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Clinical Study

Three-level anterior cervical discectomy and fusion with self-locking stand-alone polyetheretherketone cages

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ABSTRACT

Anterior cervical plating is regarded as standard practice after multilevel anterior cervical discectomy and fusion. However, plate implantation in the anterior cervical spine poses a substantial risk of hardware-related complications. We retrospectively analyzed the efficacy and outcomes of 15 consecutive patients treated with a 3-level anterior cervical fusion using self-locking stand-alone polyetheretherketone (PEEK) cages. Patients were evaluated preoperatively and postoperatively using the Japanese Orthopedic Association (JOA) scale scores and radiographs. Clinical results were assessed using Odom's criteria. The mean JOA score (± standard deviation) improved significantly from 7.3 ± 1.5 points to 14.1 ± 1.3 points ($p < 0.05$) at the final follow-up. The outcomes were excellent for four patients (26.7%), good for nine patients (60%) and fair for two patients (13.3%). None of the patients experienced a poor clinical outcome. Thirteen patients achieved a solid fusion, after an average time of 5.7 months. The radiographic fusion rate of this procedure was 93.3%. Of 45 cages inserted in total, only four (8.89%) cages, in three patients, were found to have subsided. The degree of spinal curvature before surgery differed significantly from that immediately after surgery, and from that at the final follow-up examination ($p < 0.05$). Self-locking stand-alone PEEK cages packed with excised local osteophytes and calcium sulfate are safe and effective. This procedure can effectively restore cervical lordosis, obviate the complications related to graft harvest and screw-plate fixation, and lead to satisfactory outcomes.

1. Introduction

Anterior cervical discectomy and fusion (ACDF) has yielded good results for the treatment of cervical degenerative disc disease and is accepted as the standard operative procedure. Success of the procedure relies on a thorough decompression and development of a solid osseous fusion. Traditional interbody fusion using iliac crest bone can maintain the patency of the neuroforamen and ensure solid fusion, and an iliac crest autograft is the gold standard for interbody support.[1] However, autologous bone grafts obtained from the anterior iliac crest are associated with significant donor-site morbidity and complications, including a longer operative time, increased postoperative pain, longer hospital stays, hematoma formation and infection.[2] While the use of an allograft can eliminate donor-site problems, this type of graft is associated with high rates of pseudarthroses.[3] Continued improvements in cage technology have aimed to remove these limitations, and interbody fusion cages have been developed and widely used in clinical practice.[4]

For a single-level discectomy, a 92–100% fusion rate can be achieved with ACDF.[5] However, in multilevel discectomy, the success rate declines as the number of levels increases.[6] Lower success rates have been attributed to the increased number of grafts and interfaces that must consolidate during multilevel surgery, and the increased stresses on the multiple graft sites and the resultant motion. The interbody cage provides stability only through tensioning of the remaining ligaments; therefore, it offers little stabilization during extension because the anterior ligamentous structures are removed during the discectomy. Plate fixation may decrease the micro-movement of the cervical spine, enhance the fusion rate, and correct the spinal curve to physiological lordosis.[7] Anterior cervical plating (ACP) is often performed after multilevel ACDF as standard practice.[8] However, implantation of plates in the anterior cervical spine poses a substantial risk of hardware-related complications. The plate complication rate varies from 2.2 to 24.0% and includes hardware failure, injury of the recurrent laryngeal nerve, injury of the esophagus, injury of the spinal cord or nerve root, injury of the vertebral arteries, and wound infection.[5,9–11]

Several new devices have been developed that incorporate interbody support with supplemental fixation. These devices generally contain an interbody spacer with self-locking devices

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passing through the spacer into the endplates of the adjacent vertebral bodies, which limits the risk of cage migration and increases the rigidity of the fusion construct. ACDF performed with a stand-alone cage has proven to be a safe and effective procedure and clinical outcomes have been encouraging in 1- and 2-level procedures.[12,13] However, the clinical results of stand-alone cages for 3-level ACDF have rarely been reported.

We used a self-locking stand-alone polyetheretherketone (PEEK) cage to treat and retrospectively evaluate the clinical and radiological results of 15 patients with 3-level cervical degenerative disc disease.

2. Material and methods

Fifteen consecutive patients (10 male, 5 female; mean age = 57.2 years; range = 43–71 years) with 3-level degenerative cervical disc disease were included in this review between March 2007 and March 2009. All patients gave informed consent and underwent ACDF with self-locking stand-alone PEEK cages. Preoperative clinical evaluations were performed including MRI and radiographical studies of the cervical spine. Inclusion criteria were: (i) myelopathy or radiculopathy on the physical examination; and (ii) spinal cord compression visible on MRI at three disc levels. Exclusion criteria were: (i) developmental stenosis; (ii) continuous or combined ossification of the posterior longitudinal ligament; and (iii) a history of cervical spine surgery. Before surgery, nine patients had myelopathy and six had radiculopathy. None of the patients had myelopathy and radiculopathy concurrently. All patients were refractory to conservative treatment.

Operations were performed by the same surgeon at a single institution, using a standard anterior approach to the cervical spine. The basic techniques for exposure, discectomy and decompression, performed using a right-sided skin incision, were the same as described by Robinson and Smith.[14] A microscope was used in most instances during the procedure. Extensive decompression was performed including removal of the osteophytes, herniated nucleus pulposus and discectomy. The posterior longitudinal ligament was opened transversely and osteophytes possibly compressing the nerve root were removed with rongeurs or a drill. The dura mater and nerve root origins were exposed and decompressed. The endplates were abraded before fusion and the bony endplate was preserved as much as possible to prevent cage subsidence. The appropriate size for the self-locking stand-alone cage (MC+®, LDR, Troyes, France) was determined by both preoperative templating and intraoperative evaluation using a trial cage to confirm initial stability. Cages were packed with excised local osteophytes and calcium sulfate (Osteoset®, Wright Medical Technology, Arlington, TN, USA) and inserted into the disc space using an impactor (Fig. 1). After implantation of the cage, a cervical anchoring clip was placed into the lower vertebra through the anterior part of the cage to ensure primary stabilization. ACP systems were not used for any patients. After surgery, patients were allowed to sit up on the first postoperative day and walk on the second postoperative day with a soft cervical collar, which was worn for the first 3 months postoperation.

Patients received monthly check-ups at our outpatient clinics for the first 3 months and every 3 months thereafter. Neurological function was assessed at every visit. The preoperative and postoperative Japanese Orthopedic Association (JOA) scores were recorded. An independent observer, who did not attend the surgery, interviewed the patients and evaluated the clinical results based on Odom's criteria at the final follow-up.[15] Excellent and good outcomes were considered satisfactory.

Radiographs were taken before and after surgery, at 3 months, 6 months, and subsequently every 6 months after surgery. Two-dimensional CT scan reconstructions were performed when evidence of bone fusion was observed on X-ray. Fusion was assessed by: (i) the absence of motion >2 mm between the spinous processes on flexion–extension lateral radiographs; (ii) the absence of a radiolucent gap between the graft and the endplate; and (iii) the presence of continuous bridging trabeculae at the graft and endplate junction.[16] Subsidence on the radiographs was defined as cage migration of $\geqslant$3 mm into the adjacent vertebral body. Cervical spinal curvature was determined from the lateral view of the X-ray. A straight line was drawn from the posterior border of the dens to the posterior border of C7. A second line was drawn from the posterior border of C4 perpendicular to the first line; the length of this intersected line measured in centimeters equaled the degree of spinal curvature. A length of 0 mm corresponded to straight lateral spine curvature; negative values indicated kyphotic spinal curvature and positive values indicated lordotic spinal curvature.[17]

The mean ± standard deviation were determined for cervical spinal curvature and JOA scores. All results were statistically analyzed using the Student's *t*-test. A p value <0.05 was considered significant.

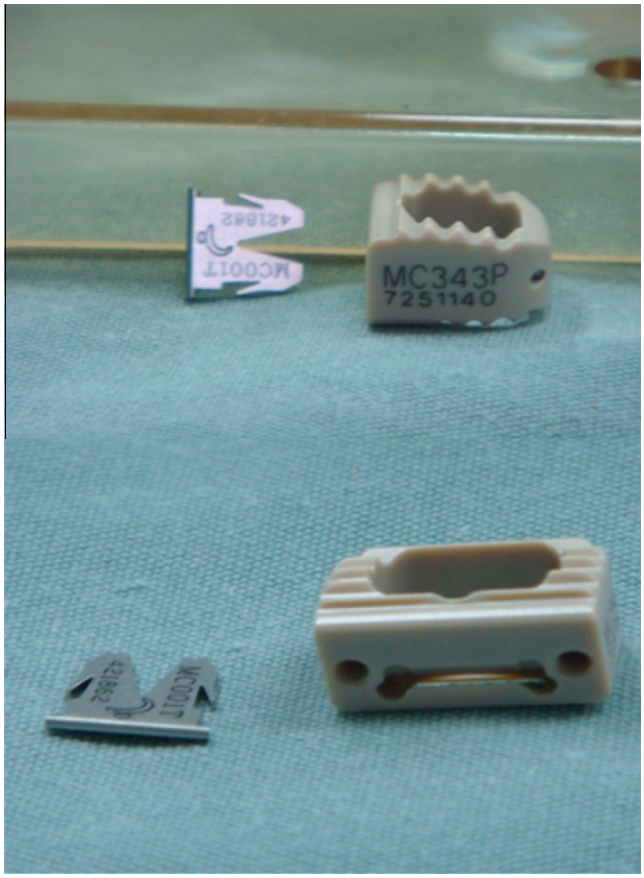

Fig. 1. The self-locking stand-alone polyetheretherketone cage consists of an interbody spacer and a titanium clip. The anchoring clip is placed into the lower vertebra through the anterior part of the cage after implantation to assist cage fixation.

3. Results

The mean follow-up period was 19.8 months (range = 15–27 months). The average operation time was 143 ± 21.5 min and the average blood loss during surgery was 102 ± 13.3 mL. All cages were implanted successfully. There were no device failures and no superficial or deep wound infections at the cervical incision site. After surgery, none of the patients experienced neurological deterioration.

Thirteen patients achieved a solid fusion and the mean time to achieve this result was 5.7 months (Fig. 2). The radiographic fusion rate of this procedure was 93.3%. Of 45 cages inserted in total, four (8.89%) cages, inserted in three patients, were found to have subsided. Patients with cage subsidence did not experience any symptoms.

The mean degree of spinal curvature was 4.93 ± 0.63 mm before surgery, 8.34 ± 0.75 mm immediately after surgery, 8.11 ± 0.34 mm 6 months after surgery, and 8.09 ± 0.91 mm at the final follow-up examination. The degree of spinal curvature before surgery differed significantly from that immediately after surgery, and from that at the final follow-up examination ($p < 0.05$) (Figs. 3 and 4).

The mean JOA score was 7.3 ± 1.5 points before surgery and significantly increased to 14.1 ± 1.3 points at the final follow-up. Postoperative clinical outcomes were assessed based on Odom's criteria and were excellent in four patients (26.7%), good in nine patients (60.0%) and fair in 2 patients (13.3%). None of the patients exhibited a poor clinical outcome and patients who did not achieve fusion still achieved good clinical outcomes.

4. Discussion

ACDF is an efficient procedure for treating cervical degenerative disc disease, and the gold standard for interbody support is an iliac crest autograft.[1] The low stabilizing effect of autologous iliac crest grafts often requires further stabilization with anterior plating; however, the use of an anterior plate system is associated with various intraoperative and postoperative complications. The application of long ACPs, particularly during multilevel cervical discectomy and fusion, is a time-consuming procedure that can compromise vital structures on the anterior aspect of the cervical spine such as the trachea, carotid arteries, and esophagus.[18] In addition, there are increased risks of hardware failure.[19]

Fig. 2. Two-dimensional CT scan used to assess fusion showing bony bridge formation around or inside the cage and increased bone density inside the cage.

Stand-alone cages were introduced to eliminate plate-related complications. However, early reports indicated that stand-alone cages could not offer immediate biomechanical stability and suggested that the cervical interbody fusion cage should be supplemented with additional external or internal supports to prevent excessive flexion–extension motion.[20] The self-locking stand-alone PEEK cage achieves this by combining interbody support and supplemental fixation into a single device. The PEEK cage has a titanium spike on the base of the frame, which is inserted into the vertebral body to assist cage fixation. In addition, retention teeth on the surface of the upper and lower frame reduce the chance of cage dislodgement. These unique structures offer a fixation mechanism that is similar to the function of a plate and screws. Scholz et al. reported that the anchored spacer provided a similar biomechanical stability to that of the established anterior fusion technique using an anterior plate and cage.[21]

Reports of multiple-level procedures show higher non-union rates and the fusion rate declines as the number of levels increases.[22] However, in our study, radiologically successful fusion was achieved by 93.3% of patients and the mean time to achieve a solid fusion was 5.7 months. This satisfactory fusion rate may be related to surgical techniques and the design of the fusion cages. Surgical techniques that enhance fusion include optimal preparation of the fusion bed and proper disc space distraction. In addition, the anatomical shape of the PEEK cage (with its upper convex part in the frontal and sagittal planes) allows a wide grafting space and close contact between the endplate bone and the implant, thus enhancing the load-bearing capacity of the graft or bone substitute which facilitates arthrodesis. The self-locking devices ensure excellent primary stability of the implant and promote early fusion. Furthermore, the elastic modulus of the PEEK cage is similar to that of bone, which theoretically helps to decrease stress shielding and increase bony fusion.

In most previous studies, cages filled with autologous cancellous bone were used. Although this likely reduces graft-harvesting complications, donor-site pain remains problematic. A second incision prolongs the operation time, and patients typically experience greater discomfort at the iliac donor site than the cervical wound. This local pain can prolong hospitalization. It would be beneficial to the patient if interbody fusion could be achieved without harvesting autograft bone from the iliac crest. Osteoset® pellets are an effective osteoconductive filler that allow ingrowth of blood vessels and osteogenic cells, facilitating physiological bone healing.[23] In our study, we used the excised local osteophytes and Osteoset® pellets to fill the cages, and we found an excellent fusion rate without donor-site morbidity. This method may be used to minimise donor-site complications.

In addition to a high fusion rate, successful treatment depends on maintenance of intervertebral height and cervical spinal curvature.[24] Cage subsidence associated with increased kyphosis can cause a reduction of the intervertebral foraminal volume and instability of the cervical spine, which results in foraminal root compression symptoms, pseudoarthrodesis and failure of a stand-alone cage.[25] Bartels et al. reported that insertion of a cervical cage effectively increased the foraminal height for as long as 1 year, contributing to decompression of the nerve root.[26] This study also showed that the PEEK cage preserved preoperative lordosis. The anatomical shape of the cage makes it possible to restore the

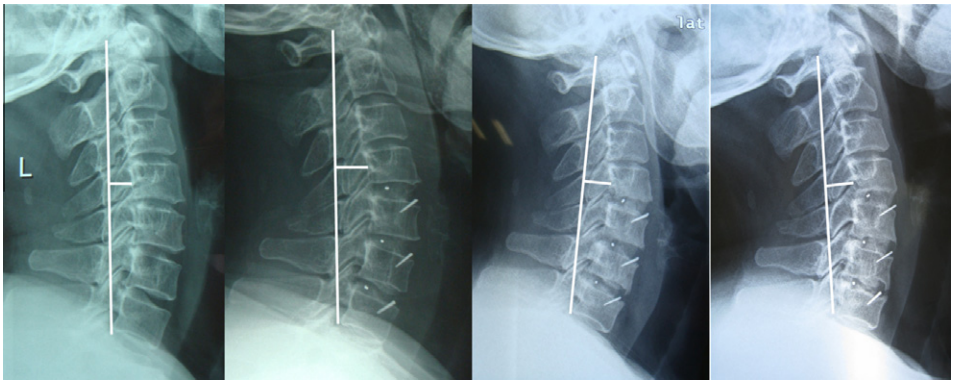

Fig. 3. Lateral radiographs (A) preoperative; (B) postoperative; (C) 6 months after surgery; and (D) at the final follow-up showing the spinal curve changes of a patient with C5–C7 myelopathy who underwent anterior discectomy and fusion with polyetheretherketone stand-alone cages.

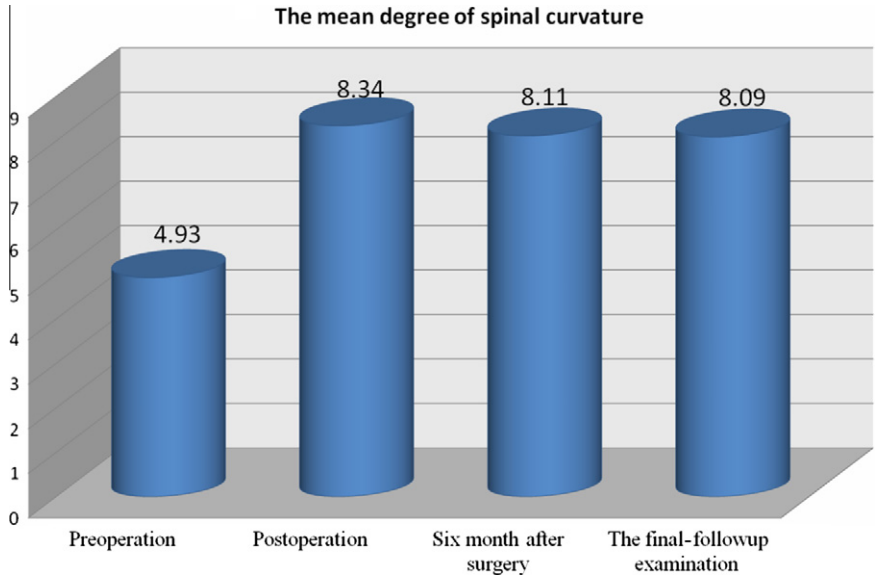

Fig. 4. A graph showing that the mean degree of spinal curvature(mm) before surgery differed significantly from immediately after surgery, and from that at final follow-up ($p < 0.05$). The between-patient differences in the degree of spinal curvature immediately after surgery, 6 months after surgery and at the final follow-up were not significant.

chosen disc height as well as the lordosis of the interbody space. A high incidence of cage subsidence and a loss of acquired alignment were reported for stand-alone cages in several studies.[27] However, in our study only four (8.89%) inserted cages subsided and all three involved patients reported good clinical outcomes. Implant subsidence may arise either from suboptimal surgical technique, including inadequate preparation of the adjacent endplates and intraoperative segmental overdistraction, or from inappropriate cage selection with biomechanically unsound positioning.[27] In our study, the bony endplate was preserved as much as possible and cages were placed ventrally to improve ventral osseous support and decrease the tendency toward kyphosis. Furthermore, the modulus of the elasticity of PEEK is similar to that of bone. This distinguishing feature is understood to prevent cage subsidence induced by metallic cages. In this study, cage subsidence occurred exclusively in older women, and this may have been due to osteoporosis in these patients. Bone mineral density of the vertebral body is important to predict the mechanical strength of the cage–endplate interface.[28,29] Accordingly, older women have a higher chance of cage subsidence due to a lower bone mineral density of the vertebral body.

This study had some limitations. The mean follow-up period was only 19.8 months. Furthermore, this study included only 15 patients for evaluation. A long-term study, with a larger number of patients, should be performed to further investigate the efficacy of self-locking stand-alone cages for the treatment of 3-level cervical degenerative disc diseases.

5. Conclusion

Self-locking stand-alone PEEK cages, packed with excised local osteophytes and calcium sulfate, can be used safely and effectively and may be an alternative to long ACP for the treatment of multilevel cervical disc disease. This procedure can effectively restore cervical lordosis, reduce the complications related to graft harvest and screw-plate fixation, and lead to satisfactory outcomes.

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References

1. Chau AMT, Mobbs RJ. Bone graft substitutes in anterior cervical discectomy and fusion. *Eur Spine J* 2009;**18**:449–64.
2. Bednar DA, Al-Tunaib W. Failure of reconstitution of open-section, posterior iliac-wing bone graft donor sites after lumbar spinal fusion. Observations with implications for the etiology of donor site pain. *Eur Spine J* 2005;**14**:95–8.
3. Deutsch H, Haid R, Rodts G, et al. The decision-making process: allograft versus autograft. *Neurosurgery* 2007;**60**(Suppl. 1):98–102.
4. Matge G. Cervical cage fusion with 5 different implants: 250 cases. *Acta Neurochir* 2003;**144**:539–50.
5. Kaiser MG, Haid RW, Subach BR, et al. Anterior cervical plating enhances arthrodesis after discectomy and fusion with cortical allograft. *Neurosurgery* 2002;**50**:229–36.
6. Hilibrand AS, Fye MA, Emery SE, et al. Increased rate of arthrodesis with strut grafting after multilevel anterior cervical decompression. *Spine* 2002;**27**:146–51.
7. Silber JS, Anderson DG, Daffner SD, et al. Donor site morbidity after anterior iliac crest bone harvest for single-level anterior cervical discectomy and fusion. *Spine* 2003;**28**:134–9.
8. Wang JC, McDonough PW, Endow KK, et al. A comparison of fusion rates between single-level cervical corpectomy and two-level discectomy and fusion. *J Spinal Disord* 2001;**14**:222–5.
9. Fountas KN, Kapsalaki EZ, Nikolakakos LG, et al. Anterior cervical discectomy and fusion associated complications. *Spine* 2007;**32**:2310–7.
10. Jung A, Schramm J, Lehnerdt K, et al. Recurrent laryngeal nerve palsy during anterior cervical spine surgery: a prospective study. *J Neurosurg (Spine)* 2005;**2**:123–7.
11. Orlando ER, Caroli E, Ferrante L. Management of the cervical esophagus and hypofarinx perforations complicating anterior cervical spine surgery. *Spine* 2003;**28**:E290–5.
12. Thome C, Leheta O, Krauss JK, et al. Prospective randomized comparison of rectangular titanium cage fusion and iliac crest autograft fusion in patients undergoing anterior cervical discectomy. *J Neurosurg Spine* 2006;**4**:1–9.
13. Zhou J, Xia Q, Dong J, et al. Comparison of stand-alone polyetheretherketone cages and iliac crest autografts for the treatment of cervical degenerative disc diseases. *Acta Neurochir* 2011;**15**:115–22.
14. Robinson R, Smith G. Anterolateral cervical disc removal and interbody fusion for cervical disc syndrome. *Bull Johns Hopkins Hosp* 1955;**96**:223–4.
15. Uribe JS, Sangala JR, Duckworth EA, et al. Comparison between anterior cervical discectomy fusion and cervical corpectomy fusion using titanium cages for reconstruction: analysis of outcome and long-term follow-up. *Eur Spine J* 2009;**18**:654–62.
16. Thome C, Krauss JK, Zevgaridis D. A prospective clinical comparison of rectangular titanium cages and iliac crest autografts in anterior cervical discectomy and fusion. *Neurosurg Rev* 2004;**27**:34–41.
17. Dogan S, Turkkan A, Kocaeli H, et al. Clinical and radiologic analysis of 3-level anterior cervical discectomy and fusion with interbody cages without plate fixation. *Neurosurg Q* 2008;**18**:188–94.
18. Sahjpaul RL. Esophageal perforation from anterior cervical screw migration. *Surg Neurol* 2007;**68**:205–9.
19. Vaccaro AR, Falatyn SP, Scuderi GJ, et al. Early failure of long segment anterior cervical plate fixation. *J Spinal Disord* 1998;**11**:410–5.
20. Shimamoto N, Cunningham BW, Dmitriev AE, et al. Biomechanical evaluation of stand-alone interbody fusion cages in the cervical spine. *Spine* 2001;**26**:E432–6.
21. Scholz M, Reyes PM, Schleicher P, et al. A new stand-alone cervical anterior interbody fusion device: biomechanical comparison with established anterior cervical fixation devices. *Spine* 2009;**34**:156–60.
22. Hilibrand AS, Fye MA, Emery SE, et al. Increased rate of arthrodesis with strut grafting after multilevel anterior cervical decompression. *Spine* 2002;**27**:146–51.
23. Moed BR, Carr SEW, Craig JG, et al. Calcium sulfate used as bone graft substitute in acetabular fracture fixation. *Clin Orthop Relat Res* 2003;**410**:303–9.
24. Kao FC, Niu CC, Chen LH, et al. Maintenance of interbody space in one- and two-level anterior cervical interbody fusion: comparison of the effectiveness of autograft, allograft, and cage. *Clin Orthop Relat Res* 2005;**430**:108–16.
25. Siddiqui AA, Jackowski A. Cage versus tricortical graft for cervical interbody fusion. A prospective randomised study. *J Bone Joint Surg Br* 2003;**85**:1019–25.
26. Bartels RH, Donk R, van Azn RD. Height of cervical foramina after anterior discectomy and implantation of a carbon fiber cage. *J Neurosurg* 2001;**94** (Suppl. 1):40–2.
27. Fujibayashi S, Neo M, Nakamura T. Stand-alone interbody cage versus anterior cervical plate for treatment of cervical disc herniation: Sequential changes in cage subsidence. *J Clin Neurosci* 2008;**15**:1017–22.
28. Barsa P, Suchomel P. Factors affecting sagittal malalignment due to cage subsidence in standalone cage assisted anterior cervical fusion. *Eur Spine J* 2007;**16**:1395–400.
29. Lim TH, Kwon H, Jeon CH, et al. Effect of endplate conditions and bone mineral density on the compressive strength of the graft-endplate interface in anterior cervical spine fusion. *Spine* 2001;**26**:951–6.