Mid-term and long-term follow-up data after placement of the Graf stabilization system for lumbar degenerative disorders

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Object. The Graf pedicle screw and ligament device is designed to provide flexible stabilization to prevent abnormal spinal movement. The purpose of this study was to investigate radiographic and clinical outcomes during a minimal 5-year follow-up period.

Methods. Between 1991 and 1997, 43 consecutive patients (whose mean age was 61 years) with lumbar degenerative disease underwent decompression and stabilization in which the Graf system was placed. Data were available for 31 patients who attended follow up for the minimal 5-year period. In a retrospective review, the authors assessed measurements on radiographs, clinical results (using Japanese Orthopaedic Association [JOA] Scale scores), and low-back pain (using a visual analog scale [VAS] score), preoperatively and postoperatively at 1, 3, 5, and/or 10 years. Radiographic measurements included sagittal and frontal range of motion (ROM), regional lordosis, and posterior disc height as well as the extent of degenerative spondylolisthesis.

Final follow-up JOA and VAS scores were significantly better than preoperative scores. Sagittal and frontal ROM was significantly reduced at 1 and 5 years, respectively, compared with preoperative values, and a gradual reduction persisted throughout the follow-up period. Compared with its preoperative status, the disc height ratio (adjacent segments to the operated level) was reduced 5 years after surgery. A significant inhibition of the vertebral slippage was detected only in the flexion position.

Conclusions. Analysis of these data indicated that the Graf system eventually leads to successful fusion, suggesting the presence of stability in all three dimensions. The use of the Graf system should continue to be evaluated as an alternative device in the treatment of lumbar degenerative disease.

Key Words • degenerative disease • spinal instability • lumbar spine • Graf system

Lumbar degenerative disease is associated with mechanical intervertebral segment instability and is regarded as an abnormal movement causing pain due to a physiological load. It is thought that the intact intervertebral disc has two biomechanical roles: the transmission of load and the control of ROM such that movement does not compromise the adjacent neural elements. Dehydration of the disc is probably a trigger in the pathogenesis of mechanical instability. Disc degeneration, especially in the nucleus pulposus, may lead to a reduction in the tensile stress of the anulus fibrosus and subsequent impairment of facet joint adaptation. Although the exact relationship between the mechanical instability and low-back pain has not yet been clarified, PLF involving the placement of autogenous bone graft with or without rigid instrumentation has traditionally been the most common surgical intervention to produce spinal stability. Various adverse effects such as enhanced stress at the segments adjacent to the fusion level, pseudarthrosis, and bone graft donor site pain, however, have been reported for spinal fusion. To avoid these disadvantages, a more flexible stabilization system has been developed based on the concept that only abnormal spinal movement should be restricted.

The Graf stabilization system is one of the first relatively widely used devices to allow flexible stabilization. It consists of a nonelastic band that acts as a ligament to connect modified titanium PSs. The procedure involved in placement of the Graf system stabilizes the unstable segment with adequate regional lordosis, preventing excessive movement. Based on this function, previous radiographic examinations in short- or mid-term follow-up studies have focused on the comparison of pre- and postoperative sagittal alignment. The authors of these studies have shown that the abnormal movement of the unstable segments was restricted throughout the observation period. Because the effect of the Graf system on frontal and sagittal alignment as separate parameters has not yet been studied, however, it remains unclear whether the altered condition is main-

Abbreviations used in this paper: ADL = activities of daily living; JOA = Japanese Orthopaedic Association; PLF = posterolateral fusion; PS = pedicle screw; ROM = range of motion; SD = standard deviation; VAS = visual analog scale.
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tained throughout a long-term period. Although the early clinical results associated with the Graf system have been encouraging, some investigators have reported that mid-term results are not as convincing. Considering this fact, long-term follow-up data are needed to determine the efficacy of the Graf system in preventing instability and adjacent-segment deterioration and in improving clinical outcomes. The purpose of the present study was to assess the postoperative radiographic and clinical status following Graf stabilization for symptomatic degenerative lumbar diseases during a minimal 5-year follow-up period.

Clinical Material and Methods

Patient Population

We reviewed data obtained in 43 patients who underwent decompression combined with Graf system–based stabilization in our university hospital between 1991 and 1997. Complete (≥ 5-year) follow-up data were available in 31 patients, and these 31 cases form the basis of the present retrospective study in which the mean follow-up period was 8.9 years. The other 12 patients (10 with lumbar degenerative spondylolisthesis [including one who underwent previous PLF] and two with lumbar spinal stenosis) were lost to follow up and were excluded from this study. Their early clinical outcomes were satisfactory; one of those lost to follow up required revision surgery at a later date for screw malposition. None of the 31 patients in the present study had previously undergone lumbar surgery. Degenerative spondylolisthesis was present in 23 patients, spinal stenosis in five, and disc herniation in three. There were 13 men and 18 women, and the mean age of the participants was 61 years (range 30–74 years) at the time of surgery. The indication for surgery was disabling low-back and/or leg pain interfering with ADL that failed to respond to a minimal 3-month course of conservative treatments. At our institution, the Graf system was used in all patients with flexion instability independent of disease (posterior disc opening > 5° and/or anterior slippage > 3 mm in flexion). The segments responsible for the clinical symptoms were identified using myelography or magnetic resonance imaging and a gait-loading test. The gait-loading test provides a more precise determination of the responsible level underlying the lumbosacral symptoms. During this test, the entrapped nerve root is intentionally aggravated. The investigator walks with the patient, checking any changes in subjective symptoms until the ambulation is discontinued when the patient’s symptoms worsen. A quick neurological examination is then performed with the patient in a standing position to determine if sensory, motor, and reflex functions have worsened compared with those at rest.

The procedure to implant the Graf system was performed at a single level in each patient (the L3–4 segment in two, the L4–5 segment in 28, and the L5–S1 segment in one). All patients underwent surgical decompression of the dura mater and/or nerve root and a laminectomy in which a facet joint–preserving technique was used. In cases in which the patients suffered radicular pain or radicular intermittent claudication preoperatively, the decompressive procedure was extended laterally to identify the affected nerve root. Using intraoperative fluoroscopy the PSs were inserted above and below the symptomatic segment, and then connected by longitudinal bands over the heads of the screws as a ligamentoplasty. The length of the band to be used was determined with a tensor that enabled the compression force to be 5 dN. Based on the results of the gait-loading test, three patients with degenerative spondylolisthesis underwent additional L3–4 decompression and L-4 nerve root unroofing but no additional instrumentation was placed. In these patients we observed quadriceps femoris muscle weakness and a decline or loss of patella tendon reflex, as well as numbness and/or pain referred to the L-4 involved area. Because radiography demonstrated no instability at the corresponding segment in these patients, the Graf system was not extended to include the additional region where decompression was undertaken. After surgery, all patients were allowed to walk on the 1st post-operative day during a 2-week hospitalization period. No orthosis was used, and patients were gradually permitted to return to work and/or normal ADL 12 weeks after surgery.

Clinical Evaluation

The extent of low-back pain and clinical outcome were evaluated using a 10-point VAS and the 29-point JOA Scale, respectively (Table 1). The patients were assessed by the orthopedic surgeons preoperatively and at the time of final follow-up examination. The maximal JOA Scale score is based on three subjective symptoms (total score 9), three clinical signs (total score 6), seven ADL measures (total score 14), and three levels of urinary bladder function (total score −6) (Table 1). The higher the JOA Scale score, the better the clinical outcome; the validity of the scoring system has been demonstrated in a recent study.

Radiographic Evaluation

Plain radiographs were obtained with patients in the standing position. This examination was complemented by the acquisition of flexion–extension and lateral bending x-ray films to investigate the extent of mobility and spondylolisthesis. Analysis of the radiographs was performed using public domain software (ImageJ; National Institutes of Health, Bethesda, MD) to assess the following: 1) regional lordosis in the neutral position, 2) sagittal ROM on flexion–extension radiographs, 3) frontal ROM on lateral bending radiographs, and 4) disc height ratio in the neutral position (calculated by posterior disc height [A] and height of posterior aspect of the cephalad vertebral body treated [B], including adjacent intervertebral spaces: disc height ratio = A/B × 100). Spondylolisthesis was defined as vertebral slippage of greater than 5 mm in the neutral position, and the percentage of slippage was calculated by measuring the distance from the posteroinferior limit of the slipped vertebra to a line through the posterior border of the caudal vertebra (C) and width of the cephalad vertebral body treated (D); thus, the spondylolisthesis percentage = C/D × 100. The slippage percentage was studied in 23 patients with degenerative spondylolisthesis shown on flexion–extension x-ray films. Radiographs were acquired at each follow-up visit in all cases, and the 1-, 3-, 5-, and 10-year radiographs were compared with preoperative x-ray films. Ten-year follow-up data were available in 19 cases. The radiographs were blindly examined by indepen-
Statistical Analysis

The paired t-test and Wilcoxon signed-rank test were conducted to compare pre- and postoperative data. Probability values less than 0.05 were considered statistically significant. Data are presented as the means ± SDs.

## Results

### Clinical Outcomes

There were no cases of thromboembolic events or acute- or late-onset deep infections. Additionally, no breakage of PSs and bands or screw loosening was observed throughout the follow-up period. The mean preoperative low-back pain VAS and JOA scores were 6.1 ± 1.4 and 14.8 ± 4.1, respectively. The final follow-up VAS and JOA scores were 2.4 ± 2.2 and 23.3 ± 4, respectively, and both represented significant improvements (Table 2). One patient, however, suffered severe posture-related radicular pain and related neurological dysfunction that was not present prior to surgery. Computed tomography scanning revealed a malpositioned screw, which was assumed to be the cause of nerve root impingement. Despite repositioning of the screw, the patient’s JOA score still reflected a poorer postoperative status than preoperative status. Because of the retrospective nature of this follow-up study, the outcome data were in part collected by the treating surgeons, and the outcomes could have been affected by this variable.

### Radiographic Outcomes

There was no case of spinal instability in which the posterior disc opening angle was greater than 10˚; there were two cases in which the spondylolisthesis was greater than 25%. The mean regional lordosis in the neutral position was 9.4 ± 5.6˚ prior to surgery. The 1-year value of 10.7 ± 4.9˚ did not reflect any significant difference compared with the preoperative measurement. The lordotic angle did not change over time, and the value at 10 years was 11 ± 6.4˚. As shown in Fig. 1 upper, the preoperative sagittal ROM (10.6 ± 3.9˚) was remarkably reduced to 4.7 ± 2.9˚ at 1 year (p < 0.01); this improvement persisted through the 10th postoperative year. The preoperative frontal ROM (5.3 ± 1.8˚) gradually decreased, and a significant reduction was observed by 5 years (p < 0.01) (Fig. 1 lower). A reduction of approximately 50% (2.4 ± 1˚) was observed at 10 years compared with the preoperative angle. The changes in posterior disc height are presented in Table 3. Compared with the preoperative counterpart value, postoperative disc heights of the surgically treated and inferior adjacent segments were significantly reduced at 3 and 5 years, respectively (p < 0.05) (Table 3). In the patients with degenerative spondylolisthesis, the Graf system–based stabilization resulted in an apparent motion inhibition only in flexion (p < 0.05) (Fig. 2 and Table 4). The mobility indicating a difference in spondylolisthesis between flexion and extension was significantly reduced in relation to the inhibition of that in flexion (p < 0.05).

### Discussion

Low-back pain has long been associated with functional decline and impaired quality of life. If instability of lumbar spine column were the pivotal cause of back pain, one would expect spinal fusion to be more successful than it...
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has been in alleviating symptoms. In the past, the value of
decompressive laminectomy and fusion was substantiated
by the rates of satisfactory outcome (90%) and solid fusion
(86% [range, 30–100%]). There is, however, prospective randomized evidence that no relationship exists
between clinical improvement and the success of the spinal
fusion with or without instrumentation. The fusion rate is
enhanced by the use of the instrumentation, although this
has not always been linked to an improved clinical outcome.
For this reason, it is hypothesized that development of a fibrous fusion might provide sufficient structural support
to prevent progressive instability.

After rigid fusion, mechanical stress affecting the segments adjacent to the fusion level is a major adverse effect
that has been known for many years. An increased stress results in adjacent-segment intervertebral disc degeneration
that may further impair the load transmission and controlled movement at the corresponding segment.
To resolve such a vicious circle, an increasing number of

<table>
<thead>
<tr>
<th>Scale</th>
<th>Preop</th>
<th>Final Follow Up</th>
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<tbody>
<tr>
<td>VAS</td>
<td>6.1 ± 1.4</td>
<td>2.4 ± 2.2†</td>
</tr>
<tr>
<td>JOA</td>
<td>14.8 ± 4.1</td>
<td>23.3 ± 4.0†</td>
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</table>

* Values are presented as the means ± SDs. The VAS scores range from 0 to 10, with lower scores reflecting less pain. The JOA scores range from 0 to 29, with higher scores indicating better function.
† Significant difference from preoperative value (p < 0.05).

Radiographic Assessment

Our radiographic studies showed that flexion–extension movement was remarkably reduced after the application of the flexible stabilization system and that the reduction of abnormal movement persisted for more than 10 years (Fig. 1 upper). The early stabilizing effect on sagittal alignment was exclusively due to the inhibition of flexion movement and was consistent with that noted in other studies. In accordance with the altered sagittal ROM, the vertebral slippage noted in patients with degenerative spondylolisthesis was inhibited in flexion, but the Graf system itself was not able to reduce the spondylolisthesis in the neutral position (Table 4). The influence of this procedure on frontal mobility was also investigated. Unlike that observed in flexion–extension, an apparent reduction of movement in lateral bending was confirmed at 5 years (Fig. 1 lower), indicating no early inhibition of movement postoperative.

<table>
<thead>
<tr>
<th>% Disc Height</th>
<th>Preop</th>
<th>1 Yr</th>
<th>3 Yrs</th>
<th>5 Yrs</th>
<th>10 Yrs</th>
</tr>
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<tbody>
<tr>
<td>H1</td>
<td>20.0 ± 6.3</td>
<td>19.5 ± 5.4</td>
<td>19.6 ± 5.0</td>
<td>19.7 ± 5.6</td>
<td>19.8 ± 7.4</td>
</tr>
<tr>
<td>H2</td>
<td>23.1 ± 5.8</td>
<td>21.5 ± 4.3</td>
<td>18.5 ± 5.1†</td>
<td>17.4 ± 5.1‡</td>
<td>16.1 ± 6.3‡</td>
</tr>
<tr>
<td>H3</td>
<td>22.0 ± 6.2</td>
<td>20.3 ± 6.8</td>
<td>20.1 ± 5.7</td>
<td>19.2 ± 7.0‡</td>
<td>19.5 ± 7.3§</td>
</tr>
</tbody>
</table>

* Values are presented in percentages as the means ± SDs.
† H1 = height of the adjacent intervertebral space cephalad to the instrumented one; H2 = height of the intervertebral space instrumented; and H3 = height of the adjacent intervertebral space caudal to the instrumented one.
‡ Significant difference compared with preoperative value (p < 0.01).
§ Significant difference from preoperative value (p < 0.05).
ed segment; however, the reduction is much greater in flexion–extension than in lateral bending and axial rotation.\textsuperscript{34,36} These findings might partially explain why Graf stabilization, with relatively mild compression, did not exert early effects on lateral bending in the present study. Thus, analysis of the results suggests that the inhibition of frontal and sagittal ROM is progressive and that the instrumented segment seems to be fused after 5 years (Fig. 1). Even after successful rigid instrumentation–augmented fusion, investigators have reported that there are several degrees of remaining spinal flexibility, and this corresponds to the findings in the present study.\textsuperscript{23} A rigid fusion alters the adjacent-level biomechanics, leading to increased mechanical demands and subsequent degeneration.\textsuperscript{23,24} In a recent retrospective study on PLF, Ghiselli and colleagues\textsuperscript{10} reported that the rate of adjacent-level symptomatic degeneration warranting either additional decompression or arthrodesis was predicted to be 16.5\% at 5 years and 36.1\% at 10 years after surgery. Indeed, we found a significant reduction in disc height at the level caudal to the instrumented segments at 5 years compared with the preoperative height (Table 3). Nevertheless, the reduced disc height had no effect on the consequent clinical symptoms or the need for additional surgery. These findings suggest a modest and gradual degeneration of the adjacent segments following implantation of the Graf system. Because the Graf system is eventually thought to create a rigid fixation, we cannot exclude the possibility that the involved procedure may not prevent adjacent segment–related disease after 10 years.

### Clinical Assessment

Early and midterm postoperative data derived from a comparison between the Graf system with decompression and decompression alone\textsuperscript{22} and between the Graf system and anterior interbody fusion\textsuperscript{22} encouraged us to conduct the present study.\textsuperscript{21,22,27} The overall reoperation rate associated with the use of Graf system stabilization has been reported to be 21\% and insignificant improvement in Oswestry Disability Index and VAS scores have been observed at the midterm follow-up interval.\textsuperscript{31} The previously reported revision rate is higher and the clinical outcome worse than those in the present study.\textsuperscript{4} Throughout the follow-up period in our series, only one patient suffered radicular pain due to screw malpositioning and consequentially needed additional surgery. In a 3-year follow-up study in which a coauthor (S.K.) participated, two of 46 patients underwent reoperation and screw repositioning.\textsuperscript{22} The most commonly recognized complication has been radicular pain due to narrowing of the lateral recess at the instrumented segment caused by the increase in lumbar lordosis. Taken together, these findings intimate that a modest alteration in lordotic angle or appropriate unroofing of the affected nerve root could help avoid the need for reoperation.

We found that the Graf system can confer stabilization in both sagittal and frontal alignment, suggesting a trend toward the development of fusion. Although adjacent-segment disc degeneration as a result of this procedure was confirmed radiographically, there was no need for therapeutic intervention. It has been reported recently in prospective studies that total-disc arthroplasty in cases of degenerative disc disease restores normal disc motion and disc height for a minimum of 2 years.\textsuperscript{2,9} One may surmise, then, that such an optimal condition is maintained during the long term and thus we regard total-disc arthroplasty as an alternative technique to minimize adjacent-segment de-
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generation. The use of currently available devices, however, is limited in cases of spondylosis and spondylolisthesis because of suboptimal clinical outcomes.

One disadvantage of the present study was that some clinical follow-up data were obtained by the treating surgeons, thus introducing the possibility of bias into the assessment. Furthermore, design flaws include the absence of matched groups with which to compare the outcomes. Despite these possible limitations, assessment of the low-back pain and function scores indicated that favorable outcome was maintained during a mean follow-up period of approximately 9 years. Accordingly, it seems that flexible Graf system stabilization is a worthwhile procedure in cases of degenerative lumbar disorders and that it represents an alternative to rigid spinal fusion in patients with low-back pain and sciatica. We believe that this procedure is indicated in patients with spinal instability in whom low-back pain is the predominant complaint. We recommend prospective randomized studies to evaluate the extent of degeneration and vertebral slippage to determine the efficacy of Graf system–based spinal stabilization.

Conclusions

Analysis of the present mid- to long-term follow-up data showed that stabilization with the flexible Graf system inhibited flexion–extension and lateral bending ROM; the system’s effect on clinically related symptoms at adjacent segments was less pronounced. In such a condition, acquired stability is necessary to promote fusion. In addition, low-back painVAS and JOA scores were improved throughout the follow-up period. Therefore, the Graf system stabilization may be an alternative to rigid spinal fusion.

Disclosure

The authors have no financial involvement with the makers of the Graf system.

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