Clinical Results and Rationale for Lumbar Interbody Fusion with Threaded Titanium Cages

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ABSTRACT

The purpose of this study was to research the use of Titanium cage implantation as a spacer for re-expansion and maintenance of disc height in association with interbody fusion. Between June 1992 and May 1993, twenty patients (14 males and 6 females, mean age of 38.8 years with range 26 to 65) were implanted at 22 levels (9 at L4-5 and 13 at L5-S1). After removal of disc material and preparation of the intervertebral space by tapping the end plates, 2 cages were implanted per level and packed with autogenous bone. Follow-up spine X-rays were done at 6 weeks, and 3, 6, 12 and 24 months and yearly thereafter. Disc height was measured pre, intra and postoperatively.

Ten levels demonstrated improvement of disc space from a mean of 6.8mm pre-operatively to 11.1mm postoperatively. Ten levels were maintained at 11.7mm. In 1 patient, both spaces collapsed postoperatively. At 3 to 5 years follow-up, the results on disc height were maintained and X-rays showed satisfactory fusion. There were no cases of infection, radicular deficit or CSF leak. The functional states improved on the Prolo scale. Posterior lumbar interbody fusion (PLIF) with Titanium cages was found to be a safe and efficacious technique. The rationale for maintaining or improving the disc space with cages is discussed.

Key word: spine, degenerative disc disease, interbody fusion

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INTRODUCTION

The concept of stabilizing the lumbar spine with interbody fusion is not new. As early as 1945, Cloward reported "A new treatment of ruptured intervertebral disc" at the Annual Meeting of the Hawaii Medical Association [2]. He published a definitive paper on the procedure in the Journal of Neurosurgery in 1953 [3]. The technical difficulties cited have precluded its widespread acceptance among surgeons. The incidence of nerve root traumatism associated with neurological deficits and the incidence of cerebrospinal fluid leak were emphasized. Non-union or bony graft extrusion were reported as well as collapse of the bone graft with segmental stenosis [5, 11, 18]. In his book on
posterior lumbar interbody fusion, Lin [11] in 1981 found only three teaching centers performing PLIF in the U.S.A. However, with the development of interbody fusion cage devices, the technique deserves to be reexamined and the results with these new procedures need reassessment.

In degenerative disc disease or following surgical discectomy, segmental stenosis occurs due to a combination of disc herniation, posterior osteophyte formation, facet overriding and hypertrophy and infolding of the ligamentum flavum [7]. All these factors combine to compromise the nerve root as it goes through the intervertebral foramen resulting in recurrence of radiculopathy.

The use of titanium cage implantation as a spacer for re-expansion and maintenance of the disc height in association with interbody fusion was reported by this author at the Congress of Neurological Surgeons in Montreal in 1996 [9]. The results on bony fusion from preliminary analysis of the U.S. study using the Ray Threaded Cage were reported in Dr. Ramani’s Textbook of Spinal Surgery [10].

PATIENTS AND METHODS

Between June 1992 and May 1993, 20 patients were operated at 22 levels for lumbar interbody fusion using 2 threaded titanium cages at each level. Ages varied from 26 to 65 with a mean of 38.8 years. There were 14 males and 6 females. All patients presented with symptomatic lumbar disc disease associated with low back and leg pain. The pre-operative symptomatology had been present for a number of months varying from 5 to 72, with a mean of 18.5 months. Pre-operative neurologic status was as follows:

Motor deficit: 2 patients
Sensory deficit: 4 patients
Positive straight leg raising test: 16 patients
Decreased or abolished deep tendon reflex: 14 patients

Surgery was done at L4-L5 level in 9 cases and at L5-S1 in 13 cases. Seven patients had had previous discectomy at the same level. Three patients presented with degenerative grade 1 spondylolisthesis. Neuroradiologic testing consisted of MRI (20 cases), CT scan (17 cases), CT myelogram (1 case) and CT discogram (8 cases).

SURGICAL TECHNIQUE

The procedure is done under general anesthesia with the patient positioned in knee-chest to decrease epidural bleeding. Fluoroscopic control is used to mark the level(s) to be fused in order to accurately place the surgical incision. X-ray control also permits assessing the physiologic curvature of the spine.

The appropriate level is then exposed bilaterally using a standard laminectomy technique. The operative microscope is used, along with micro-techniques and bipolar coagulation to fully identify the nerve roots in the epidural space. The disc material is then removed bilaterally and a drill is used to obtain satisfactory purchase into the end plates. Using dilators of increasing diameters, the vertebral bodies are distracted to obtain a satisfactory disc height. Disc height as well as a physiologic lordosis of the spine are controlled with fluoroscopy. Threads are then cut into the opposing vertebral surfaces using a bone tap. The space is then ready to receive the threaded cage which is screwed to lie beyond the posterior vertebral cortices. The cage is then packed with autogenous bone and the incision closed in layers.

INSTRUMENTATION

The threaded fusion cages are hollow titanium alloy cylinders which are perforated on 70% of their cylindrical walls. Product compression tests have shown that each cage can be loaded up to 900 Newtons for up to 10 million cycles without failures. The device is MRI compatible. The Ray threaded fusion cage is a registered mark of Surgical Dynamics, a subsidiary of United Surgical Corporation, Norwalk, Connecticut.
ILLUSTRATIVE CASES

Patient 3 is a 38 year old female with a thirteen month history of back pain with bilateral leg pain secondary to a car accident while she was pregnant. Following delivery, the symptoms did not abate. Examination showed paravertebral muscle spasm with decreased range of motion and pain, mostly in extension. The straight leg raising test was positive on the right. The right ankle jerk was decreased and she had hypoesthesia to pinprick in the right S1 territory. She was a failure of conservative treatment. The MRI revealed a L5-S1 disc herniation with desiccation (loss of water content of the nucleus pulposus) and posterior osteophytes resulting in S1 nerve root compression, worse on the right side. At surgery (9-1-1992), the herniated disc was removed bilaterally as well as the L5 osteophytes. Following distraction of the disc space from 6mm (Fig. 1) to 11mm (Fig. 2), 2 Titanium Cages (14 x 26mm) were inserted. Following surgery, her Prolo scores improved from 4 pre-operatively to 8 at 6 months and 10 at 1 year. On long term follow-up (4 years), her functional status remains excellent (Prolo score 10) and the disc height is maintained (Fig. 3).

Patient 14 is a 51 year old male with a two year history of primarily back pain with radiation in the left lower extremity secondary to a work accident. He had a past history of intermittent low back pain treated successfully with conservative measures for

Fig. 1: Case #3. The L5-S1 disc space is collapsed at 6mm.

Fig. 2: Case #3. Reestablishment of the disc space with 14 x 26mm Titanium Cages.
the past twenty years. This time, he remained a failure of medical treatment. The straight leg raising test was positive on the left at 45 degrees for leg pain, the right side elicited back pain only. The left ankle jerk was abolished. He had no motor or sensory deficits. The radiological work-up (X-ray, CT scan, MRI) showed L5-S1 degenerative disc disease with collapse (4 mm), desiccation and midline herniation, worse on the left (Fig. 4). At surgery (1-12-1993), the herniated disc was removed bilaterally and, using interbody dilators, the disc height was jacked to 8mm and 2 cages (14 x 21mm) were inserted. Postoperatively, his Prolo scores improved from 4 pre-operatively to 5 at 3 months, 7 at 6 months and 10 at 1 year. The 1-year X-ray revealed good maintenance of the disc space (Fig. 5). The results were retained at the three year follow-up.

RESULTS

In this series of 20 cases, there were no cases of infection, radicular deficit or C.S.F. leak. One patient was re-operated to reposition a cage producing radicular pain secondary to a too superficial placement. Repositioning of the cage presented no difficulty in technique and resulted in radicular pain relief post-operatively.

Follow-up spinal X-rays were obtained at 6 weeks, 3, 6, 12 and 24 months. Yearly control was done thereafter when feasible. Criteria for fusion were no halo of bony reabsorption around the cage, maintained bony density within the cage and no visible movement on flexion-extension. The sacrolumbar junction is best studied with Ferguson views (A-P view of the spine with a 30-35 degrees cephalad inclination of the X-ray tube). In some cases, thin cut CT scans were used to demonstrate the presence of bone inside the cage but postoperative CT scan or MRI were not done routinely for economical reasons.

Disc height was measured pre, intra, and postoperatively. Ten levels demonstrated improvement of disc space from a mean of 6.8mm pre-operatively to 11.1mm postoperatively. Ten levels revealed maintenance of disc space at 11.7mm. In one patient, operated on at 2 levels (L4-5 and L5-S1), both spaces collapsed postoperatively. From a clinical standpoint, however, the patient was significantly improved and long term follow-up X-rays of the lumbar spine demonstrated a satisfactory fusion. At one year follow-up, X-rays revealed satisfactory fusion at all 22 levels. At long term...
follow up (3 to 5 years) the improvement or maintenance of disc space height remained unchanged. Clinical results according to Prolo [14] outcome scale are to be found in Table 1. The pre-operative low grades of the patients are due to the fact that, except in very rare cases, this author will not do surgery on patients who can perform their work.

**DISCUSSION AND CONCLUSIONS**

Posterior lumbar interbody fusion has been performed for over 50 years [2, 3]. Technical difficulties have precluded wide acceptance of the technique and until now, many spine surgeons prefer to stabilize the spine posteriorly. Failures in the past have included collapse of the bone graft in the disc space, reabsorption of the graft and pseudo-arthrosis. Extrusion of the graft has resulted in nerve root compression with radicular deficit. Complications with harvesting the bone graft from the hip and persistent pain at the donor site were also a deterrent to the technique. Finally, most spine surgeons are more familiar with posterior and postero-lateral approaches due to their training when these techniques were widely in use, whereas interbody fusion was only taught in a few training programs.

The place of lumbar fusion in the treatment of low back pain has also been a matter of debate. The role of the intervertebral disc as a pain generator is not unanimously recognized and many surgeons emphasize the nerve root compression component as the major factor to be addressed by surgical treatment. However, the intervertebral disc as a pain generator is slowly gaining wider acceptance [8, 13, 17] and many
Table 1
Results According to Prolo Outcome Scale

<table>
<thead>
<tr>
<th>POINTS / OUTCOME</th>
<th>PRE-OP</th>
<th>1 YEAR</th>
<th>3 YEARS</th>
<th>5 YEARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1 - Complete invalid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2 - No gainful occupation</td>
<td>16</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>E3 - Able to work, but not at previous occupation</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>E4 - Working at previous occupation on part-time or limited status</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>E5 - Able to work at previous occupation with no restrictions of any kind</td>
<td>15</td>
<td>13</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>20</td>
<td>19 (a)</td>
<td>16 (b)</td>
<td>12 (c)</td>
</tr>
<tr>
<td>F1 - Total incapacity (or worth than before operation)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F2 - Mild to moderate level of back pain and/or sciatica</td>
<td>19</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>F3 - Low level of pain and able to perform all activities except sports</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>F4 - No pain, but patient has had one or more recurrence of back pain and/or sciatica</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>F5 - Complete recovery, no recurrent episodes of back pain, able to perform all previous sports activities</td>
<td>1</td>
<td>13</td>
<td>13</td>
<td>9</td>
</tr>
</tbody>
</table>

(a) 1 patient lost for follow up.
(b) 3 patients lost for follow up (1 patient deceased).
(c) 3 patients lost for follow up (2 deceased - 3 not as 5 year follow up).
people advocate removal of the disc with or without herniation and nerve root compression [12, 16].

Recurrence or persistence of pain after discectomy is well known and in the FDA (United States Federal Drug Administration) study [10], many cases (approximately one third) were done for recurrent pain following discectomy at the same level. When deciding to perform a lumbar fusion, it seems logical to fuse the anterior column of the spine which bears 80% of the weight bearing forces. The advantages of interbody fusion include direct removal of the dysfunctional disc and preservation or restoration of the disc height. Maintenance of the disc height, especially the posterior aspect is important to achieve significant increase in the neuroforamen volume [1]. Titanium interbody devices can better preserve the disc height than bone, autogenous or heterogenous, as shown by sheep studies [15]. In interbody fusion done with bone alone, Dennis et al [5] showed a loss of disc height in all patients undergoing anterior lumbar interbody fusion. In this series, preservation of disc space whether it was maintained or restored, was obtained immediately postoperatively and the results were present at long term follow-up (4 to 5 years). We have elected to do surgery in knee-chest position. Though some surgeons are critical of the knee-chest position, a postoperative flat back syndrome was never observed in any of the cases. Indeed, in some of the cases, we were able to improve the lordotic curve of the lumbar spine in patients with previous surgery.

The extend of the laminectomy necessary to insert cages depends upon the surgeon's technique. Many surgeons prefer to perform a total laminectomy with removal of the spinous process and interspinous ligament. We prefer to preserve the midline structures (spinous processes and inter/supraspinous ligaments) because we think these structures are an important part of the posterior column. Cages can be inserted by removing 4 to 5 mm of the laminae above and below the level operated on. It is most of the time necessary to perform a partial (1/3 to 1/2) facetectomy. This is done with hammer and a 5 mm osteotome and the bone may be saved to fill the cage. In some cases, a high speed drill may be helpful to assure a more comfortable acceptance for the retractor and cages.

Using this technique, in the United States, the average size female patient will accept a 14mm diameter cage and the average male either a 14 or a 16mm cage. In this series, we inserted 12 levels with 14mm cages, 8 levels with 16mm and 18mm was used in only 2 levels.

Finally, results must be judged also on the patients' satisfaction. The immediate rigidity obtained with cages has resulted in less postoperative pain, shorter hospitalization and overall reduced cost [6]. Our results confirm these data. Results on low back surgery are best analyzed on a long term basis [4]. When asked if they would have surgery again, 11 out of 12 patients available at 5 year follow-up responded affirmatively and estimated the improvement obtained at around 85%.

Ideally, randomized studies should be performed to assess which technique of interbody fusion is best. Unfortunately, at the present time, we have no "gold standard" for spinal fusion. The need for patient informed consent makes randomization unacceptable since patients choose what appears to be the least traumatic and easier option in their mind. In the USA, the fact that postero-lateral fusion associated with pedicle screws involves the use of instrumentation which is not FDA (United States Federal Drug Administration) approved further complicates the availability of randomized controlled studies. New FDA policy may change this in the future though it does not appear likely at this time.

At this stage of our knowledge, lumbar fusion with titanium cages affords the spine surgeon with a safe, reliable technique to obtain fusion with maintenance of satisfactory disc space and lumbar curvature. Longer follow-up and larger series will be necessary to confirm that the logical goals of maintaining the intervertebral foramen open and a satisfactory lumbar lordosis will translate into good clinical results and improved patient satisfaction. In our limited personal
experience with 20 cases done between 1992 and 1993, the results appear to confirm that these goals can be achieved with satisfactory clinical results.

REFERENCES
Editor-in-Chief’s comment:
Hiroshi Abe
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Lumbar Interbody Fusion with Threaded Titanium Cages by this author have afforded to obtain good fusion and maintenance of satisfactory disc space and lumbar curvature.

Japanese neurosurgeons have experienced some cases by this method but still small number of cases compared with the neurosurgeons in the United States. We would like to know more detailed surgical technique of this interbody fusion with titanium cages such as the width of laminectomy, with or without facetectomy, and how to insert the cages.

We have to study the indication of this method because I do not think all patients of lumbar disc disease or spondylosis need this interbody fusion. Absolute indication for this method should be the patients with instability or spondylolisthesis.

Co-Editor’s comment:
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Posterior lumbar interbody fusion (PLIF) using autogenous graft had long been advocated but never been widely accepted because of various technical difficulties and complications.

Threaded fusion cages (TFC) which are made of titanium and MR-compatible are a newly developed device for PLIF.

The author described reasonable clinical outcome both neurologically and radiologically in 20 patients with discogenic disease and degenerative grade I spondylolisthesis who underwent PLIF with TFC. We also have the same kind of experience in this procedure and recently reported 15 patients of low grade spondylolisthesis with disabling lumbago and intermittent claudication. (Mizuno J, Nakagawa H: Threaded Fusion Cage for Lumbar Spondylolisthesis. Neurol Med Chir 38 (3): 1998, in press.)

We now accumulated clinical experience of more than 30 patients who were treated with PLIF with TFC or BAK. There are some pitfalls in this procedure. In order to insert a cage of 14mm in outer diameter of which size is told necessary for good fusion, it is mandatory to perform almost complete facetectomy especially when the midline structures are preserved in the relatively small vertebrae of Japanese patients. Therefore, our surgical indication for this procedure is limited to discogenic disease with segmental instability or low grade spondylolisthesis.

PLIF with cages in aged patients with osteoporosis or with a long history of hemodialysis is very difficult because of fragile bone structures, therefore palliative partial laminectomy or additional instrumentation such as transpedicular screw fixation must be taken into consideration.