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Intervertebral disc distraction with a laparoscopic anterior spinal fusion system

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Abstract The BAK spinal fusion system has been applied to laparoscopic anterior lumbar interbody fusion. The system, consisting of a pair of cylindrical implants with threads, placed symmetrically about the sagittal plane, functions by tensioning the annulus fibrosis. Cylindrical plugs of increasing size are inserted prior to the implant placement. As the procedure may affect spinal posture and disc height, we measured changes due to incremental plug insertion using human cadaveric spine specimens (L5–S1, $n = 4$). Multi-directional flexibility of the construct was also measured as a function of plug size. The disc height change was found to increase initially and then to level off at 13-mm diameter plugs. In the sagittal plane, the intervertebral posture first shifted towards kyphotic then came back to the initial lordotic posture with plugs of bigger size.

However, changes in disc height and spine posture were not statistically significant. Comparing the neutral zone (NZ) flexibility after inserting the plugs to the intact values, neither the flexion/extension nor the axial rotation NZ showed any significant change. In lateral bending, the NZ decreased after the insertion of 13-mm plugs ($p < 0.05$). Insertion of plugs of increasing size from 9 mm to 12 mm decreased the range of motion (ROM) in all directions ($p < 0.05$). Insertion of 13-mm and 14-mm plugs decreased the flexion/extension and lateral bending ROM, but not the axial rotation ROM, probably indicating some injury to the annulus fibers.

Key words BAK plugs · Biomechanics · Laparoscopy · Lumbosacral spine · Spinal stability

Introduction

Discogenic low back pain and instability derived from degenerative disc disease have been treated with surgical fusion. Several operative techniques, such as posterolateral fusion, posterior lumbar interbody fusion (PLIF), and anterior lumbar interbody fusion (ALIF), have been used [2, 4–6, 16]. The recent innovation of laparoscopic surgery has made the anterior approach less invasive, promising shorter hospital stays and reducing the cost of hospitalization [12]. Therefore, laparoscopic lumbar interbody fu-

sion has become an interesting option for the treatment of low back pain.

To achieve bony fusion, adequate bone grafting and certain initial fixation are required. The BAK interbody fusion system (Spine Tech, Minneapolis, Minn.) is particularly appropriate for laparoscopic use [18]. It is a titanium cage that is able to hold bone graft and is screwed into the disc space, grabbing both end plates. Therefore, this device, while mechanically stabilizing the functional spinal unit, can avoid the need for autologous cortical bone graft. This device showed good bony fusion in horse cervical spine [3]. In biomechanical studies using an ani-

mal model, the BAK device increased stiffness by 115% compared to the intact spine [17] and it doubled the stiffness in a PLIF model compared to using bone graft alone [1]. In a recent study of the multi-directional stabilizing potential of the BAK device in human specimens, the motion was decreased by nearly 50% in flexion, lateral bending, and axial rotation, but not in extension [13]. The early clinical report revealed a good fusion rate of 92% in single-segment stabilization [9, 10].

In this laparoscopic procedure, it is recommended to distract the disc space, before implantation of the device, by inserting a pair of bullet-shaped plugs of increasing size. The instant fixation achieved with these implants is believed to be due to not only the screw thread hold but also the disc distraction. On the other hand, insertion of these plugs may result in a change of posture and disc height. This is clinically important, as the malalignment of the spine, caused by surgery, can result in prolonged low back pain [7, 11].

The purpose of this biomechanical study was to quantify the disc height changes and intervertebral posture changes due to the insertion of plugs of increasing size. Multi-directional flexibility changes, representing potential instability, were investigated to assess the contribution of disc distraction to the stability of the spinal motion segment.

Materials and methods

Four fresh frozen human cadaveric lumbosacral spines (L5–S1) were prepared preserving the osteoligamentous structures. The average age of the specimens was 39 years. Each specimen was mounted in a polyester resin cast with the mid-disc plane oriented horizontally. L5–S1 functional spinal units (FSU) were selected because this level is treated most often with laparoscopic technique [12, 18].

Experimental procedure

Bullet-shaped plugs, 9–14 mm in diameter, supplied by the manufacturer were used. Two holes, 8 mm in diameter and 22 mm apart, were drilled in the mid-disc plane from the anterior, in accordance with the instructions of the manufacturer (Spine Tech). Before insertion of the plugs, nucleotomy was performed to an adequate extent through the holes. Then increasingly bigger plugs, in 1-mm increments starting from 9 mm diameter, were inserted. Distraction was performed on the left side of the specimen first, followed by the right side (Fig. 1). Before and after each plug insertion, the FSU disc heights were measured and multi-directional flexibility was tested.

Multi-directional flexibility test

The multi-directional flexibility test consisted of applying six pure moments (flexion, extension, bilateral axial torque, and bilateral bending) and measuring the ensuing motions. Maximum moment of 10.0 Nm was reached incrementally in four steps. Three load and unload cycles were applied [14]. A relaxation period of 30 s was allowed after each load step. A compression force of 98 N was applied as preload to the center of the upper vertebral body. Intervertebral motion was recorded during the third load cycle using an optoelectronic motion measurement system (Optotrak, Northern Digital, Waterloo, Canada). The average rotation measurement error of this system has been determined to be 0.14° [8]. Multi-directional flexibility test was performed at the intact stage and after

Fig. 1 Lateral and antero-posterior radiographs of a pair of plugs inserted into the L5–S1 specimen

Fig. 2 Flexibility test procedure for each of the six pure moments. Three loading cycles help determine the neutral zone (NZ), elastic zone (EZ), and range of motion (ROM)

insertion of each pair of distraction plugs. To describe the nonlinear load-displacement behavior of the spine specimens, three well-established motion parameters – neutral zone (NZ), elastic zone (EZ), and range of motion (ROM) – were computed (Fig. 2). The NZ is the displacement from the neutral position to the zero-load point of the third load cycle, representing the laxity of the intervertebral motion segment [14]. The ROM is the displacement from the neutral position under maximum load, representing the maximum physiological motion of the intervertebral segment. The EZ is the difference between the ROM and NZ. The NZ and ROM were measured 300 and 420 seconds respectively after the start of loading. This long time period effectively minimized the viscous component of the viscoelastic character of the spine.

Disc height measurement and posture

Four marker pins were inserted on each of the top and bottom mounts (Fig. 3). The pin placements were: anterior, posterior, and left and right side. Between each pair of pins (on top and bottom mounts), height was measured using calipers (resolution was 0.01 mm). Thus, there were a total of four heights, H1, H2, H3, and H4, corresponding to the four pin placements. Disc height change at the center of the vertebral body was obtained by averaging the changes in the four heights. The posture changes (sagittal and frontal plane) were obtained from the same four height measurements.

Fig. 3 A, B Posture measurement with four pins inserted into specimen mounts. Four heights and two distances were measured. **A** Lateral view (*H1* posterior height, *H2* anterior height, *D1* anterior-posterior distance). **B** Anterior view (*H3* right-side height, *H4* left-side height, *D2* left-right distance)

The sagittal angle, being less than 5°, was calculated with sufficient accuracy by the following equation:

$$\text{Sagittal angle (degrees)} = 57.3 \times (H1 - H2)/D1$$

where *H1* = vertical distance between the anterior top and bottom vertebral pins; *H2* = vertical distance between the posterior top and bottom vertebral pins, and *D1* = horizontal distance between the anterior and posterior pins (Fig. 3 A).

The frontal angle was computed by the same equation by replacing *H1*, *H2*, and *D1*, respectively, by *H3*, *H4*, and *D2* (Fig. 3 B).

Statistical analysis

All the data were analyzed with repeated measures analysis of variance ANOVA. The post hoc Fischer PSLD test was used to determine significant difference, and significant difference level was set at 95%.

Fig. 4 Average disc height change as a function of plug size. Error bars indicate one standard deviation

Fig. 5 Posture change in the sagittal plane. Change as a function of inserting single or double plugs of increasing size. Error bars indicate one standard deviation

Fig. 6 Posture change in the frontal plane. Change as a function of inserting single or double plugs of increasing size. Error bars indicate one standard deviation

Results

The disc height increased by 2.23 mm (SD 0.62) from the post-nucleotomy stage to 9-mm plug insertion. It gradually increased to 3.00 mm (SD 1.15) up to the 13-mm plug, and then leveled off (Fig. 4).

The posture alteration by plug insertion was observed in sagittal (kyphosis and lordosis) and frontal (scoliotic) planes. In the sagittal plane, the spine shifted to 2.0° of kyphosis, compared to the intact, after the 9-mm plug insertion (Fig. 5). The kyphotic posture gradually reduced with bigger plug insertions.

The posture change in the frontal plane was significantly altered from the intact slope when only one plug was inserted on the left side (Fig. 6). The insertion of the second plug on the right shifted the posture back to nearly

the original state. There was no significant difference in posture between different plug sizes.

The multi-directional flexibility results as functions of plug size are shown in Table 1. For neutral zone (NZ), no significant change was observed in flexion/extension or in axial rotation (Table 1 A). In lateral bending, compared to the intact, the NZ was significantly smaller after the insertion of the 13-mm plugs. To compare the effects of plug size on different motion types, the changes in NZ were normalized with respect to the intact (Fig. 7 A).

The elastic zone (EZ) in flexion/extension and axial rotation decreased significantly with all size plugs with respect to intact (Table 1 B). In lateral bending, EZ decreased significantly only with 13- and 14-mm plugs.

The range of motion in flexion/extension and lateral bending decreased significantly after each plug insertion (Table 1 C). In axial rotation, the ROM decreased significantly compared to the intact; with all plugs from 9 mm up to 12 mm in diameter. To compare the effects of the plug size on different motion types, the changes in ROM were normalized with respect to the intact (Fig. 7 B).

Discussion

The BAK and other plug-type fusion devices are believed to provide two functional improvements to a compromised functional spinal unit [8, 15]. They can increase stability at the insertion site in multiple directions to enhance the fusion potential. Simultaneously, they can increase the disc height and open the intervertebral foramen. There is some concern from a clinical viewpoint that these devices may introduce changes in the spinal posture, namely an increase/decrease in lordosis. Our study investigated all three aspects of the plugs inserted from the anterior, simulating laparoscopic surgery. Although the manufacturers recommend a particular implant size, there are no scientific studies that provide the basis for these recommendations.

Table 1 The average (standard deviations) of neutral zone, elastic zone and range of motion (in degrees) of intact specimens and after insertion of a pair of plugs of 9 mm to 14 mm in diameter. Sta-

tistically significant differences ($p < 0.05$) with respect to the intact specimens are indicated by an *asterisk*

	Intact	9 mm	10 mm	11 mm	12 mm	13 mm	14 mm
A. Neutral Zone							
Flexion/extension	1.87 (0.61)	1.75 (0.77)	1.76 (0.53)	2.12 (0.22)	1.29 (0.64)	1.52 (0.88)	1.83 (0.77)
Axial rotation	0.32 (0.14)	0.25 (0.07)	0.26 (0.07)	0.12 (0.33)	0.26 (0.10)	0.24 (0.07)	0.29 (0.04)
Lateral bending	1.28 (0.58)	0.83 (0.27)	0.97 (0.38)	0.79 (0.26)	0.85 (0.26)	0.85 (0.47)*	0.77 (0.35)
B. Elastic zone							
Flexion/extension	17.33 (3.16)	13.04 (2.56)*	12.17 (1.86)*	9.76 (1.47)*	10.19 (1.82)*	8.82 (1.11)*	9.01 (2.46)*
Axial rotation	3.55 (1.01)	2.67 (0.80)*	2.30 (0.72)*	2.13 (0.50)*	1.90 (0.21)*	1.82 (0.28)*	1.87 (0.19)*
Lateral bending	10.49 (1.88)	7.10 (1.23)	5.83 (1.69)	5.15 (2.44)	4.88 (2.64)	4.04 (1.77)*	4.17 (1.50)*
C. Range of motion							
Flexion/extension	19.19 (3.19)	14.79 (2.91)*	13.92 (2.38)*	11.88 (1.26)*	11.48 (2.01)*	10.34 (1.33)*	10.84 (2.67)*
Axial rotation	3.87 (1.13)	2.91 (0.87)*	2.55 (0.79)*	2.24 (0.60)*	2.17 (0.31)*	2.06 (0.33)	2.16 (0.21)
Lateral bending	11.77 (1.63)	7.93 (1.49)*	6.80 (2.06)*	5.94 (2.66)*	5.73 (2.90)*	4.89 (2.22)*	4.95 (1.84)*

Fig. 7 A, B Results of the flexibility test: ratio of motion after the plug insertion to the intact motion expressed as a percentage. **A** Neutral zone (NZ), **B** range of motion (ROM). Error bars indicate one standard deviation

We found a tendency for the disc height to increase up to the insertion of 13-mm plugs, but the increases were not significant. However, because our spine specimens were not degenerated to the extent that would normally require such surgery, the percentage disc height increase reported in the present study may be an underestimate. We also found that the insertion of plugs changed the spine posture initially into a kyphotic one by 2.0° , which was then reduced to 0.5° with 13-mm plugs. It seems that the initial stiffness of the posterior elements is less than that of the anterior elements, allowing the FSU to flex upon plug distraction. With increased plug size, posterior elements became taut and overcame the stiffness of injured anterior annulus, causing the FSU to extend and to return

to its original posture. Again, the changes in the kyphosis/lordosis may be different when dealing with a severely degenerated FSU. In this respect, there may be some advantage to conical-shaped implants compared to the present cylindrical ones, in preserving or increasing the lordosis of the spine.

It was hypothesized that the initial stability of this screw-type device is provided not only by the interface of the screw threads and the endplate, but also by the tensioning of the annulus fibers. What are the relative contributions of these two factors? A comparison of our results with those of another study that used the same methodology, but implants, i.e., plugs with threads, is helpful in this respect. After insertion of a BAK threaded implant (15 mm outside diameter) the ROM decreased by 45.3% in flexion, 38.4% in axial rotation, and 65.4% in lateral bending [12]. In the present study the unthreaded plug (14 mm, maximum size studied) decreased the ROM by 42.0% in flexion/extension, 41.9% in axial rotation, and 57.0% in lateral bending. Thus the multi-directional stability with distraction plugs was about the same as that provided by threaded implants. The presence of threads, which provides a greater interface area with the endplates, may have some advantage in bony union rather than in enhancing immediate mechanical stability.

The major limitation of our in vitro model is the absence of muscle forces. Although a compressive preload of 98 N was applied, it does not simulate the large loads estimated to act at the L5-S1 level. The increased compressive load in vivo may enhance the mechanical stability of both the plugs and implants. We did not insert implants after the last plugs, as we believe we had produced significant soft tissue injuries in the specimen by inserting the large 14-mm plugs.

In conclusion, our study provides insight into the functioning of recently developed cylindrical implants inserted from the anterior. We used plugs of increasing size to study changes in the intervertebral geometry. The plugs do not seem to alter either the disc height or the spinal posture in the frontal and sagittal planes. The stability provided by the plugs (i.e., implants without the threads) is comparable to that provided by threaded implants. This indicates that threads do not increase the stability of the construct but may be helpful in other ways, such as enhancing bony union or preventing implant migration. Only in vivo studies could provide definitive answers in that regard.

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