Surgical Results after Soft Graf Stabilization in Lumbar Degenerative Disc Disease

Hyang Kwon Park, Sung Hak Kim

Department of Neurosurgery
Ewha Womans University Hospital
Seoul, Korea

ABSTRACT

The authors report our clinical experience and surgical results with soft Graf stabilization system in a series of 47 cases with lumbar degenerative disc disease. The aim is to determine the usefulness of a soft stabilization system associated to clinical and radiological results of this patient series. At a mean period of postoperative observation of 32.5 months, excellent, good, fair and poor results were obtained in 9 (19%), 25 (53%), 9 (19%) and 4 (9%) of the patients, respectively.

The height of disc space at that level increased from 8.2 mm to 9.0 mm in L3-4, 8.8 mm to 9.9 mm on L4-5 and 9.3 mm to 10.4 mm on L5-S1. Regional as well as global lumbar lordosis were maintained. Angulation instability was changed from -4.5° to 4° on L3-4, -6.2° to 4.8° on L4-5 and -2.2° to 9.8° on L5-S1. Translational instability was corrected from 14.5% to 12.3% on L3-4, 17.5% to 13.1% on L4-5 and 20.8% to 18.6% on L5-S1.

These results suggest that soft Graf stabilization system in lumbar degenerative disc disease would be effective and useful alternative treatment method.

Key word: soft stabilization, instability, degenerative disc disease

Spinal Surgery 15 (3) : 175~182, 2001

Introduction

In lumbar degenerative disc disease, the pain source may be largely from the disc itself, these sites include the subchondral area of the vertebral end plates, the outer layers of the annulus fibrosus [15], the facet joint capsules [17], and the soft tissues surrounding the motion segment [16]. Spinal column degeneration can be represented conceptually as a cycle, described by Kirkaldy-Willis [13]. This concept, which emphasizes the progressive improvement in a stability of motion segments after a period of arthritic destabilization, suggests a new mode of treatment.

Degenerative disc disease need not result in permanent pain, and thus that permanent fusion is not an appropriate first solution.

Obviously, all patients must have had a thorough...
course of all the conservative modalities of treatment likely to be effective prior to the consideration of surgery.

Roy-Camille [23] and subsequently Cotrel [3] demonstrated the pedicle is the anatomic component for spinal implant placement that allows the best transmission of force. The purpose of most rigid transpedicular screw systems used in low back arthrodesis is to provide immediate stability and thus improve the fusion rate.

There have been raised much questions regarding the biological effects of rigid screw implants on the spine due to their increased stiffness [19, 24].

In contrast, the Graf pedicle screw and ligament device (soft Graf stabilization) was designed to provide stabilization without fusion [9].

The underlying procedural rationale of this system is to use a supple posterior preconstraint to restore lumbar lordosis, to stabilize the posterior facet joints, and to minimize the movement of the facet joints.

It is our aim to present the clinical results as well as the radiographic findings with degenerative lumbar disc disease and to evaluate the efficacy of this modality.

### Table 1: Clinical presentation (n = 47)

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>30 (64%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>17 (36%)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>15 (32%)</td>
<td></td>
</tr>
<tr>
<td>41-50</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>51-60</td>
<td>12 (27%)</td>
<td></td>
</tr>
<tr>
<td>&gt;61</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Symptoms and Signs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low back pain</td>
<td>47</td>
<td>(100%)</td>
</tr>
<tr>
<td>Radicular pain</td>
<td>42</td>
<td>(89%)</td>
</tr>
<tr>
<td>NIC*</td>
<td>19</td>
<td>(40%)</td>
</tr>
<tr>
<td>Sensory deficit</td>
<td>36</td>
<td>(77%)</td>
</tr>
<tr>
<td>Motor deficit</td>
<td>28</td>
<td>(60%)</td>
</tr>
</tbody>
</table>

*NIC: neurogenic intermittent claudication

### Patients and Methods

Forty seven consecutive patients were evaluated. All operative procedures were performed in our institute between October 13, 1995 and April 20, 1999.

All operations were performed by the same surgeon. Because of our instability to get clear-cut indications for a soft stabilization by use of the diagnostic protocol by Graf [9], we were content with our diagnostic protocol for instability of the lumbar spine which was failed with conservative treatment. The radiological investigations consisted in plain X-rays and MRI, in order to rule out facet joint arthritis and to judge upon the degree of disc degeneration of the affected as well as of adjacent motion segments. All patients had been suffered intractable lumbar degenerative disc disease which could be localized to one or more levels.

### Description of the Soft Graf Stabilization System

This system comprises pedicular screws placed above and below the symptomatic level according to the ordinary transpedicular screw system and
connected by longitudinal bands. The titanium screws have a cancellous thread with a core diameter of 5mm, 6mm and 7mm.

The available lengths are 35mm, 40mm and 45mm. The screws have a conical section above the thread with a sintered surface. The top of the screw has a spherical flange which retains the band securely in position.

Middle pediculare screws are available in the same core size with a longer outer section to accommodate two bands that are retained in place by addition of a titanium screw cap. Titanium protective sleeves may also be used to protect the bands from abrasion by the facet joints. The bands are made of braided polypropylene. Its length varies in 2.5mm increments from 17.5mm to 50mm.

A radio-opaque marker is incorporated into the band.

**Surgical Technique**

A standard midline posterior approach was carried out in all cases.

Subperiosteal dissection was used to expose the relevant facet joints and bases of the transverse processes. The intra-operative positions of the screws were confirmed with an image intensifier.

After screw placement, a tensioning device was inserted into the recess of adjacent screw heads, and approximately 50N compression stress was applied by hand.

The appropriate band length was then read from integral scale on the device. In order to reduce the risk of early or late nerve root compression after the band application, discectomy with undercutting facetectomy was performed in all cases.

**Postoperative Measures**

At the second postoperative day, the patients were daily mobilized and got instructions for correct standing up, sitting and all daily life activities with respect to back protection.

---

**Fig. 3. A case of newly developed instability after soft stabilization.**

a: immediate radiograph
b: follow-up radiograph

**Criteria for Evaluation of Surgical Results**

Clinical and radiological examination was done at every month after surgery. The final evaluation of results was possible in all patients.

The clinical results were graded "excellent", "good", "fair", or "poor", using criteria from Prolo's scale.

Radiological evaluation was done with respect to the following radiographically detectable criteria and put into relation to the preoperative and final radiological findings. The distance of inter-vertebral disc height was measured at the midpoint of the vertebral body from pre-operative and subsequent follow-up radiographs (Fig.1). A method for measuring sagittal plane translation or angular deformity was performed (Fig.2). If the translation or angular deformity was as much as beyond the normal value, it was considered to be abnormal and statistical analysis was done by use of the student paired t-test (SPSS for windows).

**Results**

47 patients (30 males and 17 females) with ages varying from 19 to 68 years (mean 48 years) have
Table 2: Diagnosis of degenerative lumbar disc disease

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>No. of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degenerative lumbar HNP*</td>
<td>24 (51%)</td>
</tr>
<tr>
<td>Spinal stenosis</td>
<td>17 (36%)</td>
</tr>
<tr>
<td>Degenerative scoliosis</td>
<td>4</td>
</tr>
<tr>
<td>FBSS**</td>
<td>1</td>
</tr>
<tr>
<td>Spondylolysis</td>
<td>1</td>
</tr>
</tbody>
</table>

* HNP: herniated nucleus pulposus  
**FBSS: failed back surgery syndrome

been investigated and operated on by use of the soft Graf stabilization system (Table 1).

The average period of follow-up was 32.55 months (range 8 to 50 months).

The clinical result was "excellent" in 9 (19%), "good" in 25 (53%), fair in 9 (19%), "poor" in 4 (9%).

In one case, reoperation was underwent. He was a 45-year-old man suffered from spinal stenosis that treated with soft fixation at L2-5 (Fig.3). A instability was noticed at L4-5 in the review of the 8th month follow-up period, with subsequent conversion to fusion with rigid pediculor fixation and posterolateral bone fusion. His result was included in a “poor” case. Table 2 depicts the preoperative diagnosis, mostly lumbar HNP in 24 patients (51%). In the distribution of instrumented levels in each group, two levels in 19 patients (40%), one level in 18 (38%) and three levels in 10 (22%) (Table 3).

Table 4 shows the preoperative and the outcome measures of the mean intervertebral distance demonstrated that slightly increased at instrumented levels.

The improvement of translation or angular deformity was noticed in all levels which statistical significance was demonstrable (Table 5).

Clinical excellent and good results at final evaluation were obtained in lumbar stenosis and lumbar HNP, but worse results were shown in old, degenerative scoliosis patients. There was no any difference in surgical results according to the instrumented level.

There was no unusual complication except one, subsequently treated with rigid fixation system. Two patients were treated with long-term oral and parenteral antibiotics for a superficial wound infection (Table 6).

Discussion

Degenerative lumbar pathology involving the sciatic nerves is a frequent source of chronic lumbar pain [5, 12, 20, 21]. As a treatment of multiple degenerative lumbar disease, there is no doubt about wide decompressive laminectomy for neural decompression if failed all conservative treatment modalities. But, postlaminectomy instability caused by wide decompression can provoke neurologic deterioration and further stabilization procedures may be required to improve clinical symptom.

Biomechanically, the system of surgical arthrodesis and rigid posterior stabilization compromises the residual flexibility of the anterior column [27].

The use of rigid fixation system has been linked to deterioration of the adjacent vertebral levels and also was found that, in the canine model, bone mineral content was reduced in the vertebral segment to an implant [27].
Table 4: Increment of disc height

<table>
<thead>
<tr>
<th>Disc level</th>
<th>Preop(mm)</th>
<th>Postop(mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L3-4</td>
<td>8.2±0.38</td>
<td>9.0±0.42</td>
</tr>
<tr>
<td>L4-5</td>
<td>8.8±0.48</td>
<td>9.9±0.61</td>
</tr>
<tr>
<td>L5-S1</td>
<td>9.3±0.55</td>
<td>10.4±0.62</td>
</tr>
</tbody>
</table>

Mean ± SE (mm)
P < 0.05

Rolander [22] has shown alterations in the load bearing characteristics in adjacent segments after fusion. Other studies [7, 25] found increased flexion-extension at the L3-4 level in patients who had undergone previous L4-S1 fusion. This increased motion resulted in extension of the fusion in 2.4% of cases.

There is considerable controversy surrounding the indications and efficacy of the various methods of spinal fusion in the management of low back pain, with no single technique universally accepted as the gold standard [14, 27].

A central tenet of spinal fusion is that rigid stabilization is necessary for symptomatic relief. Many reports [2, 5, 6] have found no relationship between bony fusion and the clinical results.

Indications for the present procedure are thus found among the indications for arthrodesis typically performed for chronic low back pain with degenerative discopathy; degenerative disc disorder, lumbar stenosis, degenerative scoliosis and so on (Table 2). The soft stabilization system is applied in a patient without radiographically detectable facet joint arthrosis [8]. The posterior application of a semielastic, flexible device under tension, which contains the lordosis affecting the disc and facilitates degenerative collapse in a stable manner may be accomplished.

The efficacy of the soft Graf stabilization was a development caused by the opponents of the rigid fixation device, leading towards a flexible fixation system that could be used to add stability to a motion segment without fusion. This soft system represented an impressive, fascinating alternative surgical treatment to lumbar arthrodesis in the treatment of low back pathology [11, 17].

The precise mode of action of the soft system is not yet fully understood. Gardner [8] insisted and described the possible modes of action as following; 1) immobilization in extension providing stability through coaptation of the facet joint, 2) alteration of annular and end-plate load bearing, 3) posterior annular compression resulting in closure of annular tears and elimination of neoinnervation and neovascularization, 4) splinting of the motion segment to allow healing of damaged tissues, 5) band relaxation over the first 4 to 6 months, allowing some return of movement.

The mechanism by which the soft system exerts a beneficial effect in degenerative disc disease has not yet been definitely clarified.

However, Brechbühler et al [1] reported that the increase of segmental lordosis leads to a locking effect of the facet joints reducing rotatory

Table 5: Change of translation and angular instability

<table>
<thead>
<tr>
<th>Disc level</th>
<th>Angulation (°)</th>
<th>Translation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preop</td>
<td>Postop</td>
</tr>
<tr>
<td>L3-4</td>
<td>-4.5±1.1</td>
<td>14.5±0.2</td>
</tr>
<tr>
<td>L4-5</td>
<td>-6.2±0.8</td>
<td>17.5±1.8</td>
</tr>
<tr>
<td>L5-S1</td>
<td>-2.2±1.6</td>
<td>20.8±1.3</td>
</tr>
</tbody>
</table>

Mean ± SE (°/%)  
P < 0.05

Table 6: Postoperative complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound infection</td>
<td>2 (0.04 %)</td>
</tr>
<tr>
<td>Instability</td>
<td>1</td>
</tr>
<tr>
<td>New radiculopathy</td>
<td>0</td>
</tr>
<tr>
<td>Screw related problem</td>
<td>0</td>
</tr>
</tbody>
</table>
hypermobility and instability in the y-axis and the painful stimuli on the nociceptive receptors in the facet joint capsules are reduced and pain originating from posterior structures of the lumbar spine as well as pseudoradicular pain are abolished.

Strauss et al [26] biomechanically assessed that the range of motion for flexion-extension and axial rotation was significantly reduced for the main motion and for lateral bending, the main and coupled rotations were affected significantly with the Graf system.

This, combined with a degree of disc narrowing which occurs on compression, means that there is only minimal strain on the Graf implants after 3 months.

The other author [1] demonstrated that overall lumbar lordosis as well as regional lordosis of the instrumented segment were maintained after a mean period of observation of 50 months and there was no significant increase of segmental motion of adjacent segments in dynamic studies, the disc height of instrumented segments slightly decreased over the time.

Our radiographic studies demonstrated that overall lumbar lordosis as well as regional lordosis of the instrumented levels were maintained at final evaluation. The disc height and translation or angular instability was improved at the instrumented segment in comparison to the preoperative value.

We consider that the soft Graf stabilization demonstrate the protective effect and give a physiologic rigidity on the degenerative destabilized segment.

But, such alternative method to stabilize lumbar spine, the soft system has been continued to challenge the accepted fusion procedure.

The result of Hadlow et al [11] have not shown the patient outcome to be any better than that with instrumented posterolateral fusion, and also Markwalder [18] and other researcher [10] reported with disappointingly unpredictable results.

The authors think the soft Graf system procedure contain inevitable learning curve errors.

Assuming judicious case selection and adequate preoperative investigation to define the symptomatic levels are very important points and than procedural main important facts are correct insertion of the pedicle screws, correct placement and tensioning of the bands, and adequate foraminal decompression because of the immobilized motion segment in extension.

Conclusion

Rigid stabilization has been thought for the symptomatic relief in degenerative disc disease. But, many reports were published no any relationship between bony fusion and the clinical results.

The soft Graf stabilization system has some further advantages over instrumented spinal fusion. The procedure appeared to be more physiologic and less invasive and because there was no bone grafting, there was no risk of pseudoarthrosis and no donor site pain, substantially quicker operation time. Our results were sufficiently encouraging, considered to be as good as good results.

It is our aim to be on the clinical value of the soft Graf stabilization in lumbar degenerative disc disease when the operative indication for this type of surgery is clearly restricted and the pitfalls of this surgical method is considered through adequate learning curve.

References

Hyang Kwon Park, et al.: Surgical Results after Soft Graf Stabilization in Lumbar Degenerative Disc Disease


Investment / Financial Disclosure:

In preparation of this study, any author has not been a financial interest in the subject. No support in the form of grants and equipment has been or will be received.
Co-Editor's comment:
Hideaki Iizuka
Department of Neurosurgery
Kanazawa Medical University
Kanazawa, Japan

This article reported the efficacy of soft stabilization system (Graf) for lumbar degenerative disc diseases. In the surgical treatments for lumbar spine degenerative lesions, even with spondylolisthesis, there are controversies about indications and necessity of rigid stabilization. The authors presented the several advantages of the soft Graf stabilization technique over the rigid fusion. The surgical results including postoperative radiological evaluations were acceptable. The authors mentioned that indications for this procedure are degenerative lumbar disc diseases without facet joint arthrosis. More precise surgical indications should be clarified based on the long-term results.

Reviewer's comment:
Isao Yamamoto
Department of Neurosurgery
Yokohama City University School of Medicine
Yokohama, Japan

This article presents surgical results with 47 patients treated with soft Graf stabilization for degenerative disc disease. After a mean follow-up period of 32 months, excellent and good clinical results were obtained in 19% and 53% of patients, respectively. Postoperative radiographic examination revealed increased disc height, maintained lumbar lordosis and improved stability.

The most pedicle internal fixation system in lumbar arthrodesis provide immediate stability and thus improve the fusion rate. In contrast, the Graf system is designed to provide stabilization without fusion. This concept is obviously interesting. In other published report [1], the following criteria are important for a good result: 1. Segmental instability with no or mild arthritic changes of the facet joints, 2. Preferably a still intact disc or only mild loss of disc height, 3. Well trained low back muscles, and 4. A clear cut, repeatedly demonstrated pain relief on trial anesthesia on the corresponding articular nerves and wearing a trial jacket.

The mechanism of beneficial effect with the Graf system in degenerative disc disease has not yet been clarified. Some articles reported that soft stabilization system had no benefit compared with stiff fixation technique. Controlled study between the soft stabilization system and stiff fixation is needed.