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Stabilization of the craniovertebral junction with clivus plate constructs: biomechanical comparison with conventional technique

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ABSTRACT

BACKGROUND: Ventral defect caused by resection of the lesions involving the upper cervical spine was commonly reconstructed with a fabricated mesh cage. Recently, a clival screw and plate fitted to the osseous anatomy of the craniovertebral junction was developed for this pathological state.

OBJECTIVE: To evaluate the stability a clivus plate system fixation (CPSF) for the craniovertebral junction and compared with a conventional fashioned mesh cage fixation (FMCF).

METHODS: Seven human fresh cadaveric specimens (Oc-C4) were tested intact, after destabilization and after fixation as follows: FMCF and CPSF were randomly applied to the clivus to C3 segment following posterior occipitocervical fixation applied from the occiput to C4 segment, respectively. Specimens were subjected to the following tests: flexion, extension, lateral bending and axial rotation at 1.5 Nm. The range of motion (ROM) and neutral zone (NZ) from the occiput to C3 were calculated.

RESULTS: Motions were reduced significantly compare with the intact condition for both configurations under all motions. The CPSF resulted in smaller ROM in Oc-C3 segment compared with the FMCF in lateral bending (0.3° vs. 0.6° , $p=0.015$), axial rotation (0.6° vs. 1.2° , $p=0.023$) and flexion (0.1° vs. 0.3° , $p=0.019$), but similar ROM in extension (0.2° vs. 0.4° , $p=0.273$). NZs after the CPSF were 0.1° in flexion-extension, 0.1° in lateral bending and 0.2° in axial rotation, respectively. NZs

after the FMCF were the same as the CPSF (all $p > 0.05$).

CONCLUSION: The clivus plate system fixation is biomechanically superior to conventional fashioned mesh cage fixation in flexion, lateral bending and axial rotation, and offer similar stability in extension.

Key words: Craniovertebral junction; Clivus; Mesh cage; Vertebrae body reconstruction; Biomechanics

INTRODUCTION

Multiple etiologies of craniovertebral instability, including inflammation, injury, cancer and deformity may require a surgical fixation for the craniovertebral junction (CVJ) to restore the stability (1-3). Ventral resection of the lesions involving the upper cervical spine necessitates anterior and superior support with instrumentation. Commonly, the anterior reconstruction of the defect was performed by a trimmed titanium mesh cage with screws purchased into the clivus and C3 body, respectively (4-8). In fact, the area available for the mesh cage implant fixation is limited and can be restricted further when a subclival craniectomy has been performed. Furthermore, in the long run, the trimmed titanium mesh cage would raise the risk of graft related complications (screw extrusion, cage subsidence, dislodged graft, pseudoarthrosis, etc).

Recently, the present authors evaluated the feasibility and optimal trajectory for clival screw fixation (9,10) and designed a novel clivus plate to reconstruct the stability of the CVJ (11). The objective of the present study was to evaluate the CVJ stability of the clivus plate system fixation (CPSF) and compared it with conventional fashioned mesh cage fixation (FMCF).

MATERIALS AND METHODS

Design of the clivus plate

The clivus plate is made of Ti6Al4V (Waston Medical Appliance Co. Ltd, Changzhou, Jianshu, China) and consists of the clivus component, the bilateral flank component, and the vertebrae component (Figure 1). The clivus component was an inverted v-shaped arm, and anatomically fitted to the clival morphology with three 3.5 mm-screw holes. The bilateral flank component was inwardly arc-shaped, for fitting snugly into the atlas with two 3.5 mm-screw holes. The sliding grooves in the vertebrae component allowed two screws connected to a titanium mesh cage. The lower part of the vertebrae component was fixed to the C3 body with two 3.5mm-screw holes. The mean angle between the vertebrae component and clivus component was 130°. A clivus plate system fixation (CPSF) was composed of a clivus plate, a titanium mesh cage and connecting screws on the sliding grooves.

Specimen preparation

Seven specimens (Oc-C4) were obtained from fresh frozen human cadavers. There were 5 male and 2 female cadavers (mean age, 43.3 years; range, 35-50 years). On the basis of careful inspection and radiographic studies, no specimen was found to have evidence of congenital pathologic conditions of the CVJ. Any specimen with osteopenia or osteoporosis was excluded. Specimens were stored at -20°C and thawed overnight at 25°C, before testing. Musculature was dissected while the ligaments, discs and joint capsules were preserved. The C4 vertebrae and partial occiput were potted in dental stone mounts such that the C2-C3 disc space remained horizontal. During testing, specimens were regularly sprayed the saline to prevent dehydration.

Surgical Procedures

After intact testing, the entire anterior arch of the atlas was removed firstly. Soft tissue on the clivus was cleared, and the C2-C3 disc was sectioned. The dens and C2 body were skeletonized bilaterally, as well as C2 pedicles. A neutral head position was kept for the reconstruction of the ventral defect. The posterior occipitocervical

fixation (Peak Summit, Depuy Spine) was applied to each specimen with anchoring at the occiput, C1, C3 and the C4 lateral mass. The diameter and length of the occipital screw was 4.5 mm and 10 mm, respectively. The diameter of the posterior titanium rod was 3.5 mm. The diameter of the lateral mass screw was 3.5 mm with a screw length rang from 18 mm to 26 mm.

For the FMCF placing procedure, a Harms mesh cage (Depuy, Johnson&Johnson) with a diameter of 12 mm and proper length was fashioned in such a manner that the cranial end could be firmly anchored at the clival edge and the caudal end on the C3 body. The overhanging edges of the mesh were left anteriorly to allow for screw purchasing to the clivus and C3 body, respectively. After the intended screw path was measured, four 3.5-mm-diameter cortical screws were inserted (5-8 mm in length for the clival screws, 14-20 mm in length for the C3 vertebral screws). The fabricated mesh cage was applied to the decompressed specimen (Figure 2 and Figure 3A).

For the CPSF implantation procedure, a 12-mm-diameter cage (Depuy, Johnson&Johnson) was placed in such a manner that the cranial end could be stuck at the clival edge and the caudal end on the C3 endplate with a length range from 40 mm to 55 mm. The clivus plate (55-70 mm in length) was attached to the titanium mesh cage and secured to the cage by two screws with 14 mm in length through the sliding grooves. A Kirschner wire (1.0 mm in diameter) was used to drill a hole at the predetermined entry points. The threaded holes were prepared with a 2.5-mm drill bit and followed by a 3.5-mm hand tap. After measuring the screw length (10-14 mm in length for the cranial clival screw, 8-10 mm in length for the two caudal clival screws), clival screws with 3.5-mm in diameter were inserted with the screw trajectory directed 45° in the cranial direction that perpendicular to the extracranial clivus. Screws were inserted into the lateral mass along axis with the screw trajectory directed 10° laterally. Finally, the CPSF was firmly anchored to the C3. The clivus plate system was applied to the decompressed specimen (Figure 3B and Figure 4).

Biomechanical Testing

A custom-designed spine testing machine (12) was used to apply a pure moment to the specimens through an articulating arm that transferred torque from a DC motor while allowing unconstrained motion of the specimen (Figure 5). The upper vertebra (C4) was loaded with a 1.5 Nm continuous pure moments in flexion-extension, right and left axial rotation, and right and left lateral bending at a rate of 1°/s. There was no compressive preload applied on the specimen. It has been shown that this moment magnitude resulted in physiologic ranges of motion without injury to the specimens (13,14). Each specimen was subjected to three cycle loading, and motion at the third cycle was used in the processing.

The motion of upper cervical spine was monitored using two optoelectronic camera systems (Certus; Northern Digital, Waterloo, Ontario). The accuracy of this system in our facility is 0.1°. The two cameras were angled +/- 45° to the posterior view of the specimen to make sure no missing markers during motion, particularly in axial rotation. Marker carriers with four infrared light-emitting diodes (LED) were attached to the occiput, C3 and C4. The range of motion (ROM) and neutral zone (NZ) between the occiput and the C3, C3 and C4 in flexion-extension, left-right lateral bending and left-right axial rotation were calculated, respectively.

Each specimen was tested with following three configurations:

1. Intact: uninstrumented,
2. Conventional construct: destabilized with FMCF and posterior occipitocervical fixation, and
3. Clivus construct: destabilized with CPSF and posterior occipitocervical fixation.

The destabilized specimen following the resection of the upper cervical spine, including resection of the C1 anterior arch, C2 vertebral body, C2-C3 disc and atlantoaxial ligaments, to simulate a defect of the upper cervical spine. Overt instability was evident after these destabilizing procedures so that they could not be tested without risking further tearing of soft tissues. The test sequence was randomized under the same injury condition in order to minimize any deterioration of the specimens. Each specimen was tested within a day.

Statistical Analysis

The measured values of left lateral bending/axial rotation were similar to those of right lateral bending/axial rotation, thus a mean of left and right for each specimen was analyzed. The ROMs and NZs were compared among the intact, “conventional” construct and novel “clivus” constructs in all directions using the Wilcoxon signed rank test. All data are reported as mean $\pm$ standard deviation with significant level at $P<0.05$.

RESULTS

The plate and mesh cage were successfully applied to specimens. No obvious loosening or mismatch was observed. ROMs and NZs of Oc -C3 segments in the two constructs was showing in Figures 6 and Figure 7, respectively.

ROMs of the intact Oc-C3 complex were $22.5^{\circ}\pm 5.1^{\circ}$, $19.5^{\circ}\pm 10.4^{\circ}$, $10.5^{\circ}\pm 4.6^{\circ}$, $47.3^{\circ}\pm 11.3^{\circ}$ in flexion, extension, lateral bending (one side) and axial rotation (one side), respectively (Table 1). Compared with the intact, both implanted constructs resulted in significantly decrease of ROM in all directions ($P<0.05$). The conventional construct reduced ROMs to 0.3° in flexion, 0.4° in extension, 0.6° in lateral bending and 1.2° in axial rotation. Thus, the clivus constructs constrained motion to 0.1° , 0.2° , 0.3° and 0.6° in flexion, extension, lateral bending and axial rotation, respectively. The clivus constructs decreased motion significantly in flexion, lateral bending and axial rotation compared with the conventional construct ($P<0.05$). However, there was no significantly difference in extension between the two implanted status ($P>0.05$). NZs of the intact Oc-C3 complex were $7.7^{\circ}\pm 6.8^{\circ}$, $4.0^{\circ}\pm 3.1^{\circ}$, $34.4^{\circ}\pm 11.8^{\circ}$ in flexion-extension, lateral bending and axial rotation, respectively. NZs were reduced to 0.2° in flexion-extension, 0.2° in lateral bending and 0.3° in axial rotation following the conventional construct, while less than

0°~0.1° in all directions following the clivus construct. There was no significant difference in NZs between the two implanted status ($P>0.05$).

Compared with the ROMs of the intact C3-C4 complex, both the two instrumentation resulted in significantly decrease of ROM in all directions ($P<0.05$). There was no significant difference in ROMs between the two implanted status (Table 1). NZs of the intact C3-C4 complex were similar to the change of the ROMs.

DISCUSSION

Primary or metastatic tumor was the most common lesion in spinal axis (15) and required wide resection even involving the whole vertebra to prevent the local recurrence (16-19). In addition to the ventral resection of the lesions, another unique aspect of this case was the reconstruction and stabilization of the upper cervical spine. Conventionally, the entire body of C-2 was removed, such that the only bone structures available for fixation at the upper end of the construct were the anterior arch of C-1 and a remnant of the dens. However, a mesh cage or plate secured to the C-1 anterior arch, or to its remnant anteriorly can not provide adequate biomechanical support of the construct (8,20). Furthermore, these techniques are depending on nondestructive C-1 anterior arch and not applicable in case of large bone defects due to the atlantoaxial neoplasm. Thus, it is believe that direct fixation to the clivus may be a more practical and robust alternative to previously described techniques (5,8,16,21,22). Subsequently, reconstructed the anterior defect was commonly performed by securing a Harms mesh cage with screws purchased to the clivus and C3 body (4).

However, the area available for the mesh cage fixation is limited and can be restricted further when a subclival craniectomy has been performed. Furthermore, the mesh cage, fashioned to form a combined intervertebral spacer and integrated plate, will seriously affect by the complication of cage subsidence and result in loosening of screw, migration and even breakage of the mesh cage in the long term (23). Therefore,

the present authors evaluated the feasibility and optimal trajectory for clival screw fixation (9,10) and designed a novel clivus plate to reconstruct the stability of the CVJ (11).

In the present study, we performed biomechanical experiments to compare the stability of the two constructs. As we expected, both instrumentations reduced the motion significantly in all directions. The current study also revealed that clivus plate system fixation is biomechanically prior to conventional fashioned mesh cage fixation in flexion, lateral bending, and axial rotation. However, due to the posterior occipitocervical fixation construct may play the mainly roles in constrain the motion of extension, thus there was no statistical difference between the two constructs in ROM of the extension. A trend toward decreased ROM and NZ were noted, as seen in Table 1. It is unclear whether the decreased ROM and NZ will result in a clinically significant enhancement in fusion rate for the CVJ.

There are several biomechanical principles, which suggest that the implanted clivus construct should provide superior stability at the CVJ. Firstly, the CPSF consist of a clivus plate and a titanium mesh cage, which function as the fixation plate and intervertebral spacer, respectively. In the subaxial cervical spine, it is believe that the addition of anterior cervical plate fixation after interbody reconstruction enhances the rigidity and stability of the construct and, therefore, lowers the risk of graft-related complications and endplate fracture, leading to improved fusion rates (3,16). Secondly, more number of clival screws and longer screw length in clivus construct would naturally improve the pull out strength and also provide better tolerance to the higher screw loads. On the extracranial clivus (Figure 8), the clival screw holes left by the instrumented device indicated that the location of h3 for FMCF was caudal to the location of h1 and h2 for CPSF. The mean length of screw path for h1, h2 and h3 was 12.8 mm, 9.6 mm and 7.6 mm, respectively. For the FMCF, longer the overhanging edges of the fashioned mesh cranially would have a longer clival screw length, but which would resulted in longer the force arm and be prone to mesh fatigue and broken. Thirdly, mismatching between the clival screws and the mesh holes would result in the actual screw length and entry angle inconsistent with the preoperative

measurements and may decrease its mechanical stability and even lead to intracranial hemorrhage near the pons and ventral medulla oblongata, which could be fatal.

Another biomechanical advantage of the clivus plate system fixation is the avoidance of the mesh cage bending. The sharp angle of the CVJ could weaken fashioned mesh cage fixation if the mesh cage is not bent over a long segment with a gentle curve because titanium alloy is known to be notch-sensitive under repetitive fatigue loading. The clivus construct also result in a clinical advantage because the time spent on fitting and bending mesh cage is not required.

Dissection and appropriate exposure of the CVJ can be challenging. Successfully exposing and preparing the clivus for instrumentation require a comprehensive knowledge of the microsurgical anatomy of the CVJ. According to the our previous study (9,10), the mean diameter of the clival length was 26 mm, and the mean widest and narrowest diameter of the clivus was 33 mm and 13 mm, allowing purchase of three screws (3.5mm in diameter) in two rows on the clivus. In order to avoid clival screw inserted into the sphenoid sinus or the pituitary fossa, screw entry points were located at the middle and lower part of the clivus and the mean putative screw length was 9 mm based on measurement on CT images. Therefore, it is recommended that a close study of the thin-cut CT images of the clivus and surrounding structures to plan clival screw placement in clinic.

Several anterior approaches have been proposed for the CVJ, such as the transoral approach (24), the transoral-transpalatopharyngeal approach, transmandibular (25), and high anterior cervical retropharyngeal approach (26). The transoral-transpalatopharyngeal approach is the most frequently used for accessing the lower clivus, atlas, and axis. Subsequently, implantation of the present clivus plate required the transoral-transpalatopharyngeal approach with palatal or mandibular splitting procedures for additional rostral and caudal exposure (27-29). Suchomel *et al* (4) performed a combined transoral approach and created a small right-sided submandibular channel through the floor of the mouth for a straight angle to clival screws and a mesh cage placement. Rawlins *et al* (6) gain access to the anterior upper cervical spine and expose clivus through mandibular osteotomy and soft palate split to

achieve a plate fixation. And now the endoscopic approach to the clivus has become a well-established and alternative to traditional approaches. Larger exposure can be achieved with angled endoscopes (30). However, all approaches to the clivus and upper cervical spine is at risk of highly rate of complications, such as bleeding, infection, dysphagia, plate dehiscence, CSF leakage and meningitis (31,32). The feasibility and applied anatomical study of the surgical approaches for the clivus plate system fixation would be addressed detailedly in our future study.

The study design deployed repeated measurements in the same specimen to reduce variation among specimens. At the same time, the limitations of this study must be acknowledged. First, due to the limited source of specimen, the screws were re-inserted in the C3 vertebrae, and could compromise the mechanical evaluation with the three-column injury. Secondly, the in vitro biomechanical test only represented immediate postoperative effect. Fatigue test was needed to evaluate cyclic loading effect on loosening of the clivus plate system fixation. In future experiments, we intend to design clivus plate integrated with locking head screws and a specially designed titanium mesh cage matched the sliding screws by the viewpoint of improving stabilization capacity of the clivus plate system fixation for clinical application. Finally, it is unclear whether the biomechanical difference can be interpreted as a meaningful clinical difference.

CONCLUSION

In this study, we demonstrate that clivus plate system fixation is biomechanically prior to the conventional fashioned mesh cage fixation techniques with regard to the modes tested (ROM and NZ). Although, technically challenging, this technique may be an alternative to current craniovertebral fixation techniques.

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Figure legend

Figure 1. The component of the clivus plate. The clivus component (A), bilateral flank component (B), sliding grooves (C), and vertebrae component (D) are indicated.

Figure 2. Artist's illustrations showing conventional construct state. **A**, the front view; **B**, the lateral view. The anterior fabricated mesh cage placed between the clivus and C-3 endplate. The procedure was completed using occipitocervical fixation and fusion extending down to C-4 lateral mass.

Figure 3. The cadaveric specimen implanted with the conventional construct state (**A**), clivus construct state (**B**) following ventral defect at the craniovertebral junction.

Figure 4. Artist's illustrations showing clivus construct state. **A**, the front view; **B**, the lateral view. The mesh cage was fixed together with the clivus plate by two screws in the sliding grooves. The C-1 lateral mass were supported by the anterior clivus plate and the posterior C-1 lateral mass screws. The procedure was completed using occipitocervical fixation and

fusion extending down to C-4 lateral mass.

Figure 5. A photograph showing the full test setup with the counter weights.

Figure 6. Bar graph demonstrating the ROM of the Oc-C3 segment in all directions. Conventional construct indicate fashioned mesh cage and posterior occipitocervical fixation; Clivus construct indicate clivus plate system fixation and posterior occipitocervical fixation. *indicates statistical difference from clivus construct state ($P < .05$). Error bars represent SD

Figure 7. Bar graph demonstrating the NZ of the Oc-C3 segment in all directions. Conventional construct indicate fashioned mesh cage and posterior occipitocervical fixation; Clivus construct indicate clivus plate system fixation and posterior occipitocervical fixation. Error bars represent SD

Figure 8. The clival screw holes left by the instrumented devices. **h1,h2**, screw holes for CPSF placement; **h3**, screw holes for FMCF implantation.

Table 1. ROMs between the C0-C3 and C3-C4.

	Intact	Conventional construct	Clivus constructs
C0-C3			
Flexion	22.5(5.1)	0.3(0.1) *	0.1(0.1) *†
Extension	19.5(10.4)	0.4(0.2) *	0.2(0.1) *
Lateral bending	10.5(4.6)	0.6(0.2) *	0.3(0.1) *†
Axial rotation	47.3(11.3)	1.2(0.5) *	0.6(0.2) *†
C3-C4			
Flexion	6.6(4.7)	0.6(0.4) *	0.6(0.4) *
Extension	4.4(3.3)	0.5(0.4) *	0.6(0.3) *
Lateral bending	2.1(1.1)	0.3(0.2) *	0.3(0.1) *
Axial rotation	5.3(3.9)	0.5(0.3) *	0.5(0.1) *

Data are presented as mean and stand deviation. * indicates difference from the intact ($P < 0.05$), and † difference from the conventional construct ($P < 0.05$). Conventional construct indicate fashioned mesh cage and posterior occipitocervical fixation; Clivus construct indicate clivus plate system fixation and posterior occipitocervical fixation; ROM =Range of motion.