Treatment of cervical spondylotic myelopathy by anchoring polyetheretherketone cage filled with nano-artificial bone☆

Han Cheng-long, Liu Yang, Jiang Chao, Zhu Hong-xun, Yang Wei-liang

Abstract

BACKGROUND: *In vivo* and *in vitro* experiments have demonstrated that polyetheretherketone (PEEK) polymer is the best cervical fusion cage material due to its good biocompatibility, elastic modulus similar to human bone, and satisfactory plasticity and hardness.

OBJECTIVE: To assess the outcomes of polyetheretherketone (PEEK) cage filled with nano-artificial bone following anterior cervical discectomy and fusion (ACDF) in patients with cervical spondylotic myelopathy.

METHODS: In total 17 patients with cervical spondylotic myelopathy were collected from the Department of Orthopedics, First Affiliated Hospital of Harbin Medical University between May 2007 and September 2009. There were 12 males and 5 females, averaging 55 (range 42−67) years of age. All patients underwent ACDF using PEEK cage filled with nano-artificial bone. Patients' neurological functions were assessed on the basis of Japanese Orthopaedic Association (JOA) scoring system. The distance between the midpoint of the upper end plate and lower end plate was measured as interboby height. Radiographs with the neck in lateral flexion and extension were obtained to evaluate fusion results.

RESULTS AND CONCLUSIONS: Seventeen patients with cervical spondylotic myelopathy participated in the final analysis. Almost all patients had symptomatic improvement. Within postoperative several days, muscle strength of lower limb was increased, and limb was more flexible after surgery than prior to surgery. At 3 months after surgery, JOA scores were significantly increased compared to prior to surgery, the operated segments were stable and disc space height was satisfactory. In addition, no complications were found, and all cases achieved solid fusion, as confirmed by radiographs. These findings suggest that the immediate stability of the operated segments can be obtained by anchoring PEEK cage, and the nano-artificial bone-filled PEEK cage is safe, simple, and with relatively few complications. It is therefore a good choice for patients with cervical spondylotic myelopathy.

Department of Orthopedics, First Affiliated Hospital of Harbin Medical University, Harbin 150001, Heilongjiang Province, China

Han Cheng-long☆, Doctor, Associate chief physician, Master's supervisor, Department of Orthopedics, First Affiliated Hospital of Harbin Medical University, Harbin 150001, Heilongjiang Province, China
hanchenglong1973@126.com

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INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) with an iliac autograft is an effective treatment for cervical spondylotic myelopathy[1-2]. It does not only provide an enlarged neuroforamen but also offers solid spinal fusion. However, some pitfalls from the iliac bone graft are noted: such as graft collapse, nonunion, dislodgement and donor site complications[3-5]. ACDF combined with plate and screw fixation could maintain the spinal curvature and increase the graft fusion rate. But plates and screws may cause complications, such as screw breakage, screw pullout, esophagus perforation, and spinal cord or nerve injury[6-7]. In this study, we were to evaluate the safety and efficacy of anchoring polyetheretherketone (PEEK) cages filled with nano-artificial bone and to determine if it is possible to eliminate donor site and plate complications and to achieve good outcomes for cervical spondylotic myelopathy.

SUBJECTS AND METHODS

Design: A retrospective study.

Time and setting: This study was performed at the First Affiliated Hospital of Harbin Medical University between May 2007 and September 2009.

Subjects

Inclusion criteria: cervical spondylotic myelopathy with severe clinical manifestations.

Exclusion criteria: ① fracture or dislocation of cervical vertebra accompanied by spinal cord injury; ② cervical spinal stenosis.

Seventeen patients with cervical spondylotic myelopathy admitted to Department of Orthopedics, First Affiliated Hospital of Harbin Medical University were included in this study.

The included patients, 12 males and 5 females, averaging 55 (range 42−67) years of age, underwent ACDF using PEEK cages. Lesions at C_{4-5} were found in nine patients, at C_{5-6} in 12 patients, and at C_{6-7} in four patients. Clinical manifestations presented with muscle weakness of four limbs, unstable walking, limb numbness accompanying with thoraco-abdominal zonesthesia. Body examination showed hypermyotonia of four limbs, tendon hyperreflexia and positive pathological syndrome. X-ray showed that cervical physiological curve was straightened or curved, the height of intervertebral space was lost, and labio-like hyperplasia was found on the posterior margin of vertebrae. In the MRI examination, the signal of intervertebral disc on the affected segment was reduced, and dura mater was oppressed by exerted intervertebral disc or hyperplastic osteophyma. Five patients were found with signal change in the region of spinal cord.

Materials

The PEEK cages were provided by LDR, France. The nano-artificial bone, mainly composed of hydroxyapatite (HA) and polyamide (PA), was

purchased from Sichuan National Nanotechnology Limited Cooperation, China.

Methods

A transverse skin incision was used. The anterior cervical disc was approached using the method described by Robinson and Smith[8]. A Caspar screw distractor was used to allow distraction of the disc space throughout the procedure. Cervical discectomy and removal of the posterior hypetrophic osteophytes were performed thereafter. The upper and lower endplates were prepared by removing the overlying cartilage and preserving the hardest subchondral bone. An optimal PEEK cage was selected following completion of discectomy and endplate preparation. It appeared with wedge shape and hollow form. The inner cavity of the PEEK cage was filled with nano-artificial bone. The PEEK cage filled with nano-artificial bone was impacted into disc space for fusion after adequate distraction with the use of Caspar distractor. The anchor device was impacted into the lower cervical vertebrae. It could provide immediate mechanical stability. At postoperative 24−48 hours, drainage was pulled out, at postoperative 2 days, patients could leave the bed and did some activities, and at postoperative 7 days, stitches on the wound were taken out. After surgery, all patients were protected by wearing a brace for 6 weeks. Neck exercises were initiated 6 weeks after surgery and a normal activity level was progressively resumed.

Evaluation on therapeutic effects

The clinical results were evaluated with Japanese Orthopaedic Association (JOA) scoring system prior to and 3 months after surgery: upper limb motor function (4 points), lower limb motor function (4 points), sensation (6 points) and bladder function (3 points). Higher scores indicated better function. Plain anterioposterior and lateral cervical spine radiographs were taken prior to and after surgery and at 3, 6 and 12 months after surgery. The distance between the midpoint of the upper end plate and lower end plates was measured as interboby height. Radiographs with the neck in lateral flexion and extension were obtained to evaluate fusion results.

RESULTS

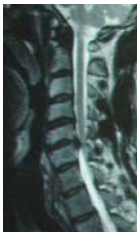
Quantitative analysis of the participants

All 17 patients were included in the final analysis, with no loss.

Therapeutic outcomes

In this series, the mean operative time was (60.6±8.3) (range 50−75) minutes and (85.3±9.4) (range 70−100) minutes for 1-level and 2-level patients, respectively, and estimated blood loss was below 50 mL in all 17 patients. No intraoperative complications were found. No fever or any inflammatory signs were found after surgery and during follow-up period. Almost all patients had an improvement in their preoperative symptoms immediately after cervical surgery. Within postoperative several days, the muscle strength of lower limb was increased, and limb was more flexible after surgery than prior to surgery. JOA score was (9.2±3.0) points prior to surgery and was (13.5±1.7) points at 3 months after surgery. The mean interbody space height was (4.7±0.9) (range, 3.4−6.2) mm prior to surgery and (5.8±0.7) (range, 5.0 to 7.2) mm after surgery. All 25 disc interspaces in 17 patients achieved solid union at final follow-up. No spinal instability or pseudarthrosis developed, and no repeated operations were needed.

A typical 47-year-old male patient complained of two-month four-limb numbness and unstable walking. In the body examination, prior to surgery, he presented with unstable walking and hypoaesthesia at the distal end of two hands and sternal angle. Bilateral gripping power was Ⅳ degree, bilateral triceps brachii muscle strength Ⅳ degree, and bilateral lower limb muscle strength Ⅳ degree. Bilateral patellar and Achilles tendon reflex was activated and muscular tension of two lower limbs was increased. Bilateral Hoffman and Babinski syndrome was positive. MRI of cervical vertebra showed that intervertebral disc protrusion was at C_{5-6}, and spinal cord was compressed. He underwent anterior C_{5-6} discectomy and fusion by anchoring PEEK cage with nano-artificial bone. In the postoperative body examination, muscle strength and sensation of four limbs recovered to normal level, muscular tension of two lower limbs was lowered, and bilateral Hoffmann syndrome was negative. MRI of cervical vertebra prior to surgery and X-ray plain film of cervical vertebra after surgery are shown in Figures 1, 2 respectively.



Intervertebral disc protrusion at C_{5-6} compressed the spinal cord

Figure 1 Magnetic resonance image of cervical vertebra before surgery

Polyetheretherketone cage anchored between the cervical vertebra stably, and interboby height increased

Figure 2 X-ray plain of lateral cervical vertebra after surgery

DISCUSSION

Cervical spondylotic myelopathy is a series of diseases caused by cervical degeneration, including intervertebral disk herniation, osteophyte formation of vertebra posterior border,

hypertrophied ligamentum flavum and other causes. ACDF combined with plate and screw fixation is a treatment for cervical spondylotic myelopathy. Anterior cervical plating could increase stability of cervical vertebrae, prevent graft dislodgement, improve graft fusion rates, and decrease the possibility of graft collapse and segmental kyphosis. But plates and screws may enlarge the scope of surgery, and increase the risk for trachea or esophagus perforation, and spinal cord/nerve/vertebral artery injury. For the long term, screw breakage, screw pullout, and plate displacement might emerge. In our study, PEEK cages were used. The main advantages include: ① The PEEK cage demonstrated absence of cytotoxicity and mutagenicity in an *in vitro* study[9]. With biocompatible, non-absorbable, and corrosion-resistant abilities, the PEEK cage is thought to be a safe biomaterial spacer for spine surgery[10]. ② The elastic modulus of PEEK is similar to bone[11-12]. This feature is thought to be able to prevent cage subsidence induced and increase the graft fusion rate. In our study, the use of a PEEK cage was found to increase the height of the disc after surgery. The mean interbody height was (4.7±0.9) mm prior to surgery and (5.8±0.7) mm after surgery. ③ The PEEK cage with anchor device could provide immediate mechanical stability in ACDF[13]. Therefore, PEEK cage has a low risk for device extrusion. The absence of any migration of the cage in our study suggests that a shorter duration of brace immobilization or even a trial with no brace might be possible. ④ The PEEK cage could be used in ACDF without anterior cervical plate fixation. So the complications of plate and screw fixation were eliminated. ⑤ The PEEK cage is radiolucent and does not produce artifacts on radiographs or CT scans[14], so it is easy to evaluate fusion status on X-ray films.

To achieve successful fusion, the fusion material embedded in the cage is another key point. Use of tricortical autograft harvested from iliac crest as interbody fusion material can provide satisfactory clinical results and fusion rates. But the complication rates of the donor site are around 20%[15]. These complications include persistent donor site pain, infection, haematoma formation, iliac crest fracture, and meralgia parasthetica. To avoid a second skin incision and to eliminate donor-site complications, cancellous allograft bone and bovine xenograft had been used to fill into the cage as interbody fusion material[16]. But they might lead to immunological rejection and transmissible disease[17-18]. In our cases, the nano-artificial bone was embedded in the PEEK cage as bone substitute. The major components of nano-artificial bone are HA and PA. HA has been used in the clinic for filling of bone defects due to its biocompatibility and bioactivity. It can form bone-bonding with living tissue through osteoconductive mechanism[19]. However, the brittleness and low fatigue strength in physiological environment limit its use for load-bearing repair or substitution[20]. PA has already been proved to possess good biocompatibility with various human cells and tissues probably owning to its similarity to collagen protein in chemical structure and active groups, and is widely used as a biomaterial.

PA exhibits excellent mechanical properties resulting from the strong hydrogen bonds between the amide groups in PA macromolecules. As a polar polymer with high polarity, PA has a relatively high affinity to and may form hydrogen bonds with nano-sized apatite[21]. The nano-artificial bone has similar composition or molecular groups to that of natural bone. The high proportion of HA and uniform distribution of n-HA granules in the PA matrix enable the material to possess good biocompatibility, high bioactivity, and enough mechanical strength[22]. In our series, all 17 patients with 25 discs achieved solid union at final follow-up. No cage subsidence or migration occurred and no complications were associated with bone graft. In the light of our findings, the PEEK cage filled with nano-artificial bone is a safe, good option for the treatment of cervical spondylotic myelopathy. It provides immediate mechanical stability, decreases surgical trauma, shortens operation time, facilitates radiological follow-up, obviates the complications of graft harvested, and finally leads to satisfactory outcomes without the need for any additional device.

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锚定聚醚醚酮融合器结合纳米人工骨治疗脊髓型颈椎病☆

韩成龙，刘　杨，姜　超，朱洪勋，杨卫良(哈尔滨医科大学附属第一医院骨科，黑龙江省哈尔滨市　150001)

韩成龙☆，男，1973 年生，黑龙江省哈尔滨市人，朝鲜族，2002 年哈尔滨医科大学毕业，博士，副主任医师，硕士生导师，主要从事脊柱外科和创伤骨科疾病的研究。

摘要

背景：聚醚醚酮聚合物在体内外实验表明，它与人体组织有良好的相容性，最接近骨的弹性模量，并具有良好的塑性和硬度，是最佳的椎间融合器材料。

目的：评价锚定聚醚醚酮椎间融合器结合纳米人工骨在脊髓型颈椎病前路间盘切除后椎体间融合效果。

方法：回顾性分析 2007-05/2009-09 哈尔滨医科大学附属第一医院骨科收治的脊髓型颈椎病患者 17 例，男 12 例，女 5 例；年龄 55(42~67)岁。均采用前路间盘切除后锚定聚醚醚酮融合器结合纳米人工骨椎间融合治疗。JOA 评分评价神经功能恢复情况；术前、术后 3 个月 X 射线检查测量椎间高度，侧位像过伸过曲位观察融合情况。

结果与结论：术后 17 例患者症状均有所改善，在术后的几天内，患者的下肢肌力增加，术后肢体的灵活性较术前改善。术后 3 个月 JOA 评分较术前明显提高，手术节段稳定，椎间高度恢复满意。无并发症发生，所有病例经 X 射线证实均达到牢固融合。结果说明锚定聚醚醚酮融合器可以使颈椎手术节段获得即刻稳定，锚定聚醚醚酮融合器结合纳米人工骨手术创伤小，手术时间短，融合效果确定，并发症较低，是治疗脊髓型颈椎病一种良好的选择。

关键词：聚醚醚酮融合器；纳米人工骨；脊髓型颈椎病；椎间融合；医学植入物
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利益冲突：课题未涉及任何厂家及相关雇主或其他经济组织直接或间接的经济或利益的赞助。

课题的创新点：脊髓型颈椎病传统手术方法需髂骨取骨、颈椎前路钢板内固定，并可能出现颈椎前路钢板及取骨区的并发症。本实验采用锚定聚醚醚酮融合器结合纳米人工骨治疗脊髓型颈椎病尚未见报道。锚定聚醚醚酮椎间融合器具有良好的生物相容性，弹性膜量与骨组织十分接近，具有良好的刚度和强度，可透过 X 射线，便于了解植骨融合的情况，术后可行 CT 及 MRI 检查了解椎管减压情况而不必担心金属伪影。操作简单方便，术野显露少，手术节段术后可以获得即刻稳定性，不需另加内固定，可避免颈椎前路钢板的使用风险，提高手术安全性，缩短手术时间。

课题评估的“金标准”：本实验应用的日本骨科学会 JOA 评分系统是评价神经功能改善的“金标准”。

设计或课题的偏倚与不足：本实验报道的病例数量偏少，尚需进一步增加病例数量给予评价。

提供临床借鉴的价值：锚定聚醚醚酮融合器结合纳米人工骨治疗脊髓型颈椎病操作简单方便，术野显露少，不需另加内固定，可避免自体骨取骨区的并发症及颈前路钢板的使用风险，提高手术安全性，缩短手术时间，患者痛苦小，有着巨大的应用潜力，但长期疗效还需进一步观察。