

Personalized Rapid Prototyping Template for Direct C1 Pedicle Screw Fixation of Unstable C1 Semi-Ring Fractures

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Abstract

Background: Placement of C1 pedicle screws carries an inherent risk of injury to the spinal cord and vertebral artery. Use of a personalized rapid prototyping template may be able to improve the safety of C1 pedicle fixation. To evaluate the clinical and radiographic outcomes of direct posterior C1 pedicle screw fixation using a personalized rapid prototyping template for unstable C1 semi-ring fractures.

Methods: From May of 2010 to September of 2015, 38 patients with unstable C1 semi-ring fractures were treated with direct posterior C1 pedicle screw fixation. A standard open technique was utilized in 20 patients (Free-hand group) and 18 patients underwent C1 pedicle screw fixation with the aid of a personalized rapid prototyping template (RP group). The operative time, intraoperative blood loss, preoperative ADI, LMD and VAS were recorded. The postoperative ADI, LMD and VAS score were recorded at 180 days postoperatively.

Results: No spinal cord or vertebral artery injuries were encountered in either group. Similarly, no post-operative instrumentation failures or cases of postoperative C1-2 instability were reported in either group. There was no statistically significant difference in intraoperative blood loss and operative time between RP and Free-hand group. In both groups, all patients obtained radiographic fusion at 6 months, reported no residual neck pain and were found to have a full range of motion at final follow up.

Conclusion: Use of a personalized rapid prototyping template for the placement of direct posterior C1 pedicle screws is safe and effective in the treatment of unstable C1 semi-ring fractures with similar radiographic and clinical outcomes to more traditional techniques.

Background

The atlas is an integral and crucial part of the craniocervical junction as a transitional structure between the occiput and cervical spine. Its unique ring shape, ligamentous attachments and articulations provide stability while allowing for an exceptional range of motion [1]. The atlas has two lateral masses with concavities that match the condyles of the occiput and the dens of the axis, forming the occipito-atlanto-axis complex. The occipito-atlanto-axis complex provides approximately 50% of its lateral rotation and flexion-extension of the entire cervical spine [2]. In order to preserve the mobility of occipito-atlanto-axis articulation, direct posterior C1 pedicle screw fixation of unstable fractures of the atlas has been reported. The personalized rapid prototyping template can quickly identify the ideal entry point and optimal trajectory for posterior C1 pedicle screw placement, theoretically minimizing the risk of injury to the vertebral artery, spinal cord or internal carotid artery. However, the safety and efficacy of this technique for treatment of unstable atlas fractures has not been reported. We therefore present in this report a retrospective analysis of 38 cases as the first case series to evaluate the personalized rapid prototyping template for direct posterior C1 pedicle screw fixation of unstable C1 semi-ring fractures.

Methods

Clinical Data

Our study was a retrospective analysis of 38 consecutively treated patients with unstable C1 burst (Jefferson) fractures from May of 2010 to September of 2015. There were 10 males and 8 females with the average age of 51.3 years (range, 23-63 y) in the Rapid Prototyping Template (RP) group and 13 males and 7 females with the average age of 53.5 years (range, 29-69 y) in free-hand (FH) group. All included patients underwent radiological evaluation preoperatively with plain cervical spine radiographs, computed tomography (CT), and magnetic resonance imaging (MRI). The mechanism of injury for the patients in this study were: motor vehicle accident in 15 cases and fall from height in 23 cases. All patients presented with neck pain, stiffness, and decreased range of motion without neurological injury. Radiographic studies confirmed that all included cases had unilateral anterior and posterior arch fracture (Semi-ring fracture, Landells type II), and all the patients had fractures and avulsion at the attachment site of transverse ligament (Dickman type II). The preoperative ADI, LMD and VAS were recorded. Our study was approved by the Regional Ethics committee of Ningbo No.6 Hospital.

Preoperative care

Initial stability and alignment was obtained with 2-3kg of inline traction for all cases. Similarly, all patients received routine perioperative antibiotics (cefuroxime 1.5 g) and were positioned in slight hyperextension with a Mayfield head positioner. After exposure, patients were randomly selected to have their C1 pedicle screws placed either free-hand (FH group) or with the help of a personalized rapid prototyping template (RP group). The three-dimension models of atlas were reconstructed by Mimics software and the ideal trajectory for C1 pedicle screws was planned to minimize risk based upon the individuals corresponding anatomical structure (**Figure 1**). Then drill guide template was materialized in a rapid prototyping machine and sterilized by low-temperature plasma.

Surgical Technique

After induction of general endotracheal anesthesia, patients were positioned prone in a Mayfield head holder as detailed above. An experienced spinal surgeon performed all cases in both groups. A midline skin incision 4-6 cm in length was made beneath the external occipital protuberance. Fascia and ligaments were dissected along the midline to reveal the posterior arch of C1; subsequently, the junction of the lower edge of C1 posterior arch and lateral mass were exposed. During the operation, the C1-C2 venous plexus was protected as much as possible. For patients in the RP cohort, the personalized rapid prototyping template was placed onto the posterior arch using the lock-and-key principle. After the pedicle screw tracts were drilled, the corridors were marked with a blunt k-wire to allow removal of the template. The paths were then tapped and pedicle screws were placed (**Figure 2**). Intraoperative fluoroscopy was used for surveillance to confirm the correct placement of all screws. The surgical method previously described by Hu et al [3] for direct C1 pedicle screw fixation of unstable atlas fractures was used in free hand group.

Assessment of Accuracy of Pedicle Screw Placement

After pedicle screws were placed into the pilot hole that was created with the customized drill template, postoperative CT scans were obtained to compare the accuracy of placement between the traditional FH group and RP group. The screw placement was examined in both the axial and sagittal plane of the CT scan and screw position was graded into four groups: screw is completely within bone (grade 0), less than 50% of the screw diameter is outside of the pedicle (grade 1), greater than 50% of the screw diameter is outside of the pedicle (grade 2), the entire diameter of the screw is outside of the pedicle (grade 3).

Postoperative treatment and follow-up

All patients were immediately mobilized and treated with external immobilization via hard collar for 8-12 weeks. Antibiotics were continued for 2 days. AP and lateral radiographs were taken at 3, 60, 90 and 180 days postoperatively. CT scans were taken at 3, 90, 180 days postoperatively. An independent radiologist reviewed the placement of the pedicle screws and assessed for pedicle breach. Thin-slice (1 mm) CT scans and 3-dimensional reconstruction were obtained to assess accuracy of screw placement and reduction (**Figure 3**) and bone healing (**Figure 4**). Dynamic flexion and extension radiographs were taken at 180 days postoperatively to detect any flaws in fracture consolidation (**Figure 5**). The operative time and blood loss were recorded at the time of surgery. Postoperative radiographic measurement of the Atlanto-Dens Interval (ADI) and the Lateral Mass Displacement (LMD) as well as the VAS pain score were documented at the 180 days post-operative visit.

Statistical analysis

Statistical analyses were performed using SPSS Statistical program, (version 17.0; SPSS Inc, Chicago, IL, USA). An independent sample *t* test was used in the comparison of operation time and intraoperative blood loss between the traditional free-hand group and RP group. A two independent-sample *t* test was used to compare the preoperative ADI, LMD and VAS to the postoperative ADI, LMD and VAS. Chi-square test was applied to assess the comparison of the screw accuracy between the free-hand group and the RP group and the chi-square correction test and fisher's exact probability test was used when the data was not suitable for chi-square test. Values are expressed as ranges, and mean \pm SD (standard deviation) as appropriate. Statistical significance of the morphometric data was determined by the use of a Student's *t* test at a 95% level of significance. A *P* value of < 0.05 was considered to be significant.

Results

A total of 36 screws were inserted in the RP group. Of those screws, 32 were completely within the pedicle (grade 0), 2 screws had less than 50% of the screw diameter breach the pedicle wall (grade 1), and 2 screws had greater than 50% of the screw diameter breach the pedicle wall (grade 2). A total of 40 screws were inserted in the free hand group. Of those screws, 25 were completely within the pedicle (grade 0), 8 screws had less than 50% of the screw diameter breach the pedicle wall (grade 1), 7 screws had had greater than 50% of the screw diameter breach the pedicle wall (grade 2) (Table 1). In the RP group the mean operative time was 75.28 min (range: 60–90 min), the intraoperative blood loss was 126.94 ml

(range: 50–200 ml) and no spinal cord or vertebral artery injuries were reported. In the FH group, the mean operative time was 89.60 min (range:70–120 min), the intraoperative blood loss was 135.50 ml (range: 80–260 ml) (Table 2) and no spinal cord or vertebral artery injuries were reported. There was no statistically significant difference in the operative time or the intraoperative blood loss between the two groups ($P > 0.05$). In all patients the postoperative CT scan at 180 days revealed satisfactory cervical alignment without implant failure (Fig. 3), with healing of the C1 fractures (Fig. 4). Further, the flexion-extension radiographs at 180 days revealed normal cervical alignment in all patients and no implant failure or C1-C2 instability was seen (Fig. 5,6). The average VAS score of the RP group decreased from 8.33 ± 1.09 preoperatively to 1.67 ± 0.97 postoperatively ($P < 0.05$). The VAS score of the free hand group decreased from 8.50 ± 1.15 preoperatively to 1.55 ± 1.19 postoperatively ($P < 0.05$) (Table 3). There was no significant difference in average VAS score between two groups ($P > 0.05$). The average preoperative LMD values for the free hand and RP groups were 8.65 ± 0.41 and 8.71 ± 0.47 mm respectively, measurements which imply a rupture of the transverse ligament. After surgery, the average LMD for the free hand and RP groups measured 1.63 ± 0.35 and 1.78 ± 0.49 mm respectively. The average ADI for the RP and free hand groups before surgery were 7.10 ± 0.86 and 6.40 ± 0.66 mm respectively, and decreased after surgery to 2.18 ± 0.49 and 2.06 ± 0.60 mm (Table 3). All patients were followed up for at least 18 months (range: 18–60 months) with a mean of 30.5 months.

Table 1
CT evaluation of traditional free-hand group VS. RP group for C1 pedicle screw placement

Screw	Free hand group(n = 20)		RP group(n = 18)	
	Number	Percent	Number	Percent
Grade 0	25	62.5	32	88.8
Grade 1	8	20.0	2	5.6
Grade 2	7	17.5	2	5.6
Grade 3	0	0	0	0
Grade 1–3	15	37.5	4	11.1

Table 2
 Perioperative differences in Free hand and RP groups

	Free hand group(n = 20)	RP group(n = 18)	P value
Grade 0	25	32	-
Grade 1–3	15	4	-
Accuracy rate	62.5%	88.9%	<0.05
Operation time(min)	89.60 ± 13.08,(70–120)	75.28 ± 9.95(60–90)	>0.05
Blood loss(ml)	135.50 ± 46.62,(80–260)	126.94 ± 49.20,(50–200)	>0.05

Table 3
 Pre and Post operative Radiographic measures and Pain scores in RP group and free hand group

	Free hand group(n = 18)		RP group(n = 20)	
	pre-operation	post-operation	pre- operation	post-operation
LMD	8.65 ± 0.41	1.63 ± 0.35	8.71 ± 0.47	1.78 ± 0.49
ADI	6.40 ± 0.66	2.06 ± 0.60	7.10 ± 0.86	2.18 ± 0.49
VAS	8.50 ± 1.15	1.55 ± 1.19	8.33 ± 1.09	1.67 ± 0.97
LMD = Lateral mass displacement; ADI = Atlanto-dens interval; VAS = Visual analog scale.				

Discussion

Fractures of the atlas have been reported to account for 25% of craniocervical injuries, 3–13% of cervical spine injuries, and 1.3–2% of all spinal injuries [4–7]. Atlas fractures have historically been treated with either external immobilization or a variation of C1-C2 or C0-C2 fusion. Current literature-based evaluations of non-operatively managed C1 ring fractures (including semi-ring fracture, Landells type II) have suggested that failed non operative treatment can lead to a non union with chronic pain, spasms of the cervical muscles and limited neck range of motion [8–10]. Unstable C1 ring fractures have traditionally been treated with C1-C2 or C0-C2 fusion because of fear of C1-C2 instability. Some recent literature suggests that customary definitions of C1 instability that focus on TAL integrity underestimate the number of fractures that require operative intervention and overestimate the number of fractures that require C1-C2 fusion [11]. Fusion of C1-C2 or C0-C2 has been widely used for treatment for unstable atlas fractures, but such treatment sacrifices significant motion, specifically C1-C2 rotation and C0-C1 flexion-extension [12]. These fusions have also been associated with an increased incidence of subsequent subaxial spine degeneration [13]. C1 posterior internal fixation can provide immediate stability to atlas fractures while preserving the motion of the occipital-atlanto-axial joint [3; 14–17]. Techniques for C1 fixation including direct posterior C1 pedicle screw fixation and lateral mass screw internal fixation. Of

these options, C1 pedicle screw fixation has been shown to have better biomechanical stability, and can reduce the possibility of C1-C2 venous plexus bleeding [18].

The traditional method for insertion of C1 pedicle screws relies on careful analysis of preoperative imaging and knowledge of anatomic landmarks to avoid errant placement [19–22]. Such techniques, however, are challenging during C1 pedicle screw placement because of variations in individual anatomy and the small margin for error when placing screws into a small bony channel [23]. Although many methods have been described that purportedly increase the precision of pedicle screw placement, cortical pedicle perforation still occurs [24–27]. To overcome difficulties related to variations in individual anatomy and decrease the risk of injury to the spinal cord, vertebral artery, and internal carotid artery, we have developed and used rapid prototyping of a customized drill template to ensure the accuracy of C1 pedicle screw placement. The template is designed to rest against the C1 posterior arch – matching the bony architecture to build a complementary fit. The stability of this fit is critical as even small deviations in fit could cause the C1 screws to deviate from the predetermined trajectory. Previous studies have found no evidence of significant deviation between the position of the screw after placement using the template and the planned trajectory [28]. This shows the accuracy of rapid prototyping drill template technology and its ability to create individualized drill templates that are accurate even in the face of relatively undistinguished bony surfaces such as the posterior elements of C1. Other associated surgical techniques, such as keeping the drill bit on the 1st side to stabilize the template while drilling the 2nd pilot hole, likely contributed to success at C1. In addition, several other factors may affect the accuracy of rapid prototyping drill template technology, including CT scans without sufficient thin cuts, human error in using the instruments or software described earlier and technical errors during surgery [29–32].

During the surgery, care must be taken to remove all soft tissues from the posterior spinal elements to ensure excellent fit between the template and the bone. It is critical that the surgeon carefully follows the direction of the drill guide and proceeds in short (1 mm) increments to ensure that the drill remains in C1 pedicle. Compared with traditional technique, the use of a personalized rapid prototyping template requires more soft tissue removal from the C1 posterior arch. However, this downside is likely much less morbid than a misplaced C1 pedicle screw. The results of this study show that 32 out of 36 screws (88.9%) were completely within the bony trajectory in RP group and 25 out of 40 (62.5%) screws were completely within the bony trajectory in free hand group. This difference in accuracy favoring the RP technique was found to be statistically significant ($P < 0.05$). In RP group the operative time was 60–90 min, with a mean of 75.28 min and the intraoperative blood loss was 50–200 ml, with a mean 126.94 ml. In free-hand group the operative time was 70–120 min, with a mean of 89.60 min, and the intraoperative blood loss was 80–260 ml with a mean of 135.50 ml. These trends of less blood loss and shorter OR times for the RP group did not reach statistical significance. Further, there was no significant difference in preoperative or 180 days postoperative radiographic or pain measures between the groups (VAS score, LMD and ADI). Fusion was documented at 6 months in all cases and no cases of cervical malalignment, instrumentation failure or C1-2 instability were reported during the study period.

The surgical indications for C1 semi-ring fracture treatment with direct posterior C1 pedicle screw fixation with the help of personalized rapid prototyping template include C1 unstable fractures - Landells type II (semi-ring) that can be reduced with traction with an intact posterior arch. When the C1 posterior arch is significantly displaced this technique of personalized rapid prototyping template can't be used because the template cannot maintain it's stability on the posterior arch of C1. In the right clinical scenario, this study shows that use of a personalized rapid prototyping template can improve the accuracy of posterior C1 pedicle screw fixation of C1 ring fractures.

Conclusion

This study reveals that it is technically feasible to use a personalized rapid prototyping template to assist in the placement of C1 pedicle screws in patients with C1 semi-ring fractures. The improved accuracy of screw placement with a reduction of pedicle breeches may lead to clinically significant improvements in surgical care if this technology becomes widely used in clinical practice. This technique may be especially useful for surgeons with less experience placing freehand C1 pedicle screws.

Abbreviations

ADI

Atlanto-Dens Interval; LMD:Lateral Mass Displacement; VAS:visual analogue scale; RP:Rapid prototyping template; FH:Free-hand; CT:Computed tomography; MRI:Magnetic resonance imaging

Declarations

Ethics approval and consent to participate

Our study was approved by the Regional Ethics committee of Ningbo No.6 Hospital

Consent for publications

Not applicable.

Availability of data and materials

The dataset used during the current study are available from the corresponding author on reasonable request.

Competing Interest

The authors declare that they have no competing interests.

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Authors' contributions

Wei-xin Dong and Yong Hu was responsible for the design and planning of the study. All authors were involved in the preparation and planning of the data analyses. William Ryan Spiker performed the language editing of this article. Wei-xin Dong did the drafting of the first manuscript with contributions from the other authors. All authors read and approved the final manuscript.

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Figures

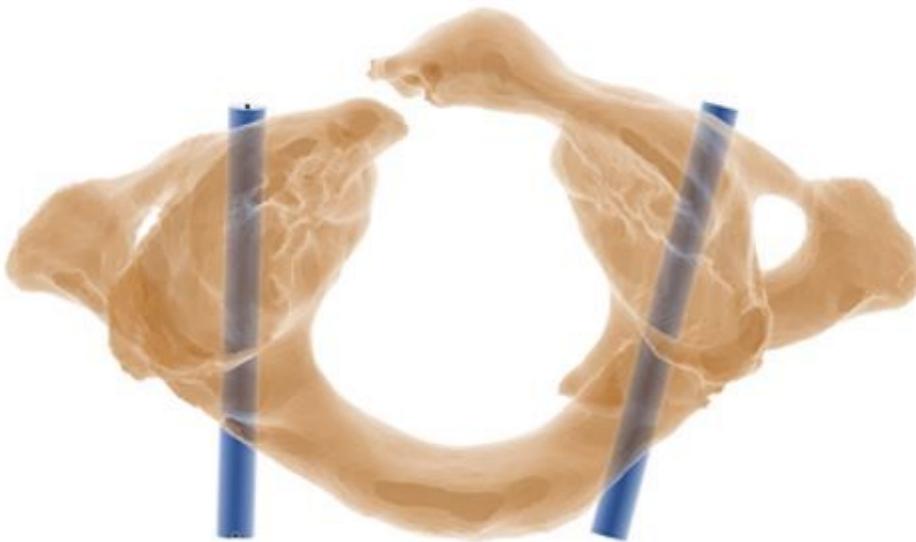


Figure 1

The ideal trajectory of C1 pedicle screws for a patient with an atlas fracture

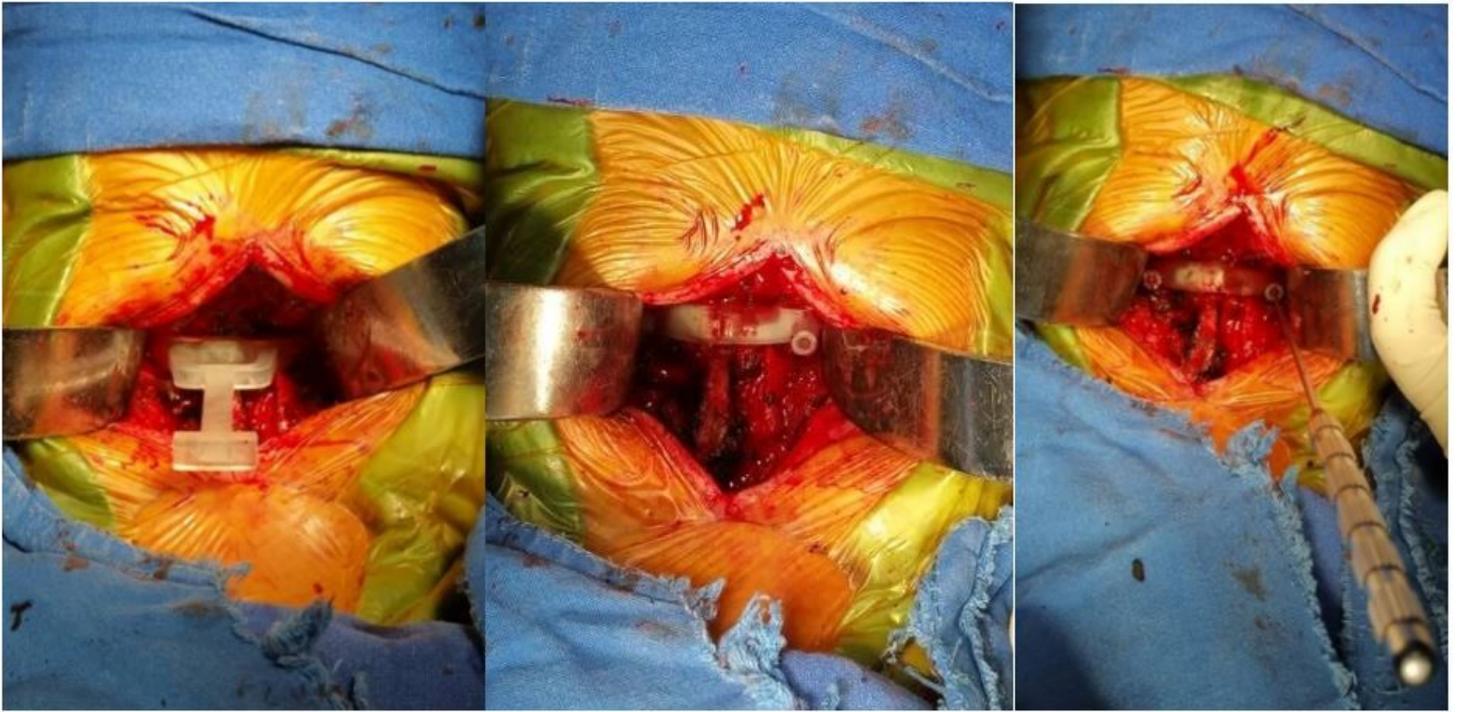


Figure 2

The intraoperative view of 3D printing drill guide template



Figure 3

Axial and sagittal view of CT scan taken 3 days postoperatively showing appropriate positioning of the C1 pedicle screws.

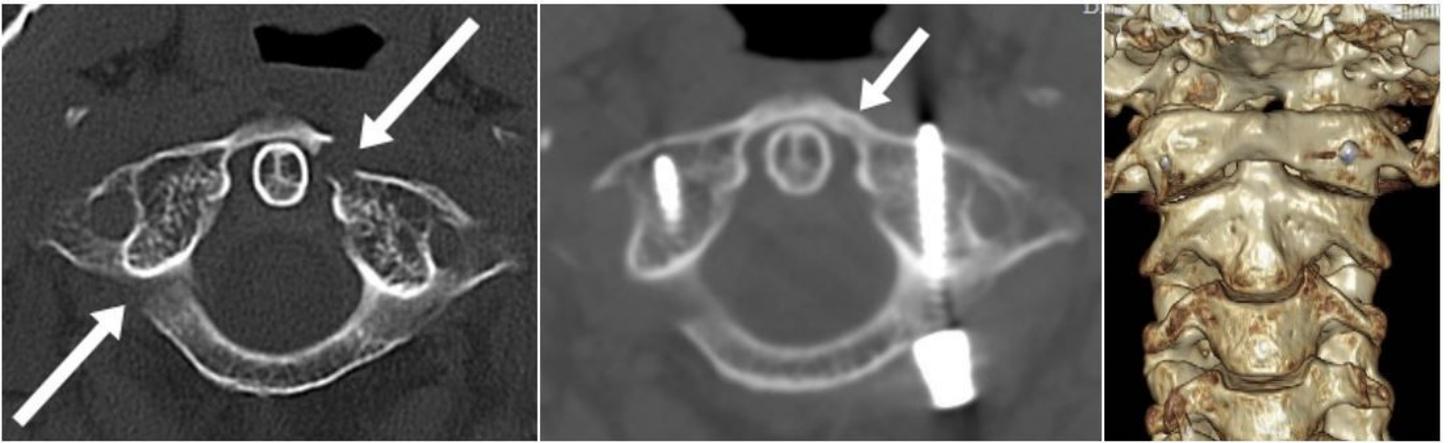


Figure 4

CT scan at 6-month follow-up after operation showing bony fusion of the fractures.



Figure 5

The flexion-extension radiographs at 6-month follow-up reveals normal cervical alignment, no implant failure and no instability at C1-C2.



Figure 6

A 48-year-old man at 6-month follow-up. Reports no pain and full range of motion of the cervical spine.