

Stand-Alone Cervical Polyetheretherketone (PEEK) Cage (Cervios) for Single to Two-Level Degenerative Disc Disease

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Objective: To study clinical and radiographic outcome of patients who underwent the Cervios cage-assisted anterior cervical discectomy and fusion (ACDF) without plate fixation in single to two-level degenerative disc disease (DDD).

Material and Method: Sixty-seven patients suffering from cervical DDD with various symptoms such as radiculopathy, myelopathy, or both were retrospectively evaluated. The cervical DDD was confirmed by plain radiographs and MR imaging. The patients underwent radiographic evaluation to assess cervical lordosis, intervertebral height (IH), fusion, and subsidence. Clinical assessment was graded using a visual analog scale (VAS), Modified JOA (Japanese Orthopedic Association) score, Neck Disability Index (NDI).

Results: There were ninety two ACDF in two levels of operation. Single-level ACDF was performed in 42 patients and two-level in 25. The outcomes revealed the significant improvement of clinical outcome and restoration of cervical lordosis. The fusion rate was 97%, whereas subsidence occurred 7.61% but produced no symptom. There was no anterior or posterior migration of the cage. Complications included transient dysphagia in three patients and superficial wound infection in two patients.

Conclusion: The present study indicates that one- to two-level stand alone Cervios cage-assisted interbody fusion without plate fixation provides improvement of clinical outcomes, restoration of lordosis and high fusion rate. However, subsidence occurred in 7.61% but did not cause clinical symptoms and the patients had to use the cervical collar postoperatively.

Keywords: Cervical spine, Cervios, PEEK cage, Stand-alone, ACDF

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Anterior approach for cervical fusion in degenerative disc disease has widely been accepted nowadays after modifications of surgical techniques originated by Smith and Robinson⁽¹⁾ and by Cloward⁽²⁾. Autologous bone graft use provides high percent of fusion rate over allografts⁽³⁾. However, autologous bone grafts obtained from the anterior iliac crest are associated with significant donor site morbidity and complications including severe acute pain, hematoma formation, infection, meralgia paresthetica, and chronic pain⁽⁴⁾.

Cervical interbody cages have been developed and applied in clinical practice to eliminate complications at the donor site. There are two basic types of cages, threaded hollow cylindrical cages (Cloward type procedure) and rectangular cages

(Smith-Robinson type procedure). The threaded cages are introduced and screwed through the endplates of the vertebral bodies, whereas the rectangular cages mimic the intervertebral space dimensions and in accordance with the anatomy of the endplates^(5,6). The cages are made of titanium, carbon fiber, or PEEK.

Anterior plate system was added in ACDF using with autologous iliac crest graft or cages, especially in multilevel surgery, to increase fusion rates and reduce the problem of graft extrusion and collapse⁽⁷⁾. Nonetheless, some studies^(8,9) reported complications such as plate migration, screw loosening, or back-out, soft tissue injury and dysphagia. Bioabsorbable anterior cervical plating then has been introduced to reduce some of the long-term complications and imaging artifacts associated with titanium instrumentation⁽¹⁰⁾. However, it is still not routinely used because of higher costs compared with the titanium plate.

Cage stand-alone concept, initiated by Bagby⁽¹¹⁾, used in the human spine since 1988, was

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started with a stainless steel basket implant for cervical spine surgery in horses, working with veterinarians.

There are few publications in the literature regarding the use of Cervios (PEEK cage) for interbody fusion in the stand-alone technique.

The purpose of the present study was to assess clinical and radiological outcome of interbody fusion with Cervios for cervical degenerative disc disease and their application in single to two-level surgery without the additional use of an anterior plate system.

Material and Method

The PEEK cage (Cervios, Mathys Medical, Bettlach, Switzerland) has a radiolucent hollow frame consisting of three titanium markers to indicate the position on plain radiographs and retention teeth on the upper and lower surface to provide initial stability. Cervios cages were produced in two types of shaped designs including curved and wedged shape, which only curved cages are available in Thailand. For the curved cage, the superior aspect of the cage is convex, whereas the inferior aspect is straight to match the anatomy of endplates of the cervical vertebra. All implants are 15 mm wide, 12.5 mm deep, and different in height (5 to 10 mm) (Fig. 1).

Between July 2004 and September 2007, 84 consecutive patients who underwent PEEK cage

assisted ACDF without plate fixation were retrospectively reviewed. This present study was approved by the ethical committee of Prasat neurological institute. All patients were operated on by a single neurosurgeon (PI). Age of the patients ranged from 29-85 years (mean 45.7 years).

Indications for surgical treatment were radiculopathy, myelopathy and radiculomyelopathy. Pre-operatively, all patients underwent MR imaging and plain radiographs including anteroposterior, lateral and lateral flexion/extension and both oblique views.

Surgical procedure was performed using standard Smith-Robinson approach. A right-sided approach was performed via a transverse incision. Discectomy and decompression were performed under an operating microscope in all cases. High-speed drill was avoided, so as to keep local bone graft and to lessen the chance of destroying endplates. The posterior longitudinal ligament was only explored in cases suspected free disc fragments according to preoperative imaging. Anterior part of the concave upper endplate was preserved and used as a natural protection for cage extrusion. The proper size of cage to be inserted is determined intraoperatively according to the curved trial implant without using Caspar retractor for avoiding oversize of cage and defect in vertebral body. The chosen cage was filled with the mixture of bone fragment obtained from osteophytes, β -tricalcium phosphate (Chronos, Mathys Medical, Bettlach, Switzerland), and local blood. After the cervical cage was placed, fluoroscopy was used to confirm the lateral position of the cage.

Postoperative period, nonsteroidal anti-inflammatory drugs were avoided in all patients because they could decrease the bone fusion rate⁽¹²⁾. Soft Cervical collar was used in each patient during the first six weeks.

Post-operatively, plain radiographs including anteroposterior, lateral, and lateral flexion/extension views were performed before discharge and at the different follow-ups.

The cervical curvature was assessed by modified method from the study of Profeta et al⁽¹³⁾. A straight line (Line A) was drawn from the inner border of the odontoid tip to the inferoposterior border of C7. Another line (Line B) was drawn from the inner border of the odontoid tip to the inner border of middle part of the C4 body (Fig. 2). The angle was measured in degree between the Line A and Line B on the pre- and post-operative images.

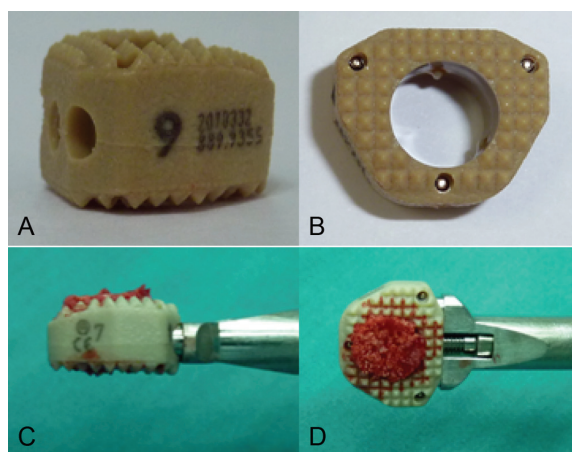


Fig. 1 Cervios cage (A) Lateral view demonstrated the superior aspect of the cage is convex, whereas the inferior aspect is straight. (B) Top view showed hollow frame consisting of three titanium markers. (C, D) Both views of impacted cage after filling with local autologous bone grafts and bone substitute mixed with blood

The intervertebral height (IH) was measured by drawing the line from the middle portion of the inferior border of the upper level of correspondent cervical spine to the middle portion of the superior border of the lower level (Line C). Length of the inferior border of the C2 was used as the reference line (Line D) (Fig. 2B). The authors calculated the proportion of the Line C/Line D (IH ratio). If the calculated proportion at the post-operative period was higher than the pre-operative, then the calculated value inferred the increase of the segmental height at the postoperative phase.

Fusion was defined according to the following criteria: 1) the absence of motion on flexion-extension radiographs and the absence of any dark halo around a cage on both AP and lateral radiographs; 2) presence of bridging trabecular bone anterior or posterior to the cage; or 3) presence of bone fusion from DynaCT scans (AXIOM Artis FD Biplane Angiosuite, Siemens Medical Solutions, Erlangen, Germany) obtained in cases where arthrodesis was questionable.

Subsidence was defined as migration of cage into the superior and/or inferior vertebral body of more than 2 mm.

Clinical outcome was assessed before and after surgery using a 10-point VAS with endpoint

anchors of “no pain” and “severe pain”, Modified JOA scoring system for cervical myelopathy⁽¹⁴⁾ and NDI⁽¹⁵⁾. An independent observer reviewed hospital charts and all radiographs of patients.

All data were reasonably verified by One-Sample Kolmogorov-Smirnov Test. Comparison of pre- and postoperative neurological status, pain status and radiographic status was performed after surgery to the time of follow-up using the Student t-test and Wilcoxon two-related sample test. A p-value of less than 0.05 was considered statistically significant difference.

Results

Seventeen patients were excluded from the present study, three had prior cervical spine surgery, three had ossification of the posterior longitudinal ligament, four had no complete data of the follow-up images, and seven underwent three to four-level stand-alone PEEK cage. Of the 67 remaining patients, 28 were men and 39 were women. Forty-four patients presented with radiculopathy, eight with myelopathy, and fifteen with radiculomyelopathy. Single-level ACDF was performed in 42 patients, and two-level in 25, resulting in the treatment of 92 ACDF levels. The C3-C4 segment was performed in 14 cases, C4-C5 segment in 22, C5-C6 segment in 47, and C6-C7 segment in nine. Follow-up period ranged from 12 to 24 months (average 18 months).

The clinical and radiographic outcomes are summarized in Table 1. The mean preoperative modified JOA score were 14.12 and the mean postoperative scores increased to 17.38.

The differences between the pre- and the post-operative JOA scores were statistically significant ($p < 0.001$). Pre-operative cervical pain was present in 40 (59.7%). The mean pre- and post-operative VAS pain scores were 7.26 and 1.51, respectively. There was a significant relief of cervical pain after surgery ($p < 0.001$). The mean pre- and post-operative NDI scores were 24.53 and 6.47, respectively, which represented a significant improvement of the post-operative quality of life ($p < 0.001$).

Of the 67 patients, the mean pre- and post-operative cervical lordosis was 4.15 and 6.38 degree, respectively. The difference was statistically significant ($p < 0.001$).

In 92 operated levels of 67 patients, the mean pre- and postoperative IH was 0.30 and 0.46, respectively. The difference of pre- and post-operative IH was statistically significant ($p < 0.001$).

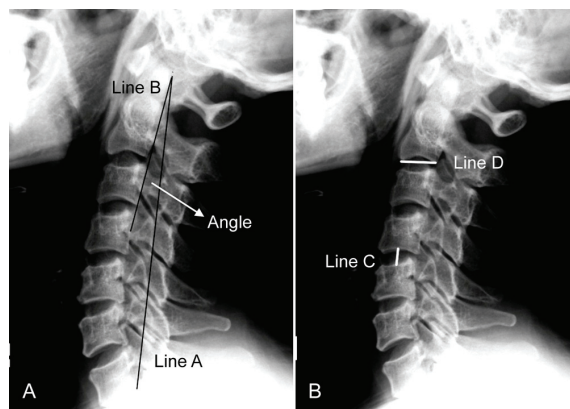


Fig. 2 (A) Scheme for evaluation of lordosis. A straight line was drawn from the posterior border of the C2 to the posterior-inferior border of C7 (Line A) and another line from the posterior border of C2 to the posterior border of C4 and the angle between these two lines was measured. (B) Scheme for evaluation of IH. Line C is the line that drawn from middle portion of inferior border of the upper level to the middle portion of the superior border of the lower level. Line D is the length of the inferior border of the C2

Table1. Summary of clinical and radiographic data

	Score (mean)	p-value
VAS score		
Pre-op	7.26	<0.001*
Post-op	1.51	
Modified JOA score		
Pre-op	14.12	<0.001*
Post-op	17.38	
NDI score		
Pre-op	24.53	<0.001*
Post-op	6.47	
IH ratio		
Pre-op	0.32	<0.001*
Post-op	0.46	
Curvature (degree)		
Pre-op	4.15	<0.001*
Post-op	6.38	

* Wilcoxon two-related sample test

DynaCT scans were obtained in 18 questionable cases. Successful fusion was achieved in 65 patients (97%). The remaining two patients did not complain of any symptoms. Subsidence occurred in seven of 92 levels (7.61%) in seven patients including C4-C5 in one, C5-C6 in three and C6-C7 in three. Subsidence and non-fusion in the same patient was noticed in one patient. Three patients wore the cervical collar irregularly. Three patients had severe narrowing disc space that needed to use an oversized cage. All subsidence took place within six months postoperatively. Nevertheless, subsidence did not cause clinical symptoms in all patients. There was no anterior or posterior migration of the cage. There were complications including transient dysphagia in three patients, and superficial wound infection in two patients, resolved with antibiotic treatment.

Discussion

The cervical cages have been developed to eliminate donor site complications⁽¹³⁾. Several studies advocated using a cervical cage with autologous iliac crest grafts harvested through a smaller incision compared with the conventional technique^(7,8,16-21). However, there were still some complications from donor site including severe pain, hematoma, and sensory deficit around the donor site. Some studies reported interbody fusion cage containing bone substitute with a high percentage of fusion rate, even though these rates were slower than autologous bone

grafts⁽²²⁻²⁴⁾. In the present study, the cervical cage was filled with autologous local bone grafts, bone substitute, and local blood, avoiding the need for a second incision to obtain autologous grafts. Therefore, donor site complications never occurred.

Stand-alone cage assisted ACDF procedure has widely been used to avoid complications from internal fixation with plating^(8,9). Bagby published the principle of distraction-compression concept, the basic principle of stand-alone interbody fusion cage⁽¹¹⁾.

Cervios, an anatomically shaped cage, is made of PEEK, a nonresorbable semicrystalline aromatic polymer, that has a modulus of elasticity similar to cortical bone^(23,25). It is designed for optimal fit into the natural concavity between two adjacent vertebral body. The aim of cervical cage is to maintain or restore the physiological lordosis and increase the height of the foramen^(7,21). Postoperative lordosis of patients who underwent ACDF with anterior plating system depends on intraoperative extended neck position. On the other hand, patients who underwent stand-alone cage can improve post-operative physiological lordosis (Fig. 3A). In the present data, 36 patients

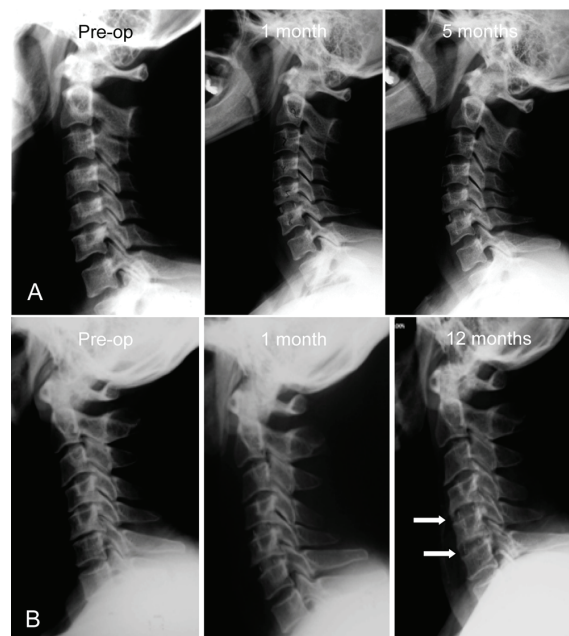


Fig. 3 Sequential lateral radiographs of cervical vertebrae showed improvement of lordotic curve and increasing of IH. (A) One-level ACDF of C5-C6 augmented with PEEK cage. (B) Two-level of C4-C5 and C5-C6. Note bony trabecular patterns at both levels (white arrows) 1 year after surgery

(48.6%) had improvement of the post-operative cervical lordosis, 12 patients (16.2%) had mild decrease in post-operative cervical lordosis (3 patients had subsidence) and 26 patients (35.1%) had the same curvature. All of these patients had no progressive symptom after follow-up. Therefore, postoperative cervical lordosis statistically increased in the present study. Successful fusion rate was achieved in 97% of the cases. The fusion characteristics in DynaCT occurred mainly in two types including a bony trabecular pattern covering anterior or/and posterior to cage and fusion process along upper and lower endplates (Fig. 4).

The Cervios cage is composed of radiolucent PEEK, bridging bone around the cage can be demonstrated on the plain radiographs, and thus the evaluation of the bony fusion is easier to access than in cases involving metal cages (Fig. 3B). It is also possible to evaluate postoperative spinal cord and nerve root condition in patients that need follow-up imaging (Fig. 5). A metallic interbody implant can produce artifacts on CT scans and MR images.

Subsidence seems to be a problem of concern with the use of stand-alone assisted interbody fusion cage^(16,17,22). Threaded titanium cages require preparation of the bony endplates with a reamer, followed by a threading device. Therefore, the integrity of endplates is partially destroyed. The PEEK cage is more elastic than titanium, reducing the possibility of subsidence of the graft into the vertebral body⁽⁷⁾. The studies of the stand-alone titanium cage then reported a high percentage of subsidence^(16,20,22,26). Some studies of stand-alone carbon fiber cage reported a high number of subsidence^(17,19) whereas some studies of stand-alone PEEK cage showed no subsidence^(18,23). Almost all clinical studies reported radiological subsidence without leading to a worse clinical outcome^(17,19,20,22,26). Fujibayashi et al⁽²⁰⁾ noted that significant subsidence occurred only with the wedge-type cage in comparison with anatomical-type cage. It is probably important for the cage to have a contact surface that approaches the anatomical curvature of the involved endplates as much as possible⁽¹⁹⁾. They also found that an over sized cage had a high rate of subsidence. In the present study by using anatomical PEEK cages, subsidence occurred in seven levels from totally 92 levels (7.61%) without producing progressive symptoms after follow-up. Surgical technique is also important factor to create subsidence by destroying the bony endplates. Then, in cases of cervical DDD with severe narrowing of disc

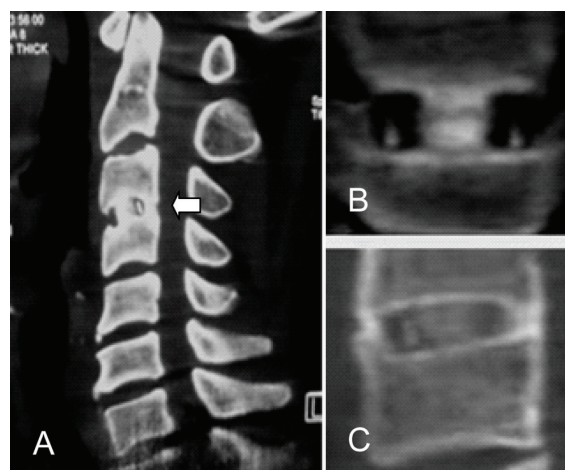


Fig. 4 Reconstructed DynaCT images of the cervical vertebrae of different patients who underwent interbody fusion cages. (A) Sagittal view showed a bony trabecular pattern at posterior to cage (white arrow). (B) Coronal view demonstrated fusion along upper and lower endplates. (C) Sagittal view also revealed a bony trabecular pattern at anterior and posterior to cage.



Fig. 5 MR imaging on T2W of a patient underwent two-level stand-alone PEEK cage. (A) Preoperative MR imaging showed moderate compression from C3-C4 and C4-C5 DDD with kyphotic deformity. (B) Postoperative MR imaging after ACDF with two PEEK cages (white arrows) demonstrated small high signal intensity in spinal cord (black arrow) with reduction of kyphotic deformity

space that needs to drill out endplates for decompression should avoid the stand-alone cage technique.

A biomechanical *in vitro* study, Wilke et al⁽²⁷⁾ simulated the patient's neck movements during the first few post-operative days by comparison between three different cage types and bone cement. They concluded that post-operative neck movements caused subsidence in all cervical interbody fusion devices. In the present study, the cervical collar was used in all patients. Some studies reported a high rate of subsidence without using a post-operative external collar^(17,22,28).

Esophageal complications and dysphagia are more common in patients treated with anterior cervical plate fixation due to an interface with esophagus. The cervical cage, which is recessed below the vertebral surface, is used as a "no profile" device that could reduce these problems⁽²⁹⁾. In the present data, only

three patients had transient dysphagia that recovered totally within the first two weeks of the post-operative period.

In case of discontinuous level of cervical DDD, such as C3-C4 and C6-C7, preservation of motion of the rest could be performed by skipping the level of stand-alone cage augmented fusion (Fig. 6).

Conclusion

Stand-alone Cervios cage-augmented ACDF in single to two-level provides improvement of clinical outcomes, restoration of lordosis, high fusion rate and avoiding donor site complications. However, subsidence occurred in 7.61% but did not cause clinical symptoms and the patients had to use the cervical collar post-operatively.

Potential conflicts of interest

The authors have no financial or other interests related to the present study.

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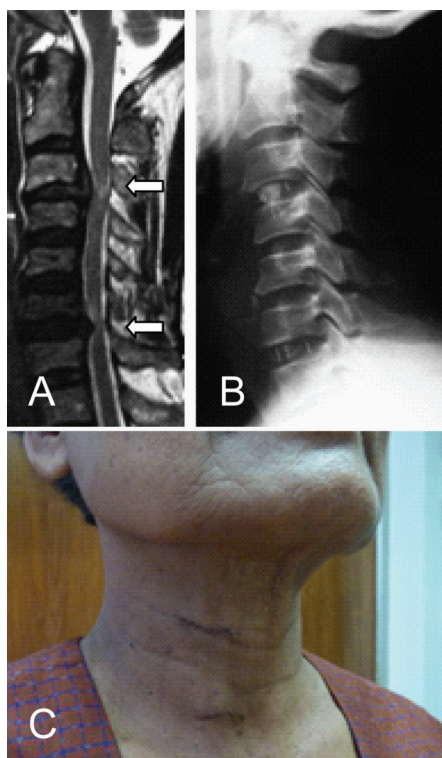


Fig. 6 A 64-year-old woman with progressive quadriplegia (A) Preoperative MR imaging showed C3-C4 and C6-C7 disc herniation, compressing spinal cord with high signal intensity on T2W (white arrows). (B) Postoperative plain radiograph (lateral view) revealed two cervical PEEK cages at C3-C4 and C6-C7. (C) Two transverse skin incisions were performed in the same operation

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การใช้ polyetheretherketone cage (Cervios) โดยลำพังสำหรับหมอนรองกระดูกต้นคอเสื่อมตั้งแต่หนึ่งถึงสองระดับ

ประเสริฐ เอี่ยมปรีชากุล, ชัยชาญ ศรีสวัสดิ์, วุฒิพงษ์ จุริโมไทย

วัตถุประสงค์: เพื่อศึกษาผลลัพธ์ทางคลินิก และภาพถ่ายทางรังสีของผู้ป่วยที่ได้รับการผ่าตัดเอาหมอนรองกระดูกระดับคอออก และเชื่อมข้อทางด้านหน้าโดยใช้ Cervios cage ช่วยเสริมโดยปราศจากเหล็กตามในโรค หมอนรองกระดูกเสื่อมตั้งแต่หนึ่งถึงสองระดับ

วัสดุและวิธีการ: ผู้ป่วยทั้งหมด 67 ราย ที่ได้รับความทุกข์ทรมานจากโรคหมอนรองกระดูกต้นคอเสื่อมซึ่งมาด้วยอาการต่าง ๆ เช่น radiculopathy, myelopathy หรือทั้งสองอย่าง ถูกประเมินโดยเก็บข้อมูลแบบย้อนหลัง โรคหมอนรองกระดูกต้นคอเสื่อมถูกยืนยันโดยใช้ภาพถ่ายทางรังสีแบบธรรมดา และคลื่นแม่เหล็กไฟฟ้าผู้ป่วยได้รับการถ่ายภาพทางรังสีเพื่อประเมิน cervical lordosis, intervertebral height (IH), fusion และ subsidence การประเมิน ทางคลินิกใช้ Visual Analogue Scale (VAS), Modified JOA (Japanese orthopedic association) score, Neck disability Index (NDI)

ผลการศึกษา: มีการผ่าตัดทั้งหมด 92 ระดับเป็นการผ่าตัดระดับเดียว 42 ราย สองระดับ 25 ราย ผลลัพธ์ทางคลินิก และการกลับคืนมาของ cervical lordosis ดีขึ้นอย่างมีนัยสำคัญ อัตราการ fusion อยู่ที่ 97% ขณะที่ subsidence อยู่ที่ 7.61% โดยที่ไม่มีอาการแสดง และไม่พบการเคลื่อนตัวมาทางข้างหน้าหรือข้างหลังของ cage ภาวะแทรกซ้อนที่เกิดขึ้นได้แก่ กลืนลำบากชั่วคราวในผู้ป่วย 3 ราย และการติดเชื้อบริเวณผิวของบาดแผล 2 ราย

สรุป: การศึกษาปัจจุบันบ่งชี้ว่าการผ่าตัดเชื่อมข้อตั้งแต่หนึ่งถึงสองระดับโดยใช้ Cervios cage ช่วยโดยลำพังปราศจากการใช้เหล็กตามช่วยทำให้ผลลัพธ์ของอาการทางคลินิกดีขึ้น, ฟื้นฟู lordosis กลับมา และทำให้การเชื่อมต่อประสบความสำเร็จในอัตราที่สูง อย่างไรก็ตาม subsidence เกิดขึ้นได้ 7.61% แต่ไม่ก่อให้เกิดอาการทางคลินิก และผู้ป่วยต้องใช้ cervical collar หลังผ่าตัด
