

Anterior Cervical Discectomy and Fusion Using Polyetheretherketone (PEEK) Cage and Autologous Bone Graft Harvested by a Minimally Invasive Technique

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ABSTRACT

Background: Following anterior cervical discectomy, a cage can be used to maintain the root foraminal height and lordosis. Different materials have been used to make cervical cages, the most recent of which is polyetheretherketone (PEEK). To date, published clinical studies about PEEK cervical cages are sparse. To induce fusion, cervical cages can be packed with autologous bone graft. Harvesting the bone graft by a minimally invasive technique helps to reduce donor site morbidity and complications.

Purpose: To study the results of anterior cervical discectomy and fusion (ACDF) using PEEK cage packed with autologous iliac bone graft harvested by a minimally invasive technique. .

Study design: A case series.

Patients and methods: 22 patients (16 males and 6 females). The mean age was 44.4 years. 14 patients had soft discs and 8 had hard discs. 12 patients had radiculopathy, 7 had myeloradiculopathy and 3 had myelopathy. 26 cages, packed with autologous iliac bone graft, have been inserted. The average follow up period was 7 months.

Outcome measures: Visual pain analogue scale (VPAS) was used to assess the severity of radicular pain both pre and postoperatively. Odom's criteria were used to assess the postoperative functional level. Any residual pain or discomfort at the graft donor site was reported. Fusion was evaluated by plain radiography. Statistical comparison of the pre and postoperative VPAS was done using paired "t" test.

Results: 10 cases were graded excellent, 6 good, 4 fair and 2 poor. Radicular pain showed dramatic improvement postoperatively. The mean postoperative VPASs at 6 weeks, 3 months, 6 months and 12 months were 2.5, 1.5, 0.5 and 0 respectively. None of the patients reported any symptoms in relation to the graft donor site. Fusion was evident in 72.7 % of cases at 3 months and 90% at 6 months. All cases reviewed at 12 months (six cases) showed radiological evidence of fusion. Complications included: temporary dysphagia (9.1%), haematoma (4.5%) and temporary recurrent laryngeal nerve palsy (4.5%). **Conclusion:** ACDF using PEEK cage packed with autologous bone graft is a safe and effective method for treating degenerative cervical disc disease. The minimally invasive technique did not result in any graft donor site morbidity.

INTRODUCTION

The management of degenerative cervical disc disease continues to be controversial. Anterior cervical discectomy is an effective and reliable treatment for nerve root or cord compression caused by disc herniation or spondylosis. Two surgical

techniques were originally described by Cloward and Smith and Robinson, both using a bone graft for inter-body fusion after cervical discectomy^(1,2). It has been argued whether it is necessary to perform fusion after discectomy. Those who oppose fusion believe that the majority of patients are well served with discectomy alone, avoiding the

complications of graft harvesting⁽³⁻⁵⁾. On the other hand, proponents of fusion feel that the interposed graft, spacer or cage, restores foraminal height and maintains cervical lordosis and stability, all of which are important to a good outcome^(3,6,7).

No surgical technique has proved superior to the other in the treatment of degenerative cervical disc disease. The results of discectomy alone were significantly better when compared with fusion with freeze-dried bone graft⁽⁸⁾. However, when autologous iliac bone graft was used, one study showed no significant difference⁽⁹⁾, whereas another showed greater fusion rate when graft was used, but without significant difference in patient satisfaction and the return to preoperative activity level⁽¹⁰⁾.

The most readily available source for autologous bone graft used in spinal fusion (the gold standard) is the iliac crest. One major disadvantage for harvesting iliac crest graft by open technique is postoperative pain at the donor site, which is reported in 5% to 80% of the patients^(9,11). In a recent study it was found that a large percentage of patients reported chronic donor site pain after anterior iliac crest bone graft harvesting, even when only a single-level fusion was performed and in addition to that, some patients suffered long-term functional impairment⁽¹²⁾. To avoid these significant problems, a number of alternatives have been developed. These included polymethylmethacrylate, synthetic grafts, allograft, and different types of cages that need only to be filled with a small amount of cancellous bone which can be harvested via a minimally invasive approach⁽¹³⁻¹⁷⁾. Titanium cages can be used alone for fusion and seems to give the same results as bone grafts⁽¹⁸⁾.

When polymethylmethacrylate was injected inside the disc space as a spacer instead of bone graft, it resulted in a significant lower bony union rate and frequently migrated into adjacent vertebrae. This substance was not recommended for surgical treatment of cervical disc disease⁽¹³⁾.

Madawi et al., compared a biocompatible osteoconductive polymer with iliac bone graft after cervical discectomy and found that the incidence of partial graft protrusion and postoperative intersegmental kyphosis was statistically higher with iliac bone, whereas the polymer acted as a good spacer⁽¹⁴⁾.

The use of allograft in one-level anterior cervical discectomy and fusion (ACDF) with rigid plate fixation yielded similar fusion rates as autograft. Nevertheless, allograft is fraught with the risks of infection, disease transmission and histocompatibility differences⁽¹⁵⁾.

A novel material is quickly gaining popularity. Polyetheretherketone (PEEK) is a hard radiolucent polymer that is used in conjunction with carbon fiber reinforcement or as pure PEEK (fig.1). Contrary to stainless steel and titanium, PEEK's modulus of elasticity is slightly lower to that of bone. Thus, its stiffness is slightly less than bone. This biomechanical advantage in addition to being radiolucent have made PEEK a hot biomaterial for implantable medical devices⁽¹⁹⁻²²⁾.

To date, studies about PEEK cervical cages in the literature are sparse. In the current study, the author presents the results of using cervical PEEK cages in a series of Egyptian patients and demonstrates a minimally invasive technique for harvesting iliac bone graft.



Fig. (1): PEEK cervical cage with titanium radiological markers, upper and lower serrations to assist with fixation to the end plates and a middle space to accommodate cancellous bone graft.

PATIENTS & METHODS

A case series study was conducted from September 2006 to October 2007. Inclusion criteria included patients with degenerative cervical disc disease (prolapse or spondylosis) resulting in significant radiculopathy (pain visual analogue scale >4) not responding to conservative treatment for at least 3 months; or myelopathy or myeloradiculopathy.

A total of 22 consecutive patients were included in the study (16 males and 6 females). The mean age was 44.4 years (range: 35-61). 14 patients had soft discs and 8 had hard discs. 12 patients had recalcitrant radiculopathy, 7 had myeloradiculopathy and 3 had myelopathy. The levels affected were two at C3/4, nine at C4/5, twelve at C5/6 and three at C6/7.

All patients had ACDF using PEEK cages packed with autologous cancellous iliac bone graft, harvested by a minimally invasive technique. 26 cages have been inserted (four patients had consecutive double level disc disease). A hard neck collar was applied immediately after surgery and maintained for 8-10 weeks postoperatively. Patients were followed up at 6 weeks initially then 3, 6 and 12

months thereafter. The average follow up period was 7 months (range: 3-12).

Visual pain analogue scale (VPAS) was used to assess the severity of radicular pain both pre and postoperatively. Odom's criteria⁽²³⁾ (table 1) were used to assess the postoperative functional level through assessment of activities of daily living, starting from 3 months postoperatively to allow enough time for recovery of the neurological tissues. The highest grade reached is the one reported. Patients were asked to report any residual pain or discomfort at the graft donor site three weeks postoperatively onwards. Fusion was evaluated by plain radiography. Statistical analysis was performed using "SPSS Version 15". Paired "t" test was used to compare the pre and postoperative VPAS

Surgical technique:

All cases were done by the author via the standard antero-lateral approach to the cervical spine. Prophylactic intravenous antibiotic (2 grams Cefotaxime) was always given during induction of anesthesia. Under fluoroscopic guidance, a transverse "skin crease" incision centered over the pathological disc was used. In the four cases with consecutive double

disc pathology, the incision was centered over the intervening vertebral body. Removal of hard discs was achieved by the aid of a burr and a set of long curettes. The posterior longitudinal ligament was opened in all cases and the dura exposed. Illumination of the surgical field was aided by a head light source. Microscopy was not used.

After disc clearance and measuring the implant size, autologous cancellous bone graft was harvested from the ipsilateral iliac crest using a minimally invasive technique as shown in figures 2 and 3. Skin incision did not exceed 1cm. The centralizer was initially hammered into the superior cortex of the iliac crest to ensure a secure path for the serrated trephine.

Table (1): Odom's criteria for postoperative functional level

Grades	Criteria
Excellent	No complaints and no handicap
Good	Intermittent relevant discomfort, not significantly interfering with work
Fair	Subjective improvement but physical activities significantly limited
Poor	Unimproved or worse

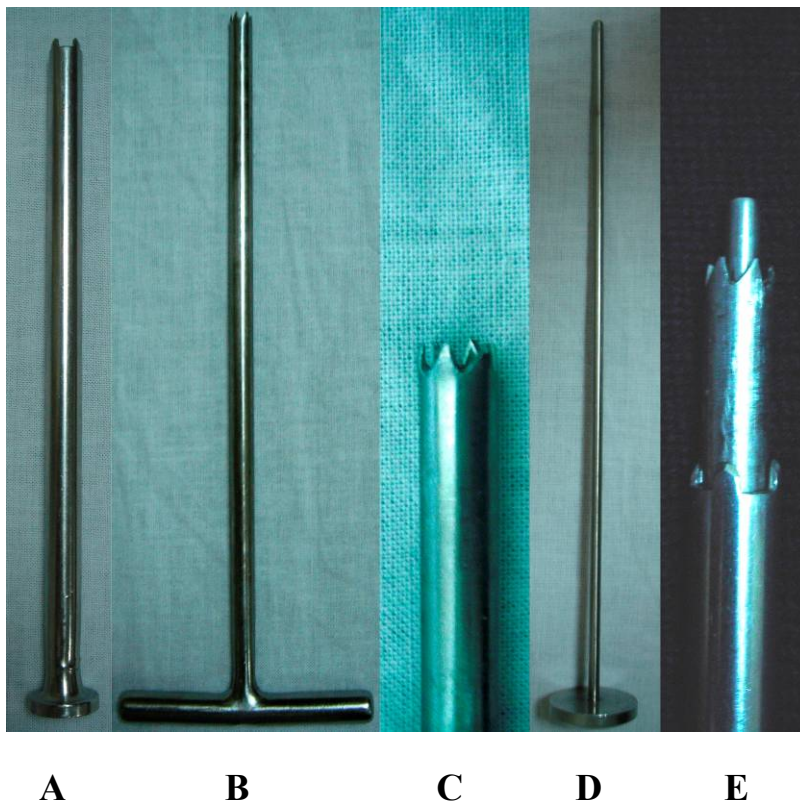


Fig. (2): Minimally invasive graft harvesting instrument set. A: centralizer, B: trephine, C: magnified trephine serrated end, D: pusher, E: the three instruments assembled

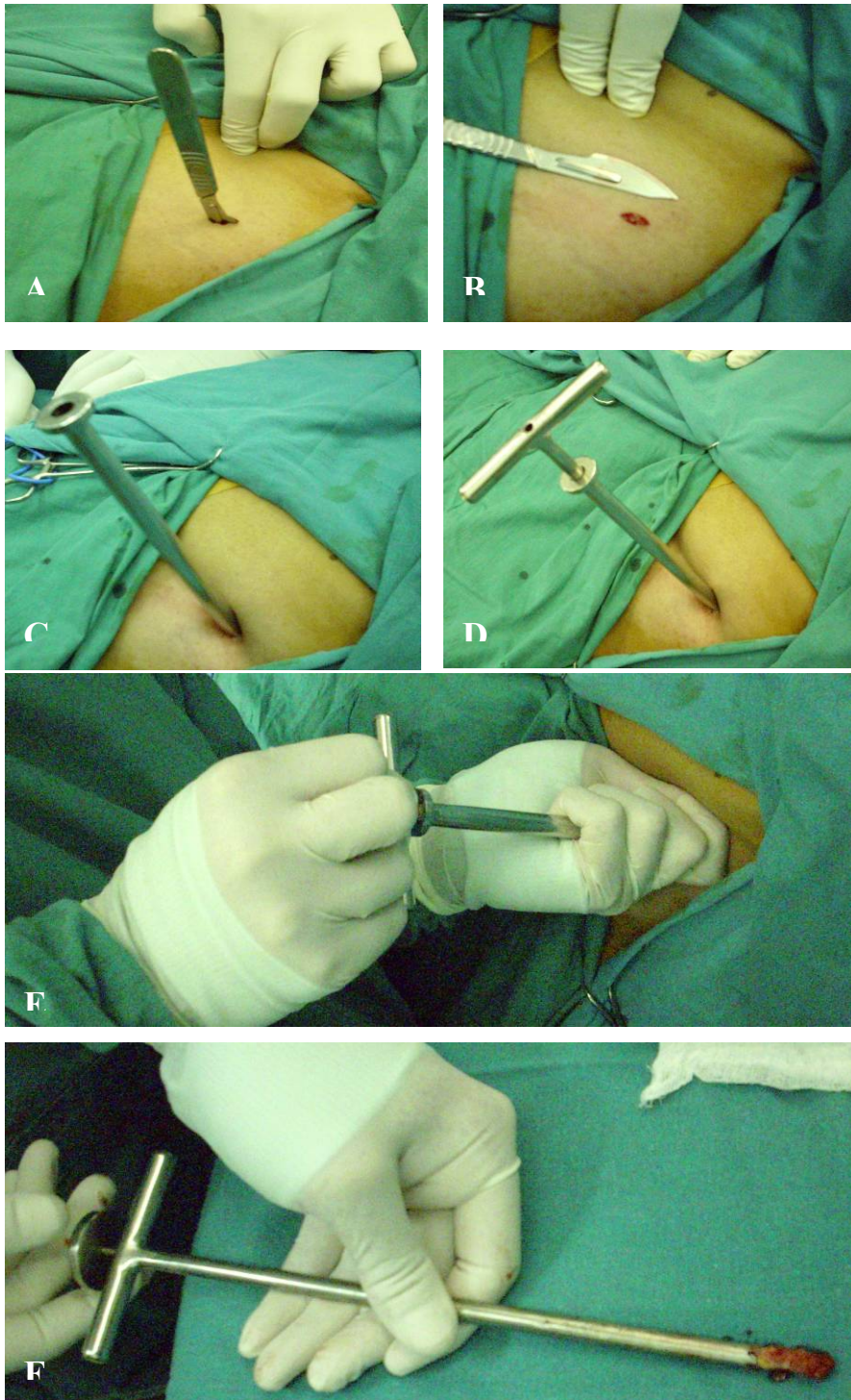


Fig. (3): *Technique of minimally invasive graft harvesting: A: stab incision, B: incision size, C: centralizer inserted, D: trephine inserted, E: graft harvesting by rotating the trephine, F: graft pushed out of the trephine.*

RESULTS

According to Odom's Criteria, ten cases (45.5 %) were graded excellent; all of them had radiculopathy only before surgery. Six cases (27.3%) were graded good, four (18.2%) fair and two (9%) poor. All the fair and poor grades occurred in cases with a preoperative element of myelopathy (table 2). The two cases with poor grade had established myelomalacia preoperatively (Fig.4).

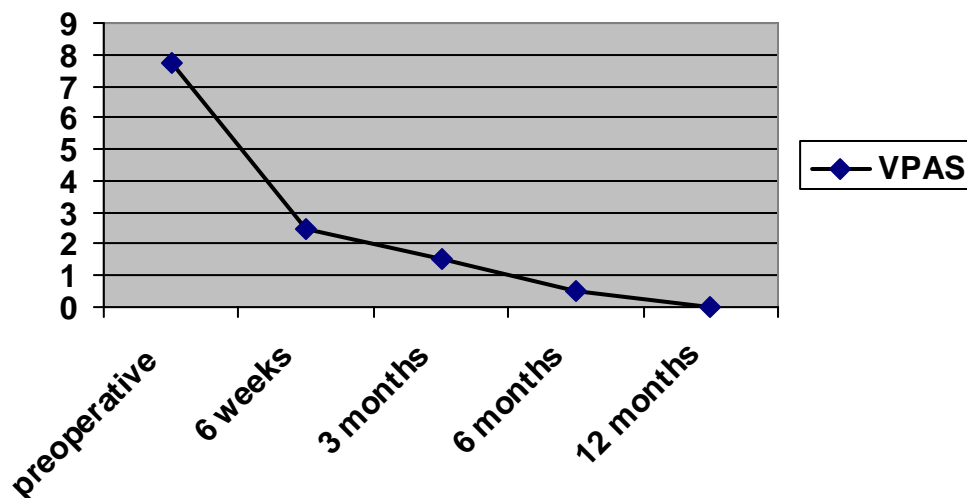
Radiular pain showed dramatic improvement postoperatively. The mean postoperative VPASs at 6 weeks, 3 months, and 6 months were 2.5, 1.5 and 0.5 respectively, mostly due to residual parasthesia and not true pain ($P = 0.015, 0.009$ and 0.006 respectively). This disappeared at latest follow up (graph 1) ($P = 0.003$).

None of the patients reported residual symptoms in relation to the graft donor site. Fusion was evident in 72.7 % of cases (16/22) at three months and 90% (9/10) at 6 months. All cases reviewed at 12 months (six cases) showed radiological evidence of fusion.

Complications included: temporary dysphagia in 2 cases (9.1%), resolved spontaneously over two weeks; haematoma in 1 case (4.5%) which did not require surgical evacuation; temporary recurrent laryngeal nerve palsy in 1 case (4.5%), presented by hoarseness of voice and failure to close the glottis for straining. This improved spontaneously over 3 months. There was no infection, migration or extrusion of the cage at latest follow-up. No mortality or major complications occurred.

Table (2): Functional outcome for each pathological presentation:

	Excellent	Good	Fair	Poor
Radiculopathy	10	2	0	0
Myeloradiculopathy	0	3	3	1
Myelopathy	0	1	1	1



Graph (1): Mean VPAS preoperatively and at progressive intervals postoperatively.

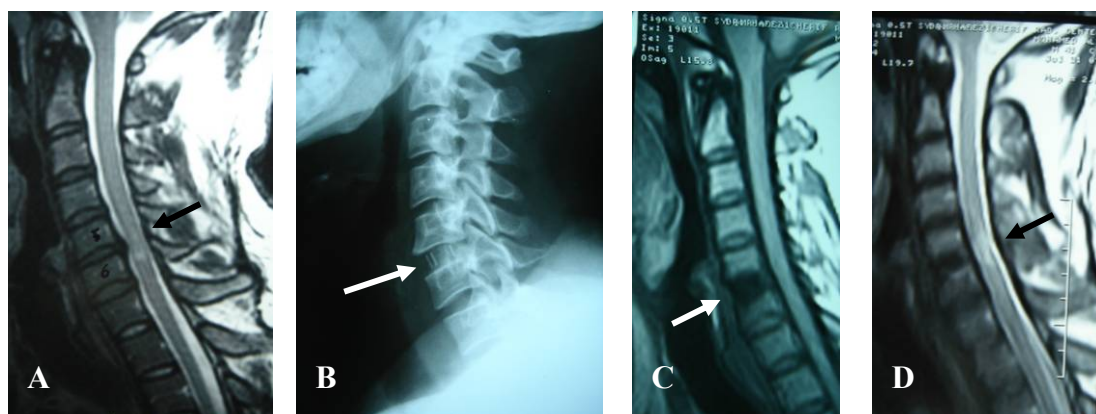


Fig. (4): A: T2 weighted sagittal MRI image showing C5/6 disc prolapse causing cord compression and resulting in cord signal change. B: 3 months follow up x-ray following ACDF with PEEK cage and autologous graft. C& D: 3 months postoperative T1 and T2 weighted MRI images showing adequate decompression but the cord signal change in T2 image did not recover.

DISCUSSION

There are several accepted methods for single and double-level ACDF. Those who perform discectomy only aim at spontaneous fusion, whereas those who insert different types of cages and/ or grafts in the disc space aim at inducing fusion whilst maintaining the anatomical dimensions. Both teams demonstrated good results and comparable rates of fusion. Thus, No study has clearly demonstrated the superiority of one method over the alternatives.

The most recent material used for ACDF is PEEK. Biomechanical studies performed on this material showed that it provided adequate mechanical stability in a simulated physiological environment and over extended loading periods⁽²¹⁾. Finite element analysis also supported its use for load-bearing intervertebral implants^(21,22). Furthermore, compared to titanium cages, the peak stresses in the bone graft increased by at least 9 folds with PEEK cages, whereas peak stresses in the endplates decreased by at least 2.4 folds. The stiffness of the

spacer did not affect the stability across the instrumented segment. Thus, PEEK cages, being less stiff than bone graft, provided stability similar to titanium cages, reduced the stresses in endplates adjacent to the cage and increased the load transfer through the graft⁽²²⁾. This can explain the high fusion rates encountered with PEEK cages.

Since 2002, only nine clinical studies about ACDF with PEEK cages have been published from all over the world^(16,24-31). In 2002 Cho et al. published their preliminary experience with PEEK cervical cages versus the conventional tricortical autologous iliac bone graft inserted by the Smith-Robinson technique. Although both groups achieved satisfactory fusion rates, PEEK cage was more effective in maintaining lordosis and the height of foramina. Also PEEK cages were associated with lower complication rates and higher percentage of the excellent grade, using Prolo scale (66.63% versus 28.75%). The authors also noticed that the PEEK material did not interfere with post operative MRI evaluation⁽²⁴⁾. The appearance of PEEK cage on MRI is shown in the

current study in Fig. 4. The same comparison was made later by Celik et al. who published results of longer term follow up in 2007. They concluded that The PEEK cages may provide sufficient preservation of foraminal height even 1.5 years after the operation⁽²⁷⁾. The ability of PEEK cages to restore and maintain the anatomical dimensions of cervical motion segments and to achieve excellent fusion rates was also shown in other studies^(26,28,29,31).

Maintenance of disc space/ foraminal height and lordosis were not analyzed in the current study because previous studies showed that mild subsidence of PEEK and titanium cages did occur but did not affect the clinical outcome^(7, 28). Furthermore, up till now there are schools performing only discectomy, leaving the disc space to collapse and end plates to come in contact with each other, aiming at spontaneous fusion. This would inevitably create segmental kyphosis, or at least segmental reduction of lordosis as well as reduction in foraminal heights, which did not seem to have affected the clinical outcome, given the good results reported for this technique^(3- 5,8-10,13).

Only three previous studies evaluated the postoperative functional outcomes following ACDF with PEEK cages, using different scoring systems^(24,29,31). Odom's criteria were used in only one previous study, which showed that 74% of patients (14/19) exhibited excellent and good clinical outcomes⁽²⁹⁾. This is comparable to the results in the current study (72.8%).

Patients presenting with an element of myelopathy represented 45.5% (ten cases) of the sample in the current study. Most of those patients were either manual workers or farmers from the low socio-economic class, who presented after establishment of an irreversible element of cord pathology

(myelomalacia) (fig.4). This explains the high incidence of Odom's fair and poor grades (27.2%). In the presence of established myelomalacia, the main aim of surgery was to stop deterioration of the neurological status rather than to improve it.

Although a high rate of successful clinical outcomes has been reported after ACDF procedures with iliac autograft, donor site morbidity can be significant and must not be ignored. Long-term patient complaints may be more closely associated with the procurement of the graft rather than the primary surgical site. Chronic pain, infection, wound dehiscence, abnormal sensation or numbness, clothes intolerance, hernias, lateral femoral cutaneous nerve injuries, and iliac wing fractures, are known to exist^(12,32-34). Results comparable to autograft have been reported when synthetic or allografts were used^(14,15). For economical reasons, it was not possible to use synthetic or allografts in the current study. However, it was possible to avoid donor site complications associated with iliac bone graft harvesting by using the minimally invasive technique. Meanwhile, the overall cost was significantly reduced and the risks of infection, disease transmission and histocompatibility differences were avoided.

In a recent large review study conducted on 1015 ACDF patients, the complication rates were: mortality in 0.1% (1 of 1015 patients, secondary to an esophageal perforation), dysphagia in 9.5%, hematoma in 5.6% (required surgical intervention in 2.4% of cases), symptomatic recurrent laryngeal nerve palsy in 3.1, dural penetration in 0.5%, esophageal perforation in 0.3%, worsening of preexisting myelopathy in 0.2%, Horner's syndrome in 0.1%, instrumentation backout in 0.1%, and superficial wound infection in 0.1%⁽³⁵⁾. This is consistent with the

complication rates in the current study minus mortality and major complications.

CONCLUSION

ACDF using PEEK cage packed with autologous bone graft is a safe and effective method for treating degenerative cervical disc disease. The high fusion rate and facilitation of radiological assessment are the results of the physical properties of PEEK material. The minimally invasive technique did not result in any graft donor site morbidity. The author recommends this technique as the standard technique for harvesting autologous bone graft, when only cancellous bone is required.

Case Presentation

34 years old male electrician presented with a 6 months history of unsteady gait with stiffness of the lower limbs and parasthesia of the

lower half of the trunk and legs. He did not report any upper limb symptoms or sphincteric troubles. Examination revealed abnormal gait and upper motor neuron signs in the lower limbs. No abnormal neurological signs were found in the upper limbs. Plain radiographs of the cervical spine were unremarkable apart from moderate disc space narrowing at C5/6 level (fig.5: A). MRI of the thoracic spine was normal but MRI of cervical spine showed postero-lateral disc prolapses at C5/6 on the right side and at C6/7 on the left side, moderately compressing the cord, more at the upper level (fig.5: C-E). He was treated by ACDF at both levels with PEEK cages and autologous iliac bone graft (fig.5: F& G). This was followed by a remarkable improvement of all his symptoms. His gait improved but did not return to normal. Six months follow up x-rays showed satisfactory fusion at both levels (fig.5: H).

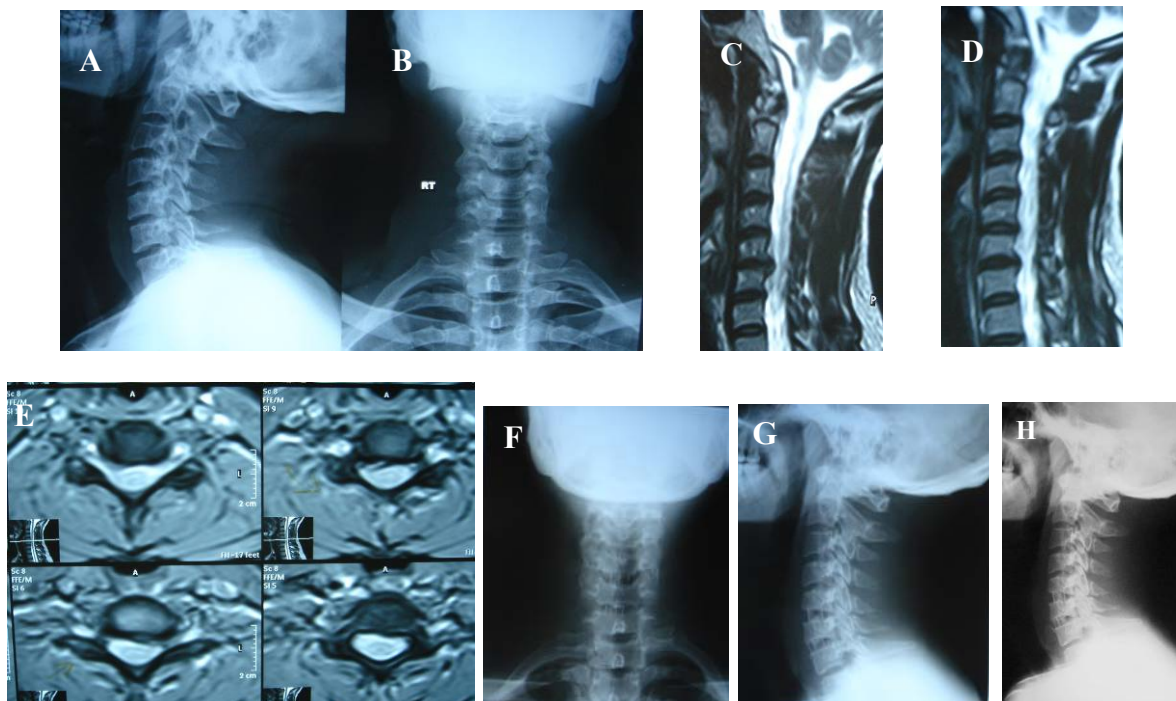


Fig. (5): A & B: Preoperative radiographs showing narrowing of C5/6 disc space; C- E: Preoperative MRI showing double level disc prolapse at C5/6 and C6/7; F & G: 6 weeks following ACDF with PEEK cages at both levels showing ongoing fusion; H: 6 months postoperative radiograph showing satisfactory fusion at both levels.

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