Complications, Pitfalls, and their management in a clinical practice setting

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Introduction

The Lumbar I/F Cage for PLIF had good results in its initial custom use (3) and was approved by the U.S. Food and Drug Administration in 1999 based on favorable results in a multi-center prospective study in which no surgeon performed more than a few dozen cases (5). Although statistical results are best determined through prospective studies, other lessons may be best learned after a few surgeons have had an opportunity to perform several hundred cases. The goal of this study is to determine results, complications, pitfalls, and guidelines that can be described when the Lumbar I/F Cage with pedicle screw fixation is used routinely in a clinical private practice setting in treatment of patients with disabling back pain secondary to degenerative disc disease.

Study group

The current study is a retrospective evaluation of the first 425 patients who have had surgery by a single group that originally included five orthopaedic spinal surgeons between February, 1999 and October 2003, when the group included three surgeons. The study was initiated in October, 2004 to assure that each patient had opportunity for a one-year follow-up. While one year is generally insufficient to determine surgical outcome on a statistical basis, it should be sufficient to identify pitfalls and complications.

Inclusion criteria included patients with disabling back pain due to degenerative disc disease at one or more lumbar levels and included patients with primary degenerative disc disease, failed discectomy, spondylolisthesis, failed fusion, and degenerative spondylolisthesis. Exclusion criteria included patients with infection of the spine; significant osteoporosis, metabolic bone disease or long-term steroid therapy, and those with a spinal malignancy.

All charts were reviewed and data placed on a computerized database by two experienced surgeons, one of who had not participated in the surgery (GF). Because the end-point of the study was the last recorded follow-up, patients were studied for variable intervals from one to four years. Many but not all x-rays were reviewed in this study. X-rays were reviewed for every patient having less than a good clinical outcome.

In two cases, the surgeon's interpretation of fusion success was reclassified as fusion failure in the database.

Demographic data were recorded including age, sex, compensation issues, neurological function, number of prior back surgeries, operated levels, operative difficulties, complications, re-operations, or revisions

Clinical evaluations included ratings of pain, function, economic status, and medication usage according to 5-point Likert scales used in the previous IDE study (5). The five-point Likert scales were added to create a 4 to 20 point modified Prolo score to define excellent (17 to 20 points), good (13 to 16 points), fair (9 to 12 points) and poor (4 to 8 points) consistent with previous literature and described fully in Chapter II.6.

Fusion success was defined as radiographic evidence of bone bridging the fusion area with no lucencies. If any lucency was seen extending across the disc interspace, the level was considered not fused. In multiple-level surgeries, all levels had to be fused in order for the patient to be considered a fusion success. Because the CFRP cages are radiolucent, bridging bone can be accurately assessed by plain radiographs.

Patients lost to follow-up

After the original review of 425 charts, one-year data was available on 327 patients (76.9%). Because 98 patients had been lost to follow-up, author GF supervised the office staff to contact these patients and obtain further information by telephone interview. The results are shown in Tables 1 and 2. Forty-seven patients were contacted and provided new information. Of these 47 patients, 26 (55.3%) were doing well and felt no need to return, and 7 (14.9%) failed to return because their surgery was unsuccessful and they were consulting other doctors. The computer database was updated to include the clinical information provided by telephone interview. Of the 31 patients sent to collection agencies, many had excellent early surgical results when last seen. If these patients were last seen less than a year post-operatively, their status was considered lost to follow-up. We are unaware of any other study determining the reasons that patients are lost to follow-up.

Clinical results

Over time additional information was obtained on several other patients, resulting in clinical follow-up of 373 of 425 or 88.2% of patients. In this group, clinical success was achieved in 292 of 357 (81.7%) and fusion success achieved in 333 of 353 (94.3%) of patients. Note that some patients had only clinical or fusion data but not both. These success statistics are consistent with numbers previously reported (1,2,3,5,14,20,22,26).

Extra bone graft

The surgical technique in Chapter IV.1. recommends placement of additional bone graft between and beside the cages whenever possible. Some surgeons recommend filling the anterior disc space with bone graft prior to placement of shorter cages (19) and some have used only local bone graft from the decompression (13,18). In the current series, all patients had surgery by a senior surgeon assisted by a second senior surgeon. The operations were performed on a co-surgeon basis in that each surgeon did the work on his respective side. Very few differences in technique or preference existed between the three principal surgeons, who will be referred to as surgeon #1, #2, and #3. All cages were filled with cancellous bone harvested through a small window in the iliac crest. One difference was that surgeon #1 did not wish to place additional bone in the disc space. He stated that placement of extra bone was "gilding the lily." In analyzing the data of the study we tried—but were unable—to prove that surgeon #1 had a lower fusion rate. Table 3 lists the clinical and fusion success rates of the three principal surgeons. Surgeon #1 appeared to have the highest fusion success rate. These differences may be real or may reflect a different intensity in identifying fusion failures.

If a very complete discectomy is done, the space is filled with blood after surgery. The side openings of the cages provide contact with bone graft, and the previously empty space becomes essentially a fracture hematoma. We have seen cases in which no extra bone was added, but on x-rays taken at two years show that the bone has extended to fill the entire disc space. We still believe that surgical principles require filling the entire disc space with as much bone as can be placed. However, if there is insufficient space, insufficient bone, or insufficient time available, the fusion rate is still satisfactory. We caution against multiple compromises of technique.

Complications

Complications in the 425 patients are summarized in Table 4 and compared with those reported in the IDE study in Table 5. There were 26 device-related complications, 13 involving the cage and 13 involving the pedicle screws. There were fewer broken pedicle screws in the current study (0.47%) than in IDE study (6.3%) and fewer loose screws in the current study (1.18%) than in the IDE (2.7%). All screws in the IDE were made of stainless steel. All screws in the current study were made of titanium. Overall, the number of screw complications trended lower in the current study. The current study confirmed the low rate of these complications reported in the original IDE studies.

Additional cage placement pitfalls were observed that deserve mention. In one patient cages were found to be undersized. Figure 1 shows a lateral x-ray of this patient. We believe that this problem was caused by incorrect identification of the disc space. Related to this problem, there were four cases referred to as false channel or malpositioned broach. Figure 2 shows a case in which the broach cut deeply into the vertebral endplates, resulting in pseudarthrosis. The appropriate technique to avoid this problem is illustrated in the technique chapter IV.1. A thin reamer or spreader is placed into the disc space and spread. If there is any question of the accuracy of the placement of this instrument, an x-ray should be taken to verify its position. The spreader is used to distract the disc space to normal disc height. “Working plates” are tightened down to hold the distraction. A round reamer prepares a round hole. The goal of reaming and broaching is merely to flatten the endplate, not to cut a deep channel. Therefore, for placement of an 11 mm cage, the disc space should be distracted to 11 mm. The 11 mm reamer should be used, followed by the 11 mm broaches.

The “guided broach” follows the round channel and makes it square. The “final broach” follows the previous channel and squares the bottom most portion of the channel. The final broach should be held with finger-tip force only and allowed to follow the previous channel. A “false channel” is created if the final broach is placed in a different direction than the guided broach, thus creating an excessively large channel that will predispose to a loose-fitting cage and pseudarthrosis. We recommend if there

is any question of the correct direction of the final broach that the final broach merely be omitted.

There were three cases of anterior placement of the cage. Figure 3 shows a lateral x-ray of one case. In most cases, the cage comes to a firm stop against the anterior anulus fibrosis. Obviously in Figure 3, the cage has penetrated through the anulus. Often the defect in the anulus is caused by stretching required for reduction of a spondylolisthesis. All three of our anterior placement problems occurred at L5-S1 and caused no adverse effect. If anterior cage displacement occurs at L4-5 or above, the surgeon should reposition the cage, often a difficult task. This may require a separate anterior approach to the spine.

In one case an anterior fracture of the vertebral body was observed (Figure 4). This occurred because the prepared channel was not sufficiently deep to contain the cage. When the surgeon hammered the cage deeper, it fractured the corner of the vertebral body. No adverse effect was noted during the healing process. We do not believe that any special precautions need to be taken post-operatively when this occurs.

In three cases the cages were classified as having migrated. Figure 5A and B show posterior migration of one cage, indicated by the position of the marker bead. This patient had four prior lumbar surgeries. He developed radicular pain approximately five months after his cage fusion. The cage was removed through a posterior exposure. Because there was very little motion, the pedicle screws were also removed. Figure 6A and B show x-rays six months later. Because flexion and extension films showed no motion, his surgeon classified him as fusion success. We have reclassified him as a locked pseudarthrosis and a fusion failure. On final follow-up he had very little back pain and no radicular pain and is considered a clinical success.

Figure 7 shows the final intra-operative x-ray of a patient treated for degenerative spondylolisthesis. The cages appear to be correctly positioned. Three months after surgery, there is a recurrent 14 mm slip In Figure 8. By five months after surgery, this slip had increased to 16 mm in Figure 9. Although the patient had no neurological

symptoms and only mild back pain, it was felt that the construct should be revised. The revision surgery was done entirely posteriorly. The pedicle screws at L4 were found to be loose due to osteoporosis. The cages were removed, the alignment restored, larger cages were placed, larger screws were placed at L4, and a second point of proximal fixation was gained at L3. A final x-ray is shown in Figure 10. The patient had no further displacement over time. Her primary surgeon interpreted her final x-rays as showing fusion; however, the authors reviewed this patient's films and listed her result in the database as pseudarthrosis.

Of the 13 patients with cage problems, ten went on to normal fusion success. Three were counted as fusion failures. One case resulted in a definite pseudarthrosis, one as a locked pseudarthrosis, and in one the fusion was uncertain and therefore counted as a fusion failure.

The patient with a malpositioned screw had degenerative disc disease at L4-5 and L5-S1 with left-sided radiculopathy. He had no prior surgery. He awoke with severe right-sided radiculopathy with no motor weakness and no left leg pain. He did not respond to steroid therapy. Three months after surgery, a CT scan in Figure 11 showed that the L5 screw on the right side penetrated the lateral wall of the vertebral body in an area close to a nerve root anteriorly. Injection of local anesthetic with contrast in Figure 12 relieved the radicular pain. Further surgery was done immediately to remove the offending screw. His final clinical result was unsatisfactory. He could sit at work most of the day without undue discomfort, but he had marked radicular pain with all activities. We believe that an MRI and CT scan should be done immediately post-operatively when a patient experiences new radicular pain after surgery. This was the only nerve root injury we encountered in the 425 cases in this study.

Blood loss and surgical time

It became immediately apparent that surgical times and blood loss numbers were considerably less in this clinical study as compared with the IDE study. In the IDE (5), the average patient had two prior failed surgeries at two levels. Average blood loss in

the IDE group was 1577 ml and average surgical time 297 minutes. In the first 60 patients in this clinical practice group (25), average blood loss for primary procedures was 269 ml for one level and 569 ml for two level fusions. In patients with prior surgery, average blood loss was 378 ml for one level and 470 ml for two level procedures. Average surgical time in the IDE study was 297 minutes. In this clinical group, average surgical time for primary cases was 202 minutes for one level and 251 minutes for two level procedures. In patients with prior surgery, average surgical time was 208 minutes for one level and 251 minutes for two level operations. In our cases, we always had two senior surgeons participate in each surgery, and we believe there is considerable time saving as compared with a senior surgeon working with a resident or fellow. In more recent cases, our surgical time for one-level primary cases is routinely under 120 minutes.

In the IDE study (5), there was no effort to limit patients' use of non-steroidal anti-inflammatory (NSAID) medications prior to surgery. In this series, we required patients to avoid traditional NSAID medications for four weeks prior to surgery. We restrict NSAID use longer than Dr. Stowell recommends in Chapter I.8. COX-2 inhibitors cause no difficulties in this regard.(reference?) Although it may be anedcotal opinion, we have found that patients who had unexpectedly high surgical blood loss were found to be taking unreported NSAID medications. In addition, we have made a conscious technical effort to control blood loss at every step of the surgery. We believe that time spent on hemostasis lowers blood loss, allows more precise implant placement, and lowers total surgical time.

In the IDE study, one surgeon routinely had blood loss figures double the average for the other surgeons. He had two cases in which the blood loss exceeded 10,000 ml and two intra-operative deaths. When a high level of blood loss is tolerated for a lengthy period of time, the bleeding may suddenly accelerate to an alarming rate due to intravascular coagulopathy. Surgeons should be knowledgeable of the principles of transfusion management summarized in Chapter I.8.

A number of products are available for use in controlling bleeding during spinal surgery. Although most surgeons have working experience with these products, many are unaware of important details in their package inserts.

Gelfoam sponge (Pharmacia & Upjohn) is a medical device intended for application to bleeding surfaces as a hemostatic agent. It is a water-insoluble, off-white, pliable product prepared from purified pork skin gelatin and water. Gelfoam powder is prepared by milling absorbable Gelfoam sponge. The mode of action of Gelfoam in controlling bleeding is mostly mechanical. Gelfoam is usually completely absorbed within four to six weeks. Gelfoam can be used dry or saturated with sterile saline. Although most surgeons saturate Gelfoam with topical thrombin, the efficacy of this combination has not been tested by the manufacturer, and the package insert states that this use “cannot be recommended.” Gelfoam also may swell on absorbing fluids, and therefore should be removed after use in laminectomy procedures. The manufacturer states, “When Gelfoam was used in laminectomy operations, multliple neurologic events were reported, including but not limited to cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.” (Pharmacia & Upjohn). Although many surgeons use a sheet of Gelfoam on top of the dura as a protective barrier during wound closure, it is probably important to avoid using leaving this product in tight bony spaces such as the spinal canal.

Bone wax (Ceremed, Inc.) is composed of 80% refined white beeswax and 20% isopropyl palmitate. Bone wax achieves local hemostasis of bone by acting as a mechanical barrier. Although it is an absorbable material, it is thought to increase the risk of infection and to persist at the bony site for years (15). It should be used sparingly, and excess material should be removed from the surgical site.

Avitene (Davol, Inc) is a microfibrillar collagen hemostat used to control blood loss when hemostasis by ligature or other conventional procedures is ineffective or impractical. Avitene is provided in a powder, in sheets and as a collagen sponge called

Ultrafoam. In a study of bleeding from knife incisions in pig spleens, the manufacturer demonstrated that Ultrafoam without thrombin performed as well as Gelfoam with thrombin. They claimed that the advantage was avoiding use of bovine thrombin and the possibility of forming antibodies to bovine thrombin that could precipitate factor V deficiency and abnormalities of hemostasis on re-exposure.

Surgicel (Ethicon, Johnson & Johnson) is an oxidized regenerated cellulose in a shear weave. Plant based, it has no animal or human components. Surgicel conforms but does not adhere to irregular surfaces. When saturated with blood, it rapidly swells into a gelatinous mass. Surgicel achieves hemostatsis because its low pH denatures albumin and globulin. It is usually absorbed without tissue reaction. The manufacturer recommends that Surgicel be removed following use in the spine. There have been at least six reports of paraplegia due to Surgicel related thoracic cord compression (7).

Floseal (Baxter Healthcare) is an absorbable hemostatic agent packaged as a kit containing an engineered bovine collagen-derived gelatin matrix component and a thrombin component. A proprietary dispersion needle is used to mix the components during use. The mixed matrix conforms to irregular bleeding surfaces and swells approximately 20% upon contact with blood or fluids. Floseal is hydrophilic and adheres to wet tissue. The particulate nature allows excess material not incorporated into the clot to be removed by gentle irrigation without disturbing the hemostatic seal. Surgeons should be aware that because of the swelling of the gelatin matrix, Floseal is not indicated for use in neurosurgical procedures. It is, however, very effective in stopping bleeding from epidural vessels made troublesome by traditional NSAID's.

Tisseel VH Fibrin Sealant (Baxter Healthcare) is made by mixing two components, delivered through a proprietary dual dispersion needle: a concentrated fibrinogen with aprotinin, and thrombin with calcium chloride. Tisseel forms a solid coagulum within three to five minutes of delivery, and reproduces the last stages of natural hemostasis, converting fibrinogen to fibrin strands, creating watertight seals. Tisseel components are derived from human plasma and bovine-derived aprotinin.

Tisseel is widely used after durotomy repair in spinal surgery to create a watertight seal. Most surgeons believe that following dural repair with Tisseel, patients can be ambulated on a normal schedule and do not need three days of bedrest, often recommended after dural repair without Tisseel.

Further surgery

The U.S. Food and Drug Administration routinely divides further surgery into three categories: re-operation, revision, and removal surgeries. Re-operation is defined as a surgical procedure in which the devices were not altered or reconfigured. Revision is defined as surgery where the devices were reconfigured, extended or replaced, but some original elements remain. Removal is when the cages or pedicle screw devices were removed. Further surgeries in this series are summarized in Table 6. Overall, 130 patients (30.6%) had 154 further operations on their lumbar spine.

Re-operations

Epidural hematoma: One patient experienced an epidural hematoma. In this patient, neurological function was normal immediately after surgery; however, he developed progressive lower extremity weakness within the first 24 hours after surgery. An MRI scan done the morning following surgery documented the hematoma. His hemovac drain appeared to be functioning normally. He had immediate surgery that day to drain the hematoma. The compression was found in an area walled off from the drain. Neurologic function improved quickly, and he regained full strength within a few weeks of the initial procedure. The importance of doing immediate imaging studies in the presence of any new radicular pain or neurologic abnormality cannot be over stressed.

Repair CSF leak: Table 7 lists re-operations by the three individual surgeons who did the vast majority of surgeries in this study. Surgeon #1 did five of six re-operations to repair CSF leaks. Our group wrote a report of six cases of post-op CSF leak associated with use of ADCON-L (Gliatech, Inc., Cleveland, OH), an anti-adhesive agent. This report was rejected for publication, but a later series of four cases was

published (18), and ADCON-L was subsequently withdrawn from the market. The cases associated with ADCON-L were all done between August and October, 1998. These were additional cases. Since the group began the routine use of Tisseel for any dural repairs, this complication has occurred in one case.

Surgeon #1 had a higher percentage of patients who had prior lumbar surgery and perineural scar formation. We agree with Wang and Bohlman (25) and Cammisa (6) that dural tears are a routine part of lumbar spine surgery and generally have no long-term deleterious effect. Although re-operation is inconvenient to everyone, none of these patients had any long-term adverse effect. These dural tears all occurred during dissection of scar and not during broaching or cage placement. Scaluto (23) reported in 2003 that placement of cylindrical cages through a PLIF approach had a 52% rate of dural tears, often at the root axilla with a 20% rate of post-operative weakness or radiculopathy. This did not occur in this series because less nerve root retraction is required for placement of rectangular CFRP cages and because full nerve root mobility was achieved before any PLIF steps were initiated.

Treatment of infection: Although Surgeon #1 had all six infections, he had a slightly lower overall re-operation rate than average for the study. Five of six infection cases occurred within a three month period in 2002. These infections involved three different hospitals and different organisms. Although surgeon #1 had all the infection cases, he was assisted by surgeons #2 and #3 in every case, and surgeons #2 and #3 both had surgical infections in non-cage cases during that time interval. In spite of intensive search, a cause was never found, and the infections quickly stopped. The overall infection rate of 1.56% is lower than that experienced in the initial IDE study and within an acceptable range. We routinely used intravenous first generation cephalosporin pre-operatively and for twenty-four hours after surgery. Factors associated with increased infection include prolonged surgical time, multiple previous surgeries, a draining wound, and chronic infections in the bladder, teeth or other areas.

We recommend that a hemovac-type drain be used in all cases. Although post-operative bleeding can usually escape through the edges of the incision, the lack of a functioning drain is associated with increased risk of epidural hematoma, chronic drainage, and increased infection risk.

In the presence of a chronic draining wound or suspected infection, the patient should be returned to the operating room, the wound opened and irrigated thoroughly, and antibiotic therapy initiated based on initial empiric selection modified later by culture results. If the implants are stable they should be left in place. We recommend that the wound be closed over hemovac drains and the patient be returned to surgery every three days until the wound is clean and cultures are sterile. If the wound is initially packed open, it may not be possible to obtain primary closure when the infection is controlled. If the infection requires open packing, it is possible to obtain secondary closure using a interconnected latissimus dorsi-gluteus maxiumus muscular cutaneous flap (11).

Revisions

Revision of cages or pedicle screws: Cage revision cases were described earlier. In an additional case, a patient who had had an L4-5 BAK fusion had been revised with bilateral pedicle screws and posterolateral fusion from L3 thru S1 with carbon cage fusion at L5-S1. He later had an anterior procedure to remove the BAK cages and replace them with a stackable CFRP cage. This case is discussed in Chapter III.2 under evaluation and revision of failed fusion cages.

Extend fusion: Further surgery was done to extend the fusion in 40 patients who had adjacent segment degeneration. A number of authors have addressed the problem of adjacent segment degeneration (12,13,16,17,19,24). In 1988 Lee (19) predicted that application of a rigid internal fixation system produced greater stress concentration in the adjacent segment. Kumar (16) studied 28 fusion patients and a matched group of 28 non-fusion lumbar surgical patients for a minimum of 20 years. The incidence of radiographic changes in the adjacent segment was twice as high in the fusion group as the non-fusion group; however, there were no statistically significant differences between the two groups in outcome measures. Lai (17) studied 101 pedicle screw fusion patients and found that those with preserved posterior complex integrity between the fused segment and the adjacent segment developed instability in 6.5% versus 24.3% without preserved posterior complex integrity. Schlegel (24) studied 58 lumbar fusion patients who had an average symptom-free interval of 13.1 years. At the point of study, these patients developed recurrent severe symptoms. Schlegel found that

segments adjacent to the adjacent segment were as likely to break down as the adjacent segments. Hambly (13) agreed that degenerative changes occurred in the second level above the fused levels with frequency equal to those occurring in the first level. Ghiselli (12) studied 215 patients who had undergone posterior lumbar fusion an average of 6.7 years earlier and reported that the rate of symptomatic adjacent segment degeneration warranting further surgery appeared to be 16.5% at 5 years and 36.1% at ten years. Our previous report of the 10-year results of patients treated with the Lumbar I/F Cage in the IDE study (1) indicated that 61% of patients had radiographic changes in the adjacent segment, but the changes were clinically significant in only 20%. Of these 15% had undergone adjacent procedures and the other patient was contemplating surgery.

In the current group, 9.4% of the group as a whole underwent adjacent segment fusion procedures with variable intervals of follow-up from one to five years. We recommend that the upper 30% of the lamina be preserved along with the ligamentous structures whenever possible, with the exception that a full laminectomy should be done if it is necessary to decompress or protect the exiting nerve root. When a portion of the lamina and the posterior ligamentous complex are preserved, a subsequent fusion surgery can often be done through an interspace having normal tissue with little difficulty from previous scar. It is our impression that patients who have had good initial results following cage fusion can again achieve good results following adjacent segment procedures. Too few of our patients have sufficient follow-up following the second cage procedure to evaluate this concept statistically.

Removals:

Pedicle screws and plates were removed in 83 of 425 patients (19.5%). This is a lower rate than experienced in the IDE study, in which pedicle screws were removed in 35.2% of patients. Indications for removal of pedicle screws are further discussed in Chapter III.2. discussing evaluation and treatment of failed cages. We believe that it is difficult to determine when pedicle screws are a source of pain. Certainly, if a screw is loose, it may be painful. Attempts to do a diagnostic injection to block the pain may fail to deliver the anesthetic agent to the painful screw tract; therefore, a negative injection study may not be meaningful. When pedicle screws are removed, we recommend that

the midline incision be opened to the fascial level and skin flaps developed on both sides. We recommend that bilateral fascial incision be made about 4 centimeters lateral to midline and Wiltse-type muscle splitting approaches be used to remove the screws and plates. This approach is less traumatic than opening the midline exposure, which may be required if a cross-connector was used. The procedure routinely takes less than an hour, the patient requires only a one-night stay, and he can usually return to full activities in a week or two. The only problem with this approach is that it creates a potential pocket of dead-space above the fascia that can accumulate fluid. The one patient having a reoperation for seroma had continuous re-accumulation of fluid for three months from this source. Tisseel is useful for sealing the pocket should this problem occur.

Decompression at unfused levels: Art Steffee repeatedly warned that surgeons should never end a fusion at a decompressed vertebral level. Whenever a decompression is needed above a fusion, that level should also be included in the instrumentation and fusion. Certainly this recommendation makes intuitive sense. If removing the posterior ligament complex above the fusion results in higher adjacent segment failure as Lai has observed (16), then more extensive destabilization should also result in more frequent mechanical failure of the segment.

Surgeons #1 and #2 rejected Steffee's advice. Surgeon #1 did decompression above fusions in 11 cases, and Surgeon #2 did 20 cases. Of these 31 patients, 26 were available for follow-up. Clinical success in this subset was achieved in 19 of 26 (73%). When these results are compared with the study group as a whole using the chisquare statistic, clinical success rates were not statistically different (chisquare = 1.19, p=0.275). Further surgery was done in 12 of the 26 patients with adjacent decompressions (46.1%). When these results are compared with the study group as a whole using the chisquare statistic, a statistical difference is approached (chisquare = 2.60, p=0.10). Surgery to extend the fusion to the decompressed level was done in 6 patients (23%). (John, what further surgery did the other 6/12 have?) When these numbers are compared with the study group as a whole, statistical significance is reached (chisquare = 3.89, p=0.485). Therefore, Steffee's recommendation is confirmed by this study group: do not end a fusion at a level of decompression.

L1-2 fusion

The Brantigan I/F Cage was approved by the U.S. Food and Drug Administration in February, 1999, to treat degenerative disc disease at one or two levels between L2 and the sacrum when two cages are accompanied by bilateral pedicle screw stabilization. L1-2 was excluded from the IDE study because fusion at this level is rarely required, and statistical comparisons are not available. However, occasionally lumbar fusion may be indicated at the L1-2 level because of adjacent segment degeneration following fusion to L2, major disc herniation with degeneration, failed previous laminectomy or discectomy, degenerative lumbar spondylosis, or other causes.

Twelve patients were identified of the study group who had cage fusion at L1-2 (8). In four cases, the indication was degeneration above a long fusion. In four cases the adjacent segments had not been previously fused. Because of increased risk of neurological injury to the conus medularis, the surgical procedure was modified. The entire pars interarticularis and inferior articular processes were removed bilaterally and cages were placed through a transforaminal lumbar interbody fusion approach (TLIF). Seven patients achieved clinical success (59%). Clinical results included no excellent, two good, 5 fair and 5 poor results by the modified Prolo scale reported previously (5) in Chapter II.6. Fusion was also successful in seven cases and failed in five.

Figure 13A and B shows x-rays of a patient who had undergone an L1-2 cage fusion several months earlier. The position of the implants appears satisfactory. There is 1-degree of measured kyphosis. Figure 14 shows a lateral film taken 12/29/03. The kyphosis has increased to 10-degrees. The kyphosis increased to 12-degrees in Figure 15 on 3/11/04, to 14-degrees in Figure 16 on 5/6/04, to 14-degrees in Figure 17 on 7/19/04, and to 17-degrees in Figure 18 on 9/20/04. The kyphosis increased in spite of use of a well-fitted TLSO brace. The patient deferred revision surgery in the hope that the fusion would stabilize. Revision surgery was further delayed by her workers compensation carrier.

Deformity and trauma surgeons have long recommended that a fusion should not end at L1 because of an excessively high rate of mechanical stress and failure at the thoracolumbar junction. Instead, two thoracic levels should be included in the instrumentation and fusion. We had expected that the extra stability afforded by

anterior cage placement with pedicle screw fixation would compensate for the added stresses at the this level. This expectation was not realized. The failures were not limited to patients having a long fusion ending at L1. Of the four patients having L1-2 fused with non-fused adjacent segments, two patients had frank failures and a third had to be revised because of loose pedicle screws.

Hashimoto and associates report in Chapter II.10 their favorable experience with anterior one-level fusion at the thoracolumbar junction, which appears to be much more successful. The anterior procedure may be more successful because it avoids removing the stabilizing posterior elements. In any case, it must be noted that CFRP cage fusion with pedicle screw fixation done through a traditional posterior approach has a higher than expected rate of clinical and fusion failure.

Use of single-cage PLIF

All mechanical testing of the CFRP cages assumed use of bilateral cage placement and bilateral pedicle screw fixation. The company is required to state that data do not exist to justify the use of a single cage component or unilateral pedicle screw fixation. Figure 19 shows an AP x-ray of a case done elsewhere in which the surgeon placed only a single cage at L5-S1 because the nerve root scarring from prior surgery made safe placement of a second cage questionable. Figure 20 shows a CT image. Of course, this is the correct intra-operative decision, as a second cage can be placed through an anterior approach later if required. There is clear failure of fusion through this single cage. The surgeon failed to pack extra bone around the cage, and this was not a correct decision.

Molinari reported a study in which 19 active-duty military personnel were treated with two CFRP cages and 16 treated with a single cage (22). When only a single cage was used, bone graft was inserted from a bilateral approach. Molinari reported that the results were generally good, and that patients having a single cage had equal fusion and clinical success as those having two cages.

Some patients may require a single cage fusion because of circumstances found at the time of surgery. The indications may include not enough space for a second cage (because a first cage was placed in the midline), failed previous discectomy with nerve root scarring, and conjoined nerve roots or other root anomalies preventing safe

root retraction. Also, when a three or four-level interbody fusion is done, a surgeon may prefer to use single cages at some levels to save time and blood loss. Figure 21A and B show x-rays of a case in which the first cage was placed in the midline and there was insufficient space for a second cage. This case had copious extra bone grafting and resulted in a solid fusion and clinical success.

In the current study group 31 patients were identified who had PLIF with a single Lumbar I/F Cage and VSP in at least one fusion level (9). Twenty-six of these patients had clinical success. Fusion was successful in 30 patients (97%). The single failed fusion occurred at L1-2, a level that has been recognized as an independent risk factor for failed fusion. We emphasize that when a fusion is done with a single cage, it is particularly important for the surgeon to pack additional bone in the disc space around the cage.

Use of 9 mm cages

When the Lumbar I/F Cage was first designed, the optimal dimensions were unknown. It appeared that the average width that would allow bilateral cages to be placed was 11 mm. Possible failure modes included subsidence into the vertebral bodies (which argued for maximal width of the struts) and fusion failure (which argued for maximal width of the opening for bone graft surface area). In the design of the 11 mm cage prototypes tested mechanically in cadaver spines (4) the two concerns were given equal weight: the opening was 5.5 mm wide and the strut width was 5.5 mm (or 2.75 mm each). This design performed well in cadaver spines and bore physiologic loads without subsidence.

In the design of larger and smaller cage sizes, the width of the struts was retained at 2.75 mm because of the concern for subsidence if the support area had been reduced. Thus the cage 9 mm in width has an opening for bone graft of 3.5 mm wide, proportionately 18% narrower overall than the 11 mm cage but 36% smaller in surface area for bone graft. The 9 mm cage has a bone surface area 54% less than the 13 mm cage. Because bone healing was potentially compromised with the 9 mm wide cages by the proportionally greater reduction in bone graft surface area, it is clinically important to study the clinical and fusion success of these narrow cages.

Patients may require a 9 mm wide cage because of circumstances found at the time of surgery. The indications may include not enough space for a larger width or height cage in the disc space, nerve root anomalies that may limit access to the disc space, and limited ability to retract nerve roots due to epidural scarring.

In the current study, 115 patients were identified who had PLIF at one or more levels using one or two 9 mm wide cages (10). In this group, clinical success was achieved in 93 patients (81%) and fusion success in 113 (98%). Both of the failed fusions were at L1-2, previously noted as an independent risk factor for fusion failure. Thus, concern about 9 mm cages is unwarranted.

Fusion below long scoliosis fusions

Traditional deformity surgery with Harrington rod instrumentation often included fusions from T4 to L4. These procedures done decades ago frequently result in flatback deformities and degeneration below the fusion. Figure 22A and B show AP and lateral x-rays of such a case, with symptomatic degenerative change at L4-5 below the fusion. This case was treated with a wedged Lumbar I/F Cage (2) as shown in Figure 23A and B. The old rod can be removed, but this can be an extensive procedure if the rod is completely covered with bone. In this case, the old rod was linked to the new construct. We had eight such procedures in this series. Three were lost to follow-up. Four of five were clinically successful and achieved fusion. Attempting to fuse L5-S1 when it is the only unfused lumbar segment has a lower success rate.

Surgeon #3 had eight of twelve cases at L1-2 and a fusion failure at L5-S1 below a previous long fusion, likely accounting for the apparent difference in fusion success.

Conclusions

Interbody lumbar fusion with CFRP cages and pedicle screw fixation is a significant operation that must be done with precise and careful technique. Significant complications can occur and may result in unfortunately poor clinical outcomes. Study of this large clinical series of 425 patients allows the following conclusions:

1. Satisfactory clinical and fusion results were achieved when the Lumbar I/F Cage with pedicle screw fixation was used in a large clinical series.

2. Guidelines have been presented to facilitate accurate cage placement and to minimize complications.

3. While dural tears were common, they had no long-term significance.

4. Only one patient of 425 experienced nerve root injury in spite of 138 patients having scarring from prior lumbar surgery.

5. Surgeons should not end a fusion at a level of decompression.

6. Cage fusion with pedicle screw fixation has a higher than expected failure rate at L1-2.

7. Interbody fusion using cancellous bone packed inside the cages without additional bone appears to have satisfactory fusion success.

8. Interbody fusion with single CFRP rectangular cages appears to have satisfactory fusion success if additional bone graft is packed around the cage filling the disc space.

9. Narrower 9 mm cages have equal clinical and fusion success as larger cages; however, the larger cages should be used whenever possible.

Legends

Figure 1: In this case, cages were undersized due to failure to accurately locate the disc space.

Figure 2: Broaches cut deeply into the L5 and S1 bone creating a “false channel” and an improper fit.

Figure 3: One cage was placed through the anterior annulus. If this occurred at higher levels, it should be removed through an anterior approach, if necessary, to avoid damage to the great vessels.

Figure 4: The anterior lip of L5 was fractured due to an attempt to drive the cage deeper than the prepared channel.

Figure 5: A. AP, and B. lateral view of case in which the cage retropulsed.

Figure 6: A. AP and B. lateral view after the retropulsed cage was removed. Because the segment was stable, the pedicle screws and plates were also removed. This result is felt to be a “locked pseudarthrosis.”

Figure 7: Final intra-operative view of patient with osteoporosis.

Figure 8: Three months after surgery, there was 14 mm recurrent forward slip.

Figure 9: At five months after surgery, the slip increased to 16 mm.

Figure 10: After a posterior revision, the alignment was restored.

Figure 11: The L5 screw penetrated the lateral wall of the vertebral body and caused irritation of a nerve root anteriorly.

Figure 12: After the screw tip was injected with contrast and Marcaine, the pain was temporarily blocked. Because of this, the screw was removed.

Figure 13: A. AP and B. lateral views after surgery at L1-2. There is one degree of kyphosis.

Figure 14: Ten months later, the kyphosis had increased to ten degrees.

Figure 15: Twelve months later, the kyphosis had increased to twelve degrees.

Figure 16: Kyphosis increased to fourteen degrees.

Figure 17: The kyphosis seemed to stabilize at fourteen degrees with use of a rigid TLSO.

Figure 18: The kyphosis increased to seventeen degrees. This patient required revision.

Figure 19: Use of a single cage without extra bone graft resulted in fusion failure.

Figure 20: Coronal CT demonstrates the failed fusion at L5-S1.

Figure 21: A. AP and B. lateral views of single cage case in which extra bone was placed. This resulted in solid fusion.

Figure 22: A. AP and B. lateral view of T4 to L4 Harrington rod case resulted in symptomatic degenerative changes at L4-5.

Figure 23: A. AP and B. lateral view of successful revision using wedged carbon cages.

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