Efficacy of lumbar orthoses after posterior lumbar interbody fusion—a prospective randomized study

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Abstract
Background: Lumbosacral orthoses (LSOs) are used as standard care after lumbar fusion surgery though their efficacy is unknown. The purpose of this prospective randomized controlled study was to elucidate the clinical and radiographic efficacies of LSO treatment in patients who underwent posterior lumbar interbody fusion (PLIF) of less than 3 segments.

Methods: Seventy-three patients who underwent PLIF were randomly allocated to 3 groups: 1 with custom-made LSO with metallic stays (C group); 1 with ready-made LSO without metallic stays (R group), and 1 without LSO (N group). The patients in the C and R groups were instructed to wear LSO postoperatively for 3 months. Clinical outcomes were evaluated using the Japanese Orthopaedic Association (JOA) score, JOA-back pain evaluation questionnaire (JOABPEQ), Roland-Morris Disability Questionnaire, and 100-mm visual analog scale for low back pain. Radiographic evaluation included intervertebral fusion rates and loss of correction postoperatively at 2 years.

Results: A significant difference in the clinical outcomes was observed only for the lumbar dysfunction domain of JOABPEQ postoperatively at 1 month (N vs C groups; 45% vs 10%, P = .03). Radiographic outcomes were not different between the groups.

Conclusions: No effect of orthosis treatment for less than 3 segments in PLIF was observed on clinical and radiographic outcomes. The type of orthosis also did not influence the outcomes. These results suggest that the use of LSO for PLIF can be simplified or is omissible except in patients with severe osteoporosis.

Abbreviations: JOA = Japanese Orthopaedic Association, JOABPEQ = Japanese Orthopaedic Association Back Pain Evaluation Questionnaire, LSO = lumbosacral orthosis, PLIF = posterior lumbar interbody fusion, POM = postoperative month, POY = postoperative year, QOL = quality of life, RDQ = Roland-Morris Disability Questionnaire, VAS = visual analog scale.

Keywords: Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ), lumbar spine, lumbosacral orthosis, posterior lumbar interbody fusion (PLIF)

1. Introduction
With the widespread recognition of the importance of spinal sagittal alignment,[1] achieving lumbar lordosis by restoring the height of the collapsed disc and achieving fusion without correction loss have become the main goals of spinal fusion surgery.[2,3] Posterior lumbar interbody fusion (PLIF)[4] is one of the surgical techniques used to achieve the aforementioned goals. Advancements in spinal instrumentation for PLIF (ie, a combination of intervertebral cages and pedicle screws) has significantly increased the fusion rate[2,3,5]; however, the validated biomechanical properties of modern instrumentation cannot achieve a 100% fusion rate because the induction of heterotopic bone formation requires a complex balance between the patients’ biologic factors, operative technique, and postoperative care to achieve successful fusion. Failure of fusion and the resultant loss of lumbar lordosis can lead to persistent lumbar instability and pain.[6] The postoperative use of lumbosacral orthosis (LSO) following spinal fusion surgery is one of the most common adjunct aftertreatments. The theoretical roles of LSO include reduction of surgery-related pain and biomechanical stability of the fused segments.[7–14] However, there is scarce evidence regarding the clinical and radiographic effects of LSO including the recommended wearing period and types of orthoses following spinal fusion surgery.[15]

The purpose of this prospective comparative study was to elucidate the clinical and radiographic efficacy of postoperative LSO treatment in patients who underwent PLIF of less than 3 segments.

2. Materials and methods
This study was approved by the ethical review board at our institution in March 2011 (approval number: 22-25). Of 155
patients who underwent PLIF of less than 3 segments for lumbar degenerative disease (spinal canal stenosis, spondylolisthesis, or degenerative scoliosis) between May 2011 and May 2015, those who were not capable of completing the questionnaire, had a body mass index $>30\text{kg/m}^2$, had a history of lumbar fusion surgery, had malignancy or severe osteoporosis (bone mineral density of lumbar or hip ($T$-score) $<-3.5$ standard deviations), or had a history of rheumatoid arthritis, inflammatory disease, or chronic kidney disease on hemodialysis were excluded (Fig. 1). Finally, 73 patients were included (mean age: $65.6 \pm 11.0$ years [range: 24–82]; 31 males, 42 females) and they provided informed consent to participate in this study. The surgeries were performed at our institution by 4 board certified spine surgeons. The patients were randomly allocated to the following 3 groups after they picked a card from an envelope: a custom-made LSO (C) group; a ready-made LSO (R) group; and a no orthosis (N) group. They were followed-up for 2 years after the surgeries.

2.1. Operative technique

PLIF was performed using the same cages (CALIBER CFR-PEEK cage, ROBERT REID INC, Tokyo, Japan) and pedicle screw system (CD HORIZON SOLERA Spinal System, Medtronic Sofamor Danek Co., Ltd., Memphis, TN). After bilateral facetectomy and meticulous removal of the disc materials and cartilaginous endplates, 2 cages packed with morcellized bone and block bones were implanted into the disc space followed by pedicle screw fixation.\(^{[16]}\)

2.2. Type of orthosis and postoperative wearing period

A custom-made LSO, which is commonly called “Damen corset,” consists of a nonstretchable mesh fabric with 4 aluminum stays (2 each for anterior and posterior supports) (Fig. 2A). Fitness or tightness can be controlled by adjusting the straps in the anterior and posterior portions. The ready-made LSO consists of an elastic cloth with contoured 4 aluminum rods at the site of the back while an individually adjustable compression acts upon the lumbar spine (LumboLoc, Bauerfeind, Zeulenroda, Germany) (Fig. 2B). The fitness or tightness can be controlled by adjusting the stretch of the elastic orthosis, which is stabilized by Velcro at the desired position. The size and fitness were adjusted by an orthotist preoperatively and instructed on how to apply the orthosis. Patients in the C and R groups wore the orthoses constantly for 3 months postoperatively except during bathing and sleeping.

2.3. Evaluation of clinical outcomes

Neurologic status was assessed using the Japanese Orthopaedic Association (JOA) score (29-point system),\(^{[17]}\) the JOA back pain evaluation questionnaire (JOABPEQ)\(^{[18]}\) (Appendix 1, http://links.lww.com/MD/C916), and the Roland-Morris Disability Questionnaire (RDQ).\(^{[19,20]}\) The JOABPEQ is a newly-developed patient-based quality of life (QOL) outcome measure and comprises of 24 questions. The outcomes were calculated as 5 functional domains: pain-related disorders, lumbar dysfunction, gait disturbance, social life disturbance, and mental health problems, with higher scores indicating better QOL (100-point system). Effective ratio (ratio of patients with $\geq 20$ acquired points) for each of the 5 domains was calculated according to the instruction for the analysis using JOABPEQ.\(^{[21]}\) The RDQ was analyzed by using the Japanese deviation calculation.\(^{[22]}\) Visual analog scale (VAS, 0–100mm) for low back pain, pain in lower extremity, and numbness in lower extremity, (0–100mm) were also investigated.
All the clinical outcomes were assessed preoperatively and at postoperative 1 month (POM1), 3 months (POM3), 6 months (POM6), 1 year (POY1), and 2 years (POY2).

2.4. Radiographic evaluation

2.4.1. Assessment of fusion. The presence of interbody fusion was assessed using both dynamic lateral plain radiographs and multiplanar reconstruction computed tomography images at POY2. Fusion was defined as present when both of the following criteria were fulfilled, which were modified from a previously reported method[23]: formation of new bone bridging between the upper and lower vertebral bodies or fusion mass formation with no radiolucency around the cages; and flexion-extension angle at the fused segments on lateral radiographs ≤ 5°.

2.4.2. Correction loss at the fused segments. Correction loss at the fused segments was defined using the following 3 parameters at POY2 compared with those just after the surgery on lumbar lateral radiograph in the neutral standing position: change in the vertebral height (ΔH, mm), defined as the distance between the midpoint of the upper endplate of the upper fused vertebra and the midpoint of the lower endplate of the lower fused vertebra; change in the fusion angle (ΔA, degree), defined as the angle between the line parallel to the upper endplate of the upper vertebra and the line parallel to the lower endplate of the lower vertebra; and the change in the distance of translation (ΔT, mm), defined as the translation of the posterior border of the upper vertebrae from the lower vertebrae.[24]

Loosening of a pedicle screw was defined as the presence of a clear zone of more than 1 mm around the screws on multiplanar reconstruction computed tomography images.

2.5. Complications

Data was collected regarding peri- and postoperative complications that occurred within 2 years of the surgery, such as dural tears, neurological complications, superficial or deep wound infections, and the need for revision surgery.

2.6. Bone density analysis by dual-energy X-ray absorptiometry

Bone density (T-score) of the lumbar spine and femur was evaluated preoperatively using dual-energy X-ray absorptiometry.

2.7. Statistical analyses

Statistical analyses were performed using StatView for Windows version 5.0 software (SAS Institute, Cary, NC). Kruskal–Wallis test and Fisher exact probability test were used for between-group comparisons, and the Wilcoxon signed-rank test was used for within-group comparisons. P-values (P) less than .05 were considered significant.

3. Results

The patients between the groups were different in terms of the sex ratio, preoperative JOA scores, and the subscale of pain-related disorders in JOABPEQ regardless of prospective randomization in this study (Table 1).

3.1. Clinical outcomes

The postoperative JOA scores were not different between the groups. Significant improvements in the JOA scores were observed in all the groups at POM1, and the improvements were maintained till POY2 (Fig. 3). The effectiveness ratio of each subscale in JOABPEQ demonstrated that there was a significant difference in the subscale for lumbar function between the N group (45%) and C group (10%) only at POM1 (P = .030). There was no significant difference in the other subscales at any time points between the groups (Fig. 4). The scores of RDQ were also significantly improved in all the groups at POM3 (Fig. 5). VAS score for low back pain, pain in lower extremity, and numbness in lower extremity showed significant improvements in all the groups at POM1 (Fig. 6).
Table 1

| Patients' demographics. | C group (n = 22) | R group (n = 31) | N group (n = 20) | P-value |
|------------------------|-----------------|-----------------|-----------------|---------|
| Age, yr                | 67.3 ± 13.1     | 65.4 ± 13.5     | 64.2 ± 12.3     | .30     |
| Male/female            | 5/7             | 16/13           | 8/12            | .03     |
| Diabetic mellitus      | 4.5% (1/22)     | 22.5% (7/31)    | 20% (4/20)      | .19     |
| Body mass index, kg/m² | 23.1 ± 3.0      | 24.4 ± 3.1      | 23.5 ± 3.0      | .29     |
| Bone mineral density (T-score) | -             | -               | -               | -       |
| Lumbar                 | -0.9 ± 1.4      | -0.9 ± 1.7      | -0.6 ± 1.6      | .63     |
| Hx                     | -1.2 ± 1.2      | -0.4 ± 1.2      | -0.5 ± 1.2      | .09     |
| Diagnosis              | DS: 14          | DS: 15          | DS: 8           | .29     |
| LSCS: 2                | LSCS: 7         | LSCS: 7         | -               | -       |
| SS: 1                  | SS: 5           | SS: 1           | -               | -       |
| JOA score              | 12.2 ± 4.1      | 13.0 ± 4.1      | 9.3 ± 3.6       | <.01    |
| JOABPEQ                | -               | -               | -               | -       |
| ASD-related disorders  | 36 (0–100)      | 43 (0–100)      | 21.5 (0–71)     | .04     |
| Lumbar dysfunction     | 71 (12–100)     | 67 (0–100)      | 37.5 (0–83)     | .11     |
| Gait disturbance       | 18 (0–93)       | 29 (0–93)       | 25 (0–48)       | .25     |
| Social life disturbance| 38 (0–78)       | 46 (0–73)       | 34 (0–57)       | .15     |
| Mental health problem  | 48.5 (9–81)     | 46 (13–83)      | 43.5 (15–72)    | .61     |
| RDQ (points)           | 38.8 ± 10.9     | 36.1 ± 13.6     | 33.4 ± 14.5     | .36     |
| 100 mm-VAS             | -               | -               | -               | -       |
| Low back pain          | 45.7 ± 31.1     | 48.8 ± 27.0     | 55.1 ± 30.2     | .37     |
| Pain in lower extremity| 67.7 ± 23.1     | 57.8 ± 27.3     | 59.2 ± 32.8     | .50     |
| Numbness in lower extremity | 62.2 ± 31.2     | 47.7 ± 32.3     | 58.6 ± 30.6     | .18     |
| Surgical interventions | -               | -               | -               | -       |
| Fusion site(s)         | 1 level:16      | 1 level:25      | 1 level:15      | .77     |
| Fusion site(s)         | 2 levels:6      | 2 levels:6      | 2 levels:5      | -       |
| Fusion site(s)         | L2-3-1          | L2-3-1          | L2-3-1          | .96     |
| Fusion site(s)         | L3-4-7          | L3-4-7          | L3-4-4          | -       |
| Fusion site(s)         | L4-5-17         | L4-5-22         | L4-5-16         | -       |
| Fusion site(s)         | L5-S1-3         | L5-S1-7         | L5-S1-4         | -       |
| Operation time, min    | 186.4 ± 63.7    | 194.1 ± 41.9    | 173.1 ± 43.2    | .24     |
| Estimated blood loss, g | 371.3 ± 260.2   | 320.3 ± 175.7   | 294.8 ± 174.5   | .88     |
| Hospital stay, d       | 18.4 ± 4.7      | 16.6 ± 3.9      | 20.7 ± 2.9      | .30     |

Numerical variables are described as mean ± standard deviation, and the JOAPEQ are described as median (range).

*Clusters of pain, disability, and quality of life.
†Fisher exact probability test.

3.2. Radiographic evaluation

Measurements of radiographic parameters at POY2 are shown in Table 2. The fusion rate was 96% in the N group, 92.8% in the C group, and 94.5% in the R group. No significant difference was observed between the groups. Other radiographic parameters also showed no difference between the groups.

3.3. Postoperative complication

One patient in the N group underwent revision surgery for dislocation of the grafted block bone which resulted in radiculopathy. One case of deep wound infection was observed in the R group; however, it was treated with a course of antibiotics without additional surgical treatment.

4. Discussion

In this prospective randomized study, we investigated the effects of postoperative LSO treatment in patients treated with PLIF for <2 levels. We found that custom-made LSO treatment demonstrated a significant disadvantage of lumbar dysfunction according to the JOAPEQ at 1 month postoperatively compared with patients who did not receive LSO treatment. There was no other significant advantage or disadvantage in both clinical and radiographic outcomes regarding postoperative use of LSO.

The concept of LSOs originated from women’s undertgarments in the medieval era and was used in the aftertreatment of lumbar surgery in the twentieth century. In 1957, Norton et al[12] first reported the immobilizing effects of several LSOs. The theoretical rationale for the use of orthoses after lumbar surgery includes mitigation of postoperative surgical site pain and improved fusion rate by stabilizing the lumbar spine.[17–14] However, the stabilizing effect of lumbar orthoses has been reported to be limited, especially at the lower lumbar spine.[25] In a recent study, Utter et al[26] quantified the effects of 2 commonly available orthoses (off-the-shelf, soft, and semirigid thoraco-LSOs) on lumbar spinal motion by video fluoroscopic analysis and reported that a semirigid thoraco-LSO can reduce intervertebral motion at the L3-L4 and L4-L5 levels by as much as 32% to 50%, and semirigid and soft LSOs by 15% to 20% at the L4-L5 level. However, none of the orthoses could achieve a significant reduction in the motion at the L5-S1 level. Axelson et al demonstrated that a thoraco-LSO with a thigh-cuff extension is required to stabilize the motion of the whole lumbar spine, including the L5-S1 segment, though it limits the patient’s daily activities significantly.[27] Given the above scientific evidence regarding the effect of bracing on lumbar stabilization, the practical effects of LSO treatment after lumbar surgery are supported by not only the biomechanical stability provided by LSO but also by self-limitation of activity by the patients.

As to the effect of orthosis treatment on pain control, there has been no report to demonstrate its effects on pain relief during the postoperative period. The results in this study were consistent with those of previous reports, which reported that LSO treatment did not change postoperative low back pain irrespective of orthosis treatment. There is strong evidence regarding the effectiveness of lumbar belt in improving the functional status, pain level, and use of analgesics in patients with subacute low back pain.[24] The discrepancy in the effectiveness of LSO treatment between 2 morbidities may be explained by the difference in the source of pain. The pain in patients treated with spinal fusion may mainly originate from tissue damage caused by...
the surgery, and the pain in patients with acute low back pain originates from mobile segments including the facet joints and degenerated intervertebral discs. Therefore, LSO treatment is more effective for acute low back pain than postoperative pain by providing biomechanical stability.

Regarding the effects of LSO on fusion rates, there is only 1 comparative study in patients treated with noninstrumented posterolateral lumbar sacral fusion (PLF). Johnsson et al reported in their case–control study of PLF that longer orthosis treatment (5 months) increased the fusion rate than shorter orthosis treatment (3 months). In the present study, PLIF which provides anterior column support and posterior reconstruction with the help of interbody cages and pedicle screw systems, respectively, was used for lumbar spinal fusion. The robust biomechanical reconstruction by PLIF could make LSO less necessary compared with noninstrumented PLF, which cannot provide the initial biomechanical strength.

One prospective-randomized trial analyzed the effects of a lumbar canvas corset with 2 molded posterior metallic supports following instrumented posterolateral lumbar fusion surgery. Yee et al reported that there was no significant advantage or disadvantage of postoperative lumbar corset based on patient-reported generic and disease-specific functional measures. In this study, the rate of lumbar dysfunction in JOABPEQ in the C group was significantly lower compared with that in the N group only at postoperative 1 month; there was no significant difference in JOABPEQ at other time points and other clinical outcome measures. In JOABPEQ, patients are asked regarding lumbar dysfunction in 6 questions (Q2-1 to Q2-6 in Appendix 1, http://links.lww.com/MD/C916). As an inevitable consequence of using custom-made fabric orthosis which is not stretchable in comparison with a ready-made elastic, the motions of putting on socks or stocking and bending forward, kneeling, or stooping can be difficult for patients in the C group.

**Figure 4.** Effectiveness ratio for each of 5 domains: pain-related disorders (A), lumbar dysfunction (B), gait disturbance (C), social life disturbance (D), mental health problem (E) in the JOABPEQ on the C group (long plot line), the R group (solid line), and the N group (short plot line). JOABPEQ = JOA-back pain evaluation questionnaire, POM = postoperative month, POY = postoperative year.

**Figure 5.** Time-dependent change in Roland-Morris Disability Questionnaire scores on the C group (long plot line), the R group (solid line), and the N group (short plot line). POM = postoperative month, POY = postoperative year, Pre-OP = preoperative value.
Regarding the duration of LSO use, Bible et al. carried out a questionnaire study in spine surgeons attending the “Disorders of the Spine” conference dealing with postoperative bracing after spinal surgery for degenerative conditions. They reported that bracing treatment was continued for a total of 3 to 8 weeks and the most common reason for surgeons to prescribe orthoses was restriction of patient activity. In this study, the patients in the C and R groups were instructed to wear the orthoses for 3 months; however, clinical effectiveness was not observed compared with the no-orthosis group. These results suggest that the use of LSO for aftertreatment in PLIF ≤ 2 segments can be omitted.

The present study has some limitations. First, we compared only 2 orthoses that were both classified as soft corset; the use of hard corset or corset with a thigh cuff might produce different results. However, we believe that the 2 orthoses analyzed in this study are the most common types used for aftertreatment in lumbar surgery. Second, 1 patient in the no orthosis group required revision surgery because of migration of the grafted bone block. However, in this case, the interbody spacer migrated into the upper vertebral body within a week after the surgery because of the endplate was violated during the surgery. We believe that this additional surgery could not be staved off considering the lack of anterior support even with the use of orthoses for lumbar stabilization. Finally, small number of patients in this study can cause type 1 error. Therefore, further study with sufficient sample size is required for the generalization of our results.

In conclusion, this prospective randomized study investigated the effectiveness of orthosis treatment in patients treated with ≤ 2 levels PLIF and demonstrated that there was no effect of orthosis treatment on the clinical and radiographic outcomes. The effectiveness did not vary according to the type of orthoses. These results suggest that the use of LSO as aftertreatment can be simplified or omitted except in patients with severe osteoporosis.

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