Introduction

Nowadays, the fusion surgery is a routine treatment for lumbar spine disorders, such as segmental instability, degenerative scoliosis and spinal stenosis. As a conventional therapy, the fusion surgery was considered to be superior to conservative treatments in long-term investigation [1-3]. Due to the technological or material advances such as transpedicular fixation and polyetheretherketone cage, successful fusion has been achieved in more and more patients. The solid fusion, however, did not always produce the satisfactory clinical outcome. One relevant clinical problem after the fusion surgery was the adjacent segmental degeneration [4, 5]. Previous biomechanical studies have proven that the redistribution in load and motion after a fusion procedure usually led to adjacent disc degeneration [6]. Therefore, how to delay the progress of adjacent segmental degeneration is of great importance to the surgical treatment of lumbar degenerative disorders.

Recently a variety of interspinous spacers have been introduced as the alternative to traditional surgical procedures [4, 7]. Such interspinous device as Coflex™ (Paradigm Spine, LCC, New York) promised to restore the foraminal height, maintain the interspinous space and establish segmental stability. Ever since its invention by the French orthopedic surgeon Jacques Samani in 1994, Coflex™ have served for treating mono- and bi-segmental symptomatic spinal canal stenosis in combination with interlaminar decompression. It was also reported that the device may alleviate the adjacent segmental diseases after fusion [8]. However, whether the implantation of Coflex™ after fusion would decelerate the disc degeneration was not investigated.

Original Article
Magnetic resonance imaging on disc degeneration changes after implantation of an interspinous spacer and fusion of the adjacent segment

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Abstract: The aim of the study was to investigate the changes of the lumbar intervertebral disc degeneration by magnetic resonance imaging (MRI) after the implantation of interspinous device and the fusion of the adjacent segment. A total of 62 consecutive patients suffering L5/S1 lumbar disc herniation (LDH) with concomitant disc space narrowing or low-grade instability up to 5 mm translational slip in L5/S1 level were treated with lumbar interbody fusion (LIF) via posterior approach. Thirty-four of these patients (Coflex group) received an additional implantation of the interspinous spacer device (Coflex™) in the level L4/L5, while the rest of 28 patients (fusion group) underwent the fusion surgery alone. Clinical and radiographic examinations were performed at pre- and postoperative visits to compare the clinical outcomes and the changes of the L4/L5 vertebral disc degeneration on MRI in both Coflex and fusion group. Although both Coflex and fusion group showed improvements of the clinical outcomes assessed by the Oswestry Disability Index (ODI) after surgery, patients in Coflex group had more significant amelioration ($P < 0.05$) compared to fusion group. During follow up, the postoperative disc degeneration changes in Coflex group assessed by the relative signal intensity (RSI) differed from those in fusion group ($P < 0.05$). The supplemental implantation of Coflex™ after the fusion surgery could delay the disc degeneration of the adjacent segment.

Keywords: Coflex, adjacent segmental degeneration, spinal fusion
Disc degeneration changes by MRI

In the present study, clinical and radiographic examinations were employed pre- and postoperatively to investigate the clinical outcome, and at the same time, the disc degeneration on MRI was assessed.

Materials and methods

Patients

Between January 2008 and September 2013, a total of 62 consecutive patients (30 males and 32 females) were enrolled into this study and retrospectively reviewed. The inclusion and exclusion criteria were made a list in Table 1. All the patients were diagnosed as “L5/S1 LDH with disc space narrowing or segmental instability, L4/L5 disc degeneration”. Segmental instability was defined as segmental kyphosis of > 5˚ and/or anterior slip of > 5 mm on standing lateral radiograph of maximal flexion. Following criteria were set for L4/L5 disc degeneration: 1) Pfirrmann grade II-III disc degeneration [9]; 2) No disc herniation or canal stenosis that required a fusion or decompression surgery; 3) No high intensity zone (HIZ); 4) No instability on preoperative flexion-extension plain radiographs in L4/L5 segment. The study was approved by the ethics committee of Shanghai Jiaotong University Affiliated Sixth People’s Hospital.

The patients were divided into 2 groups, Coflex group and fusion group. Fusion group (28 patients) was treated with L5/S1 interbody fusion surgery alone, while Coflex group underwent the same surgery plus Coflex implantation in the level L4/L5. All the procedures were performed by a single group of surgeons.

Procedures

The patients were placed in a prone position and the surgical interventions were performed under general anesthesia. All the subjects underwent the fusion surgery in L5/S1 segment through the standard posterior midline approach. The standard procedure involved L5/S1 bilateral pedicle screws implantation, unilateral L5 laminectomy, L5 and S1 nerve root decompression, ligamentum flavum removal, facetectomy undercutting as well as interbody fusion. The interbody fusion was performed with a single cage packed with autologous bone, which was harvested from the laminectomy. During the entire surgery, both supraspinous ligament and spinous process were kept intact for the fixation of Coflex™ device. In Coflex group, after the L5/S1 interbody fusion was completed, the Coflex™ device was fixed in the spinous process of L4 and L5. The skill of Coflex™ implantation was simple. After resecting the interspinous ligament and the bony overgrowth of the spinous process, the trial templates were used to define the appropriate size, then the Coflex™ was placed into the interspinous space with amount of interspinous distraction. Intraoperative c-arm monitoring was employed to determine the appropriate templates according to the segmental kyphosis and the interspinous distraction.

Evaluation of ODI and RSI

The Oswestry Disability Index (ODI) of all the patients were recorded to evaluate the clinical outcome, at the same time, while the relative signal intensity (RSI) of L4/L5 disc was employed to assess L4/L5 the disc degeneration changes, the RSI of the disc was measured and calculated by the method of Luoma [10], and the formula was as follows:

\[
RSI = \frac{(S_A \times n_A + S_B \times n_B)}{(n_A + n_B)}
\]

SIA, SIB were defined as the signal intensity of above (A) and below (B) the central intranuclear cleft in the disc respectively, the value of SICSF was calculated as the signal intensity of the cerebrospinal fluid (CSF) in the anterior part of the adjacent dural sac behind each vertebrae, while nA and nB represented the number of measured pixels, respectively.

Statistical analysis

All statistical analyses were performed using SPSS, version 18.0 (SPSS Inc, Chicago, USA).
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Normality was compared between the groups by using the Mann-Whitney U test. For binomial distribution, the McNemar test was used. Non-parametric variables between the two groups were analyzed by the chi-square test. A P value < 0.05 were considered to be significant.

Results

Clinical characteristics of patients

In Coflex group, there were 16 males and 18 females, with a mean age of 32 years (ranged from 22 to 43 years). In fusion group, there were 14 males and 14 females with a mean age of 36 years (ranged from 24 to 49 years). No significant differences were observed in terms of demographic data such as sex, age, body mass index (BMI), and duration of the disease. No different disc degeneration observed in both groups before surgery. The mean follow-up was 57 months (range: 48-64 months).

ODI and RSI assessment

Before surgery, there was also no significant difference in terms of the ODI, the L4/L5 angles, and the RSI between the two groups before surgery.

As shown in Table 2, the mean preoperative ODI was 48 (range: 38-59) in fusion group and 54 (range: 42-63) in Coflex group. The mean ODI value at follow-up reduced to 30 in

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Figure 1. A 31-year old female patient diagnosed as L5/S1 disc herniation and L4/L5 disc degeneration. A, B. The plain radiographs at the 48-month follow-up. C, D. Sagittal T2-weighted MRI images preoperatively and 48-month postoperatively.
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fusion group (range: 18-44) and 20 (range: 5-38) in Coflex group, respectively. This reduction was more significant between the two groups ($P < 0.01$).

Before surgery, the mean L4/L5 segmental lordosis was 21.2 (range: 16-26) in fusion group and 22.4 (range: 17-28) in Coflex group. The mean L4/L5 angle value at follow-up was 20.5 (range: 14-27) in fusion group, while the mean segmental angle was 16.5 (range: 15-23) in Coflex group (Table 2). There was a significant difference between the two groups ($P <0.05$).

As shown in Table 2, a mean preoperative RSI in fusion group was 0.71 (range: 0.69-0.78) and dropped significantly to 0.54 (range: 0.60-0.71) at the follow-up. In Coflex group, the mean preoperative RSI was 0.70 (range: 0.65-0.76) and decreased significantly to 0.65 (range: 0.61-0.72, $P < 0.05$) at the follow-up. We found a significant difference between the two groups in terms of the postoperative RSI of L4/L5 disc.

Complications

Until to the last follow-up, no implantation related complications such as spinous process fracture, malpositioning of Coflex™ device were observed, no patient reported a late fusion in the adjacent level.

MRI analysis

A 31-year old female patient was diagnosed as L5/S1 disc herniation and L4/L5 disc degeneration. The plain radiographs and sagittal T2-weighted MRI images were obtained preoperatively and 48-month postoperatively (Figure 1).

Discussion

The conventional surgical treatment for LDH was the resection of herniated nucleus pulposus combined with the expansion of nerve root canal. With the concomitant disc space narrowing or segmental instability, an interbody fusion was proved to be necessary to restore the disc space height, the spine stability as well as the spine alignment [11, 12]. As a routine clinical treatment, lumbar arthrodesis surgery was widely performed. However, the unintended effect of adjacent segment degeneration has aroused concern as the data of long-term follow-up become available [1]. Growing evidence in the spine literature showed that the overall motion of lumbar spine decreased after the fusion, while the percentage of the adjacent segment motion for the entire lumbar motion increased, the motion stress in the adjacent segment was stronger than the other segments [5, 6, 13]. Recently, a prospective randomized study by Ekman and his colleague also demonstrated that the pre-existed degenerative changes in the adjacent level would increasingly deteriorate due to the fusion surgery [14].

Partly for the purpose of ameliorating the situation of the adjacent segment degeneration, a variety of dynamic stabilization systems including Coflex™, have been introduced to the spine community. Some experts also carried out the hybrid surgery [15, 16], such as LIF+DIAM™, to investigate the efficacy of the hybrid procedure to delay the adjacent segment degeneration, some preliminary results were achieved. However, whether the application of hybrid construct in the degenerated adjacent segment can delay the process of disc degeneration was not a thoroughly investigated issue.

According to the results of our study, the clinical outcomes improved in these 2 groups after the surgery. The ODI decreased more significantly in Coflex group compared to fusion group, with a significant difference ($P < 0.05$).

In this study, we focused on the disc degeneration rather than the entire adjacent segment degeneration, which was a part of a project designed to investigate the effect of Coflex™ on the adjacent segment. Radiologically, lumbar disc degeneration has been defined as decreased signal intensity on T2-weighted MRI images combined with a loss of disc space height [3]. MRI is capable of showing disc desiccation changes based on a loss of signal intensity, an increase or decrease in signal intensity in correspondence with an increase or decrease in water content, respectively [17], while disc height loss is due to a breakdown of the structures surrounding the nucleus pulposus. Therefore, the disc signal intensity as well as the disc height was considered as the objective indicators associated with disc degeneration [3].

In order to evaluate the disc degeneration sensitively, disc signal intensity was measured and
calculated rather than the disc height, because slight or mild disc degeneration may occur with no loss of disc height, which only can be detected in a MRI scanning. In addition, increasing evidences have demonstrated that decreased water content is one of the most highly associated findings with disc degeneration [18, 19]. Rather than the more prevalent indicator like Pfirrmann scale, we employed the RSI to evaluate the disc degeneration accurately. According to Luoma’s definition, the RSI of a disc ≤0.82 revealed a mild to severe disc degeneration. In the present study, the mean preoperative RSI value was not different between the 2 groups, however, RSI in fusion group decreased significantly at the follow-up. As a result, it can be reasonably concluded that the disc degeneration deteriorated over the follow-up period after the fusion of caudal segment in fusion group, whereas the additional Coflex™ device implantation could delay the deterioration of L4/L5 disc degeneration according to the results of signal intensity.

There was a general consensus among the spine community that a degenerated disc could not regenerate on its own, while the external devices could provide the optimal conditions favorable to disc viability. It is well known that the easiest way to restore the height of the disc is interspace distraction, but so far, little is known about the biomechanical and biological effects of such distraction. Previous biomechanical studies demonstrated that the Coflex™ implantation could unload the facet joints, restore the foraminal height [20]. Regarding segmental angulation, the mean L4/L5 angle value before surgery was 22.4 in Coflex group and decreased to 16.5 at follow up, Coflex™ led to a significant loss of lordosis, which is not consistent to another biomechanical study [21]. Previous case reported the lumbar disc rehydration after the implantation of a posterior or dynamic stabilization system in a single patient [8], the Coflex™ device, however, could not provide the optimal conditions for the disc degeneration, and failed to delay the disc degeneration after the fusion of caudal segment.

In summary, this clinical study showed that the supplemental implantation of Coflex™ after the fusion surgery could delay the disc degeneration of the adjacent segment compared with the single fusion surgery.

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Disclosure of conflict of interest

None.

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