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Clinical Article

The BioFlex System as a Dynamic Stabilization Device : Does It Preserve Lumbar Motion?

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Objective : This study examines whether functional motion is present at one or more years after Bioflex System placement. BioFlex System is a flexible rod system which has been used to preserve motion at the area of implantation. There has not been a scientific study showing how much motion is preserved after implantation.

Methods : A total of 12 consecutive patients underwent posterior dynamic stabilization using the BioFlex System. Six patients were treated using a L3-4-5 construct and other six patients using a L4-5-S1 construct. Follow-up ranged from 12 to 33 months and standing neutral lateral, extension, flexion and posteroanterior (PA) radiographs were obtained at 3, 6, 9, and 12 months and at more than 12 months postoperatively. Range of motion (ROM), whole lumbar lordosis, and ROMs of motion segments from L2 to S1 were determined.

Results : Patients with a L3-4-5 construct demonstrated a decrease in mean ROM for whole lumbar decreased from 40.08 to 30.77. Mean ROM for L3-4 (6.12 to 2.20) and L4-5 (6.55 to 1.67) also decreased after one year. Patients with a L4-5-S1 construct demonstrated L4-5 (8.75 to 2.70) and L5-S1 (9.97 to 3.25) decrease of mean ROM at one year postoperatively. Lumbar lordosis was preserved at both L3-4-5 and L4-5-S1 constructs. Clinical results showed significant improvements in both study groups.

Conclusion : The present study provides preliminary information regarding the BioFlex motion preservation system. We conclude that the BioFlex System preserves functional motion to some degree at instrumented levels. However, although total lumbar lordosis was preserved, ROMs at implantation segments were lower than preoperative values.

KEY WORDS : BioFlex · Dynamic stabilization · Degenerative spondylolisthesis · Lumbar stenosis · Segmental instability.

INTRODUCTION

Spinal fusion with rigid fixation is the conventional surgical treatment for chronic lower back pain and instability. These techniques attempt rigid stabilization to achieve solid fusion rather than the restoration of segmental mobility. However, solid fusion and the elimination of mobility may overload adjacent segments, and cause high morbidity and complication rates, such as, stress-shielding, adjacent segment degeneration, fatigue fractures, and hardware failure[3,5,7].

Dynamic stabilization was introduced in 1994 as a motion preserving technique to overcome the disadvantages of fusion and to provide sufficient stability or restore normal mobility and avoid adjacent segment degeneration. Various devices have been examined in this context, but results have been contradictory and prevent conclusions concerning the merits of dynamic stabilization[9].

Nitinol is an alloy of nickel and titanium that belongs to a class of materials called shape memory alloys. Ni and Ti are the chemical symbols for nickel and titanium, and the "nol" of Nitinol stands for the Naval Ordnance Laboratory where the material was discovered[3]. Nitinol implants have the following characteristics; high elasticity, high tensile force, flexibility (below 10°C) but rigidity (above 30°C), and biological compatibility[3]. A new dynamic stabilization system (BioFlex System; Bio-Spine, Seoul, Korea) consisting of titanium pedicle screws and a Nitinol rod (American Society for Testing and Materials F2063) was developed in Korea in 2005 (Fig. 1)[3]. The rod diameter used in this system is 4 mm, and the coiled shapes allow physiological stability during flexion, extension, and lateral bending. The

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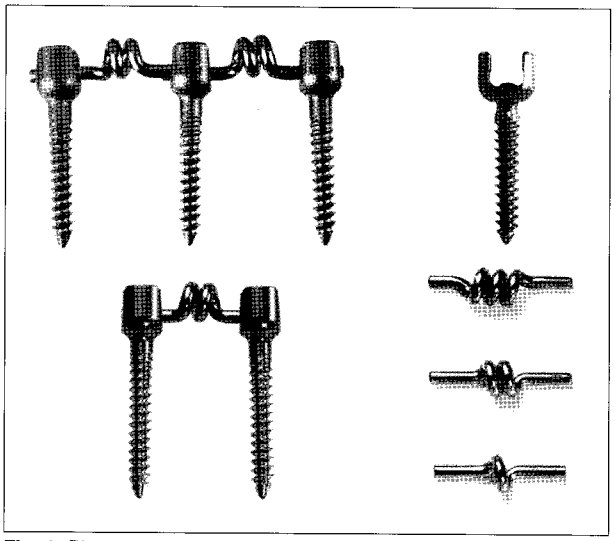

Fig. 1. Photographs showing the components of the BioFlex dynamic stabilization system. In the upper right corner, the photograph shows the BioFlex screw head design. Its two grooves enable the insertions of two Nitinol rods per segment when more than one segment is stabilized (Reprinted with permission from Bio-Spine Corp.).

BioFlex System has been approved by the Food and Drug Administration (FDA) as a semi-rigid fixation system (510 Number; K072321). However, the original concept was that it be used as a dynamic stabilization system.

BioFlex System is a flexible pedicle screw-based dynamic stabilization system which has been used off-label to treat degenerative lumbar conditions with the goal of preserving motion in the implantation region. However, no scientific study has determined to what extent motion is preserved after implantation. Accordingly, in the present study, we measured postoperative motion in series of 12 patients fitted with Bioflex System implantation over at least one year of follow-up.

MATERIALS AND METHODS

Between November 2005 and August 2007, we retrospectively studied patients who had undergone posterior dynamic stabilization by one surgeon using the BioFlex System at single institute. We included patients who had symptomatic degenerative disc disease, degenerative spondylolisthesis, and stenosis with segmental instability unresponsive to an adequate trial of nonoperative treatment according to the levels. The patients who had lytic spondylolisthesis, degenerative spondylolisthesis of more than grade 1, or prior lumbar fusion were excluded because of severe instability.

The purpose of study was to examine whether functional motion would be present at one or more years after Bioflex System placement. To investigate the motion at the stabilized segment, above the stabilized segment, below the stabilized segment and whole lumbar spine, we applied a specific exclusion and inclusion criteria. We excluded the patients who underwent only one segment dynamic stabilization, interbody fusion, more than 3 level dynamic stabilization, and discectomy. We also excluded patients who had preoperative disc degeneration at above or below the dynamic stabilization segment.

Because of the above exclusion criteria, we only included the patients who underwent L3-4-5 and L4-5-S1 dynamic stabilization, so only 12 consecutive patients were selected for the present study. The patients were reviewed after at least one year follow-up by an independent surgeon. Clinical outcomes, back pain and leg pain, were measured using a 0 to 10 VAS scale.

Operative technique

Patients were operated upon under general anesthesia in the prone position. Decompression of stenotic and symptomatic levels was performed through a midline open approach with supraspinous and interspinous ligaments and ligamentum flavum removal. The dura was exposed and laminectomy was carried out as far as required to achieve proper spinal canal decompression. For L3-4-5 lesions, laminectomy was performed from L3 lower to L5 upper, and for L4-5-S lesions from L4 lower to S1 upper. The facet joint was preserved and foraminotomy was performed if required. After adequate decompression, a BioFlex System titanium screw was inserted in the usual manner under fluoroscopic guidance without adding any bone grafting material (Fig 2). Nitinol rods are also available for left and right sides, with appropriate left and right sided coils. There are two grooves in the screw head (one groove for each rod); the setscrew must be secured in the set housing after rod insertion (Fig. 1). If rod insertion was found to be difficult, it was immersed in cold saline (below 10°C), which makes the rod flexible and easy to handle. The rod subsequently regains its shape at body temperature.

Radiologic outcome measures

Plain radiograph and dynamic radiographs (flexion and extension views) were obtained preoperatively, and at 3 months, 6 months, and 1 year and at more than 1 year postoperatively. Lumbar lordosis (Cobb's angle from cranial T12 to cranial S1) was checked preoperatively and at final follow-ups on plain radiographs. On flexion-extension radiographs, ranges of motion (ROM: the difference between Cobb measurements taken in flexion and extension) of the whole lumbar region (from L1 to S1) and the ROMs of stabilized segments, the upper and lower segments of stabilized segments were measured. For L3-4-5 constructs,

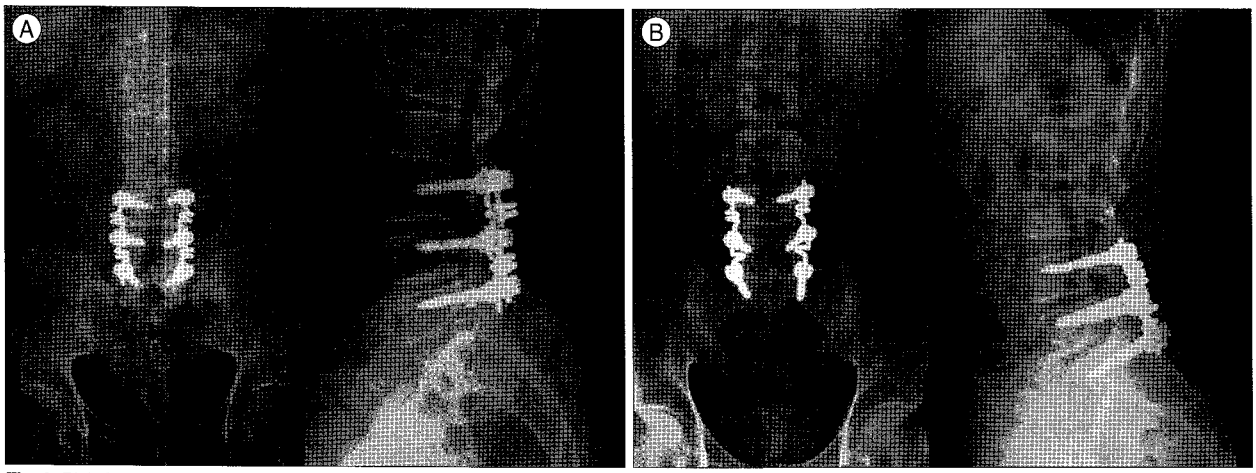

Fig. 2. Plain X-ray films showing L3-4-5 constructs (A) and L4-5-S1 constructs (B). For L3-4-5 lesions, upper laminectomy was performed from L3 lower to L5 (A), and for L4-5-S lesions it was performed from L4 lower to S1 (B).

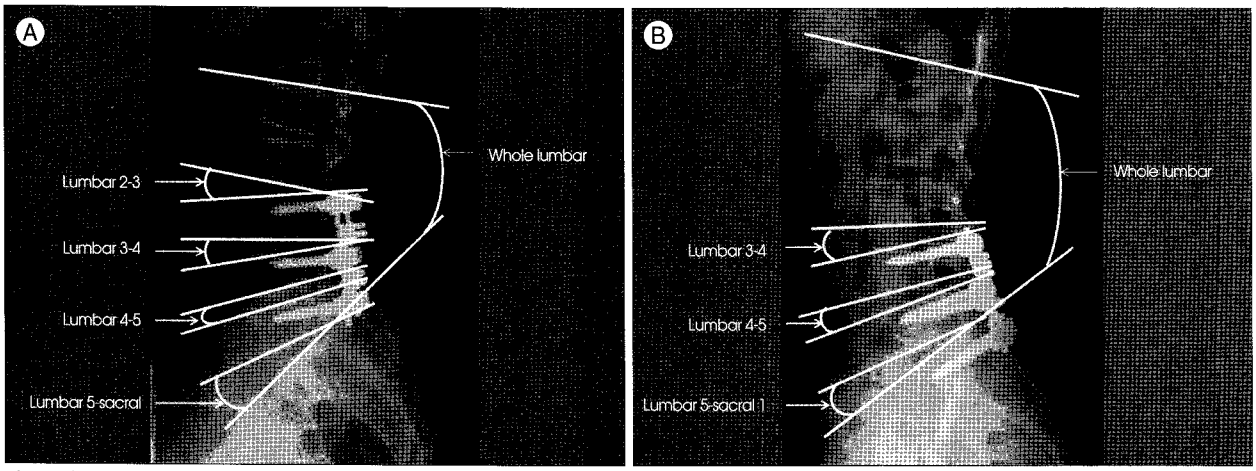

Fig. 3. On flexion-extension radiographs, ranges of motion (ROMs: the difference between Cobb measurements taken in flexion and extension) of whole lumbar segments (from L1 to S1) and the ROMs of stabilized segments, and upper and lower segments of stabilized segments we determined as described by Cobb. For L3-4-5 constructs, ROMs of whole lumbar, L2-3, L3-4, L4-5, and L5-S1 segments were measured (A), and for L4-5-S1 constructs, ROMs at whole lumbar, L3-4, L4-5, and L5-S1 segments were measured (B) preoperatively, and at 3, 6, and 12 months postoperatively.

ROMs of whole lumbar region, L2-3, L3-4, L4-5, and L5-S1 were measured (Fig. 3A), and for L4-5-S1 constructs, ROMs of whole lumbar region, L3-4, L4-5, and L5-S1, were measured (Fig. 3B).

Statistical analysis

The clinical and radiologic results were analyzed using Wilcoxon's Signed Rank test. p values of less than 0.05 were considered statistically significant. All analyses were carried out using SPSS Ver. 12.00K (SPSS, Inc., Chicago, IL, USA).

RESULTS

Twelve patients (10 females, 2 males) of mean age 57.5 years (range, 35-79 years) were included. Six patients underwent L3-4-5 decompression and dynamic stabilization using the Bioflex System (Fig. 2A), and the other six underwent L4-5-S1 decompression and dynamic stabilization using the same system (Fig. 2B). The mean follow-up period was 23.1 ± 7.7 months (ranging from 12 to 33 months).

Among the 12-segments on L3-4-5 constructs, there were degenerative spondylolisthesis (4 segments), disc herniation (3 segments) and stenosis (5 segments). Patients with L3-4-5 constructs demonstrated a whole lumbar mean ROM decrease at postoperative one-year (40.08 to 30.77, $p < 0.05$, Fig. 4A); for L3-4 (6.12 to 2.20, $p < 0.05$, Fig. 4C), for L4-5 (6.55 to 1.67, $p < 0.05$, Fig. 4D) (Table 1). Lumbar lordosis was mildly decreased and ROM of the upper adjacent (L2-3) and lower adjacent (L5-S1) segments were mildly increased, but without statistical significance (Table 1, Fig. 4B, E).

On L4-5-S1 construct (12 segments), there were degenerative spondylolisthesis (3 segments), disc herniation (6

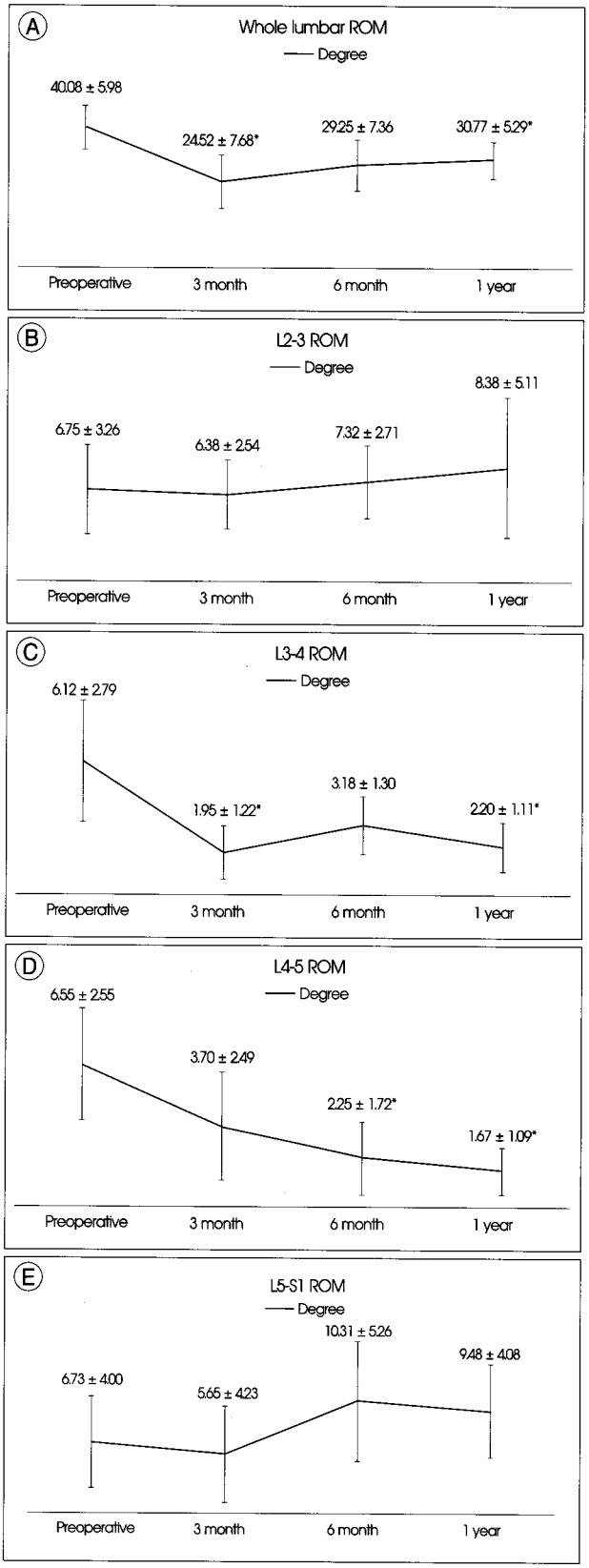

Fig. 4. Range of motion (ROM) after L3-4-5 dynamic stabilization with the BioFlex System. Whole lumbar (A), L2-3 (B), L3-4 (C), L4-5 (D) and L5-S1 (E) ROMs were measured preoperatively and at 3, 6, and 12 months postoperatively.

segments) and stenosis (3 segments). Patients with L4-5-S1 constructs demonstrated mean ROM decreases of; L4-5 (8.75 to 2.70, $p < 0.05$, Fig. 5C) and L5-S1 (9.97 to 3.25, $p < 0.05$, Fig. 5D) at one year postoperatively (Table 1). Lumbar lordosis was preserved, and mean ROMs of the whole lumbar and upper adjacent segments (L3-4) were decreased mildly, but without significance (Table 1, Fig. 5A, B).

Postoperative symptoms of both L3-4-5 and L4-5-S1 constructs (12 patients) were checked preoperatively and 12 months postoperatively. VAS leg and back pain scores improved from 7.3 ± 1.2 to 1.8 ± 0.8 and from 6.9 ± 1.4 to 2.2 ± 1.1 at 12 postop 12 months, respectively.

During the follow-up period, two notable complications were observed; loosening of cap in one case at postop 1.5 months and screw malposition in another 7 days after operation. These complications resolved immediately after reoperation.

DISCUSSION

It is well-known that rigid spinal fixation systems increase the risk of complications, such as, mechanical failure, osteoporosis, and adjacent segment degeneration[4,5]. To avoid these adverse effects, the achievement of ideal stiffness is important, and thus, dynamic stabilization devices would appear to represent a notable technologic advantage[2,3,7,11,13].

Since the introduction of the Graf soft-stabilization system in 1988, many pedicle-based dynamic stabilization devices have been introduced[11]. The disadvantage of Graf fixation is that it allows overextension, which causes the ligament flavum and joint capsules to collapse, and leads to narrowing of the neural foramen and spinal canal. The Dynesys system (Zimmer Spine) was developed later on to overcome the disadvantage of the Graf System[12]. This system involves the insertion of a polyester ploymer tube into the Graf tension band to prevent overextension, and is used worldwide as a pedicle screw-based dynamic stabilization system. However, recent biomechanical evidence suggests that the overall ROM provided by the Dynesys system is less than that of the intact spine[6,13]. Furthermore, Schaeren et al.[9] reported that adjacent segment degeneration rates in patients fitted with the Dynesys group are similar to those after fusion. Furthermore, they reported that the Dynesys system cannot prevent adjacent segment degeneration due to its high intrinsic stability[1,10].

Unlike the Graf, the BioFlex System prevents excessive lordosis during extension, and thereby, maintains a controlled ROM and allows modification of segmental neutral angle and disc height[3]. The BioFlex System consists of

titanium screws and 4 mm Nitinol rods. The rod's coils have one and two turns, and due to the mechanical properties of Nitinol and the shape of the rods, these components have super elasticity and rigidity, and thus, rod acts as a tension band at posterior spinal columns[3]. The Bioflex system has been granted FDA approval as a semi-rigid fixation system, but it was designed to achieve dynamic stabilization. The BioFlex System is a flexible pedicle screw-based dynamic stabilization system, which has been used off-label in Korean to treat degenerative lumbar conditions with the goal of preserving motion in the area of implantation.

Table 1. Summary of data according to the implantation segments

Parameters	L3-4-5 implantation (degree)	L4-5-S1 implantation (degree)
Preoperative lumbar lordosis	50.03 ± 6.85	47.42 ± 17.59
Final lumbar lordosis	44.18 ± 8.53	46.43 ± 17.35
Preoperative whole lumbar ROM	40.08 ± 5.98	36.55 ± 19.47
3 months whole lumbar ROM	24.52 ± 7.68*	21.67 ± 9.43
6 months whole lumbar ROM	29.25 ± 7.36	30.97 ± 9.23
1 year whole lumbar ROM	30.77 ± 5.29*	29.05 ± 6.75
Preoperative L2-3 ROM	6.75 ± 3.26	-
3 months L2-3 ROM	6.38 ± 2.54	-
6 months L2-3 ROM	7.32 ± 2.71	-
1 year L2-3 ROM	8.38 ± 5.11	-
Preoperative L3-4 ROM	6.12 ± 2.79	11.37 ± 7.87
3 months L3-4 ROM	1.95 ± 1.22*	6.10 ± 3.28
6 months L3-4 ROM	3.18 ± 1.30	7.78 ± 2.81
1 year L3-4 ROM	2.20 ± 1.11*	5.98 ± 4.32
Preoperative L4-5 ROM	6.55 ± 2.55	8.75 ± 3.90
3 months L4-5 ROM	3.70 ± 2.49	1.37 ± 0.64*
6 months L4-5 ROM	2.25 ± 1.72*	3.45 ± 1.81*
1 year L4-5 ROM	1.67 ± 1.09*	2.70 ± 1.64*
Preoperative L5-S1 ROM	6.73 ± 4.00	9.97 ± 4.99
3 months L5-S1 ROM	5.65 ± 4.23	2.12 ± 1.27*
6 months L5-S1 ROM	10.31 ± 5.26	3.22 ± 2.71*
1 year L5-S1 ROM	9.48 ± 4.08	3.25 ± 2.07*

*The ROM was significantly changed compared with preoperative ROM ($p < 0.05$). Significance was assessed using the Wilcoxon's Signed Rank test. ROM: Range of motion

The purpose of this study was to determine whether motion would be preserved after implantation. This is the first *in vivo* study of the BioFlex dynamic stabilization system in respect to whole lumbar ROM. The present study shows that mean ROM decreased at L3-4, L4-5 and L5-S1 (preop vs. 12 months postop), but that these segments retained movement. The ROMs of adjacent segments were found to be mildly influenced by the BioFlex system. The ROMs of L2-3 (upper adjacent segment), L5-S1 (lower adjacent segment) were found to be slightly increased at 12 months postop, whereas that of L3-4 (upper adjacent segment) was reduced, but these changes were not significant. These findings mean that the most

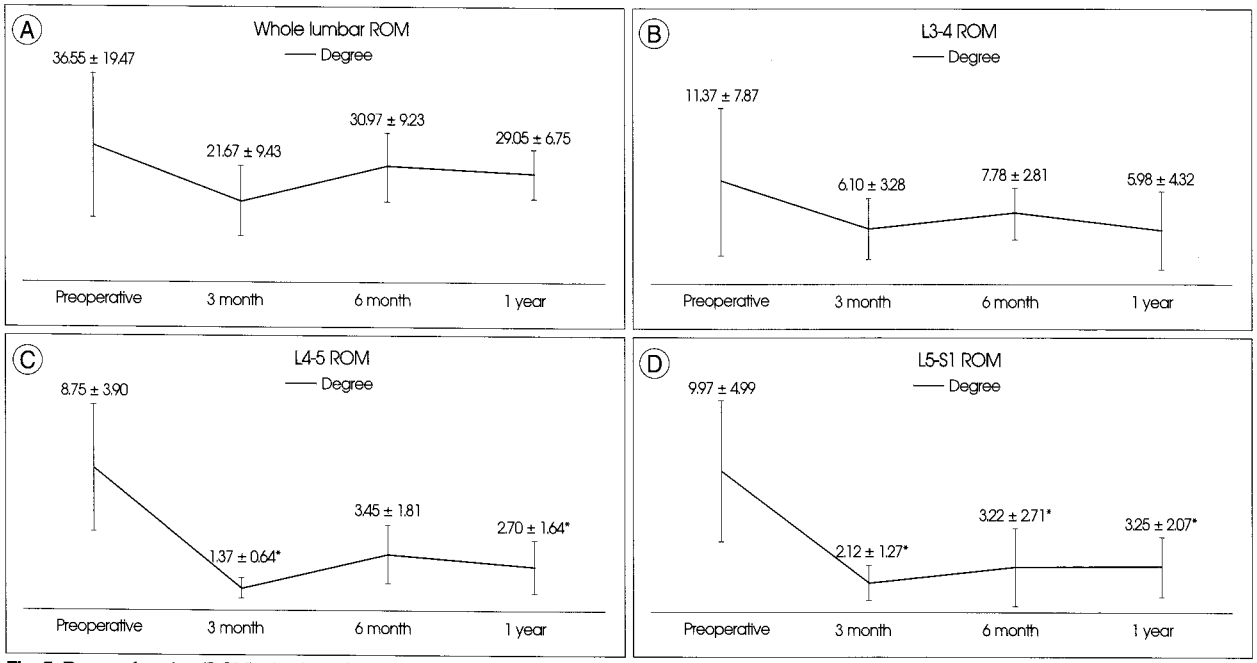

Fig. 5. Range of motion (ROM) after L4-5-S1 dynamic stabilization with the BioFlex System. Whole lumbar (A), L3-4 (B), L4-5 (C) and L5-S1 (D) ROMs were measured preoperatively and at 3, 6, and 12 months postoperatively.

important adverse effect of rigid fixation, namely adjacent segment degeneration, is less likely to occur if the BioFlex system is used. In addition, for L3-4-5 constructs, mean whole lumbar region ROM decreased significantly more than that of L4-5-S1 constructs at 12 months postop, whereas adjacent segment ROM increased more for L3-4-5 constructs than for L4-5-S1 constructs. The authors believe that because L3-4-5 is more mobile than L4-5-S1, adjacent segments were more influenced by L3-4-5 constructs.

Nevertheless, the results obtained during the present study do not allow us to claim that the smaller change in adjacent ROM for BioFlex as opposed to rigid fixation is reflected by a low rate of adjacent segment degeneration because of the short follow-up period (23.1 months) and small number of cases.

Although in a recent prospective study, Pellise et al.[8] concluded that disc degeneration at several levels cephalad to fusion appears to be more determined by individual characteristics than by fusion itself, adjacent segment ROM after fusion is undeniably an important factor of adjacent segment degeneration. Furthermore, although motion segment ROM after dynamic fixation was lower than expected, it still allowed movement, and thus, would less likely to influence adjacent segments adversely than rigid fusion. Moreover, although the present study was limited in terms of the small number of patients recruited and its short-term follow-up period, it clearly demonstrates that the Bioflex system enables dynamic stabilization.

CONCLUSION

The present study provides preliminary information regarding a motion preservation system, and in particular, on its effect on the motions of functional spinal units. Based on examinations of postoperative radiographs, we conclude that the Bioflex system substantially preserves functional motion at the instrumented level, and preserves total lumbar lordosis. Furthermore, adjacent segment ROM was found to be influenced by the Bioflex system.

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