

Clinical Article

Change of Lumbar Motion after Multi-Level Posterior Dynamic Stabilization with Bioflex System : 1 Year Follow Up

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Objective : This study examined the change of range of motion (ROM) at the segments within the dynamic posterior stabilization, segments above and below the system, the clinical course and analyzed the factors influencing them.

Methods : This study included a consecutive 27 patients who underwent one-level to three-level dynamic stabilization with Bioflex system at our institute. All of these patients with degenerative disc disease underwent decompressive laminectomy with/without discectomy and dynamic stabilization with Bioflex system at the laminectomy level without fusion. Visual analogue scale (VAS) scores for back and leg pain, whole lumbar lordosis (from L1 to S1), ROMs from preoperative, immediate postoperative, 1.5, 3, 6, 12 months at whole lumbar (from L1 to S1), each instrumented levels, and one segment above and below this instrumentation were evaluated.

Results : VAS scores for leg and back pain decreased significantly throughout the whole study period. Whole lumbar lordosis remained within preoperative range, ROM of whole lumbar and instrumented levels showed a significant decrease. ROM of one level upper and lower to the instrumentation increased, but statistically invalid. There were also 5 cases of complications related with the fixation system.

Conclusion : Bioflex posterior dynamic stabilization system supports operation-induced unstable, destroyed segments and assists in physiological motion and stabilization at the instrumented level, decrease back and leg pain, maintain preoperative lumbar lordotic angle and reduce ROM of whole lumbar and instrumented segments. Prevention of adjacent segment degeneration and complication rates are something to be reconsidered through longer follow up period.

KEY WORDS : Posterior dynamic stabilization · Bioflex system · Adjacent segment · ROM · Lumbar spine.

INTRODUCTION

Conventional surgical treatments of degenerative lumbar diseases such as spondylolisthesis, stenosis and instability consist of decompressive laminectomy, rigid fixation and bone fusion. These techniques destroy the posterior spinal elements which are much responsible for the mobility and stabilization of a spine^{1,10)}. Current surgical management needs better functional improvements. Load transmission by rigid fixation can make osteoarthritic changes in adjacent

joints¹⁴⁾. Other complications such as fatigue fractures of the vertebral body or pedicle, instrument failure, stress-shielding, adjacent segment degeneration and loss of lumbar lordosis have always been a disadvantage of rigid fixation¹⁾.

Posterior dynamic stabilization was first introduced in 1992 by Henri Graf¹¹⁾ following the need for an instrument that can stabilize operated segments, restore the mobility and prevent the adjacent segment degeneration after a decompressive laminectomy which destroys posterior spinal elements⁴⁾.

Several devices such as artificial discs, interspinous process spacers, facet replacement instruments, artificial ligaments across pedicle screws were developed throughout the years⁵⁾. Bioflex dynamic stabilization system is a pedicle screw based instrument with semi-rigid metallic device. The semi-rigid metallic device is made of class of metals known as shape memory alloys such as Nitinol. It has high elasticity, tensile

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force, flexibility (below 10°C) or rigidity (above 30°C) according to temperature changes and biological compatibility⁹.

The dynamic stabilization instrument discussed here, Bioflex (BioFlex System; Bio-Spine®, Seoul, Korea) was developed in Korea, 2005. The two components of Bioflex are titanium pedicle screws and nitinol semi-rigid rods (American Society for Testing and Materials F2063). The system was developed as a dynamic stabilization and/or fixation device with the intent of withstanding physiologic flexion, extension, lateral bending and provide as much physiological mobility after a decompressive laminectomy.

The purpose of this study was to evaluate the changes in ROM within and adjacent segments after Bioflex posterior dynamic stabilization system and clinical results throughout a year.

MATERIALS AND METHODS

Patient demographics

A consecutive series of patients underwent from one-level to three-level dynamic stabilization with Bioflex system at our institute between Nov. 2005 to Oct. 2008. A total of 27 patients (12 male, 15 female) with an average age of 59.2 years old (minimum 47-year old, maximum 80-year old) were treated for one level (3 patients), two levels (20 patients) and three levels (4 patients) (Fig. 1). The clinical indication for dynamic stabilization alone included all levels of lumbar spine (L1-S1) with chronic degenerative herniated lumbar disc (HLD) accompanying stenosis, flexion instability, spondylolisthesis during flexion, degenerative/spondylolytic spondylolisthesis and topping/bottoming off prior to previous rigid fixation.

The patients were followed up an average of 12.26 months on immediate postoperative, 1.5, 3, 6, 12 months

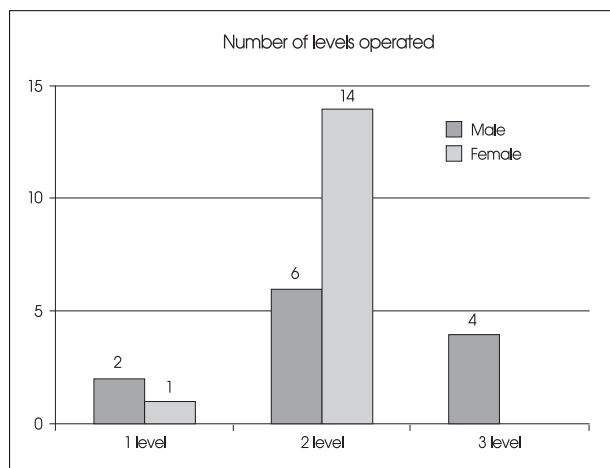


Fig. 1. A graph showing number of patients who received one, two and three level dynamic posterior stabilization with Bioflex system.

at the out-patient department by one surgeon. Radiological outcomes on whole lumbar lordosis, range of motion (ROM) of instrumented levels, ROM of adjacent (both upper and lower) instrumented levels were measured using flexion/extension, lateral radiographs on designated follow up periods. Clinical outcomes were measured on VAS score changes (0 to 10) of leg and back pain.

Surgical techniques

All of the patients were operated under the general anesthesia and in prone position on a Wilson's frame. Posterior midline approach with soft tissue and muscle dissection, removal of supraspinous, interspinous ligaments and ligamentum flavum were performed. Decompressive laminectomy, medial facetectomy and foraminotomy were carried out until proper spinal canal decompression was achieved. Discectomies were done if the disc protrusion caused symptomatic radicular pain. Titanium screws were inserted into the pedicles in the usual manner without bone grafting and spring shaped nitinol rods were applied vertically with the coil rotation different for right and left sides where the screws had been inserted. There were two grooves at the titanium screw heads, one groove for each nitinol rod. Difficulty in applying nitinol rods could be solved easily by immersing them in cold water. Nitinol has the characteristic of being flexible in cold temperatures and regaining back its form in body temperature.

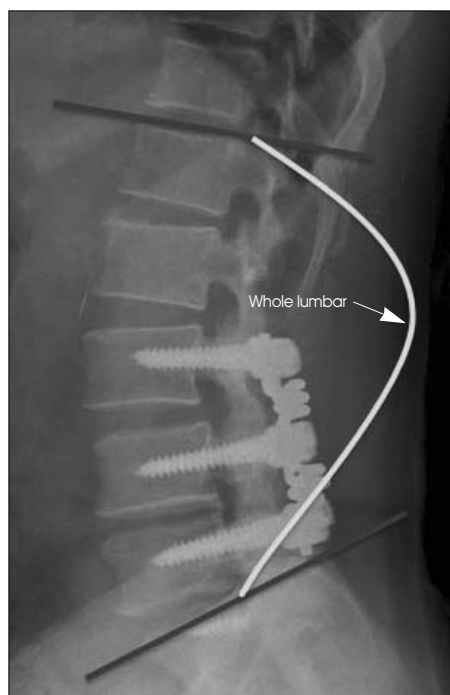


Fig. 2. Plain lateral X-ray film showing how whole lumbar lordosis was measured using Cobb's angle from upper L1 to upper S1 endplate.



Fig. 3. Plain flexion/extension X-ray films showing how Cobb's angle was measured for (A) segments with dynamic stabilization and (B) upper and lower adjacent levels. Range of motion was later calculated by the absolute value of the difference between Cobb's measurements taken in flexion and extension.

Outcome analysis

Patients were checked for clinical improvement in 10 point VAS scores preoperatively and postoperatively (12 months). Plain radiographs (AP and lateral standing) and dynamic radiographs (flexion and extension) were obtained before and after the surgery on immediate postoperative, 1.5, 3, 6, 12 months follow up period. Whole lumbar lordosis for preoperative and final follow up (12 months) was measured at the neutral lateral X-rays using Cobb's angle (from upper L1 to upper S1 endplate) (Fig. 2). ROM of each dynamic stabilization levels (Fig. 3A), ROM of their adjacent segments (Fig. 3B) and whole lumbar ROM were also measured using dynamic radiographs, Cobb's angle and calculated (the absolute value of the difference between Cobb's measurements taken in flexion and extension). For every measurement two neurosurgeons retrospectively reviewed preoperative and each period's postoperative X-rays. In case there was a disagreement between the two neurosurgeons a meeting point was made by averaging the two measurements.

Statistic analysis

Clinical and radiological results were analyzed using both t-test and Wilcoxon's signed rank test for ROM of dynamic stabilization levels, adjacent segments and whole lumbar with the help of statistical analysis program SPSS Ver. 12.00K (SPSS, Inc., Chicago, IL, USA). Only *p* values of less than 0.05 were considered statistically significant.

Table 1. Diagnosis of each instrumented level

Diagnosis	Dynamic stabilization
Normal	0
Black disc	1
HLD (needed discectomy)	5
HLD + Stenosis	8
Stenosis	19
Flexion instability with HLD	5
Spondylolisthesis during flexion	6
Degenerative spondylolisthesis	7
Spondylolytic spondylolisthesis	1
Topping off	3
Total	55

HLD : herniated lumbar disc

RESULTS

A total of 27 patients (12 male, 15 female) were treated for 55 degenerated, diseased one-level (3 patients), two-levels (20 patients), three-levels (4 patients) of lumbar disc. Fifty five treated levels received dynamic stabilization for black disc (1 level), chronic degenerative HLD (5 levels), HLD with stenosis (8 levels), stenosis (19 levels), HLD with flexion instability (5 levels), spondylolisthesis during flexion (6 levels), degenerative spondylolisthesis (7 levels), spondylolytic spondylolisthesis (1 level) and topping/bottoming off (3 levels) (Table 1).

Clinical outcomes

Visual analogue scale (VAS) scores for leg pain improved

significantly from 7.39 ± 0.98 to 2.03 ± 1.72 ($p < 0.05$) and for back pain from 6.52 ± 1.87 to 3.32 ± 1.93 ($p < 0.05$) at the final follow up of 12 months (Fig. 4).

Radiological results

Whole lumbar lordosis at the final follow up of 12 months showed significant decrease (38.3° to 35.2° , $p < 0.05$, $n = 27$), remaining within preoperative range (Fig. 5).

Whole lumbar ROM showed a half fold decrease at immediate postoperative, then it increased up until postoperative 6 months which eventually remained with no change at the last follow up. In the end the whole lumbar

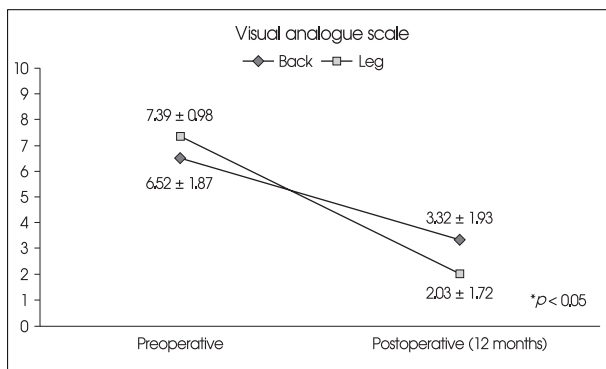


Fig. 4. A graph showing how visual analogue scale scores for leg and back pain decreased between the preoperative and the 12 month postoperative period.

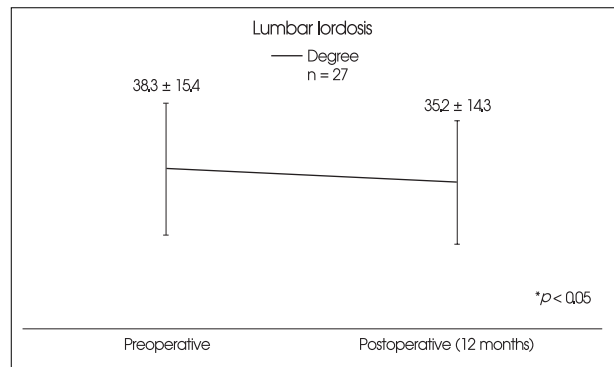


Fig. 5. A graph showing how whole lumbar lordosis changed a little throughout the 12 month follow up period.

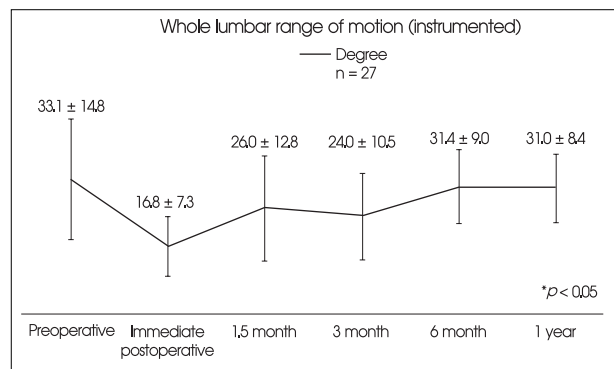


Fig. 6. Graphs illustrating changes in whole lumbar range of motion (from upper L1 to upper S1 endplate) throughout the preoperative, immediate postoperative, 1.5 months, 3 months, 6 months and 1 year follow up period.

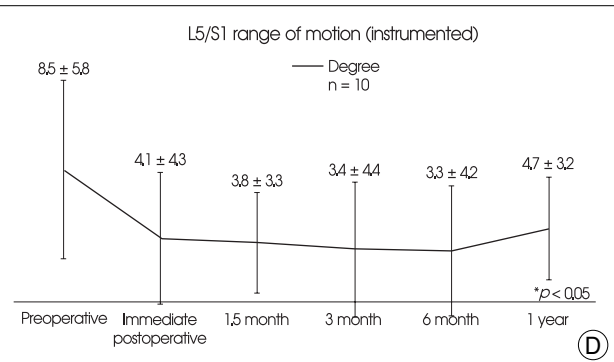
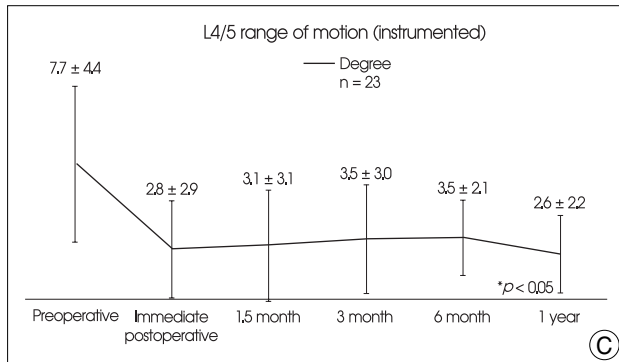
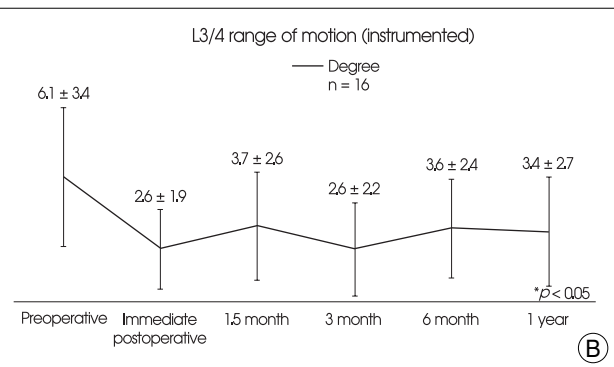
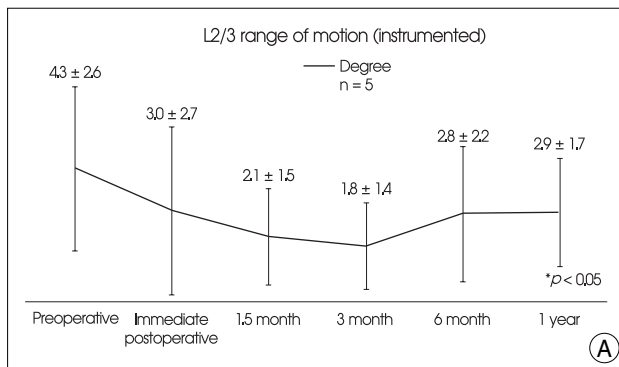


Fig. 7. Graphs illustrating changes in range of motion of each instrumented levels, (A) L2/3, (B) L3/4, (C) L4/5, (D) L5/S1 throughout the preoperative, immediate postoperative, 1.5 months, 3 months, 6 months and 1 year follow up period.

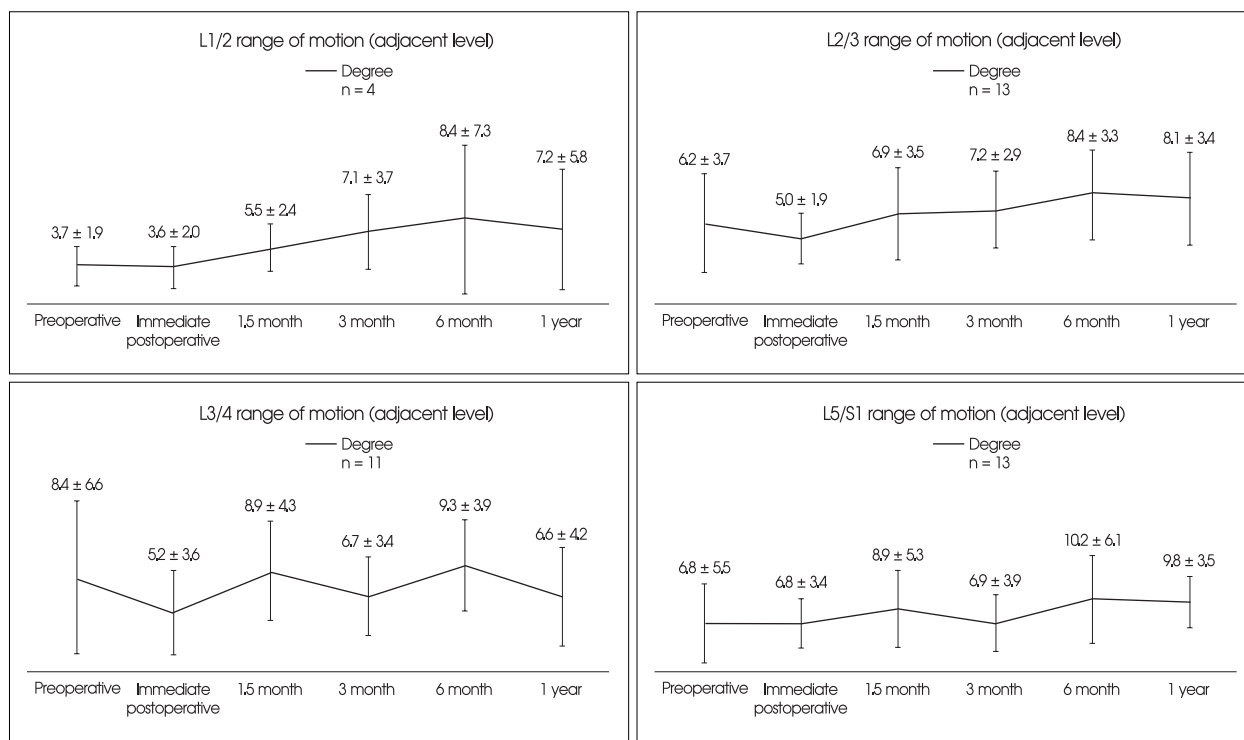


Fig. 8. Four graphs put together to represent changes in range of motion of upper and lower adjacent levels. There is no statistical significance at each adjacent level.

ROM showed a 2° decrease between preoperative and last follow up period with statistical significance on the t-test and Wilcoxon’s signed rank test (33.1° to 31.0°, $p < 0.05$, $n = 27$) (Fig. 6). ROM of each instrumented level was measured and evaluated for its significance on both t-test and Wilcoxon’s signed rank test. ROM of L2/3 (4.3° to 2.9°, $p < 0.05$, $n = 5$) (Fig. 7A), L3/4 (6.1° to 3.4°, $p < 0.05$, $n = 16$) (Fig. 7B), L4/5 (7.7° to 2.6°, $p < 0.05$, $n = 23$) (Fig. 7C) and L5/S1 (8.5° to 4.7°, $p < 0.05$, $n = 10$) (Fig. 7D) decreased at the last follow up with statistical significance. ROM of L1/2 was excluded from the statistics due to the small number of patient ($n = 1$).

ROM of the upper and lower adjacent segments of the instrumented levels such as L1/2 ($n = 4$), L2/3 ($n = 13$), L3/4 ($n = 11$), L5/S1 ($n = 13$) [T12/L1 ($n = 1$) due to small number and L4/5 ($n = 2$) because it was mostly the instrumented level were excluded from the adjacent segments] increased at the last follow up but with no statistical significance on both t-test and Wilcoxon’s signed rank test (Fig. 8).

Complications

Five cases of complications on 4 instrumented levels

Table 2. Complications, its causes and solutions*

Group	Complication	POD	Solutions
Mechanical failure	Screw fracture	1.5 months	Removal
	Rod fracture	4 months	Reapply
Mechanical failure + Surgeon’s error	Cap loosening	1 months	Retighten
Surgeon’s error	Postoperative epidural hematoma	Immediate	Hematoma removal
	Screw malpositioning	Immediate	Reposition

*Total : 5 cases, 4 levels. POD : post operative day

occurred during the follow up period including hardware failure (screw and rod fracture, 2 cases), hardware failure with surgeon’s technical error (loosening of cap, 1 case), and surgeon’s technical error (screw malpositioning and postoperative hematoma, 2 cases). Most of the cases were corrected upon revision (Table 2).

DISCUSSION

Henri Graf was a pioneer in dynamic stabilization. In 1992 he had first developed a pedicle screw-based dynamic stabilization system named after him¹¹). Though the idea was intriguing at that time, Graf (Neoligaments, Leeds, United Kingdom) failed in achieving dynamic stabilization by fixing the instrumented levels in extension, interrupting flexion by buckling the ligamentum flavum increasing

tension on the anterior longitudinal ligament leading to facet locking and increase in intradiscal pressure¹¹. Dynesys (Zimmer Spine, Minneapolis, MN, USA) system uses a plastic cylinder around the ligament to prevent overloading the disc, but it restricts extension and loses lordosis¹⁷. Interspinous process spacer devices such as DIAM (Medtronic Sofamor Danek, Memphis, TN, USA) on the other hand fixed the instrumented level in flexion and disrupted extension². Bioflex allows physiological mobility in both flexion and extension.

As shown by the data, posterior dynamic stabilization with Bioflex assisted in physiological motion of postoperatively damaged unstable spine by maintaining preoperative range in whole lumbar lordosis, showing decrease in ROM of whole lumbar and instrumented levels.

Whole lumbar lordosis was decreased, but remained within range from 38.3° to 35.2° allowing the preoperative lumbar lordotic angle. This can be thought to slow adjacent level degeneration which can accelerate in cases where long level fusion (more than 3 levels) cause flat back syndrome and nonalignment of the biophysical lordotic angle⁸. The decrease of lordosis may be related to the failure in keeping a consistent lordotic angle on a Wilson's frame during surgery.

ROM of the instrumented levels reduced at immediate postoperative, 1.5 months, 3 months and remained with no change between 6 to 12 months period. Wearing a Knight type back brace for 1.5 months with one or two level dynamic stabilization patients and for 3 months with long level dynamic stabilization patients explains why it took more than 3 months for the ROM to stabilize. So, measuring ROMs 6 months after the operation and not before would be much better to show the stabilization. Author's concept of wearing back braces for 1.5 to 3 months is intended for supplying suitable fitting period of bone-screw interface for the prevention of mechanical failure or loosening of instrumentation by active movement.

Decrease of VAS scores for leg pain were solely up to the surgeon's surgical decompression technique unless there were no biomechanical set back such as the buckling effect of the Graf instrument¹³. On the other hand VAS scores for back pain did not entirely depend on the surgeon's surgical skills. According to a recent review of the Cochrane database of the prospective randomized controlled trials rigid fixation fails to establish any significant improvement in low back pain³. In rigid fixation where more than two levels are involved back pain aggravates due to reasons such as immobilization, non-union, pseudoarthrosis, sagittal or coronal imbalance, abnormal load transmission through the metal-bone interface in cage fusion^{9,16}. In dynamic stabilization as shown by our data allowing physiological

mobilization and stabilization kept VAS scores low throughout the whole follow up period. As McAfee once mentioned 'clinical success is associated with the development of the bone around the cage, increasing the area of load transmission and reducing the load over the footprint of the cage¹²'. Dynamic stabilization does this by creating a normal loading pattern, dispersing load transmission to the dynamic stabilization devices¹⁶. Yet, longer than one year follow up is necessary to see that the VAS scores to remain low and a comparative study between rigid fixation and dynamic stabilization with Bioflex would be ideal to prove our results.

Whole lumbar ROM of the instrumented patients changed from 33.1° to 31.0° (6% reduction between preoperative and postoperative 12 month). It was a decrease of 2° with statistical significance. On the other hand, ROM of each instrumented segments showed more than a 2° decrease. L2/3 decreased from 4.3° to 2.9° (32% reduction between preoperative and postoperative 12 months), L3/4 from 6.1° to 3.4° (43% reduction), L4/5 from 7.7° to 2.6° (66% reduction), L5/S1 from 8.5° to 4.7° (44% reduction). This could lead to an increase in ROM of the segments which were not operated as it did in our paper, but with no statistical validity. Unfortunately, our study only measured the ROM of each upper and lower adjacent segments to the instrumentation. Significance could be established if ROM other than upper and lower to the instrumentation were measured and included in the data. Putting more number of patients in the data could also help. Nevertheless, prevention of adjacent segment degeneration could not be proved. This coincides with the fact that even Dynesys, one of the well known posterior dynamic stabilization instrument has not been able to prove prevention of adjacent segment degeneration^{7,15}.

There were 5 complications. Two were related to surgeon's technical error and 3 to pure hardware failures such as screw and rod fracture (7% of patients, 3% of operated levels). Including the remainder 1 case where surgeon's error and instrument failure are combined hardware problems in total occurred in 11% of patients and 4% of instrumented segments. More considerations are needed in the near future as to why these complications transpired.

Grasping through the results we can see that Bioflex can be a suitable candidate for dynamic stabilization. However, complication rates are still higher than rigid fusion and calls for future thorough analysis.

CONCLUSION

Bioflex posterior dynamic stabilization system assists in

physiological motion and stabilization at the instrumented level, decrease back and leg pain, maintain preoperative lumbar lordotic angle and reduce whole lumbar ROM by 6%. Prevention of adjacent segment degeneration could not be proved which longer follow up period is required.

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