Coflex interspinous implant placement leading to synovial cyst development: case report

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Interspinous process devices (IPDs) have been developed as less-invasive alternatives to spinal fusion with the goal of decompressing the spinal canal and preserving segmental motion. IPD implantation is proposed to treat symptoms of lumbar spinal stenosis that improve during flexion. Recent indications of IPD include lumbar facet joint syndrome, which is seen in patients with mainly low-back pain. Long-term outcomes in this subset of patients are largely unknown. The authors present a previously unreported complication of coflex (IPD) placement: the development of a large compressive lumbar synovial cyst. A 64-year-old woman underwent IPD implantation (coflex) at L4–5 at an outside hospital for low-back pain that occasionally radiates to the right leg. Postoperatively, her back and right leg pain persisted and worsened. MRI was repeated and showed a new, large synovial cyst at the previously treated level, severely compressing the patient's cauda equina. Four months later, she underwent removal of the interspinous process implant, bilateral laminectomy, facetectomy, synovial cyst resection, interbody fusion, and stabilization. At the 3-month follow-up, she reported significant back pain improvement with some residual leg pain. This case suggests that facet arthrosis may not be an appropriate indication for placement of coflex.

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KEYWORDS lumbar spinal stenosis; coflex interspinous implant; synovial cyst; surgical technique

LAMINECTOMY has been the gold-standard treatment of lumbar spinal stenosis (LSS). Decompression is augmented with fusion predominantly in cases of mechanical back pain secondary to segmental instability, severe facet arthropathy, and in patients with lumbar spondylolisthesis.³³ Patients with LSS and concomitant lower-back pain have superior clinical outcomes when treated with spinal fusion compared with decompression alone or conservatively.^{13,16} In the long term, a subset of patients may develop adjacent-level disease, requiring extension of fusion.⁹ It still is a matter of controversy whether adjacent-level disease is a result of fusion itself rather than the underlying degenerative process.²⁹ Within the past 15 years, a new nonfusion technology based on placement of a flexible interspinous process device (IPD) has emerged. This implant acts as a constant distracting force between the spinous processes, claiming “indirect decompression” of the thecal sac and nerve roots. It causes focal kyphosis at

the stenotic level, with a resultant increase in the diameter of the canal. IPD claims to preserve the range of motion at the implanted level (except in extension) and therefore is theorized to decrease adjacent-segment degeneration acceleration.³⁵

The majority of IPDs are still in the investigational phase, and currently there are 2 available FDA-approved dynamic devices: coflex (Paradigm Spine, LLC) and Superion (VertiFlex Inc.).¹¹ Large, randomized clinical trials with long-term follow-up are lacking.¹² More importantly, rates of adverse events and device failures are relatively high (9.6%–33.8%).^{8,12,24–27,32,41} Insufficient symptomatic improvement and progression of degenerative disease, such as scoliosis and spondylolisthesis, often necessitate reintervention and increase the overall cost of treatment.^{18,19,36} The indications of IPDs are largely debatable; the devices were originally developed to treat patients with symptomatic neurogenic claudication and buttock

ABBREVIATIONS IPD = interspinous process device; LSS = lumbar spinal stenosis.

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FIG. 1. Pre-coflex sagittal (A) and axial (B) T2-weighted MR images showing a diffuse disc bulge at the L4–5 level and significant facet hypertrophy with widening of the joint spaces. No listhesis is noted.

and leg pain that improves in flexion. Since then, there have been reports of expanding IPD indications for low-back pain without radiculopathy due to facet joint arthropathy or degenerative spondylolisthesis.^{5,7,10,17,36,42,44} The effect of interspinous implants on the progression of the degenerative process of the spine is unknown, and discrepancies—in both clinical and in vitro studies—indicate the need for further investigation. Herein, we report a previously unreported complication of IPD placement: massive synovial cyst development leading to thecal sac compromise.

Case Report

A 64-year-old woman complained of a 1-year history of predominantly lower-back pain and right lower-extremity

radiculopathy. MRI scans showed a central disc protrusion at the L4–5 level and significant facet joint widening and hypertrophy (Fig. 1). The patient underwent placement of an IPD (coflex) at L4–5. Her lower-back pain persisted and worsened. Due to the worsening of her symptoms, a new postoperative MRI study was obtained 3 months after coflex insertion and revealed a very large synovial cyst, causing severe compression of her cauda equina (Fig. 2). The patient was referred to us with worsening lower-back and right leg pain. Her ambulation was rather limited due to pain, and her Numeric Rating Scale (NRS) score for pain was 6. On physical examination, she had painful numbness in the right lower extremity, which was not present prior to coflex implant insertion; strength was preserved. She denied any traumatic events. A CT scan revealed an intact and appropriately placed coflex implant with bilateral distraction of the facet joints: widened distance between the L4 inferior articular process and L5 superior articular process (Fig. 3).

The patient was offered and chose to undergo coflex device removal, bilateral decompressive laminectomy, facetectomy, synovial cyst resection, discectomy with interbody fusion at the L4–5 level, and transpedicular instrumentation performed by the senior author. A large synovial cyst measuring $4 \times 2.2 \times 1.4$ cm was confirmed in the surgical pathology report. At the 3-month follow-up, the patient reported a significant decrease in low-back pain with occasional but not insignificant persistent right leg pain. Her NRS pain score improved from 6 to 2, and she was able to ambulate without difficulty. Lumbar MRI demonstrated resolution of thecal sac compression (Fig. 4), and radiographs showed intact posterior spinal hardware at L4–5 (Fig. 5).

Discussion

The coflex IPD is a type of dynamic decompression device used to treat symptomatic degenerative lumbar disease.³⁷ It is a titanium, U-shaped implant inserted between two adjacent spinous processes. The upper and lower arms

FIG. 2. Post-coflex sagittal and axial T2-weighted (A–C) and T1-weighted (D–F) MR images obtained 3 months after coflex insertion, illustrating bilateral synovial cyst herniation at the L4–5 level causing severe thecal sac compression.

FIG. 3. Post-colex midsagittal (A) and axial (B) CT scans showing the colex device at the L4–5 interspinous process. Right (C) and left (D) parasagittal scans demonstrating the distracted facet joint at the L4–5 level where the colex implant was placed. The distance between the inferior articulating process and the superior articulating process at the L4–5 facet joint was 4.2 mm compared with 1.1 mm at the L3–4 facet joint.

of the device are then fixed to the cranial and caudal spinal processes to prevent device movement. The characteristic “U” shape of the device grants its dynamic nature and helps to maintain the range of motion (flexion, axial rotation, and lateral bending) of the implanted lumbar segment.³⁸ The conceptual design of IPDs is based on the fact that symptoms of spinal stenosis improve in flexion, commonly known as shopping cart sign. By distracting the spinous processes with a spacer or implant at the stenotic level, local kyphosis is created, leading to an increase in the diameter of the spinal canal at that level by 18%–22%.^{21,30,37,40} Interspinous implants are hypothesized to exert their bio-

mechanical effect by preventing hyperextension without limiting other spinal motions.^{23,26} In extension, the spinal canal is compressed by the posterior annulus fibrosis anteriorly and by the ligamentum flavum posteriorly. After insertion, the colex implant distracts the interlaminar space; this distraction leads to supposed widening of the spinal canal by creating segmental kyphosis. Richards et al. obtained MRI scans of 8 lumbar spine specimens before and after interspinous spacer placement to investigate the ef-

FIG. 4. Sagittal (A) and axial (B) T2-weighted MR images obtained after L4–5 laminectomy and posterior lumbar interbody fusion surgery, showing resolution of the synovial cyst and the neural foraminal stenosis.

FIG. 5. Postoperative radiograph showing posterior segmental fixation at L4–5 with intervertebral graft.

fect of distraction on spinal and foraminal dimensions.³⁰ They found that after IPD insertion, the canal area was increased by 18% and the foraminal area by 25% during extension. However, this study should be interpreted with caution, as others have found “a weak correlation between the magnitude of radiographic improvement and the extent of pain relief (VAS) and clinical signs or symptoms.”^{31,34} Cases of over-distraction were associated with spinous process fracture, delayed fatigue fracture, and need for revision surgery.^{1,12}

Another purported advantage of dynamic interspinous implants is their minimal effect on adjacent-level degeneration, as shown in a small, retrospective radiographic study.³⁷ In a cadaveric in vitro study, Swanson et al. found that IPD insertion does not significantly change the pressure at the discs adjacent to the implanted level.³⁵ This work was echoed by Lindsey et al., who reported that the motion of the adjacent levels was not affected by spacer insertion.²² In a coflex postapproval clinical trial that compared the 3-year outcome of coflex instrumentation to posterolateral fusion, the reoperation rate at adjacent levels was 4.18% (9/215) of cases in the coflex group and 6.54% (7/107) in the fusion group.² More recently, in a retrospective study of 87 patients with a 5-year follow-up, Yuan et al. reported a 4.8% reoperation rate for adjacent-segment disease (ASD) associated with the coflex device compared with 11.1% of cases treated with posterolateral fusion ($p = 0.2777$).⁴³ This has not been corroborated with other long-term clinical follow-up studies.

The FDA approval of coflex was based on a clinical trial comprising 322 cases randomized to the coflex device or a pedicle screw fusion system in a 2:1 ratio.⁸ At the 2-year follow-up, both groups had equivalent clinical outcomes; however, the reoperation rate in the coflex cohort was higher (10.7% vs 7.5%, $p = 0.426$). At 5 years, reoperation rates increased to 16.3% in the coflex cohort, with the majority of revision cases due to the persistence of symptoms.²⁶ IPDs are theorized to offload the facet joint and decrease intervertebral disc pressure during extension.^{23,35,38} This quality encouraged the use of IPDs in the treatment of patients with predominantly low-back pain without neurogenic claudication or radiculopathy to limit the loss of range of motion associated with fusion. One of the recent indications of IPD is lumbar facet joint syndrome.^{5,6,15} In a prospective study by Cabraja et al., 20 patients with low-back pain caused by a diseased facet joint underwent coflex device implantation at the L4–5 level.⁶ All patients improved initially, but their conditions deteriorated 24 months after index surgery. The authors suggested that the reason for pain recurrence was the progression of degenerative diseases of the lumbar spine. With the increased usage of IPDs to treat predominantly low-back pain, there is a parallel increase in the reports of complications. Tamburrelli et al. observed for 2 years a series of 19 patients with residual pain after IPD insertion.³⁶ Of the 19 patients, 4 were suffering from predominantly low-back pain secondary to degenerative disc disease (2 patients) and adult scoliotic deformity (2 patients). The cause of IPD failure and pain persistence in these patients was “indication error.” Barbagallo et al. reported on the clinical outcomes of 69 patients treated with an interspinous

spacer for LSS.³ They found that 2 patients who presented with facet-joint arthrosis underwent revision with fusion for spinous process fracture after 1 week and 6 months in both patients. Given the limited number of published studies, the true incidence of revisions and device failures could be higher.²⁵

Reoperation due to instability was reported by Zang et al. who found that patients in 3 of 133 cases treated with the coflex device had postoperative worsening of pain due to degenerative spondylolysis or sagittal instability at a mean of 27.6 months.⁴⁴ Verhoof et al. documented a 67% reoperation rate in patients with grade I spondylolisthesis treated with an interspinous process spacer and recommended that any degree of spondylolisthesis should be considered a contraindication for X-STOP (St. Francis Medical Technologies, Inc.) spacer placement.³⁹ Recently, Bohm et al. reported on 6 cases of interspinous device removal after a mean of 35.8 months due to worsening of symptoms with recurrent LSS and/or spondylolisthesis.⁴ According to the literature, the overall reoperation rate after coflex implantation ranges widely (0%–16.3%).^{8,12,26,31,42–44} Few biomechanical reports of the effects of the coflex device on spinal segment stability are available, and most of them have demonstrated conflicting results.^{14,23,38,40} In 2006, Tsai et al. published on the impact of different loading forces at the L4–5 segment using the coflex device in cadavers. They found that the implanted segment displayed stability during flexion, extension, and axial rotation, but not during lateral bending.³⁸ In 2008, Wilke et al. found that the coflex device had a stabilizing influence on the lumbar spine specimens only during extension.⁴⁰ Most recently, Lo et al. reported that lumbar decompression with coflex placement does not stabilize the lumbar level in flexion.²³ They also described that the magnitude of the “gripping force” applied during coflex device implantation was different between the previous studies^{38,40} and was not comparable to the magnitude of force applied by the surgeon intraoperatively.

The facet joint is an essential component of the lumbar motion segment; it provides stability and facilitates load transfer between 2 adjacent pedicles. Facet joint arthropathy is common in the elderly as a result of repetitive compressive, shear, and axial loading forces.³⁷ A diseased joint is less likely to accommodate normal spinal motion and subsequently is predisposed to lumbar instability. Alternatively, implantation of an IPD clearly changes the dynamic characteristics of the motion segment; posterior column distraction decreases the lordosis of the lumbar level, changes weight-bearing points anteriorly and posteriorly, and accelerates the degenerative process.^{12,28} Moreover, except in extension, an IPD does not offer passive resistance of load in all other spinal motions.²⁰ In the case presented, it is possible that after coflex implant insertion, the distracting force overstretched the wall of the widened facet joint and increased stress tension at the capsule. With a distracted, widened facet joint and preserved motion, the mechanical compensation eventually failed at the weakest part of the joint, leading to synovial cyst development and herniation. This raises concern about one of the current indications of IPD placement: low-back pain due to painful facet arthrosis.

Conclusions

A 64-year-old patient with lumbar stenosis and painful facet arthrosis underwent placement of the coflex motion-preserving IPD. The patient's symptoms persisted and worsened, leading to repeat MRI 3 months after IPS implantation. The images revealed a massive compressive synovial cyst, which was treated with IPD removal, lumbar laminectomy, facetectomy, synovial cyst resection, interbody fusion, and transpedicular instrumentation. In patients with low-back pain due to facet arthropathy, the implantation of IPDs should be approached with caution.

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Disclosures

Dr. Sciubba: Consulting relationships with Medtronic, DePuy-Synthes, Stryker, NuVasive, K2M.

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Conception and design: Bydon, Ramhmdani. Acquisition of data: Bydon, Ramhmdani. Analysis and interpretation of data: Bydon, Ramhmdani. Drafting the article: all authors. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Bydon. Study supervision: Bydon.

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