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Paradoxical Radiographic Changes of Coflex Interspinous Device with Minimum 2-Year Follow-Up in Lumbar Spinal Stenosis

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■ OBJECTIVES: **Studies have yet to investigate long-term radiologic changes in lumbar spinal stenosis patients treated with interspinous device (Coflex). This study aimed to evaluate which radiologic parameters change significantly after surgery with Coflex and identify which parameter most affects the radiologic outcome.**

■ METHODS: **Of 101 patients with lumbar spinal stenosis treated by Coflex insertion on L4-5, the radiologic parameters of 30 patients were measured before and at least 2 years after surgery. On the basis of the development of bony erosion around Coflex, patients were divided into the erosion group ($n = 14$) or the nonerosion group ($n = 16$).**

■ RESULTS: **The mean anterior disc height (ADH) and range of motion (ROM) were significantly decreased after surgery (15.161 mm vs. 13.788 mm and 9.63° vs. 7.13°). The erosion group showed substantially higher values in preoperative ADH, postoperative posterior disc height (PDH), and intervertebral foramen height (6.52 mm vs. 8.05 mm; 5.80 mm vs. 8.03 mm; 19.20 mm vs. 21.06 mm). Postoperative ROM and ROM ratio were higher in the erosion group (5.95° vs. 8.47° and 0.659 vs. 0.938). However, only ADH showed a significant change in the erosion group after surgery (15.86 mm vs. 14.29 mm). On the contrary, ADH and PDH, as well as ROM, were significantly decreased in the nonerosion group (14.55 mm vs. 13.34 mm; 6.52 mm vs. 5.82 mm; 9.46° vs. 5.95°).**

■ CONCLUSION: **The preoperative state including relatively higher ADH, PDH, and larger ROM could induce erosion. The long-term preservation of disc height and ROM may also induce erosion. That reduction of most radiologic parameters seems to be natural after surgery, and insufficient reduction of disc height and ROM may induce adverse effects, which can increase the possibility of spinous process fracture or device malposition.**

INTRODUCTION

Lumbar spinal stenosis (LSS) is a common disease in elderly patients and can induce neurogenic intermittent claudication (NIC), lower back pain (LBP), and radiating pain.[1] It is aggravated by lumbar extension and relieved by lumbar flexion.[2] This pattern of symptoms results from narrowing of the spinal canal and intervertebral foramen on lumbar extension.[3] The prevalence of LSS is about 1.7%–8%, with a peak incidence in the fifth to seventh decades.[4] Therefore LSS is one of the most common causes of spinal surgery in the elderly. Decompressive bilateral partial hemilaminectomy with insertion of Coflex (formerly Interspinous U, Paradigm Spine, LCC, New York, New York, USA) is thought to effectively relieve these symptoms.[3] Previous studies revealed that the use of Coflex substantially prevents narrowing of the intervertebral foramen.[5] Coflex can also preserve the sagittal range of motion (ROM) at index level and adjacent levels, preventing adjacent segment disease such as lumbar instability or additional stenosis.[6] However, most previous studies have investigated short-term results 1 or 2 years after surgery or have compared Coflex with decompressive surgery or posterior lumbar interbody fusion (PLIF) surgery. Studies that

Key words
- Coflex
- Disc height
- Erosion
- Lumbar spinal stenosis
- Range of motion

Abbreviations and Acronyms
BMD: Bone mineral density
BMI: Body mass index
LBP: Lower back pain
LSS: Lumbar spinal stenosis
NIC: Neurogenic intermittent claudication
ROM: Range of motion

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investigate radiologic parameter changes and include more than 2 years of follow-up are rare. The aim of this study was to evaluate which radiologic parameters change significantly after Coflex insertion and to identify which parameter most affects the changed condition.

MATERIALS AND METHODS

Patient Population

A total of 101 patients underwent decompressive bilateral partial hemilaminectomy and Coflex insertion at our institute between August 2008 and December 2011. Among these patients, 49 underwent the operation at the L4-5 level, and ultimately 30 who had completed at least 2 years of follow-up after surgery were enrolled in this retrospective study. The main diagnosis of all cohorts was LSS on L4-5, and all patients were treated with the same procedure, decompressive bilateral partial hemilaminectomy and Coflex insertion on L4-5. An additional procedure, discectomy at L4-5, was performed on a case-by-case basis (11 patients received a discectomy, while 19 did not). All patients had mild lower back pain, prominent radiating pain, and neurogenic intermittent claudication (NIC) due to stenosis. Patients with LSS of more than 2 levels or a level other than L4-5 and patients with prior surgical treatment, trauma, infection, or any other disease affecting the spinal column were excluded.

Operative Procedure

All patients were operated on in the prone position on the Wilson frame (OSI, Union, California, USA) under endotracheal general anesthesia. A midline incision was made over L4-5, and periosteal dissection of multifidus muscle was performed. After that, bilateral partial hemilaminectomy and removal of the ligamentum flavum were performed. We confirmed the lateral margin of the thecal sac and L5 exiting roots bilaterally after dorsal decompression. Additional discectomy in L4-5 was performed when there was disc extrusion or a ruptured disc particle. We put patients into a lumbar flexion state with the Wilson frame just before Coflex insertion between the L4 and L5 spinous processes. Next, the interspinous ligaments were removed to insert Coflex. Using a trial inserter, we measured the optimal size of the Coflex implant. After Coflex insertion, the patient was returned to extension to fix the implant firmly between two spinous processes. Finally, the Coflex wings were tightened with a clamp. A larger-sized implant was used with patients who exhibited long interspinous distance, and a smaller-sized implant was used with those who showed a shorter distance. Thus the size of the implant was decided by the interspinous distance of each patient.

Radiologic Measurement of Parameters

For radiologic analysis, we compared preoperative radiographs with postoperative radiographs. The postoperative radiographs were confined to the latest radiograph, ranging from 24 to 72 months after surgery. We measured preoperative parameters including anterior disc height, posterior disc height, intervertebral foramen height, distance of interspinous processes as static factors, and range of motion (ROM) of the index level (L4-5), upper level (L3-4), and lower level (L5-S1) as dynamic factors. These parameters were also measured in postoperative radiographs with the same method (Figure 1). Erosion was defined as a radiolucent gap between spinous process and the Coflex device (Figure 2). Postoperative instability at the index level was confirmed by dynamic radiographs with diagnostic criteria including translation over 3 mm and anterior rotation exceeding 13°[7] (Figure 3). We also measured the cross-sectional area of the disc and psoas muscle at the L4-5 level with an axial T2-weighted magnetic resonance image (MRI) image (Figure 4). Given that the psoas muscle also supports the axial loading of the trunk, the magnitude of the cross-sectional area of the psoas muscle may affect disc degeneration. In addition, we confirmed the presence of vacuum disc and degenerative spondylolisthesis at the L4-5 level. Parameters not using radiographs were age, gender, body mass index (BMI, kg/m²), bone mineral density (BMD), and follow-up period (months).

Calculated Parameters

We provided calculated parameters from radiologic parameters including anterior disc height ratio (postoperative anterior disc height/preoperative anterior disc height), posterior disc height ratio (postoperative posterior disc height/preoperative posterior disc height), intervertebral foramen height ratio (postoperative intervertebral foramen height/preoperative intervertebral foramen height), and interspinous process distance ratio (postoperative distance of interspinous process/preoperative distance of interspinous process). The ROM ratios calculated include the index ROM ratio (postoperative ROM/preoperative ROM of index level), upper ROM ratio (postoperative ROM/preoperative ROM of upper level), and lower ROM ratio (postoperative ROM/preoperative ROM of lower level). These parameters were calculated using the PASW Statistic 18 software program (IBM, Armonk, New York, USA).

On the basis of the presence of postoperative erosion, patients were divided into the nonerosion group ($n = 16$) or erosion group ($n = 14$). All parameters were then compared between the 2 groups.

Statistical Analysis

A paired t-test was used to compare the differences between preoperative and postoperative values. The independent t-test and chi-square test were employed to identify which parameters varied between the erosion group and the nonerosion group. Finally, Pearson correlation analysis was performed to analyze the correlation between various parameters using the PASW Statistic 18 software program. A $P < 0.05$ was considered statistically significant.

RESULTS

Demographics and Clinical Characteristics

The mean age of this cohort was 62.2 years (ranging from 40–82 years), and there were 15 males and 15 females. This cohort contained various occupations and can represent several geographic regions. BMI ranged from 15.35 kg/m² to 31.24 kg/m², with a mean of 24.83 kg/m². BMD ranged from −3.4 to 0.4 (T-score) with a mean of −1.61 (T-score). The mean follow-up period was 39.2 months (range, 24–72 months). The mean disc area at the mid-disc height of index level (L4-5) was 2066.90 mm² (range, 1664.78–2536.36 mm²), while the area of the psoas muscle at the