



# A comparison of long-term outcomes of nanohydroxyapatite/polyamide-66 cage and titanium mesh cage in anterior cervical corpectomy and fusion: A clinical follow-up study of least 8 years

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## ABSTRACT

**Objectives:** The nanohydroxyapatite/polyamide-66 (n-HA/PA66) cage is a novel biomimetic nonmetal cage device that is now used in some medical centers, while the titanium mesh cage (TMC) is a typical metal cage device that has been widely used for decades. This study was performed to compare the long-term outcomes of these two different cages in patients undergoing anterior cervical corpectomy.

**Patients and methods:** This retrospective study involved 107 patients who underwent single-level anterior corpectomy using either a TMC (n = 52) or an n-HA/PA66 cage (n = 55) for treatment of cervical degenerative disease with a minimum follow-up of 8 years. Their radiographic data (cage subsidence, fusion status, segmental sagittal alignment, and cervical spine degeneration) and clinical data [visual analog scale (VAS) and Japanese Orthopedic Association (JOA) scores] were evaluated preoperatively, postoperatively, and at the final follow-up.

**Results:** The mean duration of follow-up was  $103.6 \pm 6.3$  months in the n-HA/PA66 group and  $102.4 \pm 4.6$  months in the TMC group. The n-HA/PA66 group and the TMC group had similar final fusion rates (97% vs. 94%, respectively). The final n-HA/PA66 cage subsidence was  $2.4 \pm 1.0$  mm with 18.2% subsidence of > 3 mm, which was significantly lower than the respective  $3.0 \pm 0.7$  mm and 40.4% for the TMC ( $p < 0.01$ ). The n-HA/PA66 group also had better JOA scores than the TMC group ( $p < 0.01$ ). No significant difference in the segmental sagittal alignment, cervical lordosis, or VAS score was observed between the two groups ( $p = 0.18, 0.42, \text{ and } 0.17$ , respectively).

**Conclusions:** The n-HA/PA66 cage is associated with excellent radiographic fusion, lower subsidence and better clinical outcomes than the TMC within 8 years after single-level anterior cervical corpectomy. With the additional benefit of radiolucency, the n-HA/PA66 cage could be superior to the TMC in anterior cervical construction.

## 1. Introduction

Cervical spondylotic myelopathy is caused by a series of pathologic mechanisms and sequence of compression of the spinal cord. Anterior corpectomy with instrumentation is reportedly a good surgical choice for patients with cervical myelopathy [1–3]. When myelopathy is secondary to anterior compression by anterior osteophytes, migrated herniated discs, and similar conditions, corpectomy is considered to be one of the best surgical options, particularly when there were one or two vertebral levels involved [4,5]. The use of a tricortical autologous

bone graft from the iliac crest is regarded as the gold standard for reconstruction of corpectomy defects. However, approximately 25% of patients underwent this procedure end up developing donor-site complications, including donor site pain, infection, and hematoma formation [6–8].

Anterior cervical corpectomy and fusion (ACCF) with a titanium mesh cage (TMC) is a safe and effective surgical treatment for cervical degenerative disease. This procedure has been performed for decades in several countries [9,10] and is associated with fewer donor-site complications and earlier biomechanical stabilization. Many studies have

**Abbreviations:** ACCF, anterior cervical corpectomy and fusion; TMC, titanium mesh cage; n-HA/PA66, nano-hydroxyapatite/polyamide66; SA, segmental lordosis; CL, cervical lordosis; IH, interbody height; IDH, intervertebral disc height; JOA, Japanese Orthopedic Association; VAS, 10-point visual analog scale; CT, computed tomography; OPLL, ossification of posterior longitudinal ligament; CS, cervical spondylosis; IVDH, intervertebral disc herniation

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reported delightful clinical outcomes of this procedure thanks to the direct decompression of the neural elements and immediate stabilization of the affected motion segments [11–13]. Nevertheless, a longer period is required to achieve solid fusion with the TMC compared to those with the conventional iliac autograft, and subsidence in TMC is constantly being observed in the early postoperative period. Unfortunately, the TMC has a fairly high subsidence rate at around 30% [9,14–16]. Severe subsidence can markedly reduce the Japanese Orthopaedic Association (JOA) recovery rate and has been reported in the literature as the most frequent complication [17].

The hollow nanohydroxyapatite/polyamide-66 (nano-HA/PA66) cage is a bionic nonmetallic cylinder manufactured with n-HA/PA66 composite, simulating the constituent form of natural bone. As a non-metallic implant, the n-HA/PA66 strut can easily be penetrated by X-rays, permitting easy evaluation of the fusion status on plain radiographs and computed tomography (CT) scans. The use of a nano-HA/PA66 cage filled with autografts for anterior cervical reconstruction was recently reported and provided more satisfactory clinical outcomes than use of the TMC. Zhao et al. [18] compared the outcomes of a cage made of titanium and an n-HA/PA66 cage during a 2-year follow-up and found lower subsidence in association with the n-HA/PA66 cage. Yang et al. [19] showed a higher bone fusion rate, no instrument failure, and better clinical results with the n-HA/PA66 cage than the TMC during a 4-year follow-up. The rims of the n-HA/PA66 cage are wider than those of the TMC with lower pressure, which reduces the incidence of cutting off the cage into the endplates and helps to prevent subsidence.

No studies have been performed to compare the long-term outcomes of TMCs and n-HA/PA66 cages. A recent study showed a much lower subsidence rate with the nano-HA/PA66 cage than TMC in patients with an average age of 47.2 years [17]. However, as the n-HA/PA66 cage is now being widely used in older patients, the subsidence rate requires further study. The purpose of this study was to compare the n-HA/PA66 cage and TMC with respect to the long-term outcomes of single-level ACCF (Figs. 1 and 2).

## 2. Material and methods or patient and methods

This retrospective study involved 107 patients who underwent single-level ACCF with an anterior plate from June 2008 to June 2010. This study was approved by our institutional review board and local ethics committee. Clinical and radiologic examinations were performed preoperatively, postoperatively, and at a follow-up of at least 8 years postoperatively. The presence or absence of bone fusion, adjacent level degeneration, and subsidence as well as several radiological parameters were examined using anteroposterior, lateral, and flexion/extension

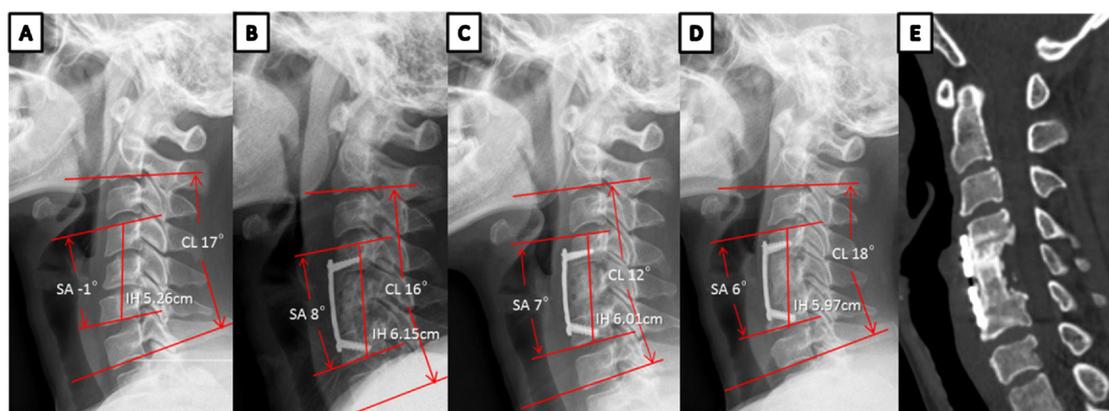
lateral plain radiographs. The inclusion criteria were a diagnosis of cervical spondylosis; resistance to conservative treatment consisting of immobilization, anti-inflammatory medications, epidural steroids, and physical therapy for 6 months; and a follow-up of at least 8 years (96 months). Patients were excluded if they had a history of rheumatoid arthritis or cervical spine surgery. In total, 131 patients who had undergone surgery for cervical stenosis during the study period were identified, and 24 were lost to follow-up 8 years after surgery. Of the remaining 107 patients, 55 were treated with an n-HA/PA66 cage and 52 were treated with a TMC. All operations were performed by two senior spine surgeons.

In all patients, cervical plain radiographs were obtained preoperatively, postoperatively, at the 1-year follow-up, and at the  $\geq 8$ -year follow-up. The following parameters were evaluated on lateral plain radiographs: cage subsidence, preoperative and postoperative segmental sagittal alignment, and C2–7 lordosis as indicated by the Cobb angle. The fused segmental height was defined as the distance between the midpoints of the superior endplate of the cephalic vertebra and the inferior endplate of the caudal vertebra in the fused segments. Loss of height of the fused segment was measured as the difference between the immediate postoperative measurements and the follow-up measurements; subsidence was defined as a  $\geq 3$ -mm loss of height. Radiographic subsidence was defined as a cage subsidence distance of  $> 2$  mm. The intervertebral disc height (IDH) was the average value of the anterior disc height and posterior disc height. Sagittal segmental alignment was defined as the angle between the line along the superior endplate of the cephalad adjacent level and the line along the inferior endplate of the caudal adjacent level. C2–7 lordosis was defined as the Cobb angle between the inferior endplate of C2 and the inferior endplate of C7. We defined the lordosis angle as positive and the kyphosis angle as negative. All of these radiographic parameters were measured by two attending surgeons who were not involved in the primary surgery, and their average value was adopted for analysis.

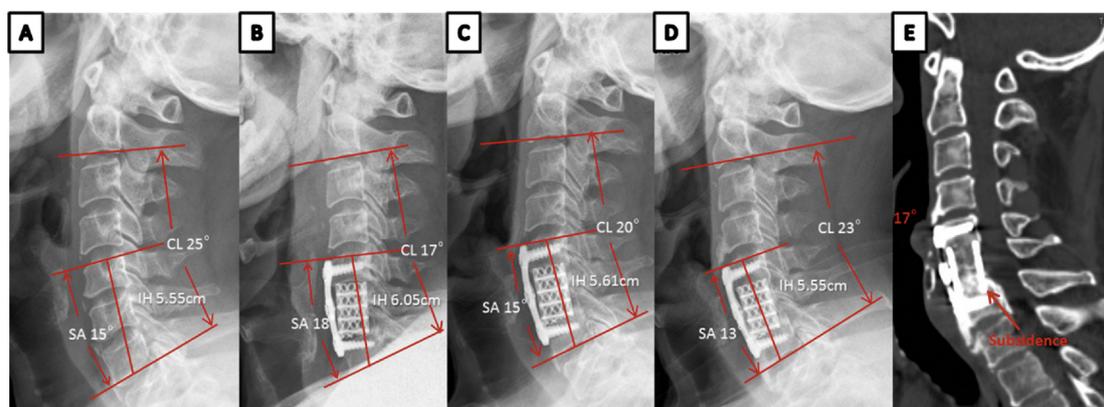
A three-dimensional CT scan was obtained for further evaluation at the final follow-up. CT scans were taken to evaluate the fusion status by two senior surgeons based on the five-grade criteria established by Brantigan et al. [20]. Grade 4 was defined as the presence of bone bridges along the entire fusion area with a density of at least the original density achieved at surgery. Grade 5 was defined as the presence of bone in the fusion area with higher density and greater maturity than originally achieved at surgery. Grades 4 and 5 were defined as fused.

The surgery time, blood loss, and complications were recorded. The JOA score and the 10-point visual analog scale (VAS) score were used to assess the neurologic status and bodily pain preoperatively, postoperatively, and at the final follow-up.

The statistical evaluation was performed using SPSS 21.0 (IBM



**Fig. 1.** A 50-year-old man who underwent 1-level corpectomy with a nano-hydroxyapatite/polyamide66 strut for cervical reconstruction. The lateral X-ray film (C) and indicated that the autogenous bone granules filling the strut had achieved bony fusion s at the 1-year follow-up. The radiographic films(D) and 3D-CT (E) scan revealed satisfying bony fusion with no obvious strut migration or subsidence at the 8.5-year follow-up.



**Fig. 2.** A 62-year-old man who underwent 1-level ACCF with a titanium mesh cage. The lateral X-ray film (C) indicated bony fusion but cage subsidence at the 1-year follow-up. The radiographic films (D) and 3D-CT (E) scan revealed satisfying bony fusion and with no obvious strut migration at the 8-year follow-up.

Corp., Armonk, NY, USA) and involved the *t*-test and chi-square test. A *p* value of  $< 0.05$  was considered statistically significant.

### 3. Results

In this study, 107 patients (54 men, 53 women) underwent single-level ACCF with a follow-up of at least 8 years. Among them, n-HA/PA66 cage was used in 55 patients and TMC was used in 52 patients. The mean duration of follow-up was  $103.6 \pm 6.3$  months in the n-HA/PA66 group and  $102.4 \pm 4.6$  months in the TMC group. No significant differences were detected in sex, age, hospital stay, blood loss, or follow-up months between the TMC and n-HA/PA66 groups (Table 1).

Radiological and clinical parameters are also shown in Table 1. No significant difference was found in preoperative interbody height, segmental lordosis [segmental angle (SA)], or cervical lordosis. The mean interbody height elongated in the TMC group from 52.6 to 60.3 mm postoperatively and then decreased to 57.2 mm at the final follow-up. In the n-HA/PA66 group, the interbody height changed from 54.1 to 62.3 mm postoperatively and decreased to 59.9 mm at the final follow-up. The postoperative fused segment heights did not differ significantly between the TMC and n-HA/PA66 groups ( $p = 0.10$ ). However, the loss of interbody height in the TMC group was greater than that in the n-HA/PA66 group at the final follow-up ( $3.0 \pm 0.7$  vs.  $2.4 \pm 1.0$  mm, respectively;  $p < 0.01$ ) with a much higher incidence rate (40.4% vs. 18.2%, respectively;  $p < 0.01$ ). There was no significant difference between the TMC and n-HA/PA66 groups in cervical lordosis postoperatively ( $17.8^\circ$  vs.  $20.5^\circ$ , respectively;  $p = 0.17$ ) or at the final follow-up ( $19.3^\circ$  vs.  $20.9^\circ$ , respectively;  $p = 0.42$ ). The two groups also showed no significant difference in the SA postoperatively and at the final follow-up, although the loss of the SA during the follow-up period was significant in both groups ( $p < 0.01$ ). Moreover, there was no significant difference between upper IDH and inferior IDH preoperatively and postoperatively.

At the final follow-up, fusion in the n-HA/PA66 group was classified as grade 5 (complete fusion) in 40 patients (72.7%) and grade 4 (probable fusion) in 13 (23.6%); 2 patients had asymptomatic grade 3 fusion (3.7%). In the TMC group, fusion was classified as grade 5 in 37 patients (71.2%) and grade 4 in 12 (23.1%); 3 patients had asymptomatic grade 3 fusion (5.7%). In total, 95% (49/52) of patients in the TMC group and 95% (53/55) of patients in the n-HA/PA66 group developed bony fusions.

The preoperative JOA and VAS scores were not significantly different between the n-HA/PA66 and TMC groups. The VAS scores distinctly improved in both groups during the follow-up period, but no significant differences were found between the n-HA/PA66 and TMC groups at the final follow-up ( $2.1 \pm 1.5$  vs.  $2.4 \pm 1.4$ , respectively;  $p = 0.17$ ). The postoperative JOA score in the TMC group was similar to that in the n-HA/PA66 group. Nevertheless, the n-HA/PA66 group

had a better outcome at 8 years postoperatively ( $14.9 \pm 1.7$  vs.  $14.0 \pm 2.0$ , respectively;  $p < 0.01$ ).

No cage migration or breakage occurred in either group at the last follow-up. No revision surgery was required for patients who did not exhibit bony fusion at the final follow-up because the anterior cervical plate and screws remained in position and the patients did not complain of discomfort.

### 4. Discussion

The n-HA/PA66 cage has been used as a bionic nonmetallic implant in reconstructive operations of the cervical spine during the past decade. The strength and toughness of n-HA/PA66 materials depend primarily on the uniform distribution of stiff nano-HA granules in the soft PA66 matrix. A previous study of the n-HA/PA66 composite demonstrated that n-HA was linked to PA66 via hydrogen bonds by formation of a carboxyl-calcium-carboxyl linkage and resulted in good mechanical properties [21]. It is also an ideal three-dimensional microstructure material, and the dynamic perfusion culture condition can greatly improve proliferation and osteogenic effectiveness [22].

As a bioactive material with the ability to promote new bone formation and provide a scaffold for osteogenesis, the n-HA/PA66 strut has advantages in ACCF. Yang et al. [17] reported a satisfactory middle-term clinical outcome of the n-HA/PA66 cage in their prospective study, with an excellent subsidence rate of 6%. The fusion rate in the n-HA/PA66 group was higher than that in the TMC group at the 1-year follow-up, but the final fusion rate was similar. Zhang et al. [14] also showed a much lower subsidence rate in the n-HA/PA66 than TMC group at the 4-year follow-up (4% vs. 24%, respectively). However, we found a higher subsidence rate in the n-HA/PA66 group (18.2%) in the present study than that found in the previous study. Additionally, patients treated with the TMC also had an extremely high subsidence rate of 40.4%. This may have been due to the higher age of the patients in this study. In the study by Yang [17], the average age of patients in the n-HA/PA66 group was only 46.8 years, compared with 56.5 years in the more recent study. Older patients tend to have a lower bone mineral density of the vertebral body, which could be a key contributor to subsidence [16,23].

The elastic modulus of the n-HA/PA66 strut was 5.6 GPa, which is similar to natural bone [24,25] and much lower than the 110 GPa of the TMC. Notionally, some stress shield caused by metallic implants can be avoided by using the n-HA/PA66 strut, which could help promote bony fusion. The elastic modulus of the cartilage endplate and cancellous bone (0.1–0.5 GPa) was lower than that of the n-HA/PA66 cage, signifying the posterior subsidence at the interface with the cancellous bone. This also suggests that an 18.2% subsidence rate is acceptable for ACCF. However, mismatch of the elastic modulus cannot completely eliminate subsidence. As a nonbionic material, the TMC requires a

**Table 1**  
Radiographic and clinical outcomes.

Variables	n-HA/PA66 (n = 55)	TMC (n = 52)	P value
Female gender	29/55	24/52	0.56
Age	56.5 ± 10.4	54.9 ± 9.5	0.43
Diagnosis			0.69
OPLL	10	13	
CS	31	27	
IVDH	14	12	
Perioperative complication	8/55	11/52	0.37
Surgery duration	126.4 ± 21.5	129.5 ± 22.7	0.47
Follow up	103.6 ± 6.3	102.4 ± 4.6	0.26
Segments(C4/C5/C6)	9/29/17	7/25/20	0.70
Fusion rate	53/55	49/52	
interbody height			
Preoperatively	54.1 ± 6.4	52.6 ± 7.2	0.25
Postoperatively	62.3 ± 6.7	60.3 ± 5.5	0.10
Final follow-up	59.9 ± 5.2	57.2 ± 4.9	< 0.01
Subsidence (mm)	2.4 ± 1.0	3.0 ± 0.7	< 0.01
Subsidence rate	18.2%(10/55)	40.4%(22/52)	< 0.01
Cervical lordosis			
Pre-op	18.5 ± 12.3	16.5 ± 11.6	0.39
post-op	20.5 ± 9.8	17.8 ± 10.4	0.17
Final follow-up	20.9 ± 10.2	19.3 ± 9.7	0.42
SA (°)			
Preoperatively	4.3 ± 5.1	4.0 ± 4.8	0.77
Postoperatively	10.7 ± 4.1	10.3 ± 4.2	0.63
Final follow-up	8.7 ± 3.8	7.8 ± 3.7	0.18
Upper IDH(mm)			
Preoperatively	4.7 ± 0.7	4.4 ± 0.9	0.11
Postoperatively	5.2 ± 0.8	5.2 ± 0.5	0.82
Final follow-up	4.5 ± 0.5	4.4 ± 0.6	0.45
Inferior IDH(mm)			
Preoperatively	5.0 ± 0.7	4.9 ± 0.8	0.37
Postoperatively	5.7 ± 1.2	5.7 ± 1.1	0.75
Final follow-up	4.8 ± 0.9	4.4 ± 1.0	0.09
JOA (point)			
Preoperatively	9.5 ± 2.5	9.7 ± 2.7	0.74
Postoperatively	15.4 ± 1.6	15.1 ± 1.8	0.41
Final follow-up	14.9 ± 1.7	14.0 ± 2.0	< 0.01
VAS (point)			
Preoperatively	7.3 ± 1.6	7.2 ± 1.4	0.76
Postoperatively	2.9 ± 1.5	3.2 ± 1.1	0.24
Final follow-up	2.1 ± 1.5	2.4 ± 1.4	0.17

n-HA/PA66 means Nano-hydroxyapatite/polyamide66.

TMC means Titanium mesh cage.

OPLL means Ossification of posterior longitudinal ligament.

CS means Cervical spondylosis.

IVDH means Intervertebral disc herniation.

SA means Segmental lordosis.

IDH means intervertebral disc height.

JOA means Japanese Orthopedic Association.

VAS means 10-point visual analog scale.

longer period to achieve solid fusion; thus, subsidence was more frequently observed. Jang et al. [13] found that cage subsidence occurred in 93.3% of their patients treated with a TMC after anterior cervical corpectomy and reconstruction, although the fusion rate was 100%. Because of the greater loss of height of the fusion segments, severe subsidence was correlated with poor neurologic outcomes and subsidence-related complications. Severe subsidence of the TMC damaged the inherent stability of the fixed segments and increased the stress load on the screw-plate structure. No significant difference was found in cervical lordosis between the TMC and n-HA/PA66 cage groups. With several subsidence and a significantly lower interbody height, the cervical lordosis remained stable in the TMC group. Subsidence predominately occurred at the posterior rim of the TMC for the reason that the loss of height of the posterior border was much greater than that of

the anterior border, which may also explain the similar cervical lordosis with the n-HA/PA66 group [13].

There was no significant difference in the VAS score between the n-HA/PA66 cage group and TMC group. Additionally, the JOA score was lower in the TMC group at the 8-year follow-up. The much higher subsidence may have contributed to this clinical result. Zhang et al. [14] showed no significant difference in the JOA score between the two groups in the middle- and long-term follow-ups with one- and two-level ACCF. The higher subsidence and lower preoperative JOA scores in patients who underwent two-level ACCF may explain the difference between their clinical result and the findings in our study. In addition, the n-HA/PA66 cage exhibits excellent biocompatibility and osteoconductive ability. Considering the lower elastic modulus with reduced loss of fused segmental height and earlier bony fusion in the n-HA/PA66 than TMC group, the n-HA/PA66 cage might take the place of the TMC. Apart from the similar fusion rate at the final follow-up, use of the n-HA/PA66 cage showed better clinical results than use of the TMC in single-level corpectomy.

This study has several limitations. We evaluated only 107 patients who underwent ACCF with either the n-HA/PA66 cage or TMC. The number of patients in each group was low. Furthermore, the choice of the two different cages was not randomized, and the final results were influenced by physician-related factors to a certain degree. The long-term comparison between the n-HA/PA66 cage and iliac crest bone is still needed to be done in the near future. A multicenter study with the use of iliac crest bone, larger samples and longer follow-up is required to evaluate the long-term clinical result of n-HA/PA66 cage.

## 5. Conclusions

The long-term follow-up in the present study showed that the n-HA/PA66 cage was associated with less subsidence and better clinical results than the TMC at 8 years after single-level ACCF. With the additional benefit of radiolucency, lower elastic modulus, better osteoconductivity, and better osseointegration, the n-HA/PA66 cage may be a more promising choice than the TMC in ACCF.

## Conflict of interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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