Comparison between Polyetheretherketone (PEEK) Cages Versus an Iliac-Crest Autograft Used in Treatment of Single or Double Level Anterior Cervical Discectomy

AYMAN E.A. GALHOM, M.D.
The Department of Neurosurgery, Faculty of Medicine, Suez Canal University

Abstract

Background: Anterior cervical discectomy with fusion (ACDF) is challenging with respect to both patient selection and choice of surgical procedure.

Objective: The aim of this study was to evaluate the clinical outcome of ACDF, with respect to both patient selection and choice of surgical procedure: Fusion with an autologous iliac crest graft (ICG) versus fusion with an artificial cage made of polyetheretherketone (PEEK) filled with hydroxyapatite (HA).

Patients and Methods: From January 2007 to January 2011, 40 consecutive patients referred to the Department of Neurosurgery, Suez Canal university hospital were recruited for the study and randomized into two treatment groups. Clinical assessment of pre-operative clinical data and postoperative status using Nurick scale for myelopathy, Odom's criteria for functional outcome, and Visual Analogue Scale (VAS) for both neck and arm pain. Radiological fusion was assessed by X-ray. Operative complications were reported.

Results: Eighteen patients were operated for one level discectomy and fusion with either ICG or PEEK cages with HA and 22 patients for two levels. There were 24 (60%) males and 16 (40%) females. The age of the patients ranged from 30-72 years, a mean ± SD 45±8.34. At the 2 years clinical follow-up, there were significant post operative improvements of Nurick scale, and VAS comparative to preoperative record. According to Odom criteria, 18/20 patients (90%) were graded excellent-good in the cage group compared to 16/ 20 patients (85%) in the group with bone graft. The relation was note statistically significant between the two groups p<0.35. A significant difference was found in VAS for arm pain between the two groups at 24 months with less pain in the cage group (p<0.02). Fusion occurred in 17/20 patients (85%) and 29/34 (85.2%) segments of the PEEK group, while it was 18/20 (90%) of the ICG group and 25/28 (89.2%) segments.

Conclusion: Iliac bone graft is still effective with favorable outcome as PEEK cage with HA in treatment of cervical disc. However, the former had higher fusion rate but the latter lack of donor site morbidity.

Key Words: Cervical fusion — Polyetheretherketone (PEEK) cages — Iliac bone graft.

Introduction

SPINAL fusion offers the surgeon an opportunity to remove the pathologic process, eliminate painful motion and obtain decompression of the neural elements [ii. Fusion is at present the gold standard treatment for herniated cervical discs. Currently, over 95% fusion rate occurs after application of anterior cervical implants [2]. The indications for anterior cervical discectomy fusion (ACDF) include radiculopathy, myelopathy, myelo-radiculopathy and traumatic instability involving single or multiple levels [3].

There are various techniques for performing ACDF depending on surgeon preference; including the Cloward technique or discectomy, and interposition graft [4,5]. The interposition graft used may include autologous bone, allograft, and synthetic material or cages. Cervical cages of different materials have been used; titanium, Polyetheretherketone (PEEK), and carbon fiber [6]. Different fusion materials have been used too, as iliac crest autograft (ICG) [6], allograft [2], demeneralized bone matrix [7], hydroxyapatite (HA) [8], and bone morphogenetic proteins [9]. There are different complications of using graft alone; graft collapse, extrusion, and pseudarthrosis [6]. Anterior cervical discectomy and fusion further modified by using anterior locking plates ACDFP for stabilization [3]. The additional costs involved in ACDFP have led investigators to examine for any significant difference in fusion and clinical outcome between ACDF and ACDFP patients [3,8,9].

Although generally successful with a low incidence of major complications, nonunion rates...
following attempted ACDF range from 0% to 20% for single-level fusions, but may be as high as 50% after multilevel procedures depending on the number of levels fused and the type of bone graft used. The pseudarthrosis rate is affected by the number of operative levels, the type of graft used, and the surgical technique. Although some patients with pseudarthrosis may be asymptomatic, failure to achieve a solid fusion can lead to continued pain and poor functional outcome.

In this study, we try to compare single or double level ACDF with PEEK Cages filled with HA (a calcium phosphate) versus an ICG without plate. We compare the two for sagittal alignment, cervical lordosis, graft subsidence, fusion rate, and adjacent-level ossification.

Patients and Methods

From January 2007 to January 2011, 40 consecutive patients referred to the Department of Neurosurgery at our hospital were recruited for the study and randomized into two treatment groups. The duration of preoperative symptoms ranged from 2 months up to one year on conservative management including medical treatment and physiotherapy.

The parameters registered the day before surgery included age, sex, symptom duration before surgery (months), previous surgery for Cervical discectomy, previous neck trauma, working status, radicular and neck pain, myelopathy, and paresis. The pain category was scored using a VAS [12]. Nurick scale was used for myelopathy [13]; pre-operative and post-operative, Odom’s criteria for functional outcome [14], Tables (1,2).

Table (1): Nurick Scale A six grade system (0-5) based on the ‘difficulty in walking’.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>Signs or symptoms of root involvement but without evidence of spinal cord disease</td>
</tr>
<tr>
<td>1</td>
<td>Signs of spinal cord disease but no difficulty in walking</td>
</tr>
<tr>
<td>2</td>
<td>Slight difficulty in walking which does not prevent full-time employment</td>
</tr>
<tr>
<td>3</td>
<td>Difficulty in walking which prevented full time employment or the ability to do all housework, but which was not so severe as to require someone else’s help to walk</td>
</tr>
<tr>
<td>4</td>
<td>Able to walk only with someone else’s help or with the aid of a frame</td>
</tr>
<tr>
<td>5</td>
<td>Chair bound or bedridden</td>
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Table (2): Odom’s criteria.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Criteria</th>
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<tbody>
<tr>
<td>Excellent</td>
<td>All pre-operative symptoms relieved, abnormal findings improved</td>
</tr>
<tr>
<td>Good</td>
<td>Minimal persistence of pre-operative symptoms, abnormal findings unchanged or improved</td>
</tr>
<tr>
<td>Fair</td>
<td>Definite relief of some pre-operative symptoms, other symptoms unchanged or slightly improved</td>
</tr>
<tr>
<td>Poor</td>
<td>Symptoms and signs unchanged or worse</td>
</tr>
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</table>

Patient with cervical recurrent disc, trauma, neoplasia, and infection excluded from the study. Diagnostic work-up: Cervical MRI, cervical X-ray, and some cases needed CT cervical spine with sagittal reconstruction. The parameters registered during surgery included: Number of levels fused (single-level, or two-level), level fused (C3/C4, C4/C5, C5/C6, or C6/7) and fusion type (ICG or PEEK cage). The patient followed-up clinically and radiological at 6,12, and 24 months. Surgery-related complications were reported.

Anterior cervical discectomy and fusion:

Prior to surgery, the patients were randomized to surgery using either autologous bone from the ICG or using fusion PEEK cage. No additional plate fixation was used.

Standard Smith-Robinson procedure [15] was used. Under general anesthesia, patients were positioned supine, with interscapular roll to induce some extension. After opening and marking the space required, a Cloward retractor was positioned, and intervertebral Caspar retractor was inserted. The levels of interest were verified using fluoroscopy. In most patients, an operating microscope was used and the disc was removed with curette and Kerrison Punch. During the discectomy, special attention was paid to avoiding damage to the bony layer of both adjacent end-plates in case we prepare for cage insertion. Both the end-plates were subsequently sharply punctured by a fastigiated metal instrument in their centre part (decoration) to facilitated fusion within the cage. Removal of the posterior longitudinal ligament and the final decompression of the nerve roots were performed using small rongeur. Bilateral nerve root decompression was always performed, even in patients with unilateral symptoms. After the procedure, distraction was applied and fusion was attained with either tricortical ICG or PEEK cage. During cage insertion, care should be taken to avoid compression of the adjacent segment verified by fluoroscopy, Fig. (2).
Iliac crest auto graft ICG:

The tricortical ICG was harvested from the right iliac crest. Care was taken to preserve the anterior 2cm of the iliac crest and the lateral cutaneous femoral nerve. The bone grafts were harvested using a gigli saw and a graft cutter, and the bone bed was waxed with bone wax (Ethicon, Johnson & Johnson, USA). Wound drainage was routinely used.

The cage was filled with synthetic bone lml HA mixed with blood. After discectomy and decompression of the nerve root, the graft or the cage was placed and the wound was closed. Drain was inserted and a hard collar was prescribed to be used 6 weeks postoperatively in both groups. Almost all patients were discharged from our hospital 48-72 h after surgery. All patients were encouraged repeatedly to participate in normal activities 6-8 weeks after surgery.

Plain X-ray films were taken with the patient positioned supine immediately postoperatively, after 2, 6, 12 weeks and after 6, 12 and 24 months. All lateral radiographs were performed in standardized sitting positions. The patients were sitting at the stool with arms hanging down loosely or with applied traction in order to display the cervicothoracic area if necessary. The films were digitized and the data were computerized.

Pseudoarthrosis (non union) was considered if there were no continuous bridging bone trabeculae between the end plate, and the presence of translucency between the graft and the vertebral end plate [16]. Subsidence at the radiographs was defined as cage migration of 3mm or more into the adjacent vertebral body. The migration along the superior and/or inferior end-plates was labeled as settling of the Implant [17]. Because of intra-individual variations of the magnification factor in the radiographs, the total vertical height of the two fused vertebral bodies was corrected for magnification differences by using the anteroposterior diameter of the upper vertebral body on the lateral cervical radiograph [18], Fig. (1).

Segmental kyphosis was measured as the angle between the posterior borders of the two vertebral bodies on the lateral radiograph. If the difference of the interbody angle on the flexion and extension radiographs was not greater than 2 degrees, non union was assumed [17].

Database and statistical analyses:

Statistical analysis was performed using SPSS version 11. Descriptive statistics were applied in mean ± standard deviation (SD) for quantitative data and number (%) for qualitative data. Differences in proportions were tested by using the chi-squared test. Fischer’s exact test was used wherever the expected value was less than five. Student’s t-test was used to test mean differences between groups. A paired t-test was used to compare the pre- and post-treatment. Statistical significance was determined at 95% level of confidence. Results were considered statistically significant if the p-value was less than 0.05.

Results

The study included 40 patients. Eighteen patients were operated for one level discectomy and fusion with either ICG or PEEK cages or 22 patients for two levels. These numbers were reversed, as 4 patients with single level discectomy fusion developed adjacent segment disease that required surgeries. One patient had first bone graft and on the second session when she developed adjacent level she had cage due to donor site morbidity. Interesting enough, she had fibrous union for cage and solid bony union for ICG, Fig. (4). There were 24 (60%) males and 16 (40%) females. The age of the patients ranged from 30-72 years, a mean ± SD 45±8.34. There were 10 (25%) smokers. The differences between the two groups showed in Table (3).

There were 12 patients (30%) with radiculopathy, 10 patients (25%) with myelopathy, and 18 patients (45%) with radiculomyelopathy. Regarding the levels operated, there were 14 C3-4 levels, 18 C4-5 levels, 26 C5-6 levels, and 4 C6-7 levels. The total levels done were 62 levels. Duration of symptoms ranged from 1.5 months to 12 months; mean±SD was 8±3.23 months. Patients were followed-up for a period of 6 months to 24 months, mean±SD 10.3±3.4 months.

At the 2 years follow-up, we reported a significant post operative improvement of Nurick scale, and VAS for arm and neck pain comparative to preoperative record, Table (4). According to Odom criteria, 18/20 patients (90%) were graded excellent-good in the cage group compared to 16/20 patients (85%) in the group with bone graft. No patient as graded poor. The relation was note statistically significant between the two groups p<0.35. A significant difference was found in VAS for arm pain between the two groups at 24 months with less pain in the cage group (p<0.02). However, no significant difference between the two groups was found regarding VAS for neck pain (p<0.34) but, neck pain more noticed in cage group.
Comparison between Polyetheretherketone (PEEK) Cages

There were some transient complications; dysphagia is reported in 5 patients (12.5%) and improved within the first 2 weeks, superficial wound infection at the graft site reported in 2 patients (5%), transient vocal cord dysfunction in once case, and iliac graft site pain in 4 patients (10%), Table (5).

Cage subsidence of 3mm occurred in 3 cases (7.5%) and 5/62 (8%) Segments, (Fig. 1). The loss of segmental lordosis from immediately after surgery to the last follow-up 3° in 14/62 segments (22.5%) while 77.5% shows no progression of angle after fusion, (Fig. 3). The mean loss of segmental lordosis from immediately after surgery to the last follow-up was 5.6°±2.9° in the cage group, and 6.3°±2.7° in ICG group. All cases of subsidence occurred in the lower anterior end plate. While, ICG loss of segmental lordosis occurred due to graft bony resorption during follow-up, and one case after graft extrusion and removal, (Table 5).

Distance (interrupted arrow) a/e of upper vertebrae (C2) are multiple b and f to correct magnification.
- Anterior segment height b and f.
- Posterior segment height c and g.

Fusion occurred in 17/20 patients (85%) and 29/34 (85.2%) segments of the PEEK group, while it was 18/20 (90%) of the ICG group and 25/28 (89.2%) segments, (Figs. 1,3-5). The average age of the non fusion group of the whole series (4 patients) was older 48.8±4.3 comparative to the average age at the fusion group (26 patients) 42±5.3, and p-value <0.221 (statistically non significant), (Fig. 2). There were 10 smokers at the study, 7 of them were at the fusion group, p<0.42, statistically non significant. At the non fusion group, all patients complain of chronic neck pain that mandate analgesic.

Table (3): Preoperative demographic data.

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Cage</th>
<th>Bone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean, range)</td>
<td>43 (35-72)</td>
<td>42 (30-64)</td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Smokers</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Durations of symptoms, months (mean, range)</td>
<td>8 (1.5-12)</td>
<td>8 (3-12)</td>
</tr>
<tr>
<td>Follow-up, months (mean, range)</td>
<td>9 (6-24)</td>
<td>10 (8-24)</td>
</tr>
</tbody>
</table>

Table (4): Operative outcome.

<table>
<thead>
<tr>
<th></th>
<th>Cage</th>
<th>p+ value</th>
<th>Iliac bone graft</th>
<th>p# value</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS arm PO (Mean, Range) Pst2</td>
<td>7.0 (2.3-8.9)</td>
<td>&lt;.003</td>
<td>6.2 (0.5-9.3)</td>
<td>&lt;.002</td>
<td>&lt;.002</td>
</tr>
<tr>
<td>VAS cervical PO (Mean, Range) Pst2</td>
<td>7.2 (3.3-9.8)</td>
<td>&lt;.004</td>
<td>6.9 (3.9-9.5)</td>
<td>&lt;.007</td>
<td>&lt;.34</td>
</tr>
<tr>
<td>Nurick scale PO (Mean±SD) Pst2</td>
<td>3.3±1.3</td>
<td>&lt;.002</td>
<td>3.2±1.2</td>
<td>&lt;.005</td>
<td>&lt;.45</td>
</tr>
<tr>
<td>Odom’s Prl (Mean±SD) Pst2</td>
<td>1.2±0.8</td>
<td>&lt;.008</td>
<td>1.3±1.4</td>
<td>&lt;.003</td>
<td>&lt;.35</td>
</tr>
</tbody>
</table>

Table (5): Complications.

<table>
<thead>
<tr>
<th>Complications</th>
<th>Cage</th>
<th>Iliac bone graft</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vocal cord dysfunction</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dysphagia (transient)</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Subsidence</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Non union</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Progressive kyphosis</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Graft extrusion</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Iliac graft (Donor site) morbidity</td>
<td>–</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
Fig. (1): X-ray image postoperative for a female patient operated for CD 3/4, 4/5 with PEEK cages and hydroxyapatite for 2 levels. Two cages show subsidence on early image 1 at the lower vertebra. Complete fusion on follow-up II and III. The anterior segmental height (B,F) and posterior segmental height (C,G) were measured as the distance between the upper end plate of the upper vertebra and the lower end plate of the lower vertebra at the anterior and posterior margins. Magnification differences were corrected by the ratio between the anteroposterior diameters at the middle of the upper vertebral body on each plain radiograph a/e. Every length measured on the plain radiographs was multiplied by the ratio a/e.

Fig. (2): X-ray and MRI of a patient operated for 2 level cervical disc at C3/4 and C5/6 A. She shows fibrous union the upper level c3/4 and bony trabeculae fusion of the lower level c5/6 with adequate discectomy on follow-up MRI B. Noticed cages inserted without over distraction to avoid compression of adjacent segment at c2/3 and c4/5 discs (operative note).
Comparison between Polyetheretherketone (PEEK) Cages

Fig. (3): Patient had cd at c4/5 (A,B) and had cage (C). (I) See segmental cobb’s angle (C). One year later, he developed adjacent level c5/6 that mandate surgery with cage and the upper level is fused (II). The cobb's angle didn't changes and no loss of segmental lordosis (E).

Fig. (4): Female patient with c6/7 disc and had iliac bone graft with solid fusion. A Later she developed adjacent level discase at c5/6 and she had cage with fibrous non bony fusion with adequate cord decompression B.
Discussion

Fusion is usually carried out with an intervertebral bone graft to restore disc height and to ensure primary stability of the motion segment. Discectomy alone may lead to inferior clinical results due to loss of disc height, narrowing of the neural foramen and to malalignment of the cervical spine because of the resulting kyphosis of the motion segment [19,20]. The local loss of cervical lordosis is deemed to be a risk factor contributing to progression of degenerative changes in adjacent segments. Mechanisms by which kyphotic malalignment contributes to accelerated degenerative process may involve both the change of dynamic kinematics of cervical spine [21].

A fusion cage should not only ensure primary stability between the vertebrae but also allow bone ingrowth to achieve secondary stability without losing the structural integrity of the segment [22]. In this study, fusion occurred in 17/20 patients (85%) and 29/34 (85.2%) segments of the PEEK group. It has been reported that the cage achieves excellent fusion rates ranging from 93.1-100% [7,17,21,23,24,25,26].

Cage subsidence is a concern in that the decrease of the foraminal volume, cervical spine instability and loss of segmental lordosis can lead to adjacent segment degeneration [27]. Cage subsidence of 3mm occurred in 3 cases (7.5%) and 5/62 (8%) segments in this study. Although it doesn’t affect fusion, it affects mainly segmental lordosis. Bartels et al. [28] showed that the incidence of cage subsidence was significantly higher for C6-7 fusion level than that for the other fusion levels. The distance from the anterior rim of the upper vertebra to the cage was significantly larger and the contact surface ratio of the cage versus the endplate was significantly smaller in the subsidence group [27].

Hydroxyapatite, because of their chemico-physical similarities to the bone mineralization phase, they provide an excellent osteoconductive scaffold for bone regeneration. Kim et al., using a 30% porous HA graft, found all implants had achieved fusion at 6-12 months, with good clinical results and no graft collapse [29]. However, 3/70 cases encountered graft dislocation early on due to inappropriate sizing. In another study using HA but with plating, complete fusion occurred in 100% of one-level and 98% of two-level procedures [30]. Chang et al. [23] used of radiolucent cages containing cancellous autogenous bone graft versus HA in cervical spine fusion. The study found no statistically significant differences in fusion rates or in patient post-operative satisfaction in terms of financial or functional aspects.

Anterior cervical decompression and fusion with autologous bone graft has been the standard treatment for cervical discectomy for more than 50 years [26].

Successful fusion is osteogenesis, osteoinduction and osteoconduction. These properties create a scaffold for bone regeneration and new bone development.
deposition, respectively. Only autograft possesses all of these features [9]. The literature also reports a consistent rate of 1-12% non-fusion for single-level anterior discectomy and autogenous bone fusion, 20-27% for two-level, and approximately 30-56% for three-level fusions [24,25,31,32]. That’s why plate fixation has been added for adequate fusion [3,33,34].

However, Connolly et al. [33] reported a 100% fusion rate for both plated and nonplated one-level ACDF patients with autograft. The authors concluded that plate fixation does not enhance fusion rate nor does it improve clinical outcome in one-level ACDF.

Using fusion cage and fixation, Hacker et al. [36] compared cage fixation and ACDF in a multicenter randomized study including both one- and two-level degenerative disc disease with radiculopathy but found no significant difference in clinical outcome between the two groups. In another nonrandomized single level study, a stand-alone cage was compared to ACDF with plate fixation and a similar result between the two groups was demonstrated [37].

For multilevel, fusion rates are superior in the ACDFP group (99%) than in the ACDF group (93%). In addition fusion is at a faster rate [3]. However, plating has complications. Plate complication rate varies from 2.2-24.0% [24,34,35] and includes screw pullout, screw breakage, injury of the laryngeal nerve, injury of esophagus, injury of spinal cord or root, injury of vertebral artery, and wound infection. Additionally, the operative time is usually longer, and more cost to patient or health authority.

This study found, with others [26], that fusion is higher in ICG group rather than PEEK group with HA. However, clinical outcome for radicular pain is statistically significant better in cage group. Due to donor site morbidity, and relatively shorter operation time, and nearly the equivalent clinical results between cage and bone graft, many authors prefer cages for this type of fusion to ICG [6,7,18,22,26,38].

According to the previous data, and based on the current literature, ACDF with ICG or PEEK cage had no significant different in fusion rate. ACDF with ICG (both single-level and two-level ACDF) is still safe and effective with higher fusion rate and low cost if adequate patient selection and proper surgery. Cage fusion, however, probably provide favorable clinical outcomes for brachialgia and no donor site complication, but surgeon should follow guideline to avoid subsidence and its squeal.

Conclusion:

Anterior cervical discectomy and fusion is considered ideal for treating cervical disc prolapse in terms of clinical improvement, restoration of cervical lordosis, bone fusion, and in long term follow-up. Iliac bone graft is still effective in treatment of radicular pain and myelopathy in selected patient with cervical disc disease. PEEK cage with HA had some favorable clinical outcome and fusion as ICG but lack of donor site morbidity.

References


