Spinal Restabilization Procedures
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CHAPTER 18

Anterior cervical interbody fusion using PEKEKK composite cages

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1. INTRODUCTION

The anterior surgical approach to the cervical spine has proven to be safe and successful [1–5] for disorders such as cervical osteochondrosis and intervertebral disc herniation, and has gained wide acceptance since its introduction in the 1950s [6,7]. The primary advantage of this procedure is that it allows a direct approach to the pathology without necessitating manipulation of the underlying neural structures.

Bony non-union rates for single-level decompression and fusion vary from 3 to 20% and generally increase with the number of surgical levels operated upon [3,8–12], although we have found the contrary to be true in our practice [13]. A successful fusion depends upon the osteoinductive capacity and mechanical strength of the interbody bone graft. Autograft material is reported in the literature to increase the number of successful fusion outcomes, but its application can result in varying degrees and types of donor site morbidity [14]. The use of allograft material obviates donor site complications, but unfortunately most of the osteoinductive proteins are largely removed during allograft preparation and sterilization [14]. In addition, graft collapse was reported to be higher with the use of freeze-dried allografts (30%) than with the use of autograft material (5%) [15].

Graft extrusion is a complication seen with both autografts and allografts [16,17]. To prevent the occurrence of graft collapse and/or extrusion, and to provide immediate postoperative stability, anterior cervical plating has been used in conjunction with the graft materials. However, it can be the cause of complications including esophageal perforation and hardware failure [18–22]. Despite the numerous choices available for the surgical application of anterior interbody fusion, the need exists for a reliable device that will provide structural integrity, while at the same time allowing the fusion process to proceed optimally.

The purpose of developing cervical interbody cages was to separate the dual mechanical and biological requirements of interbody fusion and thereby provide an ideal environment for bony fusion. This study presents the prospective results of the use of a composite cervical cage (GII™, Co-Ligne, Zurich, Switzerland) for the treatment of degenerative cervical disc disease.

2. MATERIALS AND METHODS

2.1. The implant

The Co-Ligne cervical GII™ cages (Figure 1) are available in numerous sizes. Cage heights of 5 mm, 6 mm and 7 mm are available, with no inherent lordotic angulation, while cages with an approximately 5° lordotic arc are available with anterior heights ranging from 6 mm to 10 mm. Cage lengths and widths are supplied in combinations of 12 mm and 15 mm.

The cages are made from the material Osta-Pek™, which is a carbon fiber reinforced polymer (PEKEKK). Biocompatibility testing has shown this

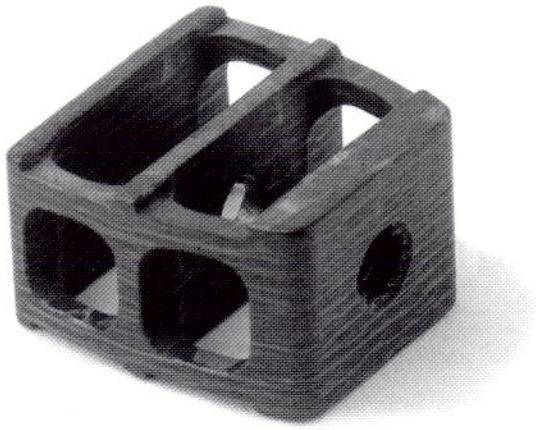

Figure 1. ACIF cage in Osta-Pek.

material to be appropriate for physiologic spinal use [23,24]. The design has been dynamically tested at a 778 N load level to 5,000,000 cycles without failure.

2.2. ACIF operative technique

The patient is positioned in the dorsal decubitus position with head support and with head rotation 15° to the right; the shoulder should rest on a soft fabric block. Traction to the shoulders may be used when surgery is performed on the lower cervical spine. The type and length of skin incision depends upon the number of levels to be treated. For one- and two-level surgeries, a transverse incision is often sufficient, but for most three-level surgery and greater, a slightly oblique incision anterior to the sternocleidomastoid muscle is used.

Fluoroscopy is used to confirm the operative level(s), and dissection of the subcutaneous tissue is performed using electrocautery. The muscles are split and moved towards the midline with blunt retractors, while the vascular structures are moved slightly to the side. Vessels from Faraboeuf's common trunk of the primitive carotid artery are sectioned after ligation. When the cervical approach is low and the omohyoid muscle cannot be retracted, stop sutures are placed around this muscle and it is sectioned. These sectioned ends will be connected end-to-end in the final phases of the operation.

Subsequent dissection is made using a mounted swab to reveal the longus colli muscle. The operative location can be ascertained using a blunt metallic point combined with fluoroscopic confirmation. A central opening is made in the longus colli and the edges of the incision are split to expose the anterior aspect of the cervical vertebrae.

Once the vertebral bodies are exposed, a Caspar style retractor screw is inserted into the vertebral bodies above and below the segments to be fused. The retractor screw length is chosen to assure that the tip does not extend beyond the posterior wall of the vertebra and thus into the central spinal canal. This position is also verified under fluoroscopy.

The anterior longitudinal ligament is incised and cervical disc excision is then performed. The vertebral endplates are prepared using a curette or burr to expose the subchondral bone underlying the vertebral endplates(s). This will insure a good blood source presence for the autologous bone graft material that is subsequently placed within the cage device. Using a Caspar style retractor, the intersegmental disc space is distracted and the related spinal ligaments are placed in tension. If necessary, herniated disc tissue and posterior osteophytes are removed and/or a foraminotomy performed at this time. Based upon the patient's clinical needs for canal revision, the posterior longitudinal ligament can be incised and, if so, any extruded herniated material is removed using a curette or burr.

Some surgeons will use only a left-handed approach, regardless of the level to be fused, because of the risk of recurrent laryngeal nerve damage. The authors believe that this can be reliably avoided providing that a thorough access preparation has been made. The two most important concerns are the exposure and median opening of the longus colli muscle over the segment(s) to be fused and careful positioning of the retractor blades under the muscles. In doing so, the visceral mass containing the recurrent laryngeal nerve and esophagus are moved medially and the carotid artery with its sympathetic fibers are moved laterally out of harm's way. This procedure also obviates the need of worrying about the cervical vessels. Ligation and sectioning of a thyroid artery are rarely necessary.

Cages are selected according to the height of the interbody or disc space once in distraction. The ideal position of the chosen cage is first checked using a trial implant. The most important factor in determining cage size is the stability achieved after release of the distraction provided by the Caspar style retractor. When the appropriate height and width have been established, a cage corresponding to this size is filled with cancellous autologous bone from a prepared iliac crest donor site. Depending on the number of spinal segments to be fused, 2–4 cm^3 of cancellous

bone will typically be needed to fill the cage(s). The iliac crest donor site is then infiltrated with anesthetic and adrenaline prior to closure in order to reduce the occurrence of immediate postoperative graft site pain.

Before final impaction of the cage into the disc space, the epidural space is checked by injection of a contrast agent through a curved cannula with lateral radiography or fluoroscopy; any debris and roughness on the adjacent segments can be detected in this way and can then be removed. The interbody space remains filled with the contrast agent, so the depth of the cage can be measured indirectly from the radiographs.

While still anesthetized, the patient is fitted with a flexible cervical brace. This is placed more to remind the patient of the need for self-restraint than for actual external stabilization. The patient remains in intensive care during the first postoperative hours. As with all cervical spine fusions, postoperative respiratory or neurological complications can be encountered. They must be treated immediately in the usual fashion.

Patients are authorized to effect limited mobilization next to their bed on the evening following their intervention. Complete mobilization under physiotherapeutic monitoring is then scheduled for the following day. After 2 or 3 postoperative days, radiographs are taken to check and record the position(s) of the cage(s) and the vertebral body alignment. The patient is normally discharged on the 5th day; the sutures (or skin clips) having been removed.

Patients are required to wear the flexible cervical brace day and night for 6 weeks, and not to start physiotherapy before the 3rd or 4th week following surgery. The first clinical and radiographic follow-up takes place at 6 weeks postoperatively, and subsequent follow-ups are scheduled in accordance with the multicenter protocol (e.g., 3, 6, 9 months, etc.). The patients are considered convalescent until the 6-week timepoint. More rigorous mobilization exercises should begin only when proof of ossification has been obtained radiographically.

3. RESULTS

3.1. Data collection and analysis

A multicenter database has been used for over 13 years to record patient outcome after interbody fusion using this technique. Four case report forms are used to document patient demographics, primary and secondary diagnoses, operative details, complications, fusion status, medication usage and so on. Five-point scales are used to document neck pain, arm pain, neurologic status, and patient function at pre- and postoperative timepoints. Table 1 lists the possible scores and corresponding definitions for the endpoints. Note that each of the five endpoints is scored separately for a single patient at a single timepoint. For example, a patient at the preoperative visit may have a neck pain score of 1 (severe), an arm pain score of 2 (moderate), a neurologic score of 3 (sensory deficit), a working capacity score of 2 (50%) and a level of independence score of 2 (house work).

There have been 204 cervical patients enrolled in the database to date. Of these, 106 are prospectively enrolled patients with a minimum follow-up of 6 months. A review of the primary diagnoses for this group revealed that 99 (93%) had a degenerative condition requiring surgery, while the remainder had either congenital, postsurgical revisionary or traumatic indications. Of the 99 degenerative patients, 36 had a one-level fusion (1LF) and 56 had a two-level fusion (2LF); these patients are the subject of this article. Paired Student *t*-tests were used to compare pre- and postoperative patient endpoint means determinations, and ANOVA were used to compare endpoint improvements between groups.

Table 1

Definitions for the 5-point scales used pre- and postoperatively to evaluate patient outcome

Score	Neck and arm pain	Neurologic	Working capacity (%)	Level of independence
0	Intolerable	Muscle function 0	0	Immobile
1	Severe	Muscle function 1–2	25	Dressing
2	Moderate	Muscle function 3–4	50	House work
3	Mild	Sensory deficit	75	Light work
4	None	Normal	100	Heavy work

3.2. Outcomes

All patients were enrolled prospectively and had a minimum 6-month follow-up. The patient demographic and operative data are listed in Table 2. No autologous or banked blood products were used during any of the surgical procedures, and there were no operative or implant complications in either group. In the results below, the determination of the presence or absence of radiographic fusion was made by the operating surgeon at each follow-up timepoint, and was based upon the presence of a continuous trabecular bony structure with no associated radiolucencies vertically through the cage, together with the observation of bone quality within the cage that matched that within the adjacent vertebral bodies. When the anterior disc space height was greater than the posterior height, the level was considered lordotic. Alignment was determined to be good when the posterior walls of C_2 through C_7 formed a smooth, continuous arc on radiographs. Postoperative disc height correction was determined by comparing the postoperative disc height of the operative and the adjacent intersegmental levels. A partial correction indicated that the adjacent disc height was greater than that restored at the operative level, while a complete correction indicated that the two were the same. Loss of correction was determined when there was a loss of greater than 1 mm in the restored disc space height as compared to immediate postoperative radiographs, and when there was a measurable, progressive loss of cervical lordosis.

Table 2
Patient demographics and operative data

	One-level	Two-level
Patients:		
Total	36	56
Male, female	17, 19	19, 37
Mean follow-up:		
Days	488	674
Years	1.3	1.8
Age (years):		
Mean	51.0	55.0
Minimum	31.0	32.9
Maximum	71.4	74.6
Secondary diagnosis (a patient may have more than one):		
Central stenosis	20	39
Lateral stenosis	23	38
Instability	11	21
Herniation	23	38
Mean hospital stay (days):		
Total	7.8	7.5
Postoperative	6.2	6.4
Mean operative time (min):		
Anesthesia	101.4	123.1
Surgery	78.6	101.9
Mean blood loss (ml)	25.9	27.5

Of the 92 patients in this series, a right hand approach was used in 44% (17 1LF, 24 2LF). Thirty-five 1LF patients received a decompression and an ancillary anterior plate was used in two patients. In the 2LF group, an anterior plate was used in six patients and all patients received a decompression. Early in the series, plates were used routinely to insure that no cage migrated. However, their use was abandoned as it was found to be unnecessary and an unwarranted expense. Autogenous iliac crest graft material was used to fill the cage(s) in all patients. Lordotic cages were used more often in the 1LF (86%) than in the 2LF (61%) group. The C_5–C_6 and C_6–C_7 levels were the most commonly operated for both groups. The number of and specific levels of decompression, cage usage and instrumentation are summarized in Table 3. Partial or complete lordosis and disc space height corrections were properly achieved in all patients in all groups.

Complaints of immediate postoperative graft site pain occurred in 13.5% of the 1LF patients, but in only 5.4% of the 2LF patients; all resolved with time. Transient dysphagia was seen in one 2LF pa-

Table 3
Distribution of procedure and implants according to operative level

	Decompression		Insertion of cages		Instrumentation	
	One level	Two level	One level	Two level	One level	Two level
C_3–C_4	2	6	2	6	0	0
C_4–C_5	9	22	9	22	1	0
C_5–C_6	11	49	11	49	0	3
C_6–C_7	13	33	14	33	1	3
Total	35	110	36	110	2	6

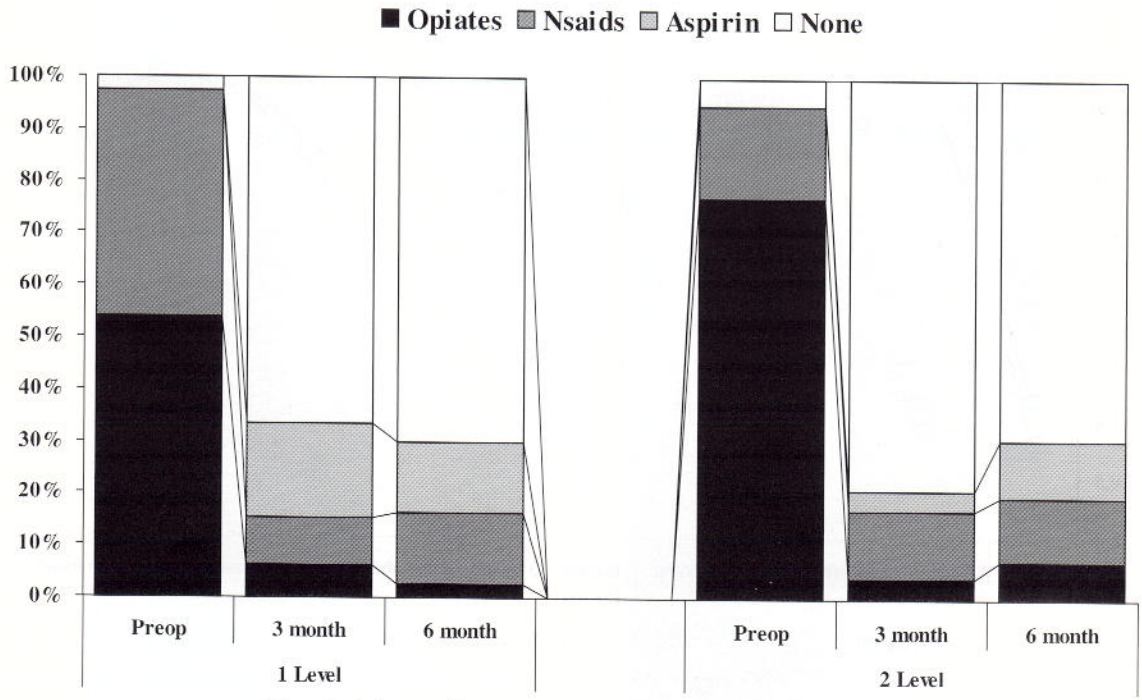

Figure 2. Patient medication use (as percentage of group population).

tient. Three 2LF and two 1LF patients had a loss of sagittal intersegmental alignment at the operative level, but it was without clinical consequence. In an osteoporotic 2LF patient, loss of height and lordosis occurred, but she is radiographically fused and her postoperative improvement in all endpoints has been maintained through the 18-month follow-up. Degenerative changes at an adjacent segment have been noted in two patients from each group; in three of these, there has been no reintervention based on an absence of clinical need. In one of the 1LF patients, an ACIF at an adjacent level was performed. At her 3-year follow-up, this patient was not taking medication, had mild neck pain, no arm pain and had returned to her previous profession. There have been no reinterventions in the 2LF group.

All patients in both groups were judged to have a radiographic evidence of fusion by the 6-month follow-up. Of the 1LF patients, 84% returned to their previous professions, 5% changed profession, 8% are receiving disability and the balance are unemployed. Eighty-four percent of the 2LF patients returned to their previous profession, 4% changed profession, 9% are on disability and the remainder remain unemployed. Medication use and severity for each recorded evaluation timepoint is shown in Figure 2. Prior to surgery, only one 1LF (3%) and three 2LF (5%) patients were not taking any medication. By the 6-month follow-up, this non-medicated figure had increased to 70% in both groups.

The primary endpoint mean values for the two groups are shown in Figure 3, and the mean functional endpoints are shown in Figure 4. The score definitions for these endpoints are listed in Table 1. Compared to the preoperative mean score, the next postoperative mean score for each endpoint is statistically significantly improved ($P < 0.001$) within each group. The postoperative neck pain, arm pain and neurologic scores for all patients in both groups improved by at least one point relative to the preoperative scores. We found no statistical difference between the two groups in any of the endpoints at any of the timepoints, however, this statistical insignificance was accompanied by relatively low statistical power.

Regarding patient satisfaction, 76% of the 1LF patients felt their outcome was good and the remaining 24% felt they were improved. In the 2LF group, 84% graded their outcome as good, 13% as improved and two patients (4%) felt they were not greatly improved. No patients in either group felt they were made worse by the surgery.

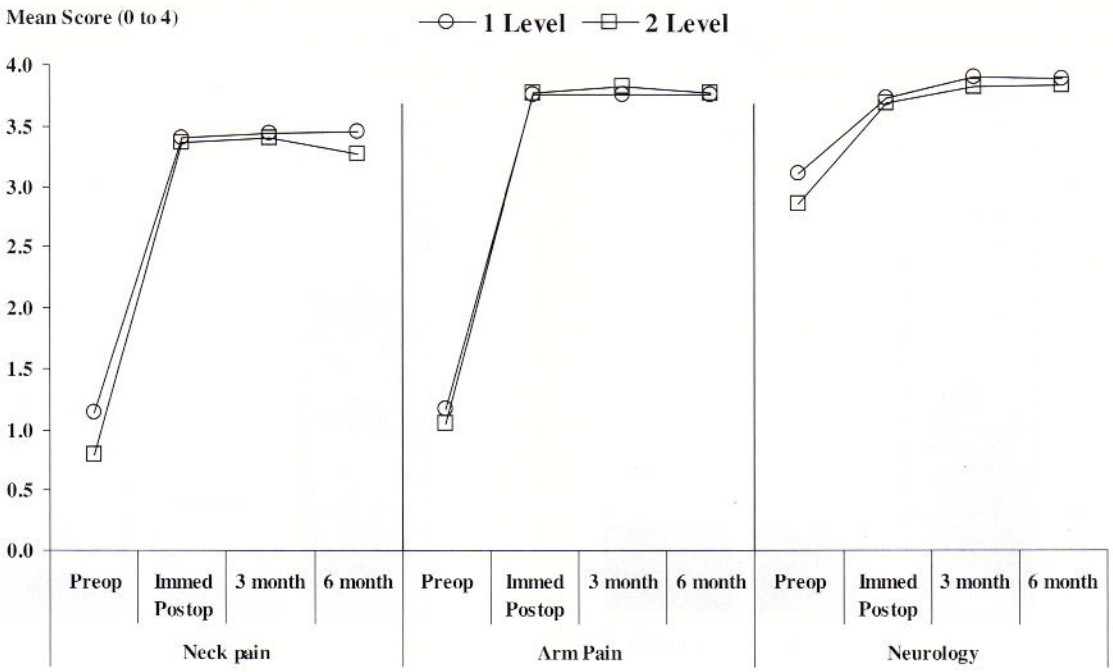

Figure 3. Mean primary endpoint scores.

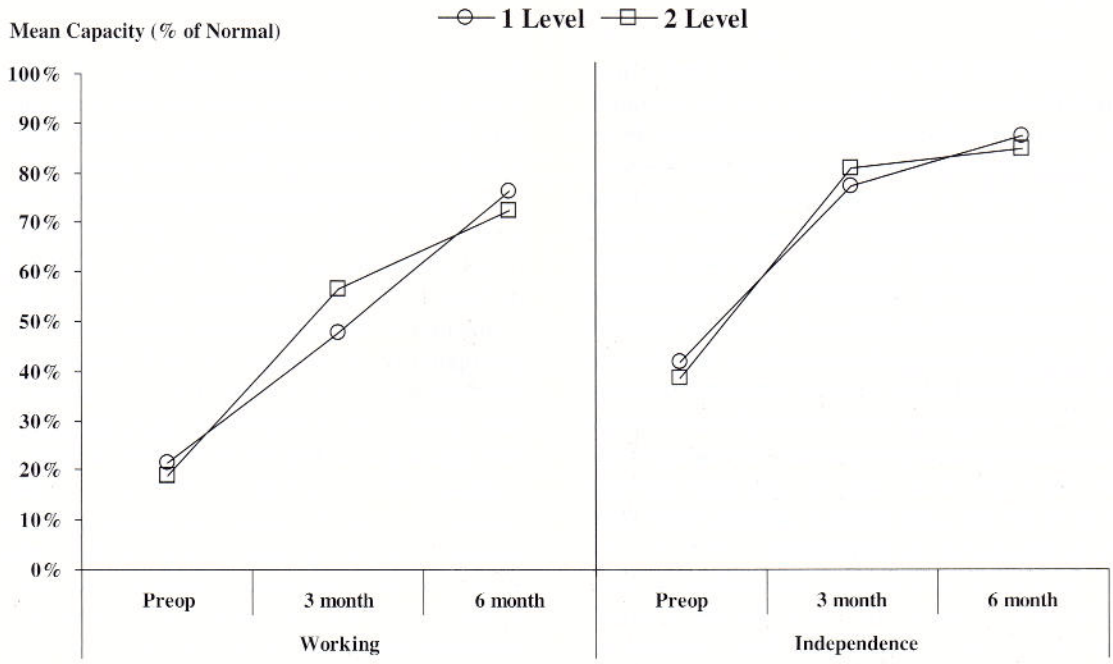

Figure 4. Functional capacity endpoints.

3.3. Illustrative case

A 52-year-old female presented with intolerable arm and severe neck pain. Working capacity was 0% and medication usage consisted of mild opiates taken more than twice per day. Radiographic and clinical examinations revealed degenerative disc disease (DDD) with lateral central spinal canal stenosis and intersegmental instability (Figure 5, left) at the C_4–C_5 and C_5–C_6 levels. The patient received a two-

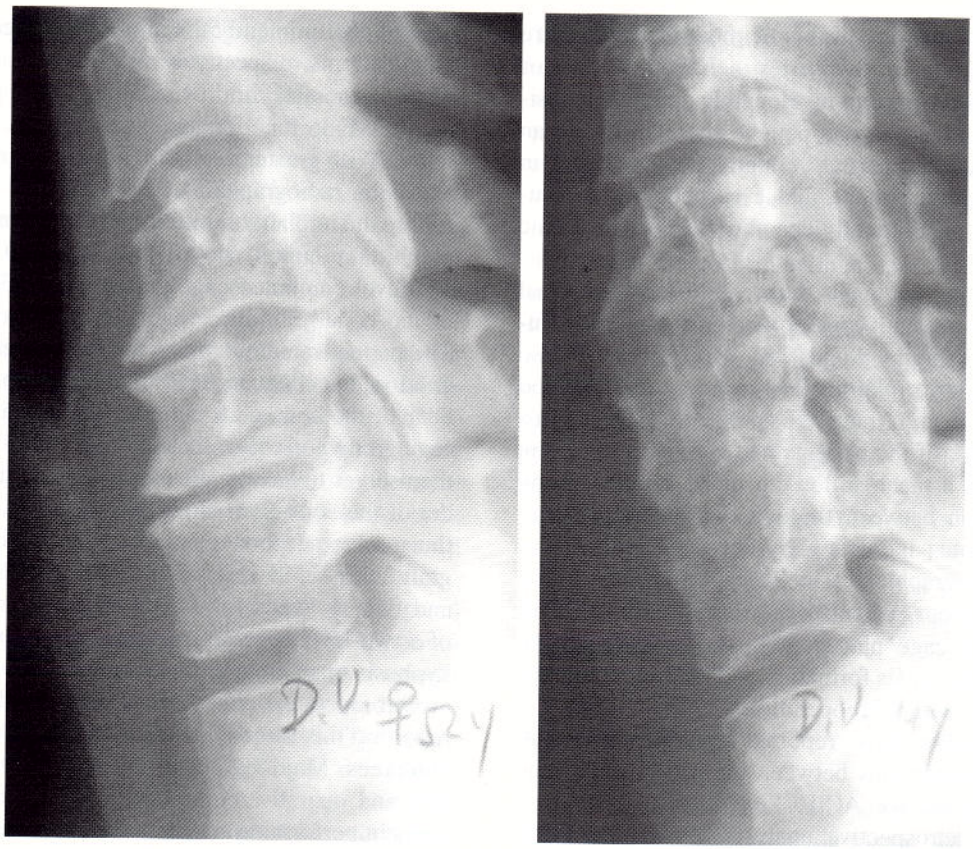

Figure 5. Illustrative case: pre- (left) and 4-year postoperative (right) X-rays.

level ACIF using two 7 mm, non-lordotic cages filled with iliac crest autograft. There were no operative, implant or late complications. At the 3-month follow-up, the patient was no longer taking medication and the prior neck and arm pain, neurologic examination and mobility independence had returned to normal levels. Radiographic fusion was determined at the 3-month follow-up. The 4-year postoperative radiographs are shown in Figure 5 (right) where bony interbody consolidation can be seen. In this case, interbody bone graft material implanted bilaterally extrinsic to the cage obscures the radiolucency of its structural elements. She has returned to her previous profession and her patient satisfaction level is good.

4. DISCUSSION

Despite the perception that interbody fusion of the cervical spine is more easily attained than in the lumbar spine, there is no identifiable gold standard for this procedure. Following their introduction for use in the lumbar spine, interbody fusion cages for use in the cervical spine are growing in popularity. To date, five studies have investigated the clinical and radiographic use of these devices.

Brooke et al. [25] reported a series of 19 patients treated with a wedge-shaped, carbon fiber cage. With a mean follow-up of 16.7 months, they found a 100% fusion rate, neck pain improvement in 82% and a loss of radicular symptoms in all patients. Donor site graft pain occurred in one patient and there were three short-term complications including swallowing difficulty and hoarseness.

Matgé [26] has updated a previously published series [27] using a titanium-threaded cylindrical cage in patients with one- or two-level cervical DDD. Follow-up ranged from 1 to 4 years and included 135 cervical patients with 175 operated levels. Excellent improvement in neck and radicular pain was found within the first 3 months. Ninety-five percent of the patients with radiculopathy had a good to excellent outcome at 1 year. According to their definition of fusion (i.e., no radiolucency around the device and no motion on flexion–extension radiographs), there

was a 100% fusion rate by 12 months. There were five reoperations in this series including a posterior decompression for two myelopathic patients, repositioning of a cage in one patient, the addition of an anterior plate for partial vertebral body collapse in an osteoporotic patient, and a corpectomy and fusion for an insufficiently decompressed myelopathic patient.

Thirty-four patients with multi-level cervical DDD were treated with corpectomy and cage fusion in a report by Majd [28]. Thirty patients also received anterior plating. The mean operative blood loss was 215 cm^3 (range 50 to 600). Using Odom's criteria, 80% of the patients had a good or excellent outcome at a mean follow-up of 32 months. Bony trabeculation between/through the cage and vertebral endplates indicating a successful fusion was found radiographically in 97% of the patients by 6 months. Four patients experienced complications including a cage placed in kyphosis, cage migration, pseudarthrosis formation and radiculopathy; the latter three required reoperation.

Two studies have reported clinical and radiographic comparisons between the use of cages and autograft-alone for ACIF. Profeta et al. [29] performed a retrospective analysis of cervical DDD patients treated with either tricortical iliac autograft or a conical threaded interbody cage. With 58 patients in the bone graft group and 52 in the cage group, they found a greater improvement in neck and arm pain in the cage group than in the bone-graft-alone group (92% versus 80%). Likewise, disc height maintenance and restoration of lordosis was 94% and 85%, respectively, in the cage patients but only 83% and 52%, respectively, in the bone-graft-alone patients. There was a 100% fusion rate in the cage group, but this parameter was not reported for the bone-graft-alone group. The predominant complications included dysphagia in four patients within each group, donor graft site pain in 12 patients of the bone-graft-alone group, disc space collapse with bone graft resorption in three bone-graft-alone patients and a slight local deformity in six bone-graft-alone patients and three cage patients.

Hacker [30] as part of an FDA prospective clinical study, reported the results of 54 patients with one- or two-level cervical DDD randomized into either an iliac crest autograft group or one of two cage groups (cages with hydroxyapatite coating or the same cages without coating). The operative data included a mean blood loss of 70.7 ml for the combined cage patients and 79.4 for the bone graft patients, and an operative time of 58.1 min and 55.7 min for the cage and bone graft patients, respectively. With a mean follow-up of 36.3 months, improvement in both groups using the SF-36 function and mental health scores was found. With greater than 2° of arc motion on flexion–extension radiographs and absorption of bone adjacent to the implant or graft as the definition for radiographic non-union, they found 100% (29/29) of the one-level combined cage patients and 93% (14/15) of the bone-graft-alone patients had a solid fusion. The patient-rated outcomes for the two groups were good or excellent in 97% of the cage patients and 88% of the bone graft patients; the remainder of the cage group and 6% of the autograft group considered themselves to have a fair outcome while the remainder of the bone-graft-alone patients (6%) considered their outcome poor. Complications included donor graft site pain in 31% of the bone graft-alone-group and two revisions for a pseudarthrosis at one level of a two-level cage patient and a graft collapse with kyphosis in an bone-graft-alone patient.

Our operative data compare favorably to those reporting this same cage use as a function of patient outcomes. Majd [28] reported that increased blood loss and operative time were two of the disadvantages in performing corpectomy for the treatment of multi-level disease, but believed that the advantages of complete cord decompression, total removal of the anterior spinal canal compressive pathology and the ability to restore cervical lordosis outweighed these. In our multi-level group, we were also able to restore cervical lordosis and obtain pain relief without the additional blood loss, operative time or implant cost. In our experience, performing additional surgery simply results in increased risk and cost. Our length of hospital stay was much longer than other cage groups [28–30], but this trend is generally found between European and US institutions and is not, therefore, specific to the surgical procedure or device. While not statistically significant ($P = 0.514$), the 2LF patients tended to be older than the 1LF group; patients older than 50 comprised 51% of the 1LF group versus 71% of the 2LF group.

The majority of the radiographic fusion results used no motion on flexion–extension radiographs and either bony trabeculation or no radiolucency between the cage and the vertebral endplates to ultimately define a successful fusion. However, three of these devices are made of titanium [27,28,30], and Matgé states that the assessment of fusion using a standard radiographs is difficult with the metallic implant [27]. Early in our series, we abandoned the

use of flexion–extension radiographs as the increased density of bone through and lateral to the radiolucent cage is apparent on lateral films. This phenomenon was substantiated in the report by Brooke [25]. All other series reported 100% fusion rates for one-level surgery, and this result was found in ours as well. In our two-level group, we found a 100% fusion rate, which is consistent with our earlier finding that, with the use of anterior cervical cages, fusion rate did not decrease with the number of fusion levels [13].

As each study used a different measurement for pain and/or functional outcomes a direct comparison between the groups would, at best, be difficult to make. However, within each study the vast majority of patients improved relative to their preoperative condition. In our series, the mean preoperative neck pain, arm pain and working capacity scores improved between 2 and 3 points by the 6-month follow-up timepoint. Independence and neurologic mean scores improved to between 85% and 97% of normal by that time. These pain and function improvements are further validated by the decrease in medication usage and dosage in both patient groups. There was a slight, but not statistically significant increase in neck pain in the 2LF group between the 3- and 6-month follow-up. We attribute this to an increase in patient activity following removal of the soft collar at 4 to 6 weeks.

It has been reported that scraping or burring the endplates results in a higher successful arthrodesis rate [4]. However, we feel that it is important to abrade only the center of the endplate at the host/graft interface. In doing so, the cage surface is allowed to rest on the stronger cortical shell of the vertebral body, and by this means, a loss of correction due to subsidence can be avoided [31]. This is particularly critical in the osteoporotic patient, although even careful attention might not prevent some loss of correction. In our series, the only patient to lose restored height and lordosis was an osteoporotic patient but, as in another report [26], we found that a loss of correction does not absolutely preclude a good clinical outcome.

Fortunately, the complication incidence in these series was low. We had no implant or operative complications. Dysphagia was the only local complication in our series, and was the more predominant reported complication in the reviewed literature, but occurred in only ten patients overall in two reported studies [25,29].

One of the incentives in using interbody fusion cages is to minimize the donor graft site morbidity. The two studies that compared autograft material alone to cage fusion found high incidences of donor site pain in the autograft groups (21% [29] and 31% [30]). The design of the cages used in these studies is such that drill reamings from the patient's adjacent vertebral bodies can be used to fill the cages prior to implantation. However, because the GII™ cage does not breach the cortical endplate, we rely on morsels of cancellous bone harvested from iliac crest. We have found that by local infiltration of the graft donor site with local anesthetic and adrenaline prior to closure, the occurrence of immediate postoperative graft site pain can be reduced. In our combined group of patients, 8.6% reported transient donor site pain.

Fortunately, major complications in anterior cervical surgery are exceedingly rare. The reoperation rate in our series (1.1%) was slightly lower than the 2.7% to 8.8% range of cage patient reoperations in the reviewed literature.

5. CONCLUSIONS

A relative limitation of this study is that the radiographic determination of fusion was not made by an independent reviewer. However, the ability to radiographically assess fusion is enhanced via the inherent cage radiolucency. Regardless of these considerations, we are investigating the possibility of independent review for future data analysis and to verify the integrity of the current results. The age difference between the two populations is another point for further study. A pertinent question might be: Does the older age of the 2LF patients indicate a need for hesitancy in performing a single-level fusion at an earlier age? At this time, we believe that to delay a single-level fusion for fear of exacerbating adjacent-level degeneration is not warranted. We are reviewing data to ascertain if this principle can be realistically supported.

The goals of the use of an interbody fusion device are to provide maintenance of intersegmental correction of spatial relationships and stability, and to offer an optimal environment for interbody fusion by separately addressing the dual biologic and mechanical requirements of donor bone graft material. By achieving these goals, patient pain and function should readily and reliably improve. We have found this to be true in this patient series, regardless of the number of levels fused. There was a high successful radiographic fusion rate, excellent patient pain relief

and functional restoration. Donor site morbidity can potentially be reduced by using morsels of cancellous iliac bone rather than a block of tricortical graft material.

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