Original Article

A novel cervical artificial disc and vertebra system and its biomechanical property

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Abstract: Anterior cervical corpectomy and fusion is an effective procedure in the treatment of cervical spondylotic myelopathy but accompanied with motion loss in the fused levels. A novel hemisphere type of cervical artificial disc and vertebra system (H-ADVS) has been designed to preserve the intervertebral motion function after cervical corpectomy. The aim of study is to evaluate the range of motion of the goat cervical spine model after implanted with this prosthesis in comparison with the fused or intact specimen. A total of 12 male goats were included and divided into experimental and control group with 6 animals in each group. The goats in experimental group were implanted with H-ADVS. All the cervical spine specimens were harvested 6 months after the operation followed by euthanasia. Biomechanics test on the fresh cervical spine specimens was performed. Specimens in experimental group were tested as in vivo H-ADVS group. Specimens in control were tested in sequence as intact group, fusion group and in vitro H-ADVS group. The ranges of motion in flexion-extension, lateral bending and axial rotation of $C_{2.3}$, $C_{3.4}$, $C_{4.5}$ and C_{2.5} from each group were compared. Significant increased range of motion of C_{2.3} in most directions in fusion group was observed comparing with the intact group (P < 0.01). The range of motion of operative levels ($C_{2,a}$, $C_{4,5}$) in in vivo H-ADVS group and in vitro H-ADVS group were remarkably preserved comparing the intact group (P < 0.01). Significant differences in comparing the range of motion of C_{2.5} in all the specimens were detected between groups (P < 0.01). Our result suggested that H-ADVS replacement could reduce the range of motion in the upper adjacent level and restore the range of motion of the operative levels comparing with the fusion procedure. In conclusion, H-ADVS provided a new method to restore the range of motion after cervical corpectomy. However, improvements on the design of this prosthesis should be continued.

Keywords: Cervical spine, biomechanical, artificial, prosthesis

Introduction

Anterior cervical corpectomy and fusion (ACCF) has been widely used in the treatment of cervical spondylotic myelopathy (CSM) [1, 2]. During this procedure, titanium mesh cage (TMC) or bone graft was implanted after one vertebral body subtotal resection followed by the anterior fusion of the upper and lower segments adjacent to the resected vertebra via a plate together with several screws [3-6].

Although ACCF was reported with advantages of being able to provide the spinal cord with adequate decompression and stable biomechanical environment [7, 8], one obvious deficiency was that the mobility and flexibility of the cervical spine at operative levels were evidently changed when at least three cervical spine seg-

ments must be fused together during the operation [9]. An immediate consequence of this change is the redistribution of motion of the fused levels into the adjacent intervertebral spaces [8, 10]. As a result, the range of motion (ROM) of adjacent levels, pressure inside the disc and loads of the facet joint largely increased [8, 11], which has a possibility of leading to adjacent segment disease (ASD) [12, 13]. The ASD was a series of clinical symptoms or imageological changes [14]. Some patients undergone ACCF recovered with good clinical outcomes but complained of aggravating neurological symptoms such as neck pain, numbness and tingling in the hand or forearm several years after the operation [9, 14]. Similarly, imaging examination showed the development of cervical kyphosis, osteophyte formation and facet joint degeneration etc. after a period of

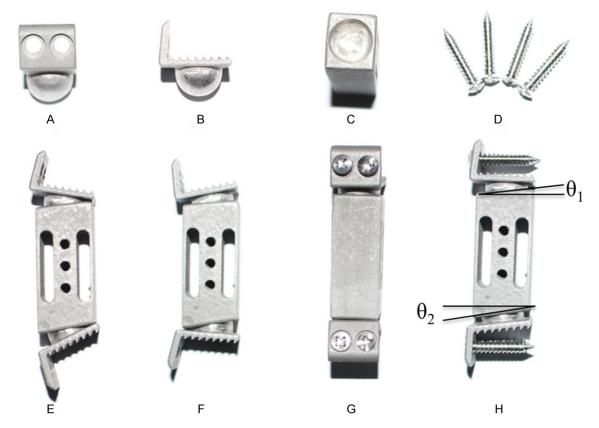


Figure 1. Photographs of H-ADVS. A. Frontal view of the artificial disc; B. Lateral view of the upper artificial disc; C. Artificial vertebra; D. Self-tapping screw; E. H-ADVS in extension; F. H-ADVS in flexion; G. Frontal view of H-ADVS; H. Lateral view of H-ADVS; θ_1 =6º, θ_2 =10º.

follow-up for the patients who had ACCF [14, 15]. At the same time, ACCF was often accompanied with subsidence of TMC [16, 17].

Non-fusion techniques such as cervical disc arthroplasty have been developed to restore the motor function of the intervertebral space [18-20]. Clinical outcomes of cervical disc replacement were positive [21-23]. However, the current motion preservation method was unsuitable for the case when vertebral corpectomy must be performed. To address this issue, a hemisphere type of cervical artificial disc and vertebra system (H-ADVS) was designed to preserve the intervertebral motion function after cervical corpectomy.

In this study, we established an *in vivo* caprine cervical corpectomy non-fusion model after implantation of H-ADVS at C_4 segment. Biomechanical test was conducted to evaluate the ROM of the caprine model implanted with ADVS 6 months after the operation (*in vivo* H-ADVS implanted) in comparison with intact, anterior plate-fixed or *in vitro* H-ADVS implanted cervical spine models.

Material and methods

H-ADVS

In this study, a hemisphere type of cervical artificial disc and vertebra system (H-ADVS) for caprine cervical spine was designed to mimic the fact that the functional spinal unit had both load bearing and movement function (Figure 1). The H-ADVS, printed by 3D laser using Ti6Al4V alloy (Bright Laser Rapid Prototyping Technology Co. Ltd., Xi'an, China), consists of one artificial vertebra and two artificial discs. The artificial vertebra is a quadrangular (14 mm in width; 35-40 mm in length; 14 mm in depth) with one hemisphere articular fovea (12 mm in diameter) cephalically and caudally. The angle is 6º between the horizontal plane and the upper surface and 10° between the horizontal plane and the lower surface. Through holes are designed at the lateral side of the artificial vertebra for the formation of bony bridge. The artificial disc, accompanied with an anterior plate, has zigzag grooves on the endplate. The hemisphere with a diameter of 12 mm is designed

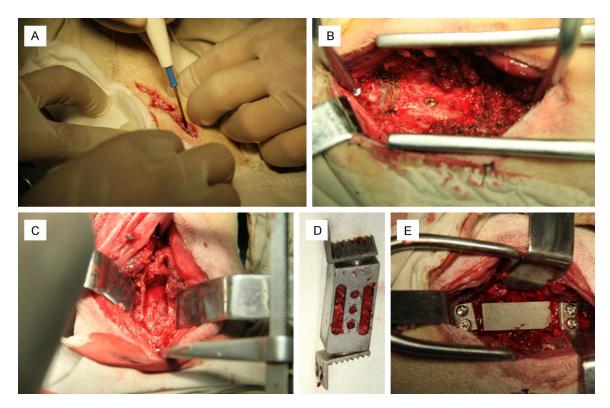


Figure 2. Process of in vivo H-ADVS implantation animal model. A. A right-sided anterolateral approach was used; B. C4 vertebra exposure; C. C_4 corpectomy was performed; D. H-ADVS was assembled and filled with autogenous bone; E. H-ADVS was implanted in C_4 vertebra accompany with self-tapping screw fixation at C_5 and C_5 .

for the matching of the articular fovea inside the artificial vertebra. The angle between the plate and the upper or lower endplate is 84° and 100° respectively. The distance between the endplate and vertebra in neutral position is 3 mm. The ROM between the disc and the vertebra is 12° in flexion, extension and lateral bending, 360° in axial rotation. The screws for fixation are 18-20 mm in length, 3.5 mm in diameter.

Animal grouping

This study was conducted under the principles of laboratory animal use and care of National Research Council Guide. All animal surgeries and experimental procedures followed the protocols approval by the ethical committee of Xi'an Jiaotong University. Every effort was made to minimize suffering.

Twelve male goats, body weight 28-38 kg, were used in the experiments. The goats were divided into control or experimental group with six goats in each group. The control group of six goats was first fed for six months. The experimental group was implanted with H-ADVS and

fed for six months after the operation. Cervical spine specimens of the two groups were harvested six months after the operation followed by euthanasia. Biomechanics experiment on the fresh cervical spine specimens was performed.

Surgical procedure and postoperative care

The operation on experimental group was performed under aseptic conditions. The goats had a three-day fasting for gastrointestinal tract emptying and a subcutaneous injection of atropine (0.02 mg/kg) before anesthesia to reduce the tracheal secretions. A venous channel was established before the operation. A negative pressure aspirator was prepared for the removal of blood during the operation. A sputum suction apparatus was used for respiratory care. All the goats were anesthetized with injection of pentobarbital sodium at 30-35 mg/kg body weight via the venous channel. After anesthetization, the goat was placed supine. A right-sided anterolateral approach was used following by penicillin sodium (100 mg/ kg) was injected immediately. After careful soft tissue dissection, an adequate exposure from

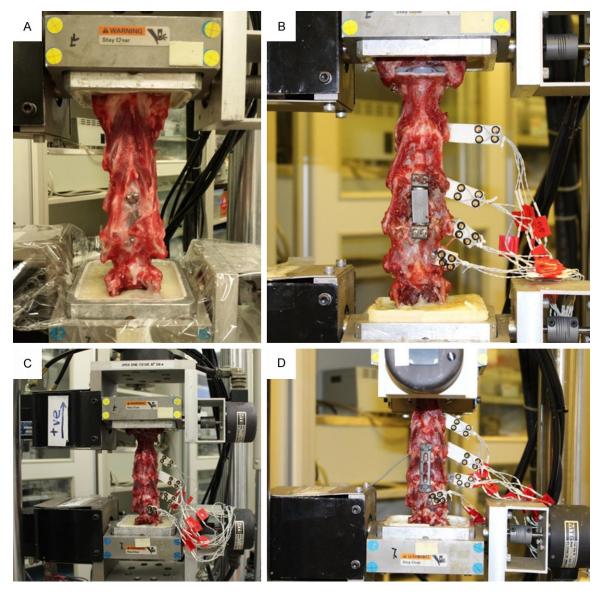


Figure 3. Photographs of biomechanical test. A. *In vivo* H-ADVS group; B. *In vitro* H-ADVS group; C. Intact group; D. Fusion group.

 ${\rm C_3}$ to ${\rm C_5}$ vertebra bodies was made. Two distraction pins were respectively placed in middle crest of ${\rm C_3}$ and ${\rm C_5}$. The ${\rm C_4}$ vertebra corpectomy was performed by using bone rongeur and curet followed by the discectomy of ${\rm C_{3-4}}$ and ${\rm C_{4-5}}$ by using nucleus pulposus forcep. Prior to the implantation of H-ADVS, the posterior longitudinal ligament was resected using Kerrison rongeurs. After distraction across ${\rm C_3}$ to ${\rm C_5}$, H-ADVS was implanted ${\rm C_4}$ following by the screw fixation at ${\rm C_3}$ and ${\rm C_5}$ vertebra. The wound was irrigated with 500 ml metronidazole solution (5 mg/ml) and closed in the standard fashion. All the goats received standard postoperative care including postoperative fluid therapy for 24

hours. Penicillin sodium (100 mg/kg) was used three days after the operation for the prevention of infection. The dressing was changed every two days till the wound was healed (Figure 2). The goats in control were just fed without operation. All the 12 goats were kept in a special animal care center (De Sheng Husbandry, Sanyuan County, Xi'an) for six months.

Biomechanical test

Surrounding muscle and soft tissue of the 12 harvested fresh caprine cervical specimens (C_1-C_7) were removed with caution while keeping the facet joints and interspinous ligaments

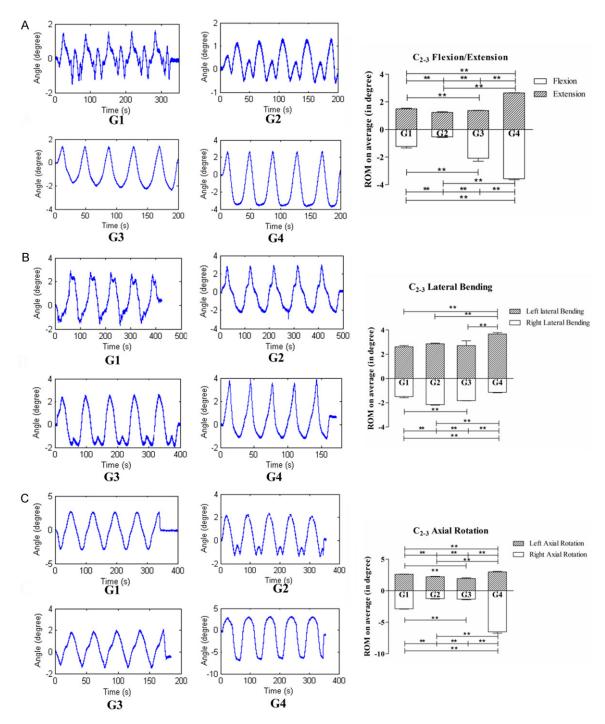


Figure 4. ROM curve of $C_{2.3}$ intervertebral space. A. ROM in flexion and extension; B. ROM in lateral bending; C. ROM in axial rotation; G1. *In vivo* H-ADVS group; G2. *In vitro* H-ADVS group; G3. Intact group; G4. Fusion group; Two asterisks mean that there is statistically significant difference and P < 0.01.

intact. All the specimens were preserved in a minus 20º laboratory freezer. Before testing, the specimens were thawed at room temperature. The cephalic and caudal vertebras were respectively embedded vertically into a mould by a mixture containing N (3-Dimethylamino-

propyl)-1, 3-propylenediamine and bisphenol A-(epichlorhydrin) (1:1). A servohydraulic material testing machine (MTS 858 Bionix machine, MTS System Inc., Minneapolis, MN, USA) and an optoelectronic three-dimensional motion capture system with three cameras (OPTOTRAK

CERTUS, Northern Digital Inc., Waterloo, Canada) were used in the test. Sixteen light-emitting diodes (LEDs) were firmly fixed to $\rm C_2$, $\rm C_3$, $\rm C_4$ and $\rm C_5$ vertebra with four LEDs in each vertebra

A1.5N-M torques produced from MTS was applied to the top of the model making the specimen moving in flexion-extension, lateral bending or axial rotation. During the testing, movements of the LEDs on vertebras were recorded by OPTOTRAK CERTUS. This device had a three-dimensional precision of 0.1 mm, a measuring distinguish ability of 0.01 mm and a sampling frequency of 100 Hz. The instantaneous spatial locations of the 16 LEDs were recorded by OPTOTRAK CERTUS. The recorded data were converted into ROM using a program written in Matlab (Mathworks, Natick, MA, USA).

ROM was obtained in all specimens. Totally, five loading cycles were completed. The average ROM of last three circles was used for data analysis. The specimens in the control group were tested in three status, firstly tested in intact (intact group), secondly tested in fixed (from $\rm C_3$ to $\rm C_5$) by an anterior plate (Fule Science & Technology Development Co., Ltd, Beijing, China) (fusion group), then tested in implanted with H-ADVS *in vitro* after $\rm C_4$ vertebra corpectomy (*in vitro* H-ADVS group). All the specimens were kept moist with 0.9% saline during the testing (**Figure 3**).

Data analysis

Data were expressed as mean \pm SD, and were analyzed using SPSS 19.0. One-way ANOVA with Bonferroni's post-hoc test were performed to ROM convert from records data of OPTOTRAK CERTUS. P value less 0.05 was considered as statistically significant.

Results

C23 ROM

 ${
m C_{2.3}}$ ROM in flexion-extension, lateral bending and axial rotation were shown in **Figure 4**. ${
m C_{2.3}}$ ROM of *in vitro* H-ADVS group was the minimum in flexion-extension while the maximum in lateral bending comparing with the *in vivo* H-ADVS group and intact group. The ${
m C_{2.3}}$ ROM in axial rotation of *in vivo* H-ADVS group was larger than the *in vitro* H-ADVS group and intact group. The ${
m C_{2.3}}$ ROM in all directions except right lateral bending of the fusion group, which is was

remarkably small, was greater than the other three groups. Significant differences were detected in comparison of the $C_{2\cdot3}$ ROM in flexion-extension, right lateral bending and axial rotation in every two groups (P < 0.01). Difference was also observed when comparing the $C_{2\cdot3}$ ROM in left lateral bending of fusion group with the other three groups (P < 0.01). No difference was observed in the $C_{2\cdot3}$ ROM in left lateral bending of the intra-group comparison of the in vivo H-ADVS group, in vitro H-ADVS group and intact group.

C₃₋₄ ROM

 ${
m C_{3-4}}$ ROM in flexion-extension, lateral bending and axial rotation were shown in **Figure 5**. The fusion group had the minimum ${
m C_{3-4}}$ ROM in all directions while the *in vitro* H-ADVS group had the maximal ${
m C_{3-4}}$ ROM in all directions except right lateral bending. Meanwhile, the ${
m C_{3-4}}$ ROM in all directions of intact group was greater than the *in vivo* H-ADVS group. Significant differences were detected in pairwise comparison of the ${
m C_{3-4}}$ ROM of the four groups in all directions except flexion between the *in vitro* group and intact group as well as the right lateral bending and right axial rotation between *in vivo* H-ADVS group and *in intro* H-ADVS group (P < 0.01).

C₄₋₅ ROM

C₄₋₅ ROM in flexion-extension, lateral bending and axial rotation were shown in Figure 6. The in vivo H-ADVS group had the maximum $C_{4.5}$ ROM in flexion while the in vitro H-ADVS group had the maximum C_{4-5} ROM in extension. The in vitro H-ADVS group had the maximum C₄₋₅ ROM in left lateral bending while the intact group had the maximum C₄₋₅ ROM in right lateral bending. The intact group had the maximum C₄₋₅ ROM in axial rotation. The fusion group had the minimum C_{4-5} ROM in all directions. Significant differences were detected in pairwise comparison of the C₄₋₅ ROM of the four groups in all directions except lateral bending between the in vivo H-ADVS group and intact group (p value was less than 0.01 in the pairwise comparison except that p value was less than 0.05 in comparison the C₄₋₅ ROM in extension of the in vitro H-ADVS group and intact group).

C₂₋₅ ROM

 ${\rm C_{2-5}}$ ROM in flexion-extension, lateral bending and axial rotation were shown in **Figure 7**. Significant differences were observed in pair-

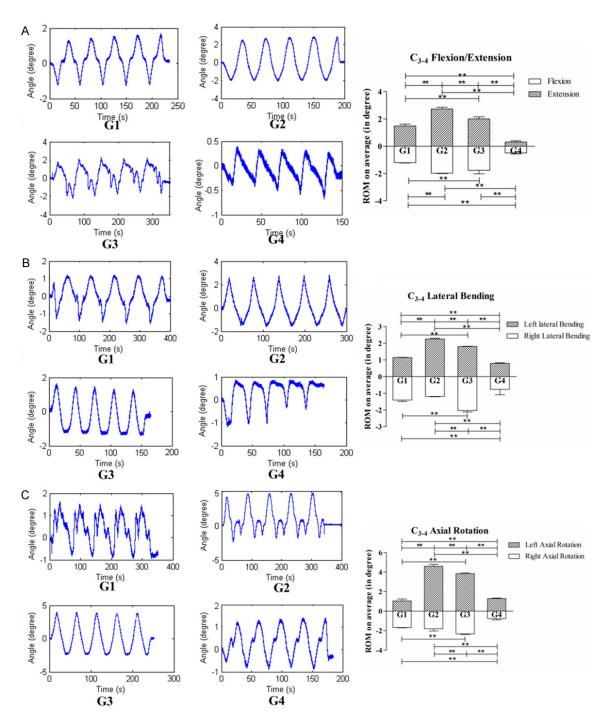


Figure 5. ROM curve of $C_{3.4}$ intervertebral space. A. ROM in flexion and extension; B. ROM in lateral bending; C. ROM in axial rotation; G1. *in vivo* H-ADVS group; G2. *in vitro* H-ADVS group; G3. intact group; G4. fusion group; Two asterisks mean that there is statistically significant difference and P < 0.01.

wise comparison of $\rm C_{2.5}$ ROM of the four groups in most of directions (P < 0.01). No difference was detected in flexion between the *in vivo* H-ADVS group and *in vitro* H-ADVS group as well as *in vivo* H-ADVS group and intact group.

Similarly, no difference was detected $\rm C_{2.5}$ ROM in right lateral bending between *in vivo* H-ADVS group and *in vitro* H-ADVS group as well as left lateral bending *in vitro* H-ADVS group and intact group. There was also no difference in $\rm C_{2.5}$ ROM

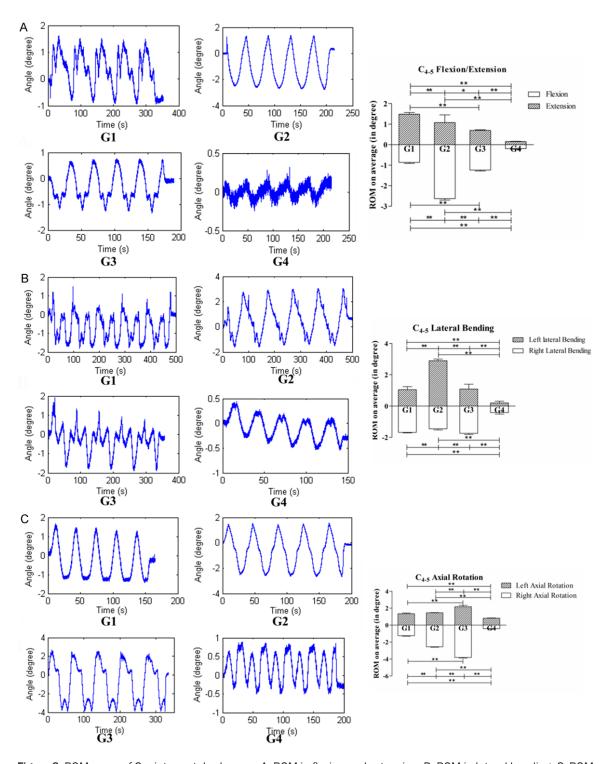


Figure 6. ROM curve of $C_{4.5}$ intervertebral space. A. ROM in flexion and extension; B. ROM in lateral bending; C. ROM in axial rotation; G1. *In vivo* H-ADVS group; G2. *in vitro* H-ADVS group; G3. Intact group; G4. Fusion group; One asterisk means that there is statistically significant difference and P < 0.05. Two asterisks mean that there is statistically significant difference and P < 0.01.

in left axial rotation between *in vitro* group and *in vitro* H-ADVS group as well as the right axial

rotation between *in intro* H-ADVS group and intact group.

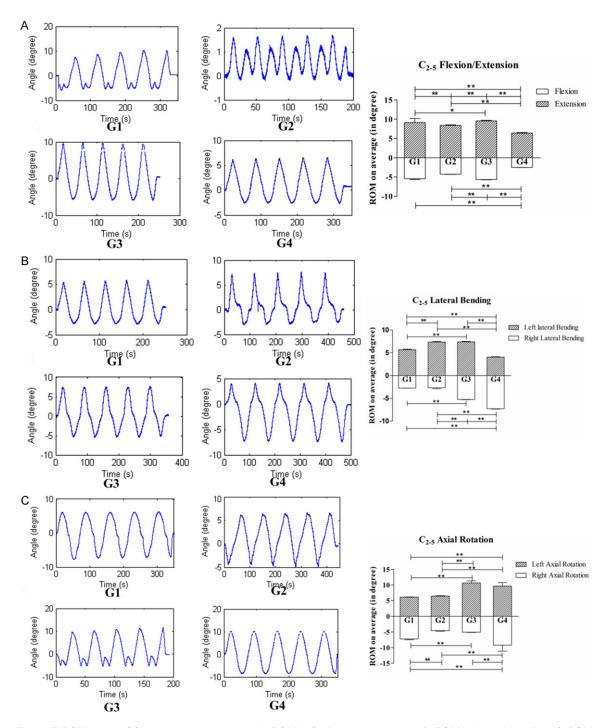


Figure 7. ROM curve of $C_{2.5}$ intervertebral space. A. ROM in flexion and extension; B. ROM in lateral bending; C. ROM in axial rotation; G1. *In vivo* H-ADVS group; G2. *In vitro* H-ADVS group; G3. Intact group; G4. Fusion group; One asterisk means that there is statistically significant difference and P < 0.05. Two asterisks mean that there is statistically significant difference and P < 0.01.

Discussion

The design of H-ADVS in this study was based on the principal that the prosthesis should have the similar stability as the vertebra and motion function as the disc [24]. The upper or lower disc of H-ADVS was fixed to the vertebra by two self-tapping screws. Meanwhile, the angle between the plate and the upper or lower endplate together with the zigzag grooves on its surface made the disc firmly attached to the vertebra. The artificial vertebra was designed

to reestablish the height of the subtotal-resected vertebra. The through holes of the artificial vertebra were implanted with cancellous bone for the purpose of initial stability and forming bony bridge in the later stage. To match the inclined disc, the upper or lower surface of the artificial vertebra also had a certain angle between the horizontal planes. The relative movement, which produced from the hemispheresocket joint between the vertebra and disc, achieved the motor function of H-ADVS. In detail, this prosthesis had 12° ROM motion in flexion-extension or lateral bending and 360° ROM in rotation. Considering previous study stated that whether the center of rotation was fixed or not had little impact on the overall kinematics [18], the instantaneous center of rotation of our prosthesis was fixed rather than variable. Titanium alloy was the frequently-used material of implant [25]. Given Ti6Al4V was reported with good strength, ductility and toughness needed for load bearing [26], the prosthesis in our study was also made of such material. Commonly, articulating surface was metal on polyethylene such as PCM [27], Pro-Disc-C [28], Mobi-C [18], and Discover [29], metal on metal such as Prestige [18], Cervicore [18] and Kineflex-C [28], ceramic on ceramic or ceramic on polyethylene [18]. Since this study was a preliminary attempt, the H-ADVS was just designed as a metal on metal this time.

ACCF was in fact a second best choice when the fusion must be performed. The increased ROM of adjacent segment as well as the loss of motion of operative levels had positive role in developing ASD. In our study, ROM of adjacent level $(C_{2,3})$ in fusion group had remarkable increase comparing with intact group and the specimens with H-ADVS implanted. The ROM of C_{3-4} and C_{4-5} in fusion group were almost disappeared comparing the other three groups. It suggested that anterior plate fusion from C₂-C₅ had a greatly effect on the ROM of the operative levels. Interestingly, the C₂₋₃ ROM was significantly increased in in vivo H-ADVS group while decreased in in vitro H-ADVS group comparing with the intact group. It suggested that ROM from operative levels redistribute into the adjacent level. Meanwhile, the C_{3-4} and C_{4-5} ROM of the specimens implanted with HADVS in most directions were significantly increased comparing with the fusion group. However, the ROM in the C₂-C₅ levels of in vivo H-ADVS was decreased in extension, lateral bending and axial rotation in comparison of the intact group. Several reasons may explain why ROM in operative levels of the specimen implanted with H-ADVS was not completely restored in some directions. Firstly, sticky tissue covered the H-ADVS after six-month implantation that limited the movement of $\rm C_{3-4}$ and $\rm C_{4-5}$ intervertebral space. Secondly, the specimens were not vertically embedded making the movement asymmetry during the test. Thirdly, the center of rotation of H-ADVS was fixed, which contributes to the decreased ROM comparing with the intact group.

The limitation of this study must be acknowledged. Although this study suggested that the H-ADVS reconstructed the height of vertebra and restored the ROM of the operative levels, this prosthesis was just designed for goat, which was greatly different with the anatomy of human beings [30]. The metal on metal prosthesis was historically reported been a poor bearing surface. Wear and immune response study were not included and long-term experimental observation was necessary for the clinical use [31].

Conclusion

This biomechanical study, comparing the ROM in the upper adjacent or operated levels of the specimens under four statuses, showed that the H-ADVS replacement could reduce the ROM in the upper adjacent level and restore the ROM of the operative levels comparing with the fusion procedure. H-ADVS provided a new method to restore the range of motion after cervical corpectomy. However, improvements on the design of this prosthesis should be continued.

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Disclosure of conflict of interest

None.

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