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Implantation of an empty carbon fiber composite frame cage after single-level anterior cervical discectomy in the treatment of cervical disc herniation: preliminary results

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Object. The authors sought to evaluate retrospectively the radiological and clinical outcome of anterior cervical discectomy followed by implantation of an empty carbon fiber composite frame cage (CFCF) in the treatment of patients with cervical disc herniation and monoradiculopathy.

Methods. Twenty-five consecutive patients (12 men, 13 women, mean age 45 years) with monoradiculopathy due to cervical disc herniation were treated by anterior cervical discectomy followed by implantation of an empty CFCF cage. On lateral flexion–extension radiographs segmental stability at a mean follow up of 14 months (range 5–31 months) was demonstrated in all 25 patients, and bone fusion was documented in 24 of 25 patients. The mean anterior intervertebral body height was 3.4 mm preoperatively and 3.8 mm at follow up in 20 patients. In these patients the mean segmental angle (angle between lower endplate of lower and upper vertebra) was 0.9° preoperatively and 3.1° at follow up. In the remaining five patients preoperative images were not retrievable.

Self-scored neck pain based on a visual analog scale (1, minimum; 10, maximum) changed from a preoperative average of 5.6 to an average of 2 at follow up; radicular pain was reduced from 7.7 to 2.1 postoperatively. Analysis of the SF12 questionnaires showed a significant improvement in both the physical capacity score (preoperative mean 32.4 points; follow up 46 points) and the mental capacity score (preoperative mean 45.8 points; follow up 57.5 points).

Conclusions. Implantation of an empty CFCF cage in the treatment of cervical disc herniation and monoradiculopathy avoids donor site morbidity associated with autologous bone grafting as well as the use of any supplementary material inside the cage. Restoration or maintenance of intervertebral height and thus segmental lordosis and a very high rate of segmental stability and fusion are achieved using this technique.

KEY WORDS • anterior cervical discectomy • anterior cervical fusion • interbody cage

COMPRESSIVE monoradiculopathy due to cervical disc herniation can be treated by different surgical methods. Controversy exists among spine surgeons and in literature reviews[24] as to whether ACD and nerve root decompression should be followed by some sort of disc replacement. Restoration of foraminal height, achieving more rapid segmental stability, and maintenance or reconstruction of physiological cervical lordosis are noted advantages of the latter method.[1,3,4,13,25] Kyphotic malalignment has been shown in one study to promote degeneration in adjacent intervertebral spaces.[12] On the other hand prolonged operating time, extrusion of an interbody device, donor site morbidity in autologous bone grafting,[20] and unknown infectious risk in allograft,[8] artificial bone, or cage material have been discussed as disadvantages of cervical interbody fusion, which has motivated spine surgeons to perform anterior discectomy only.[7,11,16,22,26] In the past years new interbody materials have been developed to overcome the disadvantages of bone grafting, graft collapse, or graft extrusion.[2–4,9,10,15,18,19,23,27]

At our institution we recently introduced and evaluated the implantation of an empty CFCF cage after single-level cervical discectomy for the treatment of compressive monoradiculopathy. We present the preliminary clinical and radiological results obtained using this new method.

Clinical Material and Methods

Patient Population

This retrospective study was based on a review of patient hospital charts, operative notes, and out-patient clinical and radiographic follow-up data. Between May 1999 and October 2001 25 consecutive patients with compressive monoradiculopathy due to cervical disc herniation were treated by ACD and implantation of a CFCF cage without any filling. There were 12 men and 13 women, and their mean age was 45 years (range 29–60 years). The inclusion criterion was severely symptomatic single-level one-sided compressive radiculopathy due to

Abbreviations used in this paper: ACD = anterior cervical discectomy; CFCF = carbon fiber composite frame; MR = magnetic resonance; VAS = visual analog scale.

cervical disc herniation, which was radiologically confirmed by MR imaging in 21 patients and computerized tomography studies in four patients. Patients with evidence of cervical instability, "whiplash syndrome," systemic infection, metabolic bone disease, active malignancy, previous surgery of the cervical spine, bilateral or multilevel symptomatic radicular compression, myelopathy and psychiatric disease have not been reviewed. The level of operation was C6–7 in 13 patients (52%), C5–6 in 11 (44%), and C7–T1 in one patient (4%). Fourteen disc herniations were on the right side (56%) and 11 were on the left (44%). At admission symptoms included neck pain in 20 (80%) of 25 patients, radicular pain in 23 (92%) of 25, motor deficit in 21 (84%) of 25, and sensory deficit in 21 (84%) of 25.

Surgical Technique

Surgery was performed after the patient received a general anesthetic. A standard anterior approach to the cervical spine was followed by microsurgical ACD, disc space distraction, opening of the posterior longitudinal ligament, and nerve root decompression. The vertebral endplates were completely cleaned of any cartilage with curettes or a high-speed drill. Cortical endplates were carefully preserved. After determination of the cage size by means of a template, an empty CFCF cage (Co-Ligne AG, Zürich, Switzerland) was inserted with its anterior edge flush or 1 to 2 mm deep to the anterior disc space margin, and then the disc space distractor was removed. The cage is a medical grade composite of long fiber carbon encapsulated in a PEKEKK (polyetherketonetherketonketon) matrix (Fig. 1); it is 12 mm wide and 12 mm deep and is available in 6, 7, or 8 mm anterior heights and 0 or 5˚ lordosis. The mean duration of surgery was 64.6 minutes (range 30–100 minutes). The mean estimated intraoperative blood loss was 80 to 100 ml.

Patients were mobilized on the 1st postoperative day and no collar application was necessary; however, the patients were instructed to avoid excessive cervical motion. Physical therapy to strengthen the cervical paraspinal muscles was prescribed 3 months after surgery.

Outcome Measures

No patient was lost to follow-up evaluation, which was at a mean of 14 months (range 5–31 months). Segmental stability was determined on lateral flexion–extension radiographs and defined as less than 2˚ motion in the operated segment, allowing compensation for experimental error and variation. Bone fusion was assumed if in addition to segmental stability, less than 50% of the intervertebral space was radiolucent or if continuous iso- or hypodense trabecular bridges between the endplates were seen on lateral radiographs (Fig. 2). The radiolucency of the CFCF cage is advantageous in the assessment of bone fusion. The pre- and postoperative anterior intervertebral body height and the segmental angle on lateral radiographs were measured. The anterior intervertebral body height was measured as the vertical distance between the anterior border of the inferior endplate and the anterior border of the superior endplate. In postoperative measurements the superior endplate frequently was not visible in its anterior aspect due to cage subsidence, so a line from the preserved superior endplate posterior to the cage was drawn parallel to the inferior endplate of the same vertebral body. The segmental angle was defined as the angle between the inferior endplate of the lower vertebra and the inferior endplate of the upper vertebra.

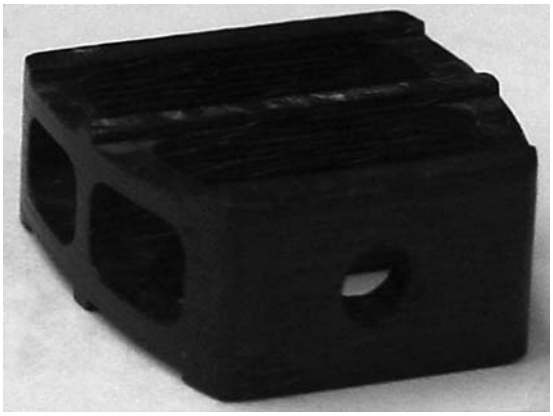

FIG. 1. Photograph showing an empty CFCF cage.

Clinical outcome was assessed by using a VAS for neck and arm pain, SF12 questionnaires, and the patient's self-rating.

Statistical Analysis

Comparison between pre- and postoperative scores of outcome measures, both radiological and clinical, was performed by means of the nonparametric Wilcoxon signed-rank test. Computation was supported by the statistical package StatView 4.5 (Abacus Concepts Inc., CA) running on a Macintosh computer (Apple, Cupertino, CA).

Results

All values are represented as the means ± standard deviations. Segmental stability was demonstrated in all 25 patients (Table 1). Bone fusion at the time of follow up was revealed in 24 (96%) of 25 patients. The mean anterior intervertebral body height was 3.4 ± 0.8 mm preoperatively and 3.8 ± 2.1 mm at follow-up evaluation in 20 patients; the difference was not significant ($Z = -0.795$). Relevant secondary loss of intervertebral height (≥ 2 mm) due to cage subsidence was found in four (20%) of 20 patients (Fig. 3). The mean segmental angle in 20 patients was 0.9 ± 3.3˚ preoperatively and 3.1 ± 4.5˚ at follow up ($Z = -2.166$, $p < 0.03$). In the five remaining patients, preoperative images were not retrievable: at follow up their mean anterior intervertebral body height was 6.4 mm, and their average segmental angle was 9.4˚.

Neck pain as scored using the VAS (1, minimum; 10, maximum) decreased from a preoperative average of 5.8 ± 4.1 to 2 ± 2.1 at follow up, with a significant difference between pre- and postevaluation ($Z = -3.340$, $p < 0.0008$). Radicular pain also significantly decreased from a preoperative mean value of 7.8 ± 2.9 to 1.9 ± 2.1 at follow up ($Z = -4.107$, $p < 0.0001$). Motor deficit was improved in 20 of 21 patients and unchanged in one patient; four patients had no motor deficit. Sensory deficit

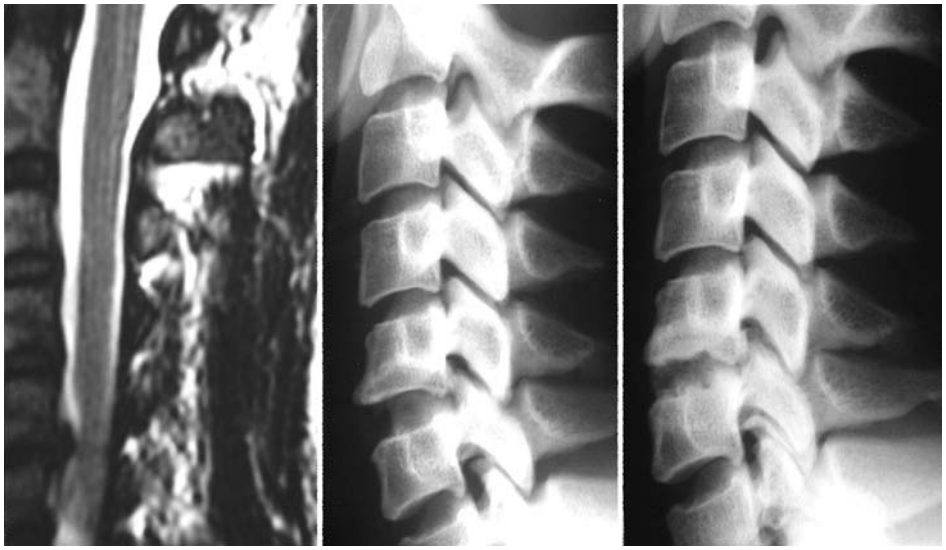

FIG. 2. Neuroimaging performed in a 40-year-old woman with right-sided C5–6 disc herniation. *Left:* Preoperative sagittal T_2-weighted MR image demonstrating a degenerated C5–6 disc with right-sided herniation. *Center:* Lateral radiograph obtained 3 days postoperatively, revealing good restoration of intervertebral height at C5–6. *Right:* Lateral radiograph obtained at 14-month follow up, demonstrating hypo- to isodense bone fusion at C5–6 without loss of intervertebral height.

was improved in 20 of 21 patients and unchanged in one patient; four patients had no sensory deficit. Analysis of the results of the SF12 questionnaires revealed significant changes in both outcome measures. Physical capacity score improved from a mean value of 32.3 ± 8.3 to 46.6 ± 9.4 at follow up ($Z = -4.100$, $p < 0.0001$); mental capacity score changed from a preoperative mean score of 44.8 ± 15 to 57.2 ± 10.4 at follow up ($Z = -3.143$, $p < 0.0017$).

Eighteen patients (72%) returned to full-time employment 1 month after surgery, whereas four patients (16%) ceased working after surgery. Self-rating was excellent in

TABLE 1

*Characteristics of 25 patients treated for cervical disc herniation by ACD and empty CFCF cage placement**

Case No.	Patient Age (yrs)	Level	Follow Up (mos)	VAS Score Preop	VAS Score Postop	Rad Pain Preop	Rad Pain Postop	PCS Preop	PCS Postop	MCS Preop	MCS Postop	Fusion	AIH Preop (mm)	AIH Postop	SA Preop (°)	SA Postop
1	36	C6/7	13	10	2	7	2	21.5	47.7	60.9	53.8	yes	4	2	2	2
2	39	C5/6	14	6.5	3.5	10	5	29.8	48.7	46.7	68.4	yes	8	13		
3	29	C5/6	8	10	2	10	1	25.3	49.1	23.4	52.1	yes	3	6	−6	0
4	54	C6/7	15	2	1	10	2	35.4	53.3	26.2	58.1	yes	4	5	3	6
5	38	C5/6	13	10	0	0	0	28.2	30.3	50.9	65.1	yes	7	14		
6	46	C6/7	15	2.5	1	6	3	38.4	49.3	56.8	46.4	yes	3	3	1	0
7	51	C6/7	5	1	1	5	1	34.4	55.3	70.3	64.5	yes	5	10		
8	42	C5/6	30	10	4	4	1	22.9	44.2	66.4	60.9	yes	3	7	−4	5
9	39	C6/7	30	8	1	9	1	35.1	47.3	47.9	59.5	yes	4	6	0	9
10	56	C7/T1	14	10	5	10	5	26.4	42.4	59.9	63.9	yes	3	1	0	−4
11	45	C6/7	12	0	0	5	1	41	56.3	66.2	63.6	yes	2	0		
12	43	C5/6	9	0	0	10	1	27	56.3	59.9	63.6	yes	3	8	4	11
13	46	C6/7	12	10	7	9	5	26.3	26.6	42.8	49.3	yes	4	4	−1	2
14	45	C6/7	11	9	3	10	4	23.5	34.9	23.4	43.7	yes	5	2	0	0
15	60	C6/7	14	5	1	10	2	25.3	35.9	29.6	54.1	yes	3	2	4	8
16	45	C6/7	9	0	0	10	1	31.9	53.5	51.9	62	yes	3	3.5	3	5
17	46	C5/6	19	0	0	7	1	47.3	55	47.2	61.3	yes	5	2	8	2
18	47	C5/6	14	9	1	9	1	49.9	47.8	32	61.7	yes	3.5	4	−3	−2
19	44	C6/7	8	1	1	8	1	28.1	54.2	57.4	58.3	yes	3	3	0	0
20	54	C5/6	12	0	6.5	10	6.5	28.8	25.2	35.3	33.3	yes	2	2	−2	−2
21	43	C5/6	17	3	1	8	1	47.3	55.3	63.7	64.5	yes	3	5	6	11
22	42	C6/7	4	6	1	8.5	1	39.3	50.3	45.8	63.1	yes	10	10		
23	60	C5/6	31	8	5	8	4	30	40.6	29.4	29.3	yes	3	2	2	2
24	36	C6/7	4	10	1	10	1	25.7	37.2	31.1	70.4	no	4	7	2	8
25	40	C5/6	10	10	1	0	0	41.5	53.6	20.4	66.1	yes	2	2	−1	−1

*AIH = anterior intervertebral height; MCS = mental capacity score; PCS = physical capacity score; rad = radicular; SA = segmental angle.

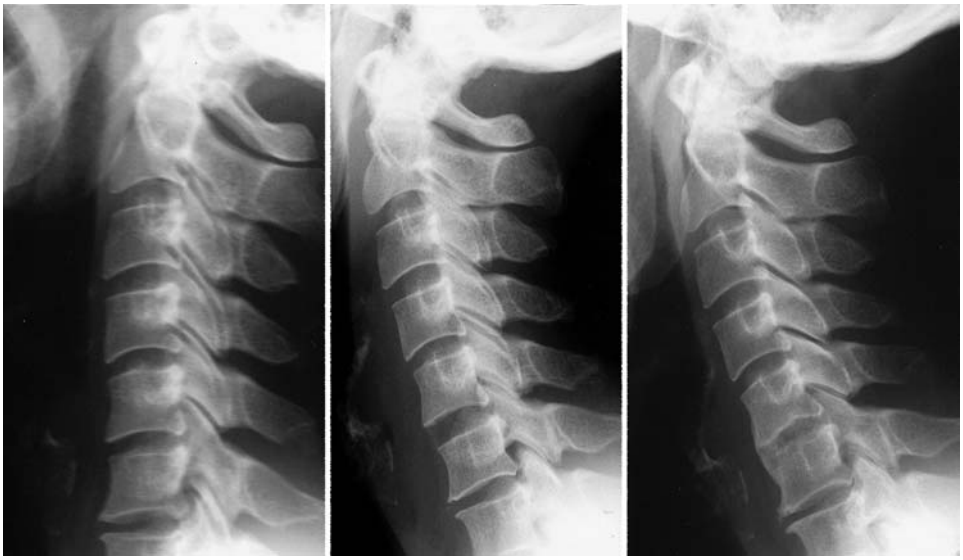

FIG. 3. Radiographs obtained in a 47-year-old woman with left-sided C5–6 disc herniation. *Left:* Preoperative lateral radiograph revealing little C5–6 disc space narrowing. *Center:* Lateral radiograph obtained 3 days postoperatively, demonstrating good restoration of intervertebral height. *Right:* Lateral radiograph obtained at 16-month follow up revealing hypo- to isodense bone fusion at C5–6; however, secondary loss of intervertebral height due to cage subsidence can also be seen.

16, good in four, fair in four, poor in one of the 25 patients. Mean hospitalization time was 5.4 days (range 3–10 days).

There were three perioperative complications: one patient experienced postoperative Claude-Bernard-Horner syndrome with partial recovery at follow up; another patient developed a deep wound infection, which was successfully treated with computerized tomography–guided aspiration of a prevertebral fluid collection and then treated with intravenous antibiotics; and one patient presented with dysphagia for 1 week, which spontaneously resolved without further treatment.

Discussion

An important development in degenerative cervical interbody surgery has taken place in the past several years. Donor site morbidity with long-term discomfort has been seen in a substantial percentage of patients;[20] thus, the use of traditional tricortical iliac crest bone grafting introduced by Robinson and Smith[17] and Cloward[6] has recently given way to interbody cages. Such cages are usually made of titanium or carbon fiber, and most surgeons fill them with autologous iliac crest or cancellous bone,[3–5,19]

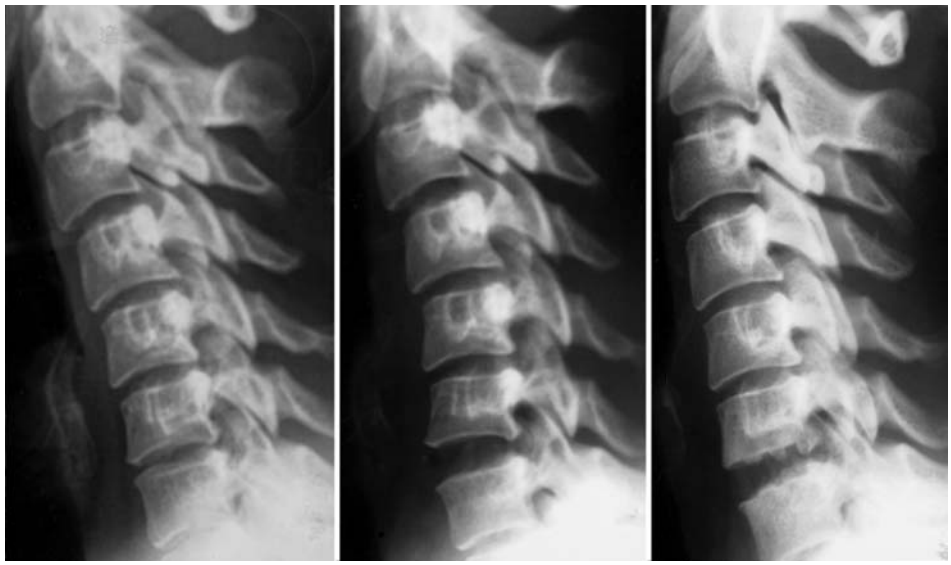

FIG. 4. Radiographs obtained in a 36-year-old woman with left-sided C6–7 disc herniation. *Left:* Preoperative lateral radiograph revealing C6–7 disc space narrowing. *Center:* Lateral radiograph obtained 3 days postoperatively, demonstrating too much restoration of intervertebral height at C6–7. *Right:* Lateral radiograph obtained 5 months postoperatively, demonstrating bone ingrowth from both vertebral endplates into the empty CFCF cage placed at C6–7.

therefore requiring a second incision and causing certain donor site morbidity. Other surgeons fill the cages with allogenic bone[9] or hydroxyapatite,[2,16,24] which theoretically increases the risk of infection by adding a second foreign material to the cage. Authors of one recent study reported filling carbon fiber cages with local bone harvested from local osteophytes or with bone dust acquired during drilling.[18] Other authors reported good long-term clinical results in 249 patients who underwent polymethylmethacrylate interbody fusion;[10] however, after a minimum of 2 years of follow up the "complete fusion rate" was only 53.8% and the "partial fusion rate" 7.7%.

Based on the finding of new bone formation around a biocompatible osteoconductive polymer[14] laboratory evidence of bone growth around removed lumbar carbon fiber interbody cages,[21] and a study reporting bone formation around a carbon fiber cage filled with iliac crest bone,[5] we hypothesized that bone ingrowth through and around an empty CFCF cage should occur and lead to segmental stability. Whether the cage actually has osteoinductive qualities in addition to osteoconductive properties remains an open question.

We observed segment stability in all of our 25 patients and bone fusion in 24. The one patient in whom we did observe bone fusion was followed for only 5 months, at which time bone ingrowth into the intervertebral space was seen from the lower and upper endplates without continuity (Fig. 4). We assume that further ingrowth will occur in the following months. After interbody fusion with autologous bone graft, isodense bone is seen on postoperative lateral radiographs, whereas usually only hypodense filling of the intervertebral space is visible on follow-up images after implantation of an empty CFCF cage (Figs. 2 and 3). We conclude that trabecular bone is formed through and/or around the CFCF cage, which is less dense than iliac crest bone grafts.

Cage subsidence in the months after implantation has been our biggest concern (Fig. 3). We have observed significant loss ($\geq$ 2 mm) of anterior intervertebral height in four (20%) of our 20 patients. Although great care was taken in preserving the cortical endplates after complete removal of the cartilage, cage subsidence did occur, most commonly into the upper endplate of the lower vertebra. We are currently changing the design of the cage by increasing the size and support surface.

No anterior or posterior cage migration or cage breakdown was observed. Operative time and hospitalization time compare favorably with those for cervical discectomy alone as well as those for interbody bone grafting and the procedure is technically feasible and uncomplicated.

According to our literature research there is one study in which the authors have reported on implantation of empty cages after cervical discectomy.[27] They report on 18 patients with cervical disc disease in whom implantation of an empty titanium cage was performed and compared the results with 18 patients who were treated with iliac crest autograft. At 1-year follow up they observed a 87% stability rate in the cage-treated group, defined as less than 2˚ motion on lateral flexion–extension radiographs. It was not possible to assess fusion because of the radiopacity of titanium. They describe cage subsidence of more than 2 mm in eight of the 23 operated levels in their series, which was more frequently seen at the beginning of the study (first four of five patients) because of extensive cortical endplate removal.

The limitations of our series are its retrospective nature, the heterogeneous follow-up times, the limited number of patients, and the lack of a comparative gold standard. Our preliminary clinical and radiological results are very clear and encouraging; therefore, we recently began a prospective randomized study in which we compare the results of implanting an empty CFCF cage with those for the Smith–Robinson technique.

Conclusions

Our preliminary retrospective evaluation of the first 25 patients shows that implantation of an empty CFCF cage in the treatment of cervical discogenic compressive monoradiculopathy is a safe and technically feasible procedure with excellent clinical and radiological results. This method avoids donor site morbidity due to autologous bone grafting as well as the use of supplementary material inside the cage. Restoration or maintenance of intervertebral disc height and a very high rate of segmental stability and fusion are achieved.

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