Comparison of revision strategies for failed C2-posterior cervical pedicle screws: a biomechanical study

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Abstract

Study purpose With increasing usage within challenging biomechanical constructs, failures of C2 posterior cervical pedicle screws (C2-pCPSs) will occur. The purpose of the study was therefore to investigate the biomechanical characteristics of two revision techniques after the failure of C2-pCPSs.

Materials and methods Twelve human C2 vertebrae were tested in vitro in a biomechanical study to compare two strategies for revision screws after failure of C2-pCPSs. C2 pedicles were instrumented using unicortical 3.5-mm CPS bilaterally (Synapse/Synthes, Switzerland). Insertion

accuracy was verified by fluoroscopy. C2 vertebrae were potted and fixed in an electromechanical testing machine with the screw axis coaxial to the pullout direction. Pullout testing was conducted with load and displacement data taken continuously. The peak load to failure was measured in newtons (N) and is reported as the pullout resistance (POR). After pullout, two revision strategies were tested in each vertebra. In Group-1, revision was performed with 4.0-mm C2-pCPSs. In Group-2, revision was performed with C2-pedicle bone-plastic combined with the use of a 4-mm C2-pCPSs. For the statistical analysis, the POR between screws was compared using absolute values (*N*) and the POR of the revision techniques normalized to that of the primary procedures (%).

Results The POR of primary 3.5-mm CPSs was $1,140.5 \pm 539.6$ N for Group-1 and $1,007.7 \pm 362.5$ N for Group-2; the difference was not significant. In the revision setting, the POR in Group-1 was 705.8 ± 449.1 N, representing a reduction of 38.1 ± 32.9 % compared with that of primary screw fixation. For Group-2, the POR was 875.3 ± 367.9 N, representing a reduction of 13.1 ± 23.4 %. A statistical analysis showed a significantly higher POR for Group-2 compared with Group-1 ($p = 0.02$). Although the statistics showed a significantly reduced POR for both revision strategies compared with primary fixation ($p < 0.001$ / $p = 0.001$), the loss of POR (in %) in Group-1 was significantly higher compared with the loss in Group-2 ($p = 0.04$).

Conclusions Using a larger-diameter screw combined with the application of a pedicle bone-plastic, the POR can be significantly increased compared with the use of only an increased screw diameter.

Keywords Cervical pedicle screw · Failure · Revision strategy · Biomechanics · Pedicle bone-plastic

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Introduction

Posterior cervical spine screw-rod instrumentation using posterior cervical pedicle screws (pCPSs) has become a mainstay in occipitocervical and cervicothoracic instrumentation ending at C2. Since Abumi et al. [1, 2] introduced the concept of the pCPS, experience with its use has increased [25, 37]. Its accuracy and feasibility were analyzed in several studies using free-hand techniques, navigation+ and distinct radiographic techniques [12, 22, 38]. Cervical pedicle screw fixation is technically demanding and requires thorough knowledge of cervical anatomy as well as proficient instrumentation skills [17]. A significant variation in pedicle morphometry increases the risk of injury to nearby neurovascular structures [18, 34, 36]. Nevertheless, in high-grade instabilities, pCPSs have become the ideal method of fixation, particularly at C2 and C7, because of the superior biomechanical anchorage characteristics of pCPS compared with anterior-only, common posterior lateral mass or intralaminar constructs [16, 21, 31, 33]. The biomechanical findings are echoed by clinical surveys reporting a higher incidence of screw loosening and loss of reduction with lateral mass screws compared with those using pedicle screws in patients with poor bone quality, severe cervical spinal injury or multilevel instability [3, 6, 37].

Because of increased usage of pCPSs within biomechanically challenging constructs, failures are observed and revision strategies are required. Recent studies on failure of CPS reported of a clinical failure rate ranging from 2.8 to 14.3 % [10, 26]. Multiple attempts at pedicle cannulation, failure upon screw insertion or in-line screw pullout by reduction-manuevers of the rod might lead to the failure of fixation, requiring a salvage procedure for the segment. A previous study on salvage procedures for pCPSs showed significant lower pullout resistance (POR) for intralaminar screws and pars screws, with a 2.5-fold reduced peak load to failure compared with the initial pCPS construct [24]. Other biomechanical studies have identified the cortical purchase of a cervical pedicle screw to determine screw strength and pullout forces [16], providing greater stability than the cancellous purchase in the vertebral body or lateral mass [21]. Hence, in the current biomechanical study, we evaluated two intrapedicular salvage techniques for failed pCPSs in a C2 model. Both demonstrated the advantage of transpedicular anchorage.

Materials and methods

Biomechanical laboratory study

Specimen preparation

Twelve fresh-frozen human cervical spine specimens (C0–C7) from 6 female and 6 male donors were acquired.

The mean age of the donor specimens at death was 71.5 ± 1.2 years (range 70–74 years). They were subjected to pretesting multislice computerized tomography scanning (Somatom Volume Zoom, Siemens, Erlangen/Germany) to rule out any structural cervical pathology and to determine the morphometry of the C2 vertebrae and pedicles intended for screw insertion. Sagittal reconstructions were performed using standard spine algorithms, and files were stored digitally (PACS Magic View VC 42, Siemens, Erlangen/Germany). None of the specimens showed evidence of infectious, neoplastic or traumatic disease or of congenital spinal deformations. Measurement of all pedicles supported the safe insertion of 3.5-mm and 4.0-mm pedicle screws. Bone mass density (BMD) was assessed by quantitative CT scans and averaged 211.2 ± 41.3 mg Ca-HA/ml (range 172–320 mg Ca-HA/ml).

All C2 vertebrae were harvested, cleared from all soft tissues, inspected for signs of external damage and then potted in polymethylmethacrylate (PMMA, Technovit 3040, Heraeus Kulzer GmbH, Wehrheim/Germany), which provides a firm grip. The vertebral end-plates were oriented perpendicular to the level of the fixation pot, sparing both pedicles and the spinous process. One wood screw was placed in the midsagittal axis through the vertebral body to increase holding strength. During the preparation process, the specimens and vertebrae, respectively, were stored in triple-sealed plastic bags at -20°C . Before testing, the specimens were thawed for 24 h to room temperature. To prevent desiccation during preparation, specimens were kept moist with saline solution. Handling specimens in the described manner does not affect their biomechanical properties [35].

Pedicle screw insertion and pullout testing

Pedicle screw insertion was done after potting the vertebrae and immediately prior to pullout testing by one of the authors using a free-hand technique. Self-tapping pCPSs 3.5 mm in diameter (Synapse, Synthes, Switzerland) were placed unicortically in a pairwise fashion with a working length of 24 mm. The working length was defined as the length of threads engaging bone and measured using a caliper. After screw insertion, biplanar radiographs were performed using an image intensifier (Siremobil Compact L, Siemens, Erlangen/Germany) to control for pedicle screw accuracy and unicortical placement. Then, the potted specimens were fixed in the center of the cross table of an electromechanical testing machine (Z010, Zwick Roell, Ulm/Germany). The pot was placed in such a manner that the pedicle screw axis was coaxial with the pullout direction on a multiangle vice affixed to a horizontal x–y translational cross table. This method of coaxial pullout strength testing was used to simulate the intraoperative and postoperative loosening of screws (e.g., after multiple

attempts of placing a pedicle screw or screw loosening by attachment of a screw to the rod).

Pedicle screws were connected to the testing machine with a special jig attached to a 5.0-mm diameter rod inserted into the screw heads and an axial preload of 20 N was applied. Pullout loading was conducted at a rate of 2 mm/min collinear to the longitudinal axis of the screws (Fig. 1). In each test, the load–displacement curve was recorded using a computerized data collection system (TestXpert V11.02, Zwick Roell, Ulm/Germany). Load and displacement data were taken continuously until the screw had been visibly removed from the vertebral body (usually approximately 10 mm). The peak load to failure was measured in newtons (N) and defined as the maximum pullout resistance (POR) of the technique tested. Furthermore work to failure (Nm) and displacement at POR (mm) was assessed from load and displacement data gained.

Revision strategies

In this biomechanical study, two salvage procedures were tested. Both techniques were tested in each vertebra, which thus served as its own internal control, reducing variability

due to bone quality. After primary bilateral pullout loading with the 3.5-mm pCPS, insertion of a 4.0-mm diameter pCPS (Synapse, Synthes, Switzerland) served as the first revision technique (Group-1). On the contralateral side, prior to insertion of a 4.0-mm diameter pCPS (Synapse, Synthes, Switzerland), a pedicle was created from bone-plastic with corticocancellous bone (Group-2). Autologous corticocancellous bone was obtained from the spinous process of each vertebra until the volume was estimated to be approximately 1 ml, and it was then mashed using a rongeur (Fig. 2). The mashed bone-sticks were placed in the C2 pedicles through the primary screw channel using a small tweezer and impactor. This procedure was followed by insertion of a standard 4.0-mm diameter pCPS (Synapse, Synthes, Switzerland). After revision screw placement, pullout testing was conducted in the previously described manner for both techniques.

Group-1 and Group-2 screws were alternately placed on the left and right pedicles. Each step was documented using biplanar radiographs to ensure the intrapedicular position of the primary pCPS and the revision pCPS. After the completion of pullout testing, vertebrae were cut along the pedicle axis to analyze the pedicle screw tract and osseous confinements after the use of pedicle bone-plastic (Fig. 3).

Statistics

For the statistical analysis, the POR between screws was compared using the absolute values (in newtons) and the POR of the revision techniques normalized to that of the primary procedure (%). Paired and unpaired Student *t*-tests were applied to test for significant differences among means. Correlation analysis using Pearson's correlation coefficient with corresponding tests was used to find significant relations among variables. A *p* value less than 5 % indicated a significant result. All analyses were performed with Statistica 6.1 (StatSoft, USA).

Fig. 1 The testing setup consisted of the potted instrumented C2 vertebra fixed to the electronic testing machine. Through manipulation with flexible cross table pull-out direction could be adjusted collinear to the *longitudinal axis* of the pedicle screw

Fig. 2 In Group 2, corticocancellous bone harvested from the spinous process was mashed with a rongeur and filled in the pedicle pathway after primary pull-out testing prior to revision screw placement

Fig. 3 All vertebrae were sawed along both pedicle axes to confirm the bony integrity of pedicles and rule out malposition of the pedicle screws after completed testing procedure

Results

Fluoroscopic control after primary screw insertion revealed a pedicle breach in two dysplastic and sclerotic pedicles, which were therefore excluded from analysis. Hence, 10 C2 vertebrae were eligible for pullout testing.

Pullout testing of the primary 3.5-mm pCPS showed a POR of $1,140.5 \pm 539.6$ N (range 137.3–1,990.9 N) in Group-1 and a POR of $1,007.7 \pm 362.5$ N (range 485.9–1,447 N) for Group-2, with the difference not reaching statistical significance ($p > 0.05$). Mean work to failure in the primary pull-out testing was 1.0 ± 0.7 Nm (range 0.4–1.4 Nm) in Group 1 and 1.0 ± 0.5 Nm (range 0.1–1.8 Nm) in Group 2 while measured displacement at POR averaged 1.8 ± 0.5 mm (range 0.9–2.4 mm) in Group 1 compared with 1.6 ± 0.4 mm (range 0.8–2.5 mm) in Group 2. Differences for both results did not yield the level of significance.

After placement of a 4.0-mm diameter revision pCPS in Group-1 as a salvage technique, the POR was 705.8 ± 449.8 N (range 209.9–1,785 N). Thus, the POR was 38.1 ± 32.9 % (range –55.5 to 52.9 %) lower compared with primary pCPS fixation. In Group-2, revision with a combination of larger diameter pCPSs with application of

the C2 pedicle bone-plastic revealed a POR strength of 875.3 ± 367.9 N (range 407.7–1,409.5 N). This represented a 13.1 ± 23.4 % reduction (range –51.24 to 10.57 %) compared with the primary screw technique ($p = 0.04$). Work to failure in the tested revision set-up for Group 1 was 0.5 ± 0.2 Nm (range 0.2–1.7 Nm) and 0.9 ± 0.5 Nm (range 0.3–1.7 Nm) in Group 2. Although not reaching statistical significance, there was a strong trend ($p = 0.08$) for the better result of the revision technique applied in Group 2, but both results were not significantly different to primary pull-out testing. Displacement at POR averaged 1.4 ± 0.5 mm (range 0.6–2.6 mm) in Group 1 compared with 1.6 ± 0.3 mm (range 1.1–2.0 mm) of Group 2, the differences between primary- and secondary pull-out testing for both groups and between the revision-techniques not being significant. The load displacement curve for pullout testing in a representative C2 vertebra is illustrated in Fig. 4.

Statistical comparison of the POR of the revision technique used in Group-1 and Group-2 revealed the significant superiority of Group-2 ($p = 0.02$) with a mean difference of 169.5 N. Although the statistical analysis showed a significantly lower POR for both revision strategies compared with the primary testing ($p < 0.001$ for Group-1; $p = 0.001$ for Group-2), the percentage loss of POR in Group-2 was significantly less compared with Group-1 ($p = 0.04$). The reduction of pullout resistance compared with primary fixation was threefold higher in Group-1 than in Group-2. Donors' BMD or age did not have a statistically significant impact on the POR in the primary and the revision procedures ($p > 0.05$).

The main results and characteristics of the study are summarized in Table 1 and Fig. 5.

Fig. 4 Representative load–displacement curve. Pedicle bone plastic–augmentation for Group 2 (4 mm CPS L Plastic) lead to a significantly lower loss of POR in Group 2 (–29.8 %) compared with –55.5 % in Revision of Group 1

Table 1 Summary of study characteristics and main results comparing two revision strategies for failed C2-pCPS

Fixation technique	Specimen characteristics	Level Tested	No. of pCPS per group	Donor Age	BMD (mg Ca-HA/ml)	Analysis	POR Mean $\pm$ SD Range	Decrease of POR Prim. vs. Revision
Group-1 Primary pCPS 3.5 mm	Fresh Frozen	C2	10	71.5 $\pm$ 1.2 years	211.2 $\pm$ 41.3	Internal control	1,140.5 $\pm$ 539.6 N 137.3–1,723.4 N	24.4 $\pm$ 30.1 % range –55.53 to +52.88 %
Revision pCPS 4.0 mm								
Group-2 Primary pCPS 3.5 mm	Fresh Frozen	C2	10	71.5 $\pm$ 1.2 years	211.2 $\pm$ 41.3	Internal control	705.8 $\pm$ 492.1 N 209.9–1,785 N 1,007.7 $\pm$ 362.5 N 485.9–1,447 N	11.2 $\pm$ 23.4 % range –51.24 to +10.57 %
Revision pCPS 4.0 mm w/ pedicle bone-plastic

Fig. 5 Mean pullout resistance after revision was 169.5 N higher for the augmented revision of Group-2 compared with the revision of Group-1. The decrease in POR was threefold higher in Group-1 compared with Group-2. Both results being significant ($p = 0.02$ and $p = 0.04$)

Discussion

To date, studies on revision strategies for failed pCPSs have only focused on extrapedicular salvage procedures with biomechanical assessment of lateral mass and intralaminar screws [5, 24]. In light of the biomechanical superiority of pCPS constructs and their favorable surgical feasibility as an endpoint anchor in occipitocervical and cervicothoracic instrumentations, the intention in our current study was retrieval of a viable transpedicular salvage strategy. Notably, Lehmann et al.'s [24] study revealed a reduced peak load to failure of 61 % for C2 pars and 36.5 % for C2 intralaminar screws compared with the initial pCPS constructs. The mean POR for pCPS as primary fixation was 497 ± 239 N, and mean POR for intralaminar screws was 312 ± 168 N when used as a salvage procedure. Cardoso et al. [5] reported that the pullout resistance and the insertional torque of intralaminar screws as a salvage technique compared with that of C7 pCPSs were reported to be lower. Although the POR reported by Cardoso et al. [5], for intralaminar screws as a salvage technique was not significantly decreased compared with the POR of the primary pCPS, the primary pullout resistance averaging 779 N was lower than in the present study for both groups. The results of the current study concur with these previous findings and suggest the clinical benefit of using a pedicle bone-plastic combined with an increased CPS diameter. In the current study, the mean POR in the revision setting was 705.8 N in group-1 and 875.3 N in group-2. Previously reported POR for lateral mass screws as a primary fixation technique was consistently drastically lower than in the current revision technique setting, ranging from 216 to 565 N [15, 16]. Therefore, a biomechanical advantage of lateral mass screws as a salvage strategy for failed pCPSs is not expectable.

The findings presented in the current study outline the value of a transpedicular revision approach with an

increased screw diameter combined with a pedicle bone-plastic. Although the pullout strength was reduced by 13.1 % in the current study compared with primary screw fixation, the decline was less than that in other techniques previously described for cervical spine constructs. Several biomechanical and clinical studies demonstrated superior stabilization capabilities regarding the limitation of motion through posterior or anterior constructs using cervical pedicle screws compared with those using intralaminar or lateral mass screws [7, 13, 23, 30, 32, 33]. In addition, the insertional torque and pullout strength were proven to be higher with pCPSs than with lateral mass screw insertion [13]. It is the cortical purchase of pedicle screws that determines the increased POR of pCPS compared with the cancellous purchase of screws in the vertebral body or lateral mass [11]. This fact results in the pullout resistance correlating with the engagement of the screw in the cortical bone of the pedicle canal [16].

Also fusion rates in subaxial cervical instrumentations performed with C2 CPS have shown to be significantly higher than with those using C2 translaminar screws [27]. Aside from these biomechanical attributes, surgical considerations have to be taken into account when a decision regarding instrumentation selection at the end-level is indicated: C2 intralaminar screws can be difficult to connect to longer constructs; the heads of the C2 intralaminar screws cover a significant amount of space directly at the fusion area of the C2 posterior elements. The failure mechanism of a C2 intralaminar screw under sagittal plane loading, with the potential for windshield-wiper-type screw movement into the spinal canal to occur during failure, has yet to be studied. Accordingly, from a clinical perspective, pCPSs at C2 should be preferred if feasible in the setting of failed posterior cervical constructs that did not have pedicle anchorages incorporated because insertion of pCPSs has been proven to be a sound revision technique. Hostin et al. [14] reported a significantly higher insertional peak and pullout strength for pCPSs (POR 566 N) as a salvage technique for failed primary lateral mass screws (POR 382 N) and compared this technique with a primary revision strategy using lateral mass screws (POR 351 N). In yet another biomechanical study, Lehmann et al. [24] showed that for a failed C2 pars screw revision technique, the use of C2 pedicle screws yielded higher insertional torque as well as POR compared with the use of C2 intralaminar screws. Biomechanically, all these attributes make transpedicular screw fixation at C2 an optimal fixation method, especially in the setting of pronounced instability.

A similar biomechanical effect as observed in the current study was also described by Hashemi et al. [8] who found a significantly smaller decrease in pullout resistance after the augmentation of failed pedicle screws with

granular calcium-phosphate particles in thoracolumbar vertebrae.

Several studies have reported on the increased biomechanical properties of pedicle screw revision strategies that use an increased-diameter screw in the thoracolumbar spine compared with other techniques [20, 29]. Although Pfeifer et al. [28] found the pullout resistance of revision pedicle screws after augmentation with milled bone inferior compared with the use of polymethylmethacrylate, the material might still serve as an alternative or complementary technique when the use of cement augmented screws is not appropriate or is contraindicated.

Irrespective of all of the favorable properties of pCPSs, investigators have called attention to the liberal use of pCPSs because of the possibility of iatrogenic neurovascular injuries [19]. Although placement of pCPSs poses a potential risk to nearby neurovascular structures, standards are established, and several studies have demonstrated a significantly decreased risk for complications through the implementation of navigation tools and surgical training, which increases accuracy [4, 21, 22]. Regarding safety concerns, the results of using pCPSs, particularly at C2, have been favorably compared with the results obtained through the use of lateral mass screws [6, 9].

Described salvage procedure only requires a small amount of bone material of approximately 1 ml which in practice can be obtained from the spinous process of C2 which does not confer clinical sequelae. This amount of bone is rather insignificant compared with autologous bone grafts required for posterior fusion which is indicated in almost all cases of revision surgery.

Especially in the setting of a revision surgery, a preoperative CT-scan is mandatory to confirm the integrity of bony pedicle confinements close to the spinal canal, transverse foramen and neuroforamen prior to revision surgery because significant pedicle breaches will preclude safe performance of the pedicle bone-plastic technique described. The current results suggest that the revision technique presented in this study might not only be a valuable tool in cases of failed pCPSs at C2 but also in cases of pedicle screw loosening in the subaxial cervical spine.

Limitations

The assessment of uniaxial pullout resistance is only one characteristic of a pedicle screw that can be tested and gives only an impression of the fixation strength between the vertebral bone and the screw surface. Cyclic fatigue loading forces that are usually applied during the mobilization of patients as well as cantilever loads were not tested. However, the pullout resistance data allow easy

comparison with other techniques and previous studies on salvage procedures of failed pCPS [5, 24].

Conclusion

With increasing use of C2 CPS as an end-point anchor in biomechanically challenging constructs, the loss of fixation must be addressed. This study is the first to address intrapedicular revision techniques for cervical pedicle screw fixations, and it therefore provides new knowledge. The results suggest better pullout resistance (POR) for increased screw diameters combined with pedicle bone-plastic compared with increased screw diameter alone although both techniques failed to attain the anchorage characteristics of primary screw fixation.

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Conflict of interest None.

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