumbar spinal stenosis patients. ||ACDF with autograph *versus* ACDF with allograft with plating for treatment of single-level spondylosis.[32] #Lumbar discectomy for patients unresponsive to conservative management *versus* continued conservative management for herniated intervertebral disc.[34] CC indicates continued conservative care; LAMI, laminectomy; QALY, quality-adjusted life-year; ICER, incremental cost-effectiveness ratio; ACDF, anterior cervical discectomy and fusion.

with allograft and plating for treatment of single-level anterior cervical spondylosis ($37,856 per QALY).[32] Furthermore, X-STOP device placement performed in the outpatient setting is dominant (less costly and more effective) compared with LAMI and is more cost-effective than total hip replacement surgery in men (60–69 years of age) with arthritis ($2004 per QALY), a procedure widely accepted as cost-effective.[33]

As with any cost-effectiveness analysis, the results are only as strong as the underlying assumptions. One assumption warranting further discussion is the definition of treatment success. For the cost-effectiveness analysis, treatment success for all the three groups (X-STOP spacer, continued CC, and LAMI) was defined as meeting all the three ZCQ criteria (symptom severity, physical function, and patient satisfaction) as defined in the X-STOP spacer clinical trial.[11,15] Tuli *et al*[35] showed that requiring success in all the three domains of the ZCQ is highly specific, but less sensitive, to actual patient preference and physician expectations than if two of the three domains are required for a clinical success. Using the more stringent definition of success, the success rates for CC and the X-STOP device were 4.8% and 55.1%, respectively.[11] Based on the ZCQ data collected by Katz *et al*,[20,36] 47.4% of patients undergoing LAMI met all the three ZCQ criteria.[35] These treatment success rates for the treatment of lumbar spinal stenosis, both operative and nonoperative, are a result of the very stringent definition of success. Tuli and colleagues[35] conclude with a recommendation to use two of the three ZCQ domains as the definition of clinical success. When the less stringent definition of clinical success for all the groups (X-STOP spacer, continued CC, and LAMI) was used in a sensitivity analysis, the resulting cost-effectiveness ratios remained favorable. In addition, when *treatment success* is defined as meeting all the three ZCQ criteria, as well as no reoperations or device-related complications ("overall treatment success"), the resulting cost-effectiveness ratios remained favorable.

Other study limitations are worth mentioning. In the base case analysis, it was assumed that X-STOP device placement would be performed on an outpatient basis. X-STOP is appropriate for outpatient or 23-hour short stay status because of the ability to perform the procedure using monitored anesthesia care (MAC) anesthesia, the minimal lateral dissection required for insertion, the lack of risk to neural structures, and the short operative time (usually less than 30 minutes for one or two levels). Although X-STOP device placement can be performed on an outpatient basis, patients with certain comorbidities may require that the X-STOP device placement procedure be performed on an inpatient basis. Sensitivity analysis considering X-STOP device placement performed on an inpatient basis continued to yield favorable cost-effectiveness ratios relative to CC and LAMI.

In addition, because the X-STOP spacer clinical trial did not include LAMI as a treatment arm, we reviewed approximately 28 articles seeking LAMI QALYs or LAMI SF-36 scores, by domain, to calculate QALYs for LAMI. However, we were unable to find LAMI QALYs or SF-36 scores, by domain, for a patient population (*i.e.*, lumbar spinal stenosis) similar to that in the X-STOP spacer clinical trial. For instance, the Spine Patient Outcomes Research Trial (SPORT) study and X-STOP spacer clinical trial patient populations differ at baseline for the bodily pain and physical function SF-36 domains (in that, the difference exceeds the respective minimum important difference as cited in the *User's Manual for the SF-36 Health Survey* for the minimum important differences).[11,37] In addition, review of the SPORT patient demographic and clinical characteristics (for the randomized group) suggests that the majority of the SPORT patients would not have been eligible for the X-STOP spacer clinical trial.[1,11] The SPORT study included patients who had not experienced symptoms for at least 6 months, patients with stenosis at level L5-S1, patients with three or more moderate-to-severe stenotic levels, and patients with mild stenosis,[1] whereas the X-STOP spacer clinical trial (and this cost-effectiveness analysis) excluded such patients.[11] To calculate the QALYs for LAMI, we therefore used the SF-36 scores from the patients in the X-STOP spacer clinical trial who failed CC and continued on to LAMI (n = 21). Despite this limitation, the baseline utility for CC, the X-STOP spacer, and LAMI are nearly equivalent at 0.61, 0.62, and 0.59, respectively (Table 1). Furthermore, because patient preferences for the comprehensive list of treatment-related adverse events for the X-STOP spacer, CC, and LAMI were not available from a single source in the literature, using a utility-based assessment approach, we elicited utility estimates from the panel. When sensitivity analyses were conducted to address these limitations by increasing the LAMI QALYs, and by excluding treatment-related adverse events and their associated utilities, the X-STOP spacer remained dominant over LAMI. Furthermore, even if we were to assume that the X-STOP spacer and LAMI had equal QALYs, X-STOP device placement performed on an outpatient basis would still provide good value because the X-STOP spacer offers considerable health care cost savings compared with LAMI.

Also, because long-term durability data for the X-STOP spacer are not yet available, it is difficult to evaluate the lasting effects of X-STOP spacer treatment on the symptoms of lumbar spinal stenosis. The data from the X-STOP spacer clinical trial show that improvement in symptom severity, physical function, and patient satisfaction was immediate and sustained for the 2 years of follow-up.[11,12] Currently, 5-year X-STOP spacer data are being collected as part of follow-up to the initial X-STOP spacer clinical trial. To estimate the impact on the cost-effectiveness ratio of the X-STOP spacer durability beyond 2 years, a sensitivity analysis was performed by decreasing the X-STOP spacer treatment success rate by 15%, per the clinical panel. The resulting cost-effectiveness ratios remained favorable relative to both CC and LAMI.

In moderately impaired lumbar spinal stenosis patients treated with the X-STOP spacer, the clinical and quality-of-life benefits yielded favorable cost-effectiveness ratios. These results support the use of the X-STOP spacer as a logical and economically viable next step in the treatment of lumbar spinal stenosis after at least 6 months of CC. Patients with prior lumbar surgery or with three or more affected levels were excluded from the X-STOP spacer clinical trial. As such, the safety, efficacy, and cost-effectiveness of the X-STOP spacer in these subgroups warrant further research.

➢ Key Points

- ❑ Cost-effectiveness analysis provides a construct for comparing different treatments that have various costs, clinical benefits, quality-of-life benefits, and risks.
- ❑ The cost-effectiveness of the X-STOP device compared with conservative care (CC) and laminectomy (LAMI) in patients having lumbar spinal stenosis with moderately impaired physical functioning has not been evaluated in the United States.
- ❑ Placement of the X-STOP spacer in the outpatient setting compared with CC ($17,894 per quality-adjusted life-year [QALY]) is more cost-effective than cervical discectomy with fusion and autograft ($37,856 per QALY). On the basis of a comparison of the X-STOP spacer data from a clinical trial and published data on LAMI, placement of the X-STOP spacer in the outpatient setting both is less expensive and provides better quality of life than that of LAMI and is more cost-effective than treatments such as hip replacement surgery ($2004 per QALY), a well-established, cost-effective procedure.
- ❑ Placement of the X-STOP spacer performed on an outpatient basis both is less expensive and yields greater QALYs than LAMI in patients having lumbar spinal stenosis with one or two affected levels, as well as in nonelderly patients (aged 50–64 years) and elderly patients (aged 65 years and older), suggesting that the X-STOP device provides good clinical outcomes and considerable health care cost savings.
- ❑ These results support the use of the X-STOP spacer as the next step in the treatment of lumbar spinal stenosis symptoms after at least 6 months of CC.

Acknowledgments

The authors thank Rachael Mann for her research contributions supporting the development of this publication.

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