

# The Use of A Hollow Polymethylmethacrylate Cervical Spacer with Plating in the Treatment of Single Level Cervical Disc Disease

Jyi-Feng Chen, MD; Chieh-Tsai Wu, MD; Shih-Tseng Lee, MD

**Background:** At present, the use of a cervical cage and plating has become an accepted and widely practiced surgical intervention for the treatment of cervical spondylosis and disc herniation. Polymethylmethacrylate (PMMA) bone cement has been used in cervical disc disease as a spacer, with good long-term outcomes, but the method does not result in solid bone fusion in all cases.

**Methods:** A prospective study was performed with 92 consecutive patients who underwent single-level anterior cervical discectomy and fusion (ACDF) with a hollow PMMA spacer, cancellous allograft and titanium cervical plate stabilization between January 2002 and December 2003. Patients were followed for a minimum of 2 years.

**Results:** The surgical procedures used were technically successful for all patients, and there were no major complications related to anesthesia or the overall surgical procedure. The fusion rate was 89.8% at the 12-month follow-up, and 100% at the 24-month follow-up. The mean intervertebral disc height was  $6.5 \pm 1.5$  mm and regained height was  $3.4 \pm 1.3$  mm at the 24-month follow-up. The mean segmental lordotic angle was  $3.7 \pm 2.0^\circ$  with an increase of  $6.1 \pm 2.3^\circ$  at the 24-month follow-up. There was no hollow PMMA spacer dislodgment or failure. However, 5 (5.4%) patients had screw loosening and 3 (3.3%) patients underwent a secondary operation for removal of the plate and screws.

**Conclusions:** The procedure for a single-level ACDF with a hollow PMMA spacer, cancellous allograft and titanium cervical plate stabilization is safe and effective. There were no complications related to the hollow PMMA spacer. This procedure has a high fusion rate, and can restore disc height and maintain normal cervical lordosis. This method achieves results similar to those of other methods.

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**Key words:** cervical spine, bone fusion, anterior cervical plate, allograft

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The concept of cervical interbody fusion for the treatment of cervical disc disease has developed progressively over the last 50 years. The basic idea is to stabilize the treated segment sufficiently to allow new bone ingrowth, and to maintain disc height and avoid graft collapse until fusion occurs.

The principal advantage of cervical cages (or spacers) is the reduction in donor site morbidity. Since a cervical cage can provide immediate load-bearing support to the anterior column, a structural bone graft is unnecessary. Instead, a less invasive autograft harvest can be performed to acquire the cancellous bone required to fill the cage and pack the disc space around the cage. There are several disadvantages to cervical cages. Many surgeons now advocate anterior cervical plating,<sup>(1-6)</sup> suggesting that increased stability across the operative segment and prevention of graft-related complications enhance the fusion rate and restore and/or maintain normal cervical lordosis. Although these advantages are supported by numerous reports on multilevel arthrodesis,<sup>(2-4,7-10)</sup> the results for anterior cervical fixation after single-level anterior cervical discectomy and fusion (ACDF) are not as convincing.<sup>(6,7)</sup> To date, there is no ideal procedure for anterior cervical fusion after single-level discectomy. Theoretically, the ideal procedure for ACDF would have no complications, promote successful arthrodesis, restore disc height, and maintain normal cervical lordosis.

From January 2002, a prospective study was designed for patients who underwent single-level ACDF with a hollow polymethylmethacrylate (PMMA) spacer filled with cancellous allograft and plate stabilization. The purpose of this study was to evaluate the efficacy of these changes, and to prove this method has the same efficacy as other methods.

## METHODS

### Patient population

Between January 2002 and December 2003, 92 consecutive patients with single-level cervical disc herniation and compressive monoradiculopathy underwent single-level ACDF with a hollow PMMA spacer filled with cancellous allograft and plate stabilization. Patients were included if they had severe symptomatic single-level compressive radiculopathy due to cervical disc herniation for more than three months, with compatible magnetic resonance imag-

ing (MRI) and clinical findings. Patients with evidence of cervical instability, whiplash injury, myelopathy, systemic infection, psychiatric disturbance, metabolic bone disease, active malignancy, previous cervical spinal surgery, or drug abuse, were excluded from the study. Eighteen patients (19.6%) who smoked were not excluded from the study. Clinical and radiographic data were collected before surgery, immediately after surgery, and at the 3-, 6-, 12- and 24-month follow-ups.

### Surgical technique

Surgery was performed after the patient had received general anesthesia. A standard anterior cervical microdiscectomy, osteophylectomy, and nerve root decompression were performed in every patient. Endplate cartilage was removed with a cutting burr and curette. The bony endplate was roughened by the burr until it was slightly oozing. We took care that the bony endplate was not removed so that it could function as a bearing surface for the implant. Fresh-frozen lamina allograft bone was taken from the bone bank and soaked in antibiotic solution for 30 minutes. Cancellous allograft was prepared from lamina bone by removing the soft tissue and cortical shell. A hollow PMMA cervical spacer<sup>(11,12)</sup> made with PMMA containing 10% BaSO<sub>4</sub> (Osteobond, Zimmer, Warsaw, Indiana, U.S.A.) with adequate height (Fig. 1) was completely filled and packed with cancellous allograft. All hollow PMMA spacers were countersunk at least 1 to 2 mm from the ventral surface of the vertebral bodies.

To achieve immediate stabilization, each patient underwent internal fixation with titanium cervical

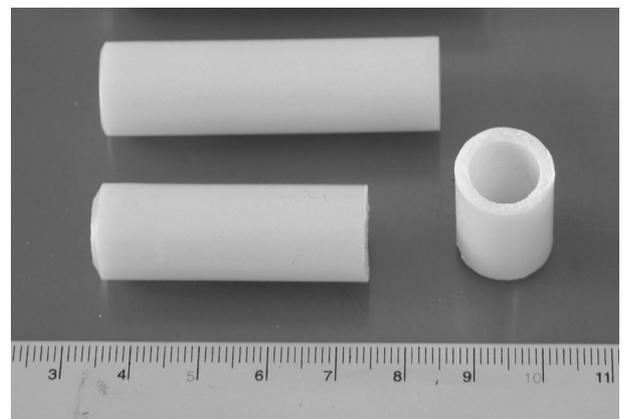


Fig. 1 The PMMA cervical cage.

plates and screws (Titanium cervical plating system, Syntec, Taiwan R.O.C.). A nonconstrained plating system was used that has some of the biomechanical characteristics of dynamic plate.<sup>(13)</sup> The graft is thought to share the compressive force with a good chance of fusion. Each patient was instructed to use a soft cervical collar for protection during the first 4 postoperative weeks.

### Outcome measures

Fusion was identified by an absence of motion between the spinous processes on flexion-extension lateral plain radiographs and no new settling, as well as continuous, bridging, bony trabeculae at the graft-host vertebral endplate junction and/or around the spacers. A pseudoarthrosis was identified radiographically by an absence of osseous trabecular bridging the graft and the host vertebral endplates or around the spaces, and motion between the spinous processes on dynamic radiographs.

The disc height and the segmental lordotic angle were measured from plain lateral radiographs on the Centricity Workstation (GE Healthcare, Chalfont St., Giles, U.K.). The disc height was measured in millimeters at the most anterior aspect of the disc. The segmental lordotic angle was defined as the angle between the cranial and caudal endplates of the upper and lower vertebrae, respectively, in the motion segment subjected to surgery. The overall clinical outcome was assessed as excellent, good, fair, or poor by the patient according to Odom's criteria.<sup>(14)</sup> Work status before surgery and at the follow-up assessments was documented. Neck and arm pain was assessed by asking the patients to quantify their degree of pain on Huskisson's visual analogue scale (VAS: 0 mm = no pain; 100 mm = worst pain possible) The group VAS values data were evaluated with repeated measures ANOVA.

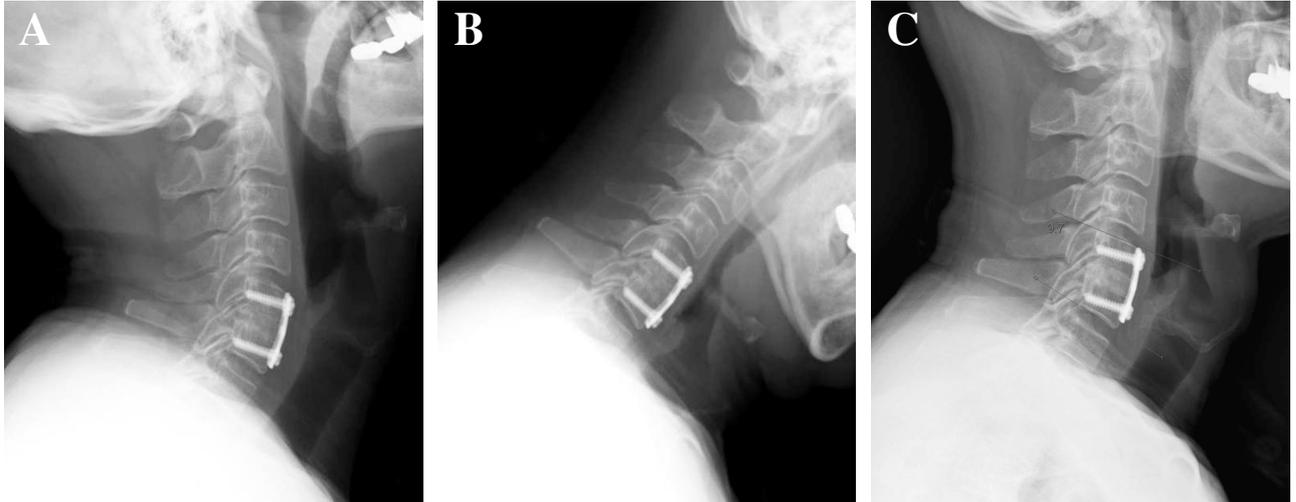
## RESULTS

A total of 92 patients completed the study and were followed at least 2 years. There were 50 men and 42 women, and their mean age was 46.7 years (range 21 to 68 years). The C3-4 level was treated in 17 patients (18.5%); C4-5 level in 23 patients (25.0%); C5-6 level in 39 patients (42.4%) and C6-7 level in 13 patients (14.1%). The surgical procedures used were technically successful for all patients, and

there were no major complications related to anesthesia or the overall surgical procedure. No hoarseness or no wound infection was noted, except for a sore throat in some patients just after surgery which subsided in a few days. There was no hollow PMMA spacer dislodgment or failure. However, 5 (5.4%) patients had screw loosening and 3 (3.3%) patients underwent a secondary operation (within a 6-month period) for removal of the screws and plate. During the revised operations, the hollow PMMA spacers had bone fusion providing good stabilization, and therefore, only the plate and screws were removed.

The fusion rate was 89.8% at the 12-month follow-up, and 100% at the 24-month follow-up. Lucency at the spacer-bone interface was seen on dynamic radiographs in 36 (39.1%) patients at the 12-month follow-up, and 13 (14.1%) at the 24-month follow-up. Fusion was identified by the absence of motion between the spinous processes on flexion-extension lateral plain radiographs with no new settling, as well as continuous, bridging, bony trabeculae at the graft-host vertebral endplate junction and/or around the spacers. The mean anterior intervertebral body height was  $3.1 \pm 1.1$  mm preoperatively,  $7.1 \pm 1.7$  mm immediately postoperatively,  $6.6 \pm 1.5$  mm at the 6-month follow-up, and  $6.5 \pm 1.5$  mm at the 24-month follow-up. The mean regained intervertebral disc height was  $3.4 \pm 1.3$  mm at the 24-month follow-up (Fig. 2). The mean hollow PMMA spacer subsidence into the vertebral body was  $0.6 \pm 0.5$  mm, from the immediate postoperative period to the 24-month follow-up. The mean segmental lordotic angle was  $-2.5 \pm 4.1^\circ$  preoperatively,  $4.8 \pm 2.6^\circ$  immediately postoperatively, and  $3.7 \pm 2.0^\circ$  at the 24-month follow-up. The segmental lordotic angle had increased  $6.1 \pm 2.3^\circ$  at the 24-month follow-up (Fig. 2).

Neck pain decreased from  $73 \pm 11$  at preoperative baseline to  $21 \pm 9$  at 6 months,  $20 \pm 11$  at 12 months, and  $25 \pm 11$  at 24 months. The reduction in pain was statistically significant between the preoperative baseline and postoperative follow-up periods. Radicular pain decreased from  $81 \pm 11$  at preoperative baseline to  $21 \pm 8$  at 6 months,  $19 \pm 7$  at 12 months, and  $18 \pm 7$  at 24 months. Radicular pain also significantly decreased between preoperative baseline and postoperative follow-up periods. No deep neck infection or viral transmission related to the used of fresh-frozen cancellous allografts was



**Fig. 2** A series of plain lateral radiographs performed in a 55-year-old male with C5-6 single level disc disease. (A) and (B) Six month postoperative dynamic views. (C) Twenty-four month postoperative follow-up. The PMMA cage is easily localized and bridging bony trabeculae are readily identified at the graft-host vertebral endplate junction and around the spacer.

noted in our patients. All patients were able to return to their previous activities and quality of life before the 6-month follow-up. The clinical symptoms improved in all followed-up patients. The self-rated clinical outcome was excellent in 78 patients (84.8%) and good in 14 (15.2%) of the 92 patients. The mean hospitalization time was 3.5 days (range, 3 to 7 days).

## DISCUSSION

Cage fusion technology originated in 1979 with the work of Bagby, who, together with veterinary surgeons, sought to treat spondylotic cervical myelopathy in horses.<sup>(15)</sup> Human applications were promoted around 1990, first in the lumbar area by Ray and Kuslich with threaded cylindrical titanium cages, and then by Brantigan with rectangular impacted carbon cages.<sup>(16-18)</sup> Smaller versions of cervical devices were introduced in France, by Robert, using achromium cage in 1993,<sup>(19)</sup> and in the U.S.A. by Kitchel in 1994.<sup>(17)</sup>

Wilke et al.<sup>(20)</sup> performed an *in vitro* study of the stabilizing effect and subsidence tendency of cervical fusion cages and bone cement during cyclic loading. Wing cages (Medinorm AG), Bagby and Kuslich (BAK) cages (Spinetec) made of titanium, carbon fiber reinforced polyaryletheretherketone (PEEK) cages (DePuy AcroMed), and bone-cement spacers

(PMMA, Sulzer) were tested. All implants were shown to have a stabilizing effect in all directions, most prominently in lateral bending. The range of motion was between 20.9% (AcroMed Cage) and 62% (BAK Cage) with respect to the intact specimen (100%). In lateral bending, flexion, and axial rotation, the AcroMed cage stabilized the most, followed by bone cement, and the Wing and BAK cages. After 700 loading cycles, height loss was 1.6 mm with the BAK cage, 0.8 mm with the Wing cage, 0.7 mm with the AcroMed, and 0.5 mm with bone cement. The authors concluded that cages have the potential to stabilize as effectively as bone cement. A small contact area, however, causes a higher subsidence risk than bone cement, but increases the fusion area, thereby increasing the chance of successful fusion. Based on these findings, the hollow PMMA spacer, with a large graft contact surface area and more bony material, was conceived in an attempt to decrease the risk of subsidence and increase the rate of bone fusion.

The PMMA used to make the cervical hollow PMMA spacer in this study contained 10% BaSO<sub>4</sub>. The optical density of the hollow PMMA spacer was 100, and it could easily be located under a fluoroscope. Bridging bony trabeculae, a sign of bone fusion, were readily observed on a plain lateral radiograph. PMMA is a polymer material, and as it is not metal, is not magnetic. Accordingly, magnetic reso-

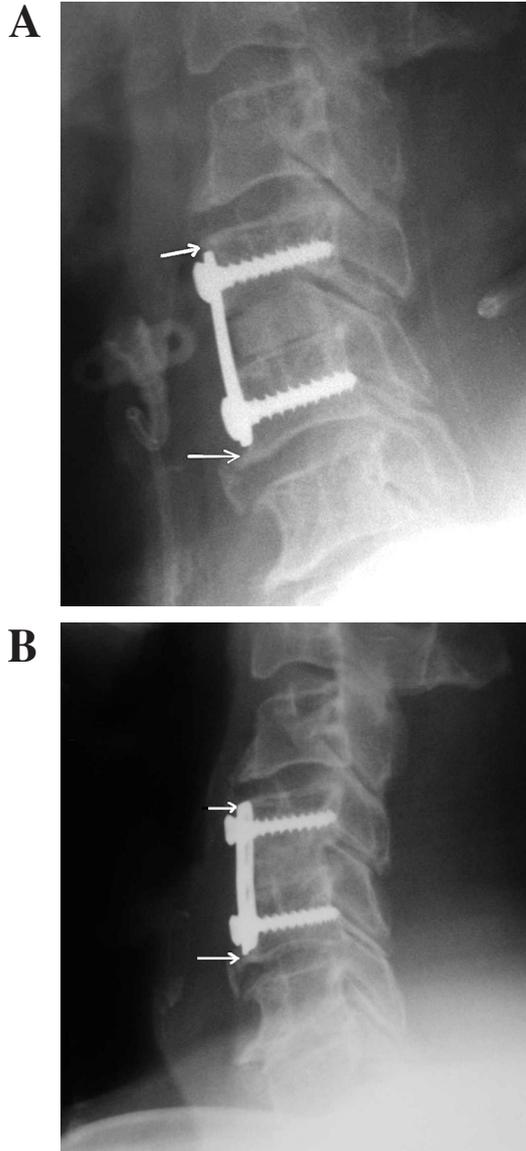
nance imaging studies are unaffected. Wing cages and BAK cages are made of titanium and are radio-opaque, making determination of fusion more difficult, with assessment based on the absence of motion in flexion and extension views. The Solis PEEK cage is made of a polymer material, however, that is completely radiolucent. Several metal pins within the Solis PEEK cage enable fluoroscopic localization of the cage's position, so, few artifacts are seen on magnetic resonance imaging scans.

Bone grafts can be classified according to their origin as autograft, allograft or xenograft, and bone-graft substitute, and they can be cortical, cancellous, or corticocancellous, each of which has advantages and disadvantages. Cortical or corticocancellous (structural) grafts are used mostly in areas of great mechanical stress because the cortical component of the graft facilitates support as well as rigid fixation.<sup>(21)</sup> Although cancellous grafts do not withstand heavy mechanical stress, revascularization occurs more predictably than it does with cortical bone grafts. Autogenous bone has become the standard for use as a graft substrate, because of its osteogenic, osteoconductive, and osteoinductive properties.<sup>(22)</sup> Structural autografts are usually harvested from the iliac crest<sup>(10,23)</sup> and numerous complications can occur.<sup>(24-26)</sup> Allograft bone has become an attractive alternative because of its lack of donor site complications and the absence of donor site pain. However, the reported pseudarthrosis rates are as high as 20% for single-level ACDF.<sup>(27-31)</sup>

In our country, it is difficult to get structural allografts because of a lack of donors. In this study, we used fresh-frozen cancellous allograft impacted into the hollow PMMA spacer to achieve bone fusion and prevent donor site complications. The cancellous allografts we used were prepared from lamina bone by removing the soft tissue and cortical shell. The lamina bone allografts were removed from healthy patients who had undergone cervical or lumbar laminectomy, and were stored at  $-80^{\circ}\text{C}$  in a freezer. The hollow PMMA space was as cortical bone substitute and impacted with fresh-frozen cancellous allografts. This block was as a structural allograft and could withstand heavy mechanical stress and improve bone fusion. Another concern with the use of live allografts, although rare, is the transmission of infection. In a literature review of 303 procedures, there was one case in which a contaminated

allograft was responsible for a clinical infection. A few case reports have noted viral transmission through allografts, with the risks apparently related to the type of allograft.<sup>(32,33)</sup> In our study, no deep neck infection or viral transmission related to the used of the fresh-frozen cancellous allografts was noted in our patients.

The placement of anterior cervical plates has become an increasingly popular technique for augmenting anterior cervical fusion. As surgeons have become more proficient with the use of anterior cervical plates, their applications have grown. Anterior cervical fusion surgery has resulted in dramatic improvements in outcomes for trauma, degenerative disease, deformities, tumors, and other pathologies. These plates have reportedly been used for correcting cervical spine instability, and preventing pseudarthrosis, graft collapse, and graft migration, as well as avoiding the use of a postoperative collar, improving anatomical and functional results and facilitating a quick return of work. In this study, each patient underwent internal fixation with a titanium cervical plating system to achieve immediate stabilization. The plating systems were nonlocking and nonrigid, in other words, screw angulation was determined entirely according to individual patient needs and the surgeon's preference. These two attributes create a cantilever-type system in which there is no fixed moment arm, allowing for subsidence of the construct because of lack of fixation at the plate-screw interface.<sup>(13)</sup> The implant is a nonconstrained plating system and has some of the biomechanical characteristics of dynamic plate (Fig. 3). The graft is thought to share the compressive force caused by this subsidence and thus is exposed to greater compression; according to Wolff's law, the graft has a greater chance of fusing.<sup>(34-37)</sup> The rigid fixation plating systems might stress shield the PMMA/bone construct resulting in a longer latency to fusion and a higher nonunion rate. The main disadvantages of the titanium cervical plate system are the high rates of screw backout and breakage, with graft subsidence.<sup>(35,38,39)</sup> In this study, there was no screw breakage but 5 patients had screw backout, and 3 patients underwent a revised operation. This may be because the elastic modulus of a hollow PMMA spacer is much closer to that of spongy bone and has a large contact surface between the cage and vertebrae,<sup>(12)</sup> and therefore there is little graft subsidence. Each patient was



**Fig. 3** (A) Immediate post-operative plain lateral radiograph. (B) Six month postoperative follow-up plain lateral radiograph revealing graft settling (arrows).

instructed to use a soft cervical collar for protection during the first 4 postoperative weeks. All patients were able to return to their previous activities and quality of life before the 6-month follow-up.

### Conclusions

There were no major complications related to anesthesia or the overall surgical procedure. There was no hollow PMMA spacer dislodgment or failure.

Five patients (5.4%) had screw backout, but none of the complications were related to the PMMA material. This method has the same efficacy as other methods. Moreover, the method has several advantages in improvement of neck pain, and lack of donor site complications, and patients do not need to use a rigid neck collar postoperatively.

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# 以骨水泥中空頸椎支架並用異體植骨和骨板來治療 單一節頸椎椎間盤病變

陳志豐 吳杰才 李石增

**背景：** 頸椎椎間盤病變病人接受前頸椎椎間盤切除術後，以椎籠合併頸椎骨板來固定頸椎，回復椎間盤高度和頸椎曲度，已廣泛被臨床醫師所接受。而骨水泥很早就被用來做為前頸椎椎間盤切除術後椎間填充物，其長期結果報告良好；但此一方法並不會產生椎體間骨融合。

**方法：** 本研究主要目的在於評估骨水泥頸椎支架並用異體植骨和頸椎骨板來治療單一節頸椎椎間盤病變的效用。本前瞻性研究在 91 年 1 月至 92 年 12 月間，92 位病患患有單一節頸椎椎間盤病變，須接受單一節前位頸椎椎間盤切除術患者，接受以骨水泥支架並用異體海綿骨植骨和頸椎骨板固定手術，病患追蹤至少 2 年以上。

**結果：** 於全部病患中，手術治療步驟都順利成功並無重大的手術或麻醉併發症產生。其骨融合率在追蹤 12 個月時為 89.8%，在追蹤 24 個月時為 100%，在追蹤 24 個月時其手術後椎間盤高度為  $6.5 \pm 1.5$  mm，且與手術前相較其椎間盤高度平均回復  $3.4 \pm 1.3$  mm。其頸椎角度在追蹤 24 個月時為  $3.7 \pm 2.0^\circ$ ；與手術前相較其頸椎曲度回復達  $6.1 \pm 2.3^\circ$ 。於全部案例中，並無骨水泥支架的滑脫或破損，但是由於病患骨質疏鬆關係其中有 5 位 (5.4%) 病患有螺釘鬆脫情形，其中 3 位 (3.3%) 需要接受第二次手術，取出頸椎骨板和螺釘。

**結論：** 此一手術步驟對於單一節頸椎病變患者而言是有效而且沒有併發症產生的。二年後追蹤病患，可以達到百分之百的骨融合率，有效回復頸椎椎間盤高度和頸椎之曲度。此一手術步驟也可達到與其他手術植入物步驟相同的效果，並有立即達到減少頸椎疼痛，無自體骨移植取骨處疼痛和手術後不需硬式頸圈固定的好處。  
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**關鍵詞：** 頸椎，骨融合，前頸椎骨板，異體植骨

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