A Preliminary Study of Three and Four Levels Degenerative Cervical Spondylosis Treated with Peek Cages and Anterior Cervical Plate

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Objective: *A retrospective study was performed in case with three and four levels degenerative cervical spondylosis that underwent anterior cervical discectomy and fusion (ACDF) with polyetheretherketone (PEEK) cages and anterior cervical plate to evaluate the efficacy and outcome.*
Material and Method: *Clinical and radiographic results of 16 patients (6 women and 10 men) between January 2006 and June 2009 with follow-up more than 24 months were evaluated. Spinal curvature, segmental sagittal angulations, construct height and the radiographic fusion success rate were measured. Odom's criteria, visual analog scale (VAS), Nurick and modified JOA (Japanese Orthopedic Association) score were used to assess the clinical results.*
Results: *There was significant difference between pre- and post-operative in degree of lordosis, segmental Cobb angle and clinical outcomes ($p < 0.01$). Clinical outcomes were classified as 'excellent' or 'good' according to Odom's criteria in 14 patients (success rate: 87.5%). Mean follow-up period was 36 months. Flexion and extension lateral radiographs showed 100% fusion rate. The construct height and sagittal alignment were maintained on the final follow-up observations. No cage failure, subsiding or dislodgement was showed on follow-up radiographs.*
Conclusion: *Interbody fusion with PEEK cages packed with bone substitute and aspirated bone marrow which additions of cervical plate eliminate the complications of graft harvest and is a good option for the treatment of patients with three and four levels degenerative cervical spondylosis.*

Keywords: *Three and four levels degenerative cervical spondylosis, ACDF, PEEK cage, Anterior cervical plate, Aspirated bone marrow*

J Med Assoc Thai 2012; 95 (7): 909-16
Full text. e-Journal: *http://jmat.mat.or.th*

Anterior approaches to the cervical spine have yielded good results for the treatment of cervical spondylosis. Furthermore, they have been widely accepted as the appropriate operative procedure. Anterior cervical discectomy and fusion (ACDF) has become a highly successful surgical procedure for cervical spondylosis associated with radiculopathy or myelopathy[1,2].

Bohlman et al reported on forty-eight patients with two-level anterior discectomy and autogenous bone fusion. The pseudarthrosis developed in thirteen cases and rate of non-fusion was approximate 27%[3]. In 1997, Emery et al reported on sixteen patients who underwent the modified Robinson anterior cervical discectomy and fusion at three operative levels. The pseudarthrosis developed in 44% and the improvement of functional outcome of those seven patients was limited until the nonunion was surgically repaired[4]. Fraser and Hartl, in 2007, conducted a meta-analysis of twenty-one studies published after 1990. Pseudarthrosis is reported in 35% of patients with three-level anterior fusion operations[5]. Anterior cervical plate fixation is suggested for multilevel cervical spondylosis to increase fusion rates from 63% to 82% and decrease the incidence of graft-related complications[6].

Allograft bone has been widely used in the cervical spine fusion, but the risk of disease transmission is of concern and more likely to be subsidence[7]. There has been an advent of various types of cages to avoid the problems associated with autologous bone grafting,

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such as persistent donor-site pain, continuous drainage and wound dehiscence[8]. A perfect cage should provide immediate structural biomechanical support, maintain spinal alignment, and foraminal height, and subsequent osteogenic integration to achieve higher or comparable fusion success rates with autografts. Polyetheretherketone (PEEK) is a non-absorbable, biocompatible polymer that modulus of elasticity is close to that of bone. The radiolucency of the PEEK cage allows for assessment of bone fusion by plain radiographs[9].

To the authors' knowledge, no study to date has been reported about clinical and radiological outcome of the three and four levels ACDF operations with the use of PEEK cages packed with bone substitute and aspirated bone marrow from the iliac crest with anterior cervical plate fixation[10-12].

The purpose of the authors' retrospective study was to evaluate the efficacy and outcome of ACDF using PEEK cages packed with bone substitute and aspirated bone marrow for three and four levels degenerative cervical spondylosis.

Material and Method

Nineteen patients were operated on by a single surgeon (Dr. Kunakornsawat S) between January 2006 and June 2009 at Lerdsin General Hospital. Only 16 patients with follow-up more than two years were included in the present study. All of the data were collected and reviewed by an independent observer with the Institutional Ethical Committee approval. Six women and 10 men with a mean age of 57.1 years (ranged from 41 to 80 years) underwent three and four levels ACDF operations with the use of PEEK cages (Bengal cervical PEEK; Johnson and Johnson, Raynham, MA or Skate cervical PEEK; Biomech-Paonan Biotech Co., Ltd., Taipei, Taiwan) packed with bone substitute (Triosite, 40% b-tricalcium phosphate [b-TCP] and 60% hydroxyapatite; Zimmer, Berlin, Germany) and aspirated bone marrow from the iliac crest. All patients had implantation of a cervical plate (Codman; Johnson and Johnson, Raynham, MA or Atlantis; Medtronic Inc., Minneapolis, MN). Indications for operation were intractable radiculopathy and/or myelopathy due to nerve root or spinal cord compression proven with the preoperative radiographs (antero-posterior and lateral) and magnetic resonance images (MRI) (Fig. 1). Patients with fractures, infections, or tumors were excluded.

Standard anterior Smith-Robinson approach was performed in all the patients. Vertebral bodies were distracted with a Caspar distractor. The intervertebral discs, cartilagenous contents, and osteophytes were removed using curette with preservation of the vertebral body endplate. The optimal PEEK cage was selected and filled the inner cavity with bone substitute (Triosite) mixed aspirated bone marrow from prepared iliac crest. Anterior cervical plate was placed in all cases. Immobilization with cervical collar was used for 1 month postoperatively. Neck motion exercises were guided and initiated for 2 weeks after collar removal and a normal activity level was progressively resumed.

Spinal curvature, segmental angle, construct height and fusion status were assessed with anterior-posterior and lateral radiographs. Cervical spine

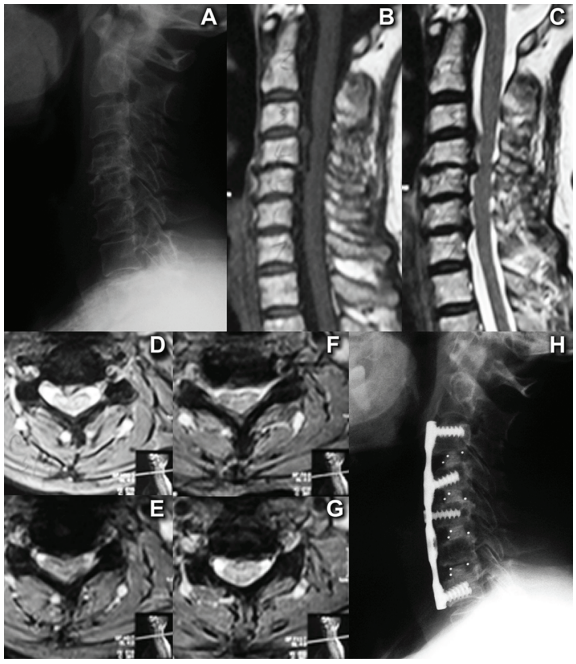

Fig. 1 A 77-year-old female had recurrent episodes of neck pain with occasional radiating pain to her right forearm for 18 months before she developed acute onset excruciating arm pain followed by a progressive sensorimotor deficit of C5, C6 and C7 on the right more than left side. (A) Preoperative MR imaging T1 (B) and T2 (C) weighted sagittal showed multiple level disc herniation without signal intensity change on spinal cord. Axial MR imaging T2 weighted showed C3-C4 (D), C4-C5 (E), C5-C6 (F) and C6-C7 (G) disc herniation, compressing spinal cord and nerve roots. Radiograph at 1 month postoperative (H). The radiculopathy resolved after 8 months follow-up. At the final follow-up 2 years after fusion, no neurologic deterioration was seen

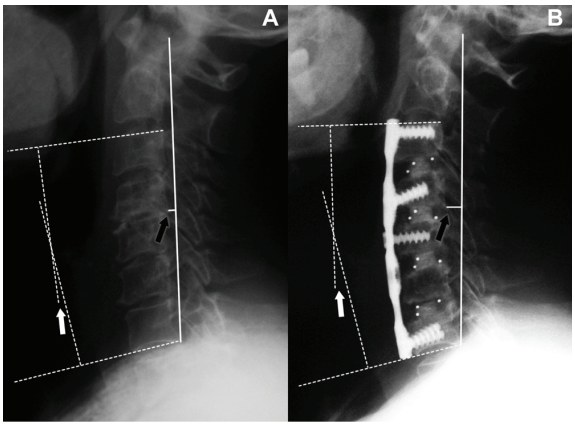

Fig. 2 Pre-operative (A) and Post-operative (B) radiographic measurements of cervical curvature (black arrow) and segmental angle (white arrow) were determined. Physiological lordosis restoration and preservation were used to follow-up as radiographic results

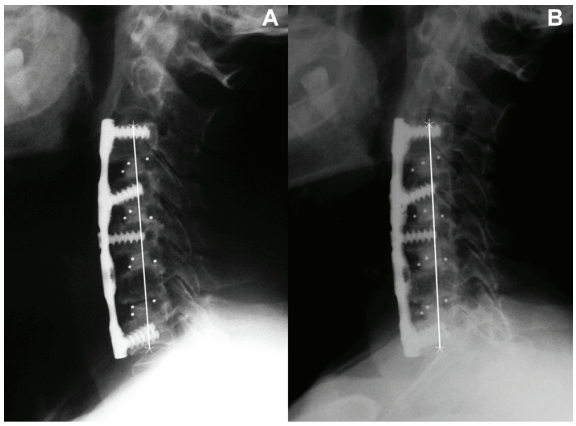

Fig. 3 Post-operative (A) and 2 years follow-up (B) construct height was measured for the graft collapse by measuring the distance from the midpoint of the upper end plate of uppermost vertebral body to the midpoint of lower end plate of lowermost vertebral body of the construct

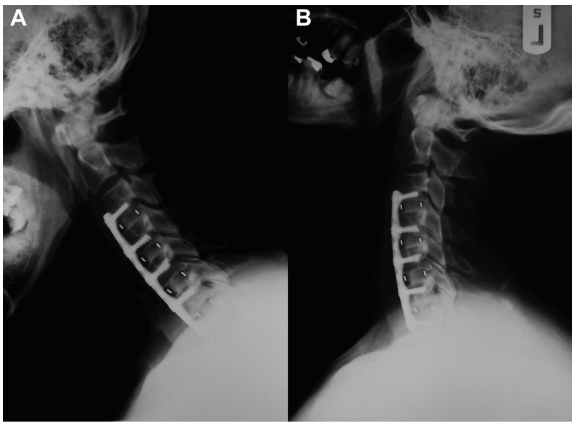

Fig. 4 Lateral flexion-extension cervical spine radiographs (A and B) obtained at 1 year after this 52-year-old man with cervical spondylosis with myelopathy in C3-C7 underwent C3-C4, C4-C5, C5-C6, C6-C7 anterior cervical discectomy and fusion. Evidence of solid bridging bone without instability on flexion-extension radiographs is demonstrated

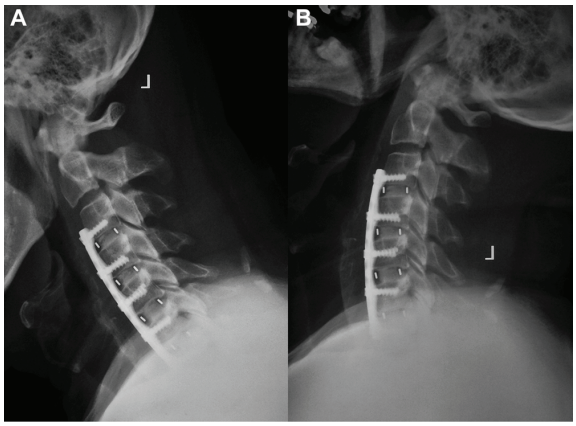

Fig. 5 Good lateral flexion-extension cervical spine radiologic evolution (A and B) in terms of fusion, spinal alignment, and stability in 2 years of follow-up was obtained from the same patients on Fig. 4

radiographs were obtained before surgery, immediately after surgery within the first week, at 2, 4, 6, 12, and 24 months postoperatively. Lateral X-rays were used to evaluate the spinal curve pre and post-operatively. The cervical curvature was evaluated according to the method reported by Profeta et al[13]. A straight line was drawn from the posterior circumference of the dens to the postero-inferior border of C7 and another line from the postero-inferior border of C4 perpendicular to the first line; its length measures the degree of spinal curvature in millimeters. Segmental angle of the fused segment was defined as the Cobb angle method, the angle formed by perpendicular lines drawn from the superior endplate of the upper vertebra and the inferior endplate of the lower vertebra of the fused segment (Fig. 2). For the measurement of graft subsidence, fusion construct length of from the midpoint of upper end plate to the midpoint of lower end plate was measured (Fig. 3).

Criteria used to determine fusion were less than 3 mm motion in fusion construct on flexion and

Table 1. Odom's criteria

Excellent	All preoperative symptoms relieved; abnormal findings improved
Good	Minimal persistence of preoperative symptoms; abnormal findings unchanged or improved
Fair	Definite relief of some preoperative symptoms; other symptoms unchanged or slightly improved
Poor	Symptoms and signs unchanged or exacerbated

Table 2. Details of the operated level

Levels	Number of cases	Mean surgical time (minutes)	Mean estimate blood loss (ml)	Mean fusion time (days)
C3-4, C4-5, C5-6	9	113	128	133.33
C4-5, C5-6, C6-7	2	123	75	130.5
C3-4, C4-5, C5-6, C6-7	5	132	183	184.5

Table 3. Results of surgery according to Odom's criteria sorted by fusion level

Odom's criteria	Excellent	Good	Fair	Poor
C3-4, C4-5, C5-6	2	5	2	0
C4-5, C5-6, C6-7	0	2	0	0
C3-4, C4-5, C5-6, C6-7	1	4	0	0

extension lateral radiographs, absence of radiolucent zones between vertebral endplates and PEEK with trabecular continuity, bridging of bone across the disc space, and sclerosis at the vertebral endplates on both sides. The authors defined fusion for present as when bone formation was observed with no motion or radiolucent zones. It defined it for probable as when bone formation was observed with no motion but a radiolucent zone was also observed. Finally, it defined it for absent as when motion was observed with no bone formation (Fig. 4, 5). All measurements were done by one of the authors (Sudprasert W).

Clinical outcomes were graded by Odom's Criteria as listed in Table 1[14]. The patients' neck pain was graded using a 10-point visual analog scale (VAS). Ratings of pain severity range from 0 (no pain) to 10 (pain as bad as you can imagine). Neurologic status was classified according to the functional grading system of Nurick[15] and the modified Japanese Orthopedic Association (JOA) system[16]. Comparison of preoperative and postoperative either clinical or radiographic outcome data and postoperative and the last follow-up were performed using the dependent Student t test.

Statistical analysis was performed to compare preoperative and postoperative outcomes using SPSS program for Windows V.16.0 (SPSS Inc., Chicago, IL, USA).

Results

Mean follow-up period was three years (ranged from two to four years). C4-5 and C5-6 were the most common operated levels. The fusion rate in the mean follow-up 150 days was defined as present in 100% of operated levels. Details of the operated levels are shown in Table 2.

The results of the surgeries graded by Odom's criteria are listed in Table 3. Clinical outcomes were classified as 'excellent' in three patients and 'good' in 11 patients (success rate: 87.5%). 'Excellent' and 'good' results are called as satisfactory outcomes. Two patients were graded as 'fair' though all these patients achieved solid fusion at the final follow-up. Analysis of clinical outcome data of these 16 patients shows that the neck pain and neurologic status were improved after surgery (Table 4). The clinical results were significantly better after the operation clinically ($p < 0.01$).

Mean preoperative spinal lordosis was 3.39 (Standard Deviation (SD) 1.56) millimeters and postoperative spinal curve was 5.24 (SD 1.72) millimeters. Mean segmental angle was 8.68 (SD 5.98) degrees preoperatively and postoperative segmental angle was 16.02 (SD 6.69) degrees. The difference was statistically significant ($p < 0.01$). Radiographic outcomes at the follow-up period are denoted in Table 5. In the 2-year follow-up, imaging showed no cage failure or subsiding. Therefore, postoperative lordosis, segmental angle, and construct height were maintained at final follow-up ($p > 0.05$).

Dysphagia was observed in two patients (12%), but the symptom subsided after 30 and 90 days follow-up periods. No patients had persistent pain at the bone marrow aspirated surgery site. There were no hardware complications in the present series of patients.

Table 4. Clinical outcome data

	Preoperative	Postoperative	p-value
Neck pain (VAS)	6.12 (SD 1.89)	2.62 (SD 2.06)	0.004*
JOA score	11.38 (SD 3.65)	13.88 (SD 2.99)	0.0001*
Nurick score	2.94 (SD 1.18)	1.94 (SD 0.85)	0.0001*

Values are means (SD = standard deviation)
* t test with significant difference in clinical outcome

Table 5. The mean values of radiological parameters measured before surgery, immediately after surgery, and at the last follow-up

	Preoperative	Postoperative	Last follow-up	p-value
Lordosis (mm)	3.39 (SD 1.56)	5.24 (SD 1.72)	5.16 (SD 1.69)	0.001*
				0.07**
Segmental angle (degree)	8.68 (SD 5.98)	16.02 (SD 6.69)	15.92 (SD 6.64)	0.001*
				0.06**
Construct height (mm)	-	67.64 (SD 12.18)	67.23 (SD 12.12)	0.08**

Values are means (SD = standard deviation)
* t test with significant difference in comparison of pre- and post-operative mean values
** t test with no significant difference were observed between postoperative and last follow-up mean values

Discussion

Anterior cervical discectomy and fusion has become a common technique used in the surgical treatment of cervical radiculopathy or cervical myelopathy associated with cervical spondylosis[1,2]. The traditional tricortical autograft from iliac crest, documenting high fusion rate, was often reported to have donor site complications[8].

The fusion rates decline as the number of operated levels increase[5]. The application of cervical plating for multilevel ACDF procedures is an attractive option due to improvement of fusion rates and reoperation rates were reduced[6]. A high fusion rate of 97% regardless of the patient's smoking history was accomplished in multilevel cervical fusion using autografts or allografts with anterior plate stabilization[17]. However, 53% pseudarthrosis rate according to technique using iliac crest graft and application of a fully constrained cervical locking plate in multilevel cervical discectomy and fusion has been reported although pseudarthrosis is not always associated with inferior outcome[18]. Despite these advantages, hardware-related complications reported from 6 to 10.7% and include malpositioning, loosening, or breakage of the plates or screws, plates impinged on adjacent levels, dysphagia, damage to the esophagus, and neurovascular structures injury[19].

Interbody cages with different materials and designs have been developed and are very popular in the treatment of degenerative cervical disc disorders because of no iliac bone harvesting and have been proven safe in anterior cervical spine surgery. The use of a titanium cage ensures early stability and high fusion rates between 96% and 98.9% are reported[13,20]. Cage subsidence and the distinct metallic artifacts they produce on postoperative imaging (MRI or CT) are the major disadvantage of titanium components. Radiolucent property of PEEK cage allows adequate evaluation of the fusion status on radiographs and the neural structures by MRI and CT post-operatively. Immediate stability and high fusion rates were achieved by cervical interbody cages with preservation of spinal lordosis[9-12]. The height and its cross sectional area of the foramina was also increased in the cervical fusion with interbody PEEK cage[10].

According to the results of polyetheretherketone (PEEK) cages for treatment of multilevel cervical spondylosis without the use of plates, screws or autogenous iliac crest bone graft reported by Demircan et al[21]. The non-fusions were seen in all two patients with a four-level operation and one in six patients with a three-level operation (fusion rate was 5/8 = 62.5%) but no clinical signs or radiographic mobility of pseudoarthrosis were observed. In the present series, augmentation with plate fixation and addition of

aspirated bone marrow from iliac crest may seem to be preferable and the fusion rate was 100%.

In the recent literature, the fusion rate of single- and multiple-level ACDF with PEEK cages was 90.5% to 100%. These excellent results were achieved by cages packed with the autologous iliac bone graft[12], bovine xenograft[22], or bi-phasic calcium phosphate ceramic[23] and additionally use of demineralized bone matrix (DBM)[21] or recombinant human bone morphogenetic (rhBMP)[24]. The presented cases, to evade the risk of disease transmission, to control the operative expense due to high cost of either DBM or rhBMP, to minimize the extent of surgery and to avoid donor-site complications, bone substitute (Triosite) mixed aspirated bone marrow, was packed into the cage cavity for maximum contact with living bone on either side of the cage. The aspirated marrow from iliac bone can enhance osteogenesis and bone fusion. In addition, fibrin clot from aspirated bone marrow could also provide an additional holding effect for all the chips, cells, and matrix. The bone substitute provides an osteoconductive matrix for ingrowth of blood vessels and osteogenic cells[25].

In the present series, clinical outcomes were rated as excellent or good in 14 out of 16 patients (success rate: 87.5%). Radiologic outcomes were improved after surgery. Furthermore, the fusion rate was 100%, which has been reported in the recent literature. Sagittal alignment and construct height were maintained on the final follow-up observations.

The limitations of study were the small number of patients and the relatively short follow-up. Any adjacent problems related to the fusion with cages and anterior cervical plate did not occur during the mean 36 months follow-up period.

Conclusion

The results obtained in the present study are encouraging the use of interbody fusion with PEEK cages packed with bone substitute and aspirated bone marrow because it is a safe and a good option for the treatment of patients with three and four levels of degenerative cervical spondylosis. The additions of cervical plate enhance the fusion rate and maintain cervical alignment. PEEK cages eliminate the complications of graft harvest and leads to favorable outcomes.

Potential conflicts of interest

None.

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การศึกษาเบื้องต้นของการรักษากระดูกต้นคอเสื่อมตั้งแต่สามถึงสี่ระดับด้วย polyetheretherketone cages และเหล็กดามกระดูกทางด้านหน้า

วีระ สุดประเสริฐ, สมบัติ คุณากรสวัสดิ์

วัตถุประสงค์: *การศึกษาเพื่อประเมินผลการรักษากระดูกต้นคอเสื่อมตั้งแต่สามถึงสี่ระดับด้วยpolyetheretherketone cages และเหล็กดามกระดูกทางด้านหน้า*

วัสดุและวิธีการ: *ผู้ป่วยจำนวน 16 ราย ตั้งแต่เดือน มกราคม พ.ศ. 2549 ถึง มิถุนายน พ.ศ. 2552 ใช้ผลลัพธ์ทางคลินิกและภาพถ่ายเอกซเรย์ก่อนการผ่าตัด หลังการผ่าตัดและอย่างน้อย 2 ปีหลังผ่าตัด เพื่อประเมิน segmental spinal curvature, sagittal angulations, construct height และ fusion rate การประเมินทางคลินิกโดยใช้ Odom's criteria, visual analog scale (VAS), Nurick and modified JOA (Japanese Orthopedic Association) score*

ผลการศึกษา: *ผลลัพธ์ทางคลินิกและภาพถ่ายเอกซเรย์แสดง degree of lordosis, segmental Cobb angle ก่อนการผ่าตัดและหลังการผ่าตัดมีความแตกต่างกันโดยดีขึ้นอย่างมีนัยสำคัญ ($p < 0.01$) การประเมินทางคลินิกโดยใช้ Odom's criteria พบว่าผู้ป่วย 14 ราย ถูกจัดอยู่ในกลุ่ม 'excellent' หรือ 'good' (ประสบความสำเร็จในอัตรา: 87.5%) อัตราการ fusion อยู่ที่ 100% โดยวิเคราะห์ภาพถ่ายเอกซเรย์ด้านข้างท่าก้มและท่าเงย เมื่อติดตามการรักษาอย่างน้อย 2 ปี ระยะเวลาติดตามการรักษาโดยเฉลี่ย 36 เดือน construct height และ sagittal alignment ยังคงเดิม โดยไม่มีความแตกต่างกันอย่างมีนัยสำคัญเมื่อเปรียบเทียบกับหลังการผ่าตัด ไม่พบความล้มเหลวของ cage เช่นการทรุดตัวลงหรือการเคลื่อนหลุด*

สรุป: *การใช้ polyetheretherketone cages ภายในใส่กระดูกเทียมร่วมกับการผสมไขกระดูกเชิงกรานและเสริมเหล็กดามกระดูกทางด้านหน้าขจัดผลข้างเคียงจากการตัดกระดูกเชิงกราน ได้ผลการรักษาที่ดีและเป็นอีกทางเลือกหนึ่งในการรักษากระดูกต้นคอเสื่อมตั้งแต่สามถึงสี่ระดับ*