BSD Journal of Spinal Disorders and Techniques Publish Ahead of Print
DOI:10.1097/BSD.0b013e31827b671f

Two-Year Evaluation of the X-STOP Interspinous Spacer in Different Primary Patient Populations with Neurogenic Intermittent Claudication due to Lumbar Spinal Stenosis

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Source of Support: Medtronic, Inc. (formerly Kyphon, Inc.), Sunnyvale, CA

No other Conflict of Interest

ABSTRACT

Study Design: Multicenter, prospective single-arm study in patients diagnosed with neurogenic intermittent claudication (NIC) due to lumbar spinal stenosis (LSS).

Objective: To collect data from 2 different primary patient populations, new participants meeting entry criteria (Continued Access Program, CAP), or subjects who had been randomly assigned to non-surgical management in the pivotal IDE study and failed to respond upon study completion (Crossover Study, COS).

Summary of Background Data: The X STOP interspinous spacer is a minimally invasive treatment option for NIC shown to improve pain, physical functioning, and/or overall quality of life.

Methods: 55 subjects were enrolled, 42 in CAP and 13 in COS. Zurich Claudication Questionnaire (ZCQ) success rates were obtained based on the number of subjects achieving a threshold level of success. Mean SF-36 domain scores were compared to baseline using repeated measures ANOVA.

Results: 80% of subjects completed the study. At 2 years, 26/43 subjects (60.5%) achieved clinically significant improvement in the Symptom Severity domain, 25/43 (58.1%) achieved clinically significant improvement in the Physical Function domain, and 31/44 (70.5%) achieved clinically significant improvement in the Patient Satisfaction domain of the ZCQ. Statistically significant improvement in mean scores was obtained in all physical domains of the SF-36 (with the exception of General Health) at 24 months. Mean improvement in ZCQ and SF-36 scores was not as pronounced in the COS cohort compared to the CAP cohort. The most frequently reported device- or treatment-related adverse event was stenosis pain reported by three subjects.

Conclusions: Overall data are consistent with the randomized pivotal IDE trial. Based on the COS cohort which was subject to several additional years of failed conservative treatment, overall success rates do not improve as greatly in patients with long-standing LSS symptoms.

INTRODUCTION

Patients suffering from degenerative lumbar spinal stenosis (LSS) with symptomatic neurogenic intermittent claudication (NIC) experience significant pain and decrements in physical functioning and overall quality of living. The X-STOP interspinous spacer (Medtronic Spine LLC, Sunnyvale, CA) is considered a minimally invasive treatment option in a range of interventions from conservative therapy to decompressive surgery with fusion.[i] The proposed mechanism of action is the limiting of extension at the individual stenotic level(s) provoking the symptoms. Specifically, biomechanical and *in vivo* evidence has shown that the X-STOP spacer effectively limits the narrowing of the spinal canal and neural foramen upon lumbar extension at the pathologic segment, without affecting endplate angulation, overall sagittal alignment, axial rotation, or lateral bending.[ii,iii,iv,v]

In a prospective, randomized, multicenter pivotal Investigational Device Exemption (IDE) trial, overall treatment success with the X-STOP device was shown to be statistically significantly greater compared to that of non-surgical management.[vi] The X-STOP device has been shown to yield superior outcomes over non-operative therapy upon one- and two-year follow-up, with effectiveness persisting at five-year follow-up of patients implanted with the device.[vi,vii,viii] Critically, key patient selection criteria in each of these studies included subjects with LSS symptoms who were able to walk at least 50 feet, sit for 50 minutes without pain, and reported symptom relief in flexion. Those with unremitting pain in any spinal position, or evidence of significant lumbar instability

(including spondylolisthesis greater than grade I) were not eligible for participation in studies that demonstrated superior X-STOP effectiveness outcomes.

The present study represents an extension of the IDE data and examines varying patient populations with NIC symptoms for 2-year follow-up. The overall patient sample consisted of two primary populations, subjects who agreed to serve as new subjects meeting entry criteria (Continued Access Program, CAP), or those who had been randomly assigned to conservative therapy in the pivotal trial and failed to respond to conservative treatment (Crossover Study, COS). Both CAP and COS cohorts met the same inclusion and exclusion criteria utilized in the pivotal study with the exception of two subjects who were enrolled under a compassionate use protocol as part of the CAP cohort.[vi]

MATERIALS AND METHODS

Patient Selection

Fifty-five patients were enrolled in a multicenter single-arm study at seven U.S. centers. Subjects enrolled into CAP included those subjects diagnosed with LSS who were candidates for the X-STOP procedure and did not previously participate in the pivotal trial. Subjects enrolled into COS included those subjects who were randomized into the control group of the pivotal trial and had completed 24-month follow-up, were not responding satisfactorily to non-operative treatment, and wished to undergo the X-STOP procedure. All patients signed an informed consent form prior to study participation and were evaluated before enrollment to determine their eligibility. Subjects were followed through 24-months post-operatively.

Key Inclusion Criteria

Patients had to be at least 50 years old and have leg, buttock, or groin pain with or without back pain that was relieved during flexion. In order to reliably assess a study population with more moderate symptoms of NIC, it was required that patients had to be able to walk at least 50 feet and sit for 50 minutes without pain.

Key Exclusion Criteria

Patients could not have a fixed motor deficit, cauda equina syndrome, previous lumbar surgery, or spondylolisthesis greater than grade I on a scale of I to IV at the affected level(s). Patients who experienced unremitting pain in any spinal position, or had significant instability of the lumbar spine, were also excluded from the study.

Outcomes Assessment

Assessments were made before treatment (baseline) and at 6 weeks, 6 months, 12 months, and 24 months following X-STOP treatment. Assessment of the primary outcome was based on data collected using the patient-completed Zurich Claudication Questionnaire (ZCQ), which consists of Symptom Severity (scale 1-5) and Physical Function (scale 1-4) domains that are completed before and after surgery and the Patient Satisfaction (scale 1-4) domain that is completed after surgery.[ix,x] Lower scores indicate an improvement. The percentage of patients in both groups who demonstrated clinically significant improvement and who were satisfied with their treatment was calculated at each follow-up time point. As previously established, clinically significant improvement was defined as a Symptom Severity score improvement of at least 0.5, Physical Function score improvement of at least 0.5, and/or Patient Satisfaction score less than 2.5 (satisfied or very satisfied).[ix,x] In addition, the mean change from baseline in the Symptom

Severity and Physical Function domains was assessed using a repeated measures ANOVA with a level of significance of 0.05.

The SF-36 questionnaire measuring quality of life is comprised of eight domains additionally combined into two aggregate domains reflecting physical and mental status (Physical Component Summary (PCS) and Mental Component Summary (MCS), respectively); higher scores indicate better health and function. Mean improvement scores for each SF-36 domain were measured by subtracting baseline scores from scores obtained at 24-month follow-up, with higher scores indicating improved quality of life. Mean SF-36 domain scores at 24-month follow-up were compared to baseline values using repeated measures ANOVA with a level of significance of 0.05.

Safety

Investigators were instructed to report all pre-operative, intra-operative, and post-operative complications, whether device-related or not. All subjects enrolled and treated are included in the analysis of safety data.

RESULTS

Demographics and Baseline Variables

The mean overall age was 69 years, with a mean age of 69.8 years in the CAP group and 66.2 years in the COS group (Table 1). 33/55 total subjects (60%) were male. Shown in Table 1, baseline Symptom Severity and Physical Function domain scores were similar and comparable between the two groups. Spondylolisthesis of Grade I or less was present in 54.8% of CAP patients and 61.5% of COS patients; the overall total percentage

of patients with spondylolisthesis of Grade I or less was 56.4%. The remaining patients had no spondylolisthesis present.

Patient Accountability

44/55 subjects (80%) completed the study. Upon 2-year follow-up, data from 31/42 of the CAP patients and all 13 of the COS patients were available for analysis (Table 2).

There were five protocol deviations at enrollment (three CAP patients did not complete six months of conservative treatment, one COS patient did not have complete relief of leg, buttock, or groin pain in flexion at baseline, and one COS patient signed a version of the consent not stamped by the Institutional Review Board). These subjects were followed per protocol and three completed the study, one withdrew, and one had an implant removal and laminectomy. Although not reported as deviations, the two compassionate use subjects each met the exclusion criteria for previous lumbar surgery (one subject was previously enrolled in the initial phase of the randomized study and had received an unwelded version of the X-STOP implant that had disassembled and required revision with a welded device; the other subject had prior decompressive surgery at the level to be implanted). Twelve of the subjects who completed follow-up reported using treatments not allowed by the study protocol following initial treatment, mainly epidural blocks/injections.

Operative Details

A total of 88 levels were implanted in 55 subjects, 22 subjects (40%) at single levels and 33 subjects (60%) at double levels (Table 3). 9/13 COS patients (69.2%) underwent double-level treatment. The procedure took an average of 71.2 minutes, and the average

blood loss was 40.7 cc. The most common level implanted was L4-L5 (51/55 subjects, 92.7%) and the second most common level was L3-L4 (36/55 subjects, 65.5%). The procedure was performed under local anesthesia in 32 subjects (58.2%), general anesthesia in 3 subjects (5.5%), and conscious sedation in 34 subjects (61.8%). Fifty subjects (90.9%) were in the hospital less than 24 hours, and four (7.3%) stayed greater than 24 hours (two subjects stayed one day and two stayed three days or more); in only one case was the hospitalization prolonged greater than 24 hours due to the procedure. The most common implant size was 12 mm followed by 10 mm.

Primary Outcomes

Success rates for each individual ZCQ domain are shown in Figure 1. At two years, 26 of 43 patients (60.5%) reported a clinically significant improvement in the Symptom Severity domain (19/30, 63.3% and 7/13, 53.8% in CAP and COS groups, respectively), 25 of 43 patients (58.1%) reported clinically significant improvement in the Physical Function domain (19/30, 63.3% and 6/13, 46.2% in CAP and COS groups, respectively), and 31 of 44 patients (70.5%) were at least somewhat satisfied (23/31, 74.2% and 8/13, 61.5% in CAP and COS groups, respectively). 58% of at least somewhat satisfied subjects (18/31) were "very" satisfied (e.g., Patient Satisfaction score less than 1.5). The total proportion of patients who satisfied all three ZCQ criteria at 24 months was 22/43 patients or 51.2% (17/30, 56.7% and 5/13, 38.5% in CAP and COS groups, respectively). The mean change from baseline in Symptom Severity and Physical Function domain scores was statistically significant for both cohorts and for the combined population at 24-month follow-up. At two years, the mean change in Symptom Severity score was 0.79 on a 5-point scale, representing a 24.5% improvement

($p < 0.001$) (0.88 or 27.3%, $p < 0.001$, and 0.60 or 18.5%, $p = 0.022$ in the CAP and COS groups, respectively). At the same time point, the mean change in Physical Function score was 0.73 on a 4-point scale, representing a 27.8% improvement ($p < 0.001$) (0.89 or 34%, $p < 0.001$, and 0.38 or 14.3%, $p = 0.031$ in the CAP and COS groups, respectively).

Secondary Outcomes

Relative to baseline, statistically significant improvement at 24 months was observed in the Physical Component Summary ($p < 0.001$) and in each of the physical SF-36 domains (Physical Function, $p < 0.001$; Role Physical, $p < 0.001$; Bodily Pain, $p < 0.001$) with the exception of General Health. In addition, statistically significant improvement was shown in Vitality ($p = 0.001$) and Social Function ($p < 0.001$). These findings were consistent for both CAP and COS cohorts with respect to Physical Function and Bodily Pain scores only. At 24 months, the COS group did not show a statistically significant change from baseline in the Physical Component Summary ($p = 0.109$), or Role Physical ($p = 0.506$), Vitality ($p = 0.427$), and Social Function ($p = 0.896$) scores, with Social Function exhibiting a decrement compared to baseline (Table 4). Neither group showed an improvement relative to baseline in General Health. Change from baseline at 24 months is shown for all SF-36 domain scores across each group in Table 4.

Safety/Complications

Investigators were able to complete X-STOP implantation in all subjects. No cases were abandoned or converted to laminectomy at the time of X-STOP surgery.

One complication of spontaneous L3-L4 auto-fusion occurred; planned placement at this level was not conducted but L4-L5 was successfully implanted in this subject as

anticipated. No other intra-operative complications were reported. There was one instrument malfunction. Additional procedures included a partial facetectomy in two subjects.

Three deaths were reported from the CAP cohort, none of which were device- or procedure-related (Table 2). One cause of death was pneumonia, another was congestive heart failure, and the third was acute cardiac arrest secondary to severe dehydration from the flu. Five subjects underwent device removals prior to study completion and received subsequent laminectomy/decompression; all were in the CAP cohort (Table 2).

There were three reported device-related adverse events, one subject with device migration/dislodgement (this event was also reported concurrently in the same subject as a procedure-related event and a device- and procedure-related event as shown in Table 5) and two subjects with stenosis pain. Three procedure-related adverse events were reported, one subject with night sweats, one with gastrointestinal bleeding, and one with device migration/dislodgement (the latter constituted one event in one subject as shown in Table 5). Reported adverse events considered to be both device- and procedure-related included device migration/dislodgement (also reported separately as device-related and procedure-related; refer to Table 5), hip pain, leg pain, stenosis pain, and two spinous process fractures in one subject. None of the subjects who reported a device and/or procedure-related adverse event was considered a ZCQ success at two years, with the exception of two patients (night sweats, leg pain). In the case of leg pain, the patient failed at least one ZCQ domain at 6 weeks and 6 months, but reached ZCQ success on all domains by one- and two-years. No treatment was required.

The most common adverse event related to the device/procedure was stenosis pain, reported by 3/55 subjects (5.5%). Only one of the cases was considered by the investigator to be definitely related to the device/procedure and resulted in laminectomy. In the other two cases, onset of symptoms was approximately six months and fifteen months following X-STOP surgery, and both cases resolved with epidural block and device revision, respectively.

DISCUSSION

Few studies to date have emphasized the role of patient selection in evaluating the X-STOP device, yet elucidating appropriate selection criteria may lead to improved success rates. Two primary populations were assessed, those who were new participants meeting entry criteria (CAP), and a smaller group which was crossed over from the pivotal trial as non-responders to conservative therapy (COS). Therefore a key distinguishing factor between the two groups was the duration of time spent in conservative therapy prior to X-STOP treatment; both groups met similar enrollment criteria.

The COS population, which had been randomized to conservative care in the pivotal trial and thereby subjected to an additional 2.5 years of failed conservative treatment, did not improve as greatly as CAP on both ZCQ and SF-36 outcome measures. Despite comparable baseline scores on ZCQ (Symptom Severity, Physical Function; Table 1) and SF-36 (e.g., General Health, Physical Component Summary; Table 4), there was an observational trend toward lower ZCQ success rates (Figure 1) and improvement on fewer SF-36 domains (Table 4) in the COS cohort relative to CAP at 24 months. Overall the findings are comparable to those from the pivotal study, which reported two-year

X-STOP success rates of 60.2% (56/93) for Symptom Severity, 57% (53/93) for Physical Function, and 73.1% (68/93) for Patient Satisfaction.[vi] Katz et al. also reported similar success rates of 63% for Symptom Severity, 59% for Physical Function, and 72% for Patient Satisfaction in subjects with decompressive laminectomy at 24 months.[vi,xi] Interestingly, patient satisfaction has been shown to be a more definitive outcome for LSS surgery than the degree of decompressive relief based on radiographic findings.[xii,xiii,xiv] The present findings corroborate previous X-STOP reports showing patient satisfaction rates of 70-74%.[xv,xvi,xvii]

The CAP cohort did not appear to demonstrably separate from the COS cohort until 24 months (Figure 1), but it is not clear what accounts for this trend given the small sample size and lack of statistical testing between groups. With a more stringent approach requiring success in all three ZCQ domains, 51.2% of all subjects achieved total ZCQ success, consistent with 48.4% of X-STOP patients and 47% of laminectomy patients in previous reports.[vi,xi] It should be noted that the Food and Drug Administration (FDA) required success in all three ZCQ domains to be achieved as an *a priori* definition for X-STOP approval.[vi] This definition of success may be less sensitive but more specific, whereas requiring success in two of three domains provides the most balance between sensitivity and specificity.[xviii] Mean change from baseline was statistically significant in both CAP and COS groups for Symptom Severity and Physical Function, indicating that both groups achieved a significant magnitude of improvement at two years. This alternate measure of ZCQ "success" provides additional means to quantify clinical benefit that is not evident by calculating the proportion of subjects reaching a threshold level of improvement.

For quality of life, both groups collectively exhibited statistically significant improvement at 24 months in SF-36 physical dimensions of health status, including Physical Function, Role Physical, Bodily Pain, and Physical Component Summary. Statistically significant improvement was also shown collectively in Vitality and Social Function relative to baseline. Under separate evaluation, COS subjects reached statistically significant improvement in only Physical Function and Bodily Pain scores at 24 months. No significant change from baseline was demonstrated by the COS group in Physical Component Summary, Role Physical, Vitality, or Social Function scores, with Social Function exhibiting a decrement compared to baseline. In contrast, CAP subjects achieved statistically significant mean improvement for each SF-36 physical domain (except for General Health) and mental domain (except for Mental Component Summary). The observed discrepancy in treatment outcomes between CAP and COS appears unlikely to be due to the notion that COS subjects may have been too progressed in the disease state, as baseline ZCQ and SF-36 scores were similar and the most severe patients assigned to conservative care in the pivotal trial eventually underwent laminectomy (approximately 25%).[vi] Patients treated with standard laminectomy as part of the Spine Patient Outcomes Research Trial (SPORT) demonstrated statistically significant improvement in Bodily Pain and Physical Function on the SF-36 at two years.[xix] However, patients also experienced increased duration of hospitalization, increased blood loss, longer surgical time, and higher intra-operative complication rates (e.g., dural tear) relative to X-STOP patients.[vi]

In a meta-analysis of the literature on surgical outcomes for lumbar stenosis, reported complications of surgery included peri-operative mortality (0.32%), dural tears (5.91%),

deep infection (1.08%), superficial infection (2.3%), deep vein thrombosis (2.78%), and any complication (12.64%).[20] None of these major complications was reported as a result of the X-STOP procedure in this trial or related studies.[6]

Several study limitations include the small sample size and the unequal size between CAP and COS cohorts, which does not allow for meaningful statistical comparisons between these two groups. Yet imputation analyses using Last Observation Carried Forward showed that despite a 20% non-completion rate, the proportion of patients who satisfied all three ZCQ criteria was 44.4%, similar to 51.2% using non-imputation methods and compared to 48.4% in the pivotal trial.[vi] A separate analysis also showed that the use of additional treatments (e.g., epidural blocks/injections) by twelve subjects did not inflate success rates, but rather decreased overall success rates. 28/55 subjects (50.9%) were from a single center. The lack of a randomized control group limits interpretation of the results, but overall the findings are consistent with the X-STOP arm of the randomized controlled pivotal study.[vi]

CONCLUSIONS

Aggregate results demonstrate significant improvements in pain, function, and quality of life associated with X-STOP treatment. Further research emphasizing long-term follow-up will be useful to help characterize the LSS population most likely to derive optimal clinical benefit. Based on a small cohort of subjects that underwent several additional years of failed conservative therapy, overall success rates may not improve as greatly in patients with long-standing LSS symptoms. Overall, the findings underscore the importance of appropriate patient selection for proper decision-making regarding surgical treatment of LSS.

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FIGURE LEGEND

Figure 1. Zurich Claudication Questionnaire (ZCQ) success rates for each individual domain are shown as the percentage of subjects achieving (a) at least 0.5 point Symptom Severity improvement, (b) at least 0.5 point Physical Function improvement, and (c) a score of less than 2.5 (satisfied or very satisfied) for Patient Satisfaction at each follow-up time point (Continued Access Program, CAP; Crossover Study, COS).

Table Error! Main Document Only.**: Patient Demographics and Baseline Variables**

Variable	CAP (n=42)	COS (n=13)	Total (n=55)
Age (years)	69.8 (11.0)	66.2 (12.1)	69.0 (11.2)
Height (in)	67.7 (3.9)	67.3 (5.0)	67.6 (4.1)
Weight (lb)	184.8 (40.8)	196.9 (42.0)	187.6 (41.0)
Gender			
Male	61.9%	53.8%	60.0%
Female	38.1%	46.2%	40.0%
Baseline SS*	3.22 (0.64)	3.24 (0.78)	3.22 (0.67)
Baseline PF*	2.62 (0.45)	2.66 (0.61)	2.63 (0.48)
Spondylolisthesis (≤ Grade 1)	54.8%	61.5%	56.4%

Note: mean (SD)

*CAP (n=41), Total (n=54).

Symptom Severity (SS) scale 1-5.

Physical Function (PF) scale 1-4.

Lower scores indicate a more favorable response.

Table 2. Patient Accountability

	CAP		COS		Total	
Variable	**n/N**	**%**	**n/N**	**%**	**n/N**	**%**
Completed Study	31/42	73.8%	13/13	100.0	44/55	80.0
Patient Withdrew	2/42	4.8%	0/13	0.0%	2/55	3.6%
Patient Lost to Follow-up	1/42	2.4%	0/13	0.0%	1/55	1.8%
Implant Removed	5/42	11.9%	0/13	0.0%	5/55	9.1%
Death	3/42	7.1%	0/13	0.0%	3/55	5.5%

Table 3. Operative Data

	CAP	COS	Total
Number of Levels Treated			
1	18/42 (42.9%)	4/13 (30.8%)	22/55 (40.0%)
2	24/42 (57.1%)	9/13 (69.2%)	33/55 (60.0%)
Operated Levels			
L1-L2	0/42 (0.0%)	0/13 (0.0%)	0/55 (0.0%)
L2-L3	1/42 (2.4%)	0/13 (0.0%)	1/55 (1.8%)
L3-L4	27/42 (64.3%)	9/13 (69.2%)	36/55 (65.5%)
L4-L5	38/42 (90.5%)	13/13 (100.0%)	51/55 (92.7%)
L5-S1	0/42 (0.0%)	0/13 (0.0%)	0/55 (0.0%)
Blood Loss			
cc, Mean	40.0	42.9	40.7
Surgical Duration			
minutes, Mean	68.5	80.1	71.2

Table 4. SF-36 Scores – Change from Baseline at 24 Months

	CAP					COS					
Domain	**n/N**	**Baseline Mean (SD)**	**N**	**Change (SD)**	**p-value**	**n/N**	**Baseline Mean (SD)**	**N**	**Change (SD)**	**p-value**	**N**
PF	41/42	31.6 (21.6)	30	26.8 (26.8)	<0.001	13/13	26.5 (23.0)	13	15.0 (17.7)	0.010	43
RP	38/42	13.8 (24.5)	28	38.4 (43.3)	<0.001	13/13	21.2 (30.4)	13	9.6 (50.6)	0.506	41
RE	38/42	58.8 (43.5)	28	19.0 (46.6)	0.040	13/13	51.3 (46.4)	13	-5.1 (44.8)	0.687	41
VT	41/42	38.5 (19.4)	29	12.7 (18.8)	0.001	13/13	39.2 (22.3)	13	3.5 (15.2)	0.427	42
MH	41/42	71.0 (20.0)	29	6.9 (11.5)	0.003	13/13	68.9 (14.8)	13	-6.2 (14.0)	0.139	42
SF	41/42	49.4 (24.0)	30	27.1 (31.4)	<0.001	13/13	48.1 (27.8)	13	-1.0 (26.0)	0.896	43
BP	41/42	31.8 (12.6)	30	24.5 (24.5)	<0.001	13/13	27.5 (19.1)	13	14.5 (23.6)	0.046	43
GH	41/42	70.3 (14.0)	30	-5.3 (14.6)	0.058	13/13	69.4 (12.9)	13	-9.9 (19.0)	0.083	43
PCS	37/42	28.1 (6.4)	27	9.5 (11.0)	<0.001	13/13	28.5 (7.3)	13	5.6 (11.7)	0.109	40
MCS	37/42	49.1 (11.2)	27	3.5 (9.7)	0.072	13/13	47.7 (11.2)	13	-4.4 (9.7)	0.125	40

P-values determined using repeated measures ANOVA

PF-Physical Function, RP-Role Physical, RE-Role Emotional, VT-Vitality, MH-Mental Health, SF-Social Function, BP-Bodily Pain,
GH-General Health, PCS-Physical Component Summary Score, MCS- Mental Component Summary Score

Table 5. Device- and Procedure-Related Adverse Events

Adverse Event	CAP		COS		Total	
	n*/N*	% (of 42)	n*/N*	% (of 13)	n*/N*	% (of 55)
Device-Related						
Device migration/dislodgement §	0	0.0%	1/1	7.7%	1/1	1.8%
Pain stenosis	2/2	4.8%	0	0.0%	2/2	3.6%
Procedure-Related						
Night sweats	1/1	2.4%	0	0.0%	1/1	1.8%
Gastrointestinal bleeding	1/1	2.4%	0	0.0%	1/1	1.8%
Device migration/dislodgement §	0	0.0%	1/1	7.7%	1/1	1.8%
Device- and Procedure-Related						
Device migration/dislodgement §	0/0	0.0%	1/1	7.7%	1/1	1.8%
Hip pain	1/1	2.4%	0	0.0%	1/1	1.8%
Leg pain	1/1	2.4%	0	0.0%	1/1	1.8%
Pain stenosis	1/1	2.4%	0	0.0%	1/1	1.8%
Spinous process fracture	2/1	2.4%	0	0.0%	2/1	1.8%

n* = Total number of reported events

N* = Number of subjects with a reported event

Events scored as Unknown are counted as related.

§ = One event in one subject (COS 07-002). Due to ongoing nature of AE reports, relationship to device and procedure changed and is reflected above. Final decision is that it was definitely device- and possibly procedure-related.

Figure (TIF or EPS Only!!! Resolution of at least 300 dpi!)