CLINICAL RESEARCH

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Accepted Available online	d: 2019.11.19 d: 2020.01.13 e: 2020.01.24 d: 2020.03.20	3 1	Interface Fixation Using versus Plate Fixation in Corpectomy and Fusion Spondylotic Myelopathy	Anterior Cervical for Two-Level Cervical		
S Da Statist Data In Manuscripi Liter	s' Contribution: Study Design A ta Collection B tical Analysis C uterpretation D t Preparation E rature Search F ds Collection G	CD 1 AD 1,2 BF 1	Xiaowen Qiu Bo Zhao Xijing He Chen Zhao Zikuan Leng	 Department of Orthopedics, The Second Affiliated Hospital of Xi'an Jiaotong University, Xi'an, Shaanxi, P.R. China Department of Orthopedics, Xi'an International Rehabilitation Medical Center, Xi'an, Shaanxi, P.R. China Department of Orthopedics, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, Henen, P.R. China 		
Corresponding Author: Source of support: Background: Material/Methods: Results: Conclusions: MeSH Keywords: Full-text PDF:			Xijing He, e-mail: xijing_h@vip.tom.com This study was supported by the National Natural Sciences Foundation of China (No. 2018YFE0114200), and the Natural Sciences Foundation of Shaanxi, China (No. 2017ZDCXL-SF-01-05)			
		-	We compared the clinical and radiographic outcomes between interface fixation using absorbable screws and plate fixation in anterior cervical corpectomy and fusion (ACCF) to evaluate the effectiveness of these 2 fixation methods for the treatment of 2-level cervical spondylotic myelopathy (CSM). From January 2014 to December 2016, a total of 220 patients who received 2-level ACCF were retrospectively collected. Among them, 108 patients were treated with interface fixation using absorbable screws (Group A) and 112 patients underwent plate fixation (Group B). Japanese Orthopedic Association (JOA) score and Neck			
		Results:	Disability Index (NDI) score were employed to compare the clinical improvement. Operative time, blood loss, surgical cost, cervical lordosis, complications, and fusion rate were also evaluated. The average follow-up time were 35.2±4.5 months in Group A and 35.9±3.9 months in Group B. There was no difference in operative time and blood loss for both groups. The JOA scores and NDI scores were similar in each follow-up (p>0.05 in all). Group A cost an average of 30% less than Group B for the operation. Both groups achieved 100% in the fusion rate with the same conditions in cervical lordosis. Group A (5/108) had a signifi-			
		clusions:	cantly lower complication rate than Group B (17/112) (p<0.05). ACCF with interface fixation using absorbable screws achieved similar clinical outcomes compared to ACCF with plate fixation for 2-level CSM. Moreover, the interface fixation using absorbable screws presented far fewer complications and cost less for the operation. Absorbable Implants • Decompression, Surgical • Orthopedic Fixation Devices • Retrospective Studies • Spondylosis			
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Background

Cervical spondylotic myelopathy (CSM) is a common disease in clinical practice. It is caused by compression of the spinal cord [1]. For single-level or 2-level CSM, the anterior approach is preferable [2]. Plate fixation is widely used in anterior cervical corpectomy and fusion (ACCF) to reduce the risk of graft subsidence and increase the fusion rate [3]. However, plate fixation also has complications, including screw loosening, dysphagia, and esophageal rupture [4]. Absorbable plates and screws are well-developed synthetic hardware, which have already been used to fix odontoid fractures [5], limb fractures [6], and cruciate ligament [7]. In cervical spine fusion, some studies also tried to fix the bone grafts with new surgical techniques and absorbable materials to avoid metallic plate-related complications [8, 9]. We previously demonstrated that interface fixation using absorbable screws could provide good clinical outcomes and has a low incidence of postoperative dysphagia. In the present study, we retrospectively compared the clinical outcomes and cost of operation between interface fixation using absorbable screws and plate fixation in ACCF to evaluate the effectiveness of these 2 fixation methods for the treatment of 2-level CSM.

Material and Methods

Patients

From January 2014 to December 2016, patients from a single institution received ACCF for 2-level CSM were reviewed. The inclusion criteria were: (A) patients had CSM involving 2 nearby levels from C3 to C7; (B) patients received ACCF with interface fixation using absorbable screws or plate fixation; (C) signs and symptoms consistent with 2-level CSM that were not responsive to conservative treatment; (D) disc herniation was confirmed by CT scan or MRI and limited to the disc level; (E) 24 months of follow-up or more. Exclusion criteria were: (A) spinal canal stenosis; (B) accompanied by ossification of posterior longitudinal ligament; (C) previous cervical spine surgery or cervical trauma; (D) severe osteoporosis.

This study was approved by the Institutional Ethics Committee. All the patients were fully informed of all the advantages and disadvantages of several types of surgical plans, including interface fixation using absorbable screws and plate fixation, which were recommended by the surgeon based on the patient's conditions such as age and height. Written informed consent was acquired from all patients after they chose the plan they preferred. All the operations were performed by the same surgeon.

Surgical techniques

After general anesthesia and intubation, all the patients received a corpectomy and removal of degenerative discs, posterior longitudinal ligament, and osteophytes under a standard anterior approach. For the interface fixation, the upper and lower vertebral bodies do not need to be exposed. After that, an iliac graft with proper length was harvested. The bone graft from the ilium should be intact and has 3 cortical faces.

For the interface fixation using absorbable screws (Group A), we first trimmed the bone graft to fit the removed part without over-distraction. Through a guiding sleeve, 2 holes were drilled, about 0.5 mm from each longitudinal end and at a 45-degree angle to the surface, in the anterior cortical face of the iliac graft. Then, the graft was put into the groove created by the corpectomy. Using the holes in the iliac graft as the guiding sleeve, we elongated the tunnel into the upper and lower vertebral bodies to 22–24 mm totally while avoiding penetrating the posterior walls of the vertebral bodies. After tapping, 2 full-thread absorbable screws (made of self-reinforced poly-L-Lactide (SR-PLLA), 22 mm long and 2.7 mm in diameter with a round top of 8 mm in diameter, Bionx Implants Inc., Whitpain, PA, USA) were inserted into each hole to secure the bone graft (Figure 1).

For the plate fixation (Group B), the graft was trimmed to fix the deleting part, too. Then, a titanium locking plate (Medtronic, Inc., Memphis, TN, USA) with proper length was chosen to fix the bone graft with adjacent vertebrae. Using the screw holes on the plate as markers, holes were drilled in nearby vertebral bodies. After tapping, titanium screws (Medtronic, Inc., Memphis, TN, USA) were inserted to secure the plate. Finally, the locker was turned over to secure all screws.

After all the fixation procedures, we flushed the incision and checked active bleeding. Negative-pressure drainage was placed before the incision was closed with plastic suture.

Postoperative management

Patients were requested to wear a neck collar to limit cervical movement for 2–3 weeks. The day after the operation, patients were allowed to sit on their beds. On day 3, patients could stand up and walk independently. When the daily drainage volume was below 10 ml, the drainage tube was removed. Then, a postoperative X-ray was taken to check the position of the bone graft and conditions of the fixation.

Outcome assessment

Operation time, blood loss, and perioperative complications, including blood vessel breakage, esophageal injury, and dura

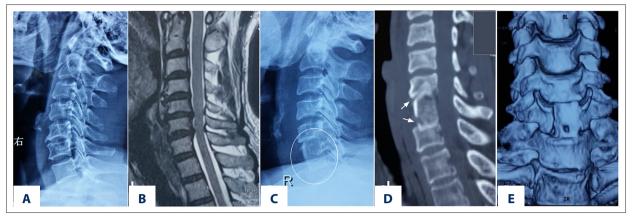


Figure 1. Illustration of a typical case: A 59-year-old male patient diagnosed with cervical spondylotic myelopathy was treated by ACCF with interface fixation using absorbable screws for 2-level CSM. (A) Lateral radiograph of cervical spine before surgery;
(B) MRI confirmed the 2 involved levels: C4/5 and C5/6. (C) Postoperatively, the graft bone was well positioned (white circle) and there was good alignment of the cervical spine. (D) Faded tunnels (white arrow) on the CT scan showed that absorbable screws were partially degraded. (E) Three-dimensional reconstruction confirmed the absorption of absorbable screws and the fusion of the grafted bone and nearby vertebral bodies.

breakage, were obtained from the surgical notes. The cost of the operation included anesthesia, surgical room, operation fee, instruments, implants, and other items used during the operation. Follow-up was conducted in our outpatient department at 3 months, 6 months, 12 months, 18 months, and 24 months after the operation, and every year thereafter. Postoperative complications such as screw loosening, screw pullout, dysphagia, esophageal rupture, pseudarthrosis, and infection were recorded. In follow-up, the Japanese Orthopedic Association (JOA) score and Neck Disability Index (NDI) score were used to evaluate the improvement of symptoms [10].

Radiographs were checked before surgery and at each followup. Three-dimensional reconstruction CT scan was performed when the X-ray demonstrated signs of bone fusion. The criteria of bone fusion were: A) there was no radiolucent gap between the endplate and graft; B) the change of interspinous distance <2 mm on lateral flexion-extension radiographs; C) continuous bridging trabeculae were observed at the interface between the endplates and the graft [11]. Radiographic conditions such as cervical lordosis, nonunion, graft subsidence, and fusion rate were also evaluated. Cobb's method was used to measure the angle formed by the lower endplates of C2 and C7 to analyze changes of cervical lordosis on a lateral plain film [12]. Nonunion was checked by whether there was a radiolucent line between the endplate and the graft on plain film or CT scans at the last follow-up.

Statistical analysis

All data were processed with Excel (Microsoft Inc, Seattle, WA, USA) and all the statistical analyses were performed using SPSS version 20.0 software (IBM Corp., Chicago, IL, USA).

Descriptive data between groups were analyzed using an independent-samples *t* test. One-way ANOVA was used to compare the pre- and postoperative intra-group data. Categorical variables like complication rates were analyzed with the chisquare test. *P*<0.05 was considered statistically significant.

Results

From January 2014 to December 2016, 220 patients who underwent ACCF for 2-level CSM were collected in this study; 108 patients (56 males and 52 females, mean age 56.1 ± 9.5 years) underwent interface fixation using absorbable screws (Group A), and 112 patients (62 males and 50 females, mean age 55.4 ± 10.2 years) received plate fixation (Group B). Demographic variables such as sex, age, or preoperative JOA score, and NDI score between Group A and Group B did not show significant differences (Tables 1, 2). Mean follow-up times were 35.2 ± 4.5 months and 35.9 ± 3.9 months in Group A and Group B, respectively.

Both groups had the same average operation time and average blood loss (Group A, 79.1 \pm 14.7 min, 156.9 \pm 38.7 ml; Group B, 84.1 \pm 12.25 min, 147.7 \pm 33.4 ml) (Table 1). There was a remarkably lower mean operative cost in Group A (6647 \pm 600 dollars) compared to Group B (9483 \pm 370 dollars) (P<0.05). There were no severe complications during surgery in either group. Both groups showed remarkable improvements in JOA score and NDI score, without significant differences between them. No significant difference was observed between the 2 groups in each follow-up (Table 2).

Table 1. General patient information.

	Group A	Group B	<i>P</i> value
Age (years)	56.1±9.5	55.4±10.2	0.77
Sex (Male/Female)	56/52	62/50	0.27
Follow-up time (months)	35.2 <u>+</u> 4.5	35.9±3.9	0.93
Operating time (minutes)	79.1±14.7	84.1±12.3	0.78
Blood loss (ml)	156.9±38.7	147.7±33.4	0.27
Cost (dollars)	6647±600	9483±370	0.00

Group A underwent interface fixation using absorbable screws and Group B underwent plate fixation.

Table 2. Comparing clinical outcomes and cervical lordosis between the 2 groups.

	Group A	Group B	<i>P</i> value
JOA scores			
Pre-operation	13.6±0.9	13.5±1.1	0.41
3 months	16.4±0.7*	16.2±0.6*	0.50
6 months	16.9±0.9*	16.5±0.8*	0.63
12 months	16.5±1.1*	16.6±0.9*	0.54
18 months	16.4±0.9*	16.5±0.8*	0.46
24 months	16.3±0.7*	16.2±0.9*	0.60
NDI scores			
Pre-operation	20.6±2.8	20.8±3.7	0.67
3 months	9.5±1.4*	9.7±1.2*	0.87
6 months	8.7±1.7*	9.0±1.5*	0.49
12 months	8.3±1.6*	8.9±1.5*	0.88
18 months	8.1±1.7*	8.7±1.1*	0.56
24 months	8.3±1.4*	9.4±1.3*	0.62
Cervical lordosis(°)			
Pre-operation	10.7±3.1	11.2±4.5	0.98
3 months	12.6±4.1*	12.9±4.7*	0.78
6 months	12.7±4.3*	12.8±4.9*	0.90
12 months	12.4±4.7*	12.5±4.5*	0.78
18 months	12.6±4.5*	12.8±5.0*	0.59
24 months	12.9±4.5*	13.1±4.9*	0.30

Group A underwent interface fixation using absorbable screws and Group B underwent plate fixation. * P value <0.05: each time point compared to pre-operation.

The fusion rates of Group A and Group B were both 100%. Preoperative cervical lordosis in both groups did not show a significant difference. The cervical lordosis in both groups demonstrated improvement after surgery and were successfully maintained in each follow-up, without significant differences (Table 2). Group A (5/108) had a significantly lower complication rate than Group B (17/112) (p<0.05). In the perioperative period, there were no complications such as dura rupture, cerebral fluid leakage, bone graft migration, hematoma, or other hardware-related complications in either group. Two patients in Group A and 1 patient in Group B had superficial infection. Bone graft subsidence and pseudarthrosis were not observed during the entire follow-up in either group. Three patients in

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Table 3. Complications.

Complication	Group A	Group B
Hematoma	0	0
Cerebral fluid leakage	0	0
Pseudarthrosis	0	0
Hardware-related complications	0	0
Dysphagia	3	16
Graft subsidence	0	0
Infection	2	1
Total	5	17

Group A underwent interface fixation using absorbable screws and Group B underwent plate fixation.

Group A (2.8%) and 16 patients in Group B (14.3%) reported dysphagia after the operation (p<0.05), and most of them recovered spontaneously within 3 months. One patient in Group B could not recover by himself and requested removal of the plate after being treated with conservative treatment for 18 months. No patients in Group A required reoperation. Detailed data are presented in Table 3.

Discussion

CSM is a common spinal disorder treated in neurosurgery or orthopedics departments. A degenerative cervical spine compresses the spinal cord and nerve roots; then, the compression causes progressive symptoms. Decompression through surgery can prevent deterioration and improve neural function [13]. For the treatment of CSM, ACCF allows direct neural decompression and helps to restore the cervical lordosis with proper intraoperative distraction [14]. ACCF can also provide good exposure to reduce the risk of spinal cord injury.

The fixing method is a very important part of ACCF to ensure affirmative fusion. Plate fixation has been used for years for its affirmative improvement of fusion rate and easy installation since it was invented [15]. However, this popular fixation method also has some drawbacks. Some drawbacks, like screw loosening and plate breakage, were overcome with improvements of metal material and design, like the locking plate [8]. Other drawbacks, including dysphagia, and imaging artifacts caused by the original design cannot be improved in the same ways [16].

Interface fixation using absorbable screws was developed to avoid the remaining drawbacks of plate fixation. Based on Kim's fixing method [17], the surgical technique used in the present study was simplified by using 2 absorbable screws to secure the bone graft to adjacent vertebral bodies. Biomechanical evaluation in cadaveric cervical spines confirmed that interface fixation with absorbable screws can achieve instant stability [18], but it had lower stability than plate fixation in lateral bending. Therefore, patients must wear a neck collar for 2-3 weeks after surgery to limit cervical movement. The absorbable screws used in this study were made of self-reinforced ploy-L-Lactide (SR-PLLA), which was polymerized with hydrogen, oxygen, and carbon in a special condition. SR-PLLA will completely degrade into water and carbon dioxide when exposed to water [19]. Studies confirmed that absorbable screws degrade completely over time (from 3 to 4 years), which is the same length as the healing process of cancellous bone fracture. The initial bending strength and shear strength are 300 MPa and 200 MPa, respectively, which are similar to those of stainless steel. Meanwhile, the elasticity modulus of SR-PLLA (8-15 GPa) is much lower compared to stainless steel and is close to that of cortical bone [20]. Thus, the physical property of SR-PLLA ensures the absorbable screws provide a secure fixation. Absorbable screws give this new fixation method another advantage, in that it does not cause imaging artifacts like plate fixation does.

In the present study, both groups had the same surgery time and blood loss, and demonstrated significant improvement in JOA score and NDI score after surgery, without significant differences between them. This is because both groups underwent the same type of surgery – anterior cervical corpectomy and fusion. This also explained how both groups achieved the same improvements in cervical lordosis. However, the improvement in cervical lordosis was not remarkable because the graft can straighten the spinal column, which reduces the restoring effort made by distraction [21]. The main difference between these 2 groups was the fixing method used. Previous studies showed that autograft fusion with proper fixation achieved 100% fusion [2,22]. The remarkable fusion rate in both groups indicated that both fixation methods can provide secure fixation to ensure fusion.

Screw loosening, screw pullout, and plate breakage are the primary concerns with plate fixation, especially in multi-level CSM [23]. However, these direct complications are not very common in plate fixation for 2-level CSM because of the shorter range of fixation and lower stress [16]. In the present study, dysphagia, not the previously mentioned complications, became the primary complication. Dysphagia do not affect the fusion rate and neural improvement, but is very annoying. Continuous dysphagia can decrease food intake and has a negative effect on emotion, thus delaying postoperative recovery. The incidence of dysphagia in Group A was remarkably lower than in Group B. This difference could be explained in 2 aspects. Firstly, tiny esophageal injury or excessive retraction of soft tissue may cause postoperative dysphagia [24]. Plate fixation needs to expose the upper and lower vertebra bodies to install the plate, but interface fixation does not. More exposure means more retraction of soft tissue and the esophagus, and different surgeons need different extents of exposure based on their techniques and experience. To avoid this influence, all the patients enrolled in this study were treated by the same surgeon. Secondly, implant plates, even lowprofile anterior cervical plates, can develop esophageal adhesion; then, strictures can cause postoperative dysphagia [25]. In contrast, the absorbable screws used in Group A prevent adhesion formation through their degradation and their significantly smaller contact surface than that of the plate [20]. These factors all suggest that the incidence of postoperative dysphagia could been significantly decreased by replacing plate fixation with interface fixation using absorbable screws.

The average cost of surgery in Group A was only 70% of that of Group B, without the subsequent cost for treating complications. CSM now is increasing in the geriatric population and even in the middle-aged population [14]. The increasing incidence of CSM obviously increases the economic burden of patients and national medical spending. The cost of implants is always a large part of the entire cost of ACCF using plate fixation because plate fixation needs at least 1 locking plate and 4 screws to secure the graft bone [8]. However, just 2 absorbable screws through the interface fixation can achieve stability

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similar to that of plate fixation. Moreover, using absorbable screws could simplified the supply because different sizes of plates are not needed.

Our study has certain limitations. First, it was a retrospective study that was non-randomized. The detailed inclusion and exclusion criteria of this study may have introduced a potential selective bias. Future prospective randomized trials should be considered. Second, there might be a regional and institutional bias, because all patients were enrolled in a singlecenter hospital.

Conclusions

Considering clinical and radiographic outcomes of 2-level CSM, interface fixation using absorbable screws appears to be more effective than plate fixation in ACCF. Moreover, the interface fixation using absorbable screws presented far fewer complications and cost less for the operation.

Conflict of interest

None.

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