3D-Printed Screw-Rod Auxiliary System for Unstable Atlas Fractures: A Retrospective Analysis

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Abstract

Objective To develop and validate a 3D-printed screw-rod auxiliary system for unstable atlas fractures.

Methods Fourteen patients who underwent occipitocervical fusion with the 3D-printed screw-rod auxiliary system enrolled in our hospital from 2017 to 2019 were reviewed. The operation time, blood loss and radiation times during the operation were recorded. The maximum fracture displacement values pre- and post-operation were measured based on CT imaging. All screw grades were evaluated after surgery. The O-C2 angle and OCI angle pre-operation, post-operation and at the last follow-up were measured. The dysphagia scale 3 and 12 months after surgery and the NDI 3 and 12 months after surgery were assessed.

Results The average surgery time, average blood loss and average radiation times for the 14 patients were 112.14 minutes, 171.43 ml and 5.07 times, respectively. There was a significant difference in maximum fracture displacement between pre- and post-operation values ($P<0.05$). A total of 56 screws were inserted; 3 screws were classified as grade 1, and the others were classified as grade 0. There was a significant difference in the O-C2 and OCI angles from pre-operation values to values 3 days after the operation ($P=0.002$, $P<0.05$); there was no significant difference in the O-C2 or OCI angle from 3 days after the operation to the last follow-up ($P=0.079$; $P=0.201$). The dysphagia scales of two patients were assessed as mild 3 months after surgery, and the others were assessed as normal. All patients' dysphagia scores returned to normal 12 months after surgery. The average NDI and average neck VAS scores 12 months after surgery were 2.53 and 8.41, respectively.

Conclusion It is clinically feasible with the assistance of a screw-rod auxiliary system to perform occipitocervical fusion for unstable atlas fractures. This novel technique can objectively restore the occipitocervical angle of patients, and there are few postoperative complications.

Introduction

Fractures of the atlas account for 3-13% of cervical spine fractures [1]. There is still much controversy about the treatment of C1 fractures [2]. The most common fracture classification is the Gehweiler classification: type I fractures are isolated fractures of the anterior ring of the atlas, type II refers to isolated fractures of the posterior arch of the atlas, type III are combined fractures of the anterior and posterior arches of the atlas, type IV refers to isolated fractures of the lateral mass, and type V refers to fractures of the transverse process [3-4]. Types III and IV are considered unstable fractures and often require surgery [4]. The surgical methods include anterior atlantoaxial fusion [5], posterior atlantoaxial transarticular screw fixation [6], posterior atlantoaxial pedicle screw fixation [7], etc. O-C2 fusion is required in patients with unstable atlas fractures complicated by atlantooccipital instability and difficulty placing lateral mass screws or pedicle screws [8-9]. In this surgery, the placement of axial screws and occipital screws accurately and safely, as well as the return to normal of the occipitocervical angle, is particularly important [10]. There is a high failure rate of screw placement based on anatomical markers [11]. Complications such as dysphagia and dyspnoea may occur when the cervical occiput is fused at an abnormal angle. Yoshid et al first reported a patient with rheumatoid arthritis who had developed serious dyspnoea and dysphagia immediately after a short occipitocervical fusion [12], which resulted in a failure of occipitocervical fixation. In this study, we used 3D printing technology to develop a set of patient-specific navigation templates for the placement of axial pedicle screws and occipital screws and a reference model of the occipitocervical angle for restoring the normal occipitocervical angle to improve the screw placement accuracy and reduce the complications caused by an inappropriate occipitocervical angle. To our knowledge, this is the first report of occipitocervical angle recovery using a patient-specific reference model of the occipitocervical angle.

The aims of this study are as follows: (i) to explore the feasibility of the patient-specific screw-rod auxiliary system for assisting with occipitocervical fixation in unstable atlas fractures; (ii) to research the insertion accuracy of the axis and occipital screws assisted by the navigation template; and (iii) to investigate the effectiveness of the patient-specific reference model of the occipitocervical angle.

Materials And Methods

Patients

This study was approved by Zigong No. 4 People's Hospital Review Board (IRB Number, 2017-002). The inclusion criteria were as follows: atlas fractures; Gehweiler classification types 3 and 4 combined with atlantooccipital instability or screw placement difficulty; aged 30 to 81 years old; and followed for more than 1 year. The exclusion criteria were as follows: patients with pathological fractures, severe systemic diseases, and severe osteoporosis.

From January 2017 to March 2019, a total of 14 patients were enrolled in our research, 11 males and 3 females, with an average age of 53.21 years and an average BMI of 23.61. Six of them were classified as having type 3 fractures, and 8 patients were classified as having type 4 fractures according to the Gehweiler classification. Seven patients showed atlantooccipital joint instability, and 10 patients experienced screw placement difficulty. One patient was diagnosed with ASIA grade D, and the others were ASIA grade E (table 1). The operations were performed by the same experienced surgeon for more than 10 years, and all patients were informed of the experimental design before the surgery and signed an informed consent form.

Model construction of the cervical occiput

CT of the cervical occiput was obtained in DICOM format and then imported into Mimics 21.0 (Materialise, Leuven, Belgium). The CT value of bone was selected as the threshold to extract the mask, and then the 3D model of the cervical occiput was calculated based on the mask (Fig 1a, d). The virtual screws were placed in the pedicle of the axis, and virtual screws of the occiput were placed in the occipital tuberosity based on the 3D models. According to the measurement and conclusion of Naoki Shoda [13], in the sagittal plane, the occiput was rotated to maintain an O-C2 angle of 14° (Fig 1b, e). The left and right splines were drawn along the occipital screws, atlas, and axis pedicle screws.

Design of screw-rod auxiliary system

The splines and virtual screws described above were imported into 3-matic (Materialise, Leuven, Belgium). The spline diameter was set to 3.2 mm as the reference model, and both terminals of each reference model were designed with a point to mark the position of the screw on the cervical occipital surface. The virtual screw diameter was set to 2.1 mm. The bone surface structure around the screw insert point was extracted and stretched to a thickness of 3 mm to serve as the basis of the navigation templates. A hollow pipe with an inner diameter of 2.1 mm and a length of 2 cm along the direction of the virtual screw was designed as the guide pipe (Fig 1c, f). Then, the base and guide pipes were united as the navigation template. The reference model and navigation template were collectively referred to as the screw-rod auxiliary system (Fig 1g).

Preoperative preparation

Including standard anteroposterior and lateral radiographs, CT and MRI were performed to assess the fracture type and the integrity of the intervertebral discs and ligamentous injuries. The preoperative operation was simulated on the 3D-printed model. The axial and occipital navigation templates were matched with the corresponding positions of the model. A diameter of 2 mm for the K-wires was drilled through the guide pipes, and the route of the K-wires was observed to verify navigation template accuracy (Fig 2a). The reference model of the occipitocervical angle was assembled to verify sagittal curvature correction (Fig 2b). The screw-rod auxiliary system was sterilized at low temperature before the operation.

Surgical technique

Anaesthesia and position: Under general anaesthesia, the prone position was recommended during the surgical procedure on a radiolucent operation table with the head fixed in a Mayfield head holder.

Approach and exposure: Via a posterior median approach, surgical exposure was accomplished from the occiput to the C2 spinous process. The muscle and subcutaneous fascia tissues were fully stripped from the bones.

Fixation or placement of the prosthesis: Occipital screw navigation templates and axial screw navigation templates were placed in the back of the corresponding bone and fixed firmly by the assistant; two K-wires were drilled step by step into the axial pedicle through the axial guide pipes. The pedicle screws were placed after the channel was detected (Fig 3a); two K-wires were drilled into the occiput through the occipital guide holes (Fig 3b). An occipital screw-plate was fixed to the keel of the sub-occipital cranium (Fig 3c).

Reconstruction: Two connecting rods were contoured to refer to the shape and length of the patient-specific reference model (Fig 3d). The next step was to firmly fix the locking caps of the C2 pedicle screw and to place the locking caps loosely on the occipital screw plate so that the rod was firmly attached to the C2 pedicle screw while sliding freely within the occipital screw plate. According to the shape of the reference model, the O-C2 angle was adjusted; according to the distance of the dots on the reference model, the occipital locking caps were tightened firmly while maintaining distraction (Fig 3c). Finally, all locking caps were securely tightened (Fig 3e). After satisfactory reduction, autologous bone grafts from the ilium were obtained for bone arthrodesis and stratified suturing of the wound.

Evaluation criteria

The surgical time, blood loss and radiation times were recorded to evaluate the operation quality. The maximum displacement of the fracture pre-operation and post-operation were measured based on CT imaging, and fracture reduction was assessed. The grading score was used to evaluate the safety of the pedicle screw [14]; grade 0: no breach; grade 1: breach less than 2 mm; grade 2: breach of 2 to 4 mm; and grade 3: breach greater than 4 mm. Grade 0 and grade 1 placements were considered successful and safe, and grade 2 and grade 3 placement indicated the possibility of nerve damage.

The angle between McGregor's line and the inferior endplate line of C2 was measured as the O-C2 angle (Fig 4a). The angle between McGregor's line and the posterior border of C4 was measured as the occipitocervical inclination (OCI) angle [15] (Fig 4b).

The dysphagia scale was evaluated as follows: "normal" refers to patients without any swallowing difficulties; "mild" refers to patients with rare, intermittent episodes of dysphagia; "moderate" refers to patients with some difficulty when swallowing some special food; and "severe" refers to patients with difficulty even swallowing liquid [16]. The neck pain visual analogue scale (VAS) and neck disability index (NDI) [4] were assessed, and scores were recorded by an independent examiner.

Statistical analysis

All statistical analyses were performed in SPSS 19.0 (SPSS Inc.; Chicago, IL, USA).

Descriptive statistics, including the mean value, standard deviation, minimum value and maximum value, were performed for age, BMI, surgical time, blood loss, radiation times, NDI and neck VAS. The paired T-test was performed to determine the maximum displacement of the fracture between pre-operation and post-operation values. One-way repeated measure ANOVA was performed to determine the O-C2 angle and OCI angle pre-operation, 3 days after the operation and at the last follow-up. The level of statistical significance was set at 0.05 (two-tailed).

Results

The average surgical time, blood loss and radiation times were 112.14 minutes (range 90 to 140), 171.43 ml (range 80 to 300) and 5.07 times (range 4 to 6), respectively. The maximum displacement of the fracture was 6.95 mm before surgery and 4.75 mm after surgery, and there was a significant difference between pre- and post-operation values (P<0.05). A total of 28 C2 screws and 28 occipital screws were placed. One left C2 screw, 1 right C2 screw and 1 occipital screw had grade 1 placement, and the other screws had grade 0 placement. There was a significant difference in the O-C2 angle (P=0.002) and OCI angle (P<0.05) between values pre-operation and those 3 days after the operation. There was no significant difference in the O-C2 angle (P=0.079) or OCI angle (P=0.201) between values 3 days after the operation and those at the last follow-up. The dysphagia scale was assessed as “mild” in 2 patients, and in the other patients, the dysphagia scale was assessed as “normal” 3 months after the operation. All patients had “normal” dysphagia scales 12 months after the operation. The average NDI and neck VAS scores 12 months after the operation were 2.53 (range 2.07 to 3.16) and 8.41 (range 7.14 to 9.75), respectively (table 2).

Discussion

Measurement of occipitocervical angle and intraoperative recovery

Masahiko Miyata et al analysed the O-C2 angle in 29 patients who underwent occipitocervical fusion and found that the O-C2 angle had a significant impact on postoperative dyspnoea and/or dysphagia [17]. Seong-Dae Yoon suggested that the OCI angle is an important parameter reflecting the occipitocervical angle in patients with anatomic abnormalities of C0-C2[18]. Naoki Shoda put forth that the McGregor line is the most reproducible and reliable method for measurement of the OCI angle [19]; Shingo Nagashima suggested the use of the Oc-Ax angle instead of the O-C2 angle when it was difficult to find the McGregor line or endplate of C2[20]. The O-C2 and OCI angles have been used as important parameters to evaluate occipitocervical angle recovery because they are easy to measure during surgery [17]. Sitoula P recommended a technology for occipitocervical fusion, and it helps restore the occipitocervical angle and maintains screw stabilization [21]. During the operation, C-arm fluoroscopy has recently been used to assess the recovery of the occipitocervical angle; however, this method has substantial subjectivity and needs multiple perspectives to adjust the angle. In this study, we used a patient-specific 3D-printed screw-rod auxiliary system to assist with screw placement and pre-bending of the rod to improve the objectivity of intraoperative confirmation and improve the reduction effect.

Advantages of the screw-rod auxiliary system

In this study, we achieved a great therapeutic effect with the screw-rod auxiliary system. First, the average operative time of the 14 patients was 112.14 minutes, and the average blood loss was 171.43 ml in this study, which was significantly less than that with this type of surgery among recent studies [22-23]. The average radiation times in the study was 5.07, which was significantly less than that in previous studies [24-25]. Second, the degree of postoperative fracture displacement was significantly less than that of preoperative fracture displacement, indicating that this technique could effectively reduce the fracture. Third, this technology to assist screw placement is safe, and no screws more severe than grade 1 were found in this study. Fourth, the occipitocervical angle was well restored to be consistent with the preoperative design and with an average O-C2 angle of 14° after surgery. The fixation was stable, since there was no significant difference in the O-C2 or OCI angle between the values post-operation and at the last follow-up. Last, dyspnoea was rarely seen in all 14 patients, and the ASIA scale fully recovered to grade E, with satisfactory NDI and VAS scores at the last postoperative follow-up.

Operation skills

Here, we provide some tips for this type of surgery. I. The simulated reduction of the fracture site should be performed before surgery, and the occipitocervical angle should be adjusted from the sagittal position and coronal position to satisfy physiological curvature. II. The base of the axial navigation template should cover the root of the axial spinous process, and the base of the occipital navigation template should cover the occipital nodule to ensure that the navigation template is firmly attached to the bone and to improve the accuracy of screw placement. III. The inner diameter of the guide pipe is reserved with a mobility of 0.1 mm for the passage of the K-wires. The length of the guide pipe should be designed to be 15-20 mm to accurately guide while avoiding excessive soft tissue stripping. IV. It is best to choose a K-wire with a limited depth and a diameter of 2 mm, and the K-wires should be deepened step by step to explore the screw corridor. V. During the operation, the soft tissue around the bone attached by the base of the navigation template should be completely removed to ensure firm attachment of the navigation template. VI. The screw on one side was inserted first, the fact that fracture recovery stabilization was established during the operation was ensured, and the screw on the other side was inserted to avoid the aggravation of fracture displacement. VII. After occipitocervical fixation, the screw position and recovery of the occipitocervical angle should be reconfirmed by C-arm fluoroscopy.

Limitations

There are some limitations of this research that should be noted. First, we measured the O-C2 angle and OCI angle in this study, but these two indicators were not sufficient to evaluate the recovery of the occipitocervical angle. Second, some complications of the patients may have been ignored, and patients’ postoperative statuses could not be fully evaluated due to the short follow-up. Finally, only 14 patients were enrolled in this study, resulting in a relatively small sample size. In a later study, we will add the anatomical measurement index and clinical observation index, prolong the follow-up and expand the sample size.

Conclusion

It is clinically feasible with the assistance of a screw-rod auxiliary system to perform occipitocervical fusion for unstable atlas fractures. This novel technique can objectively restore the angle occipitocervical angle of patients, and there are few postoperative complications.

Tables

Table 1 General information of patients treated by reference model and navigation templates

No.	Gender	Age (years)	BMI(Body Mass Index)	Gehweiler classification	Atlantooccipital joint instability	Screw placement difficulty	ASIA grade
P1	Female	58	24.6	Type3	y	y	E
P2	Female	44	26.2	Type4	y	y	E
P3	Male	81	21.7	Type4		y	E
P4	Male	49	22.8	Type4		y	D
P5	Male	71	21.5	Type3	y		E
P6	Male	75	25.5	Type3	y	y	E
P7	Female	48	23.7	Type4		y	E
P8	Male	54	21.9	Type4		y	E
P9	Male	42	23.8	Type4		y	E
P10	Male	57	22.6	Type4		y	E
P11	Male	56	24.6	Type3	y		E
P12	Male	33	22.3	Type3	y		E
P13	Male	30	27.8	Type3	y		E
P14	Male	47	21.6	Type4		y	E
Mean		53.21	23.61				
SD		14.81	1.93				
Min		30	21.5				
Max		81	27.8				

Table 2 Clinical and radiological results of patients

No.	Surgical time （min）	Blood loss （ml）	Radiation times m	Maximum displacement of fracture, preop (mm)	Maximum displacement of fracture, postop (mm)	Grade of C2		Grade of occipital		O-C2 angle			OCI angle		
						L	R	O1	O2	Pre-S	Post-3d	Post-last	Pre-S	Post-3d	Pos last
P1	100	200	4	6.21	3.23	0	0	0	0	7.56	14.23	15.17	103.23	78.23	76.
P2	110	250	6	7.78	4.14	1	0	0	1	8.56	14.54	15.10	102.52	88.96	86.
P3	110	150	4	9.37	5.50	0	0	0	0	9.61	15.13	14.52	101.51	84.84	82.
P4	90	100	4	12.23	7.81	0	0	0	0	11.73	12.56	13.56	99.09	87.63	85.
P5	120	80	6	7.84	5.5	0	0	0	0	6.06	14.35	14.12	112.74	78.52	76.
P6	140	300	5	13.42	11.51	0	0	0	0	10.13	15.32	14.28	106.92	86.54	84.
P7	100	150	4	3.54	2.13	0	0	0	0	9.85	14.12	14.86	101.88	89.41	87.
P8	120	200	6	2.85	1.24	0	0	0	0	11.14	14.82	15.55	105.42	81.13	79.
P9	110	100	6	2.98	4.34	0	0	0	0	15.23	12.23	13.25	98.56	92.36	99.
P10	90	100	4	7.25	4.26	0	0	0	0	6.71	14.12	14.79	115.27	79.56	77.
P11	120	150	6	5.23	2.25	0	0	0	0	8.17	12.34	13.86	107.29	85.54	83.
P12	120	120	6	4.23	4.10	0	1	0	0	12.89	13.44	14.10	104.23	86.45	84.
P13	140	300	6	7.56	5.36	0	0	0	0	14.83	14.78	14.98	89.19	80.56	78.
P14	100	200	4	6.82	5.23	0	0	0	0	9.63	13.96	14.25	96.53	79.31	77.
Mean	112.14	171.43	5.07	6.95	4.75					10.15	14.00	14.46	103.17	84.22	82.
SD	15.78	73.05	1.00	3.19	2.57					2.90	1.04	0.68	6.52	4.57	6.2
Min	90	80	4	2.85	1.24					6.06	12.23	13.25	89.19	78.23	76.
Max	140	300	6	13.42	11.51					15.23	15.32	15.55	115.27	92.36	99.
Statistic				T=5.4						P=0.002*			P=0.000*		
				P=0.000							P=0.079^			P=0.201^	

*, Comparison between pre-operation VS 3 days after operation

^, Comparison between 3 days after operation VS last following-up

Abbreviations

OCI: occipitocervical angle

O-C2: occipital- cervical 2

Declarations

Ethics approval and consent to participate

This study was approved by the ethics committee of Zigong Fourth People's Hospital (No. 02, 2013). All patients signed the informed consents to participate in the study.

Consent for publication

I certify that this manuscript is a unique submission and is not being considered for publication, in part or in full, with any other source in any medium.

Availability of data and materials

The device(s) is/are FDA-approved or approved by corresponding national agency for this indication. The patients' data was authorized to our research.

Competing interests

No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript. There is no conflict of interest between authors.

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Authors' contributions

Chao Wu was responsible for experimental design, writing and review, Jiayan Deng for data analysis and paper writing, Jian Pan for data preprocessing, Tao Li, Lun Tan and Haigang Hu for clinical trials.

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Figures

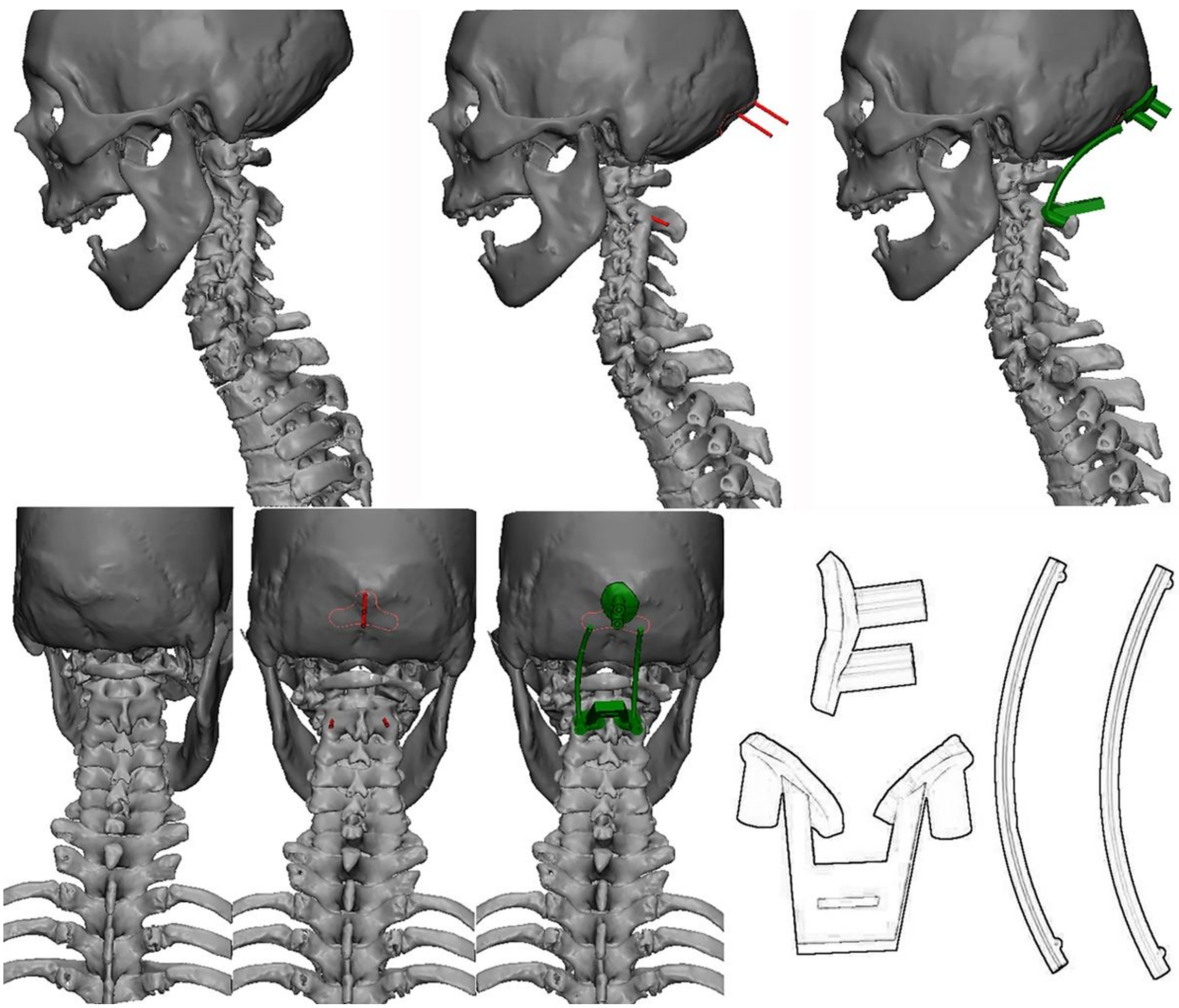

Figure 1

Model establishment and design of the screw-rod auxiliary system a, d. Constructed model of the cervical occiput, lateral view and dorsal view; b, e. The virtual occipital screws and axial pedicle screws were placed, lateral view and dorsal view; c, f. The screw-rod auxiliary system was designed based on the virtual model and screws, lateral view and dorsal view; g. Structural drawing of the separated screw-rod auxiliary system, including the reference model of the occipitocervical angle and the navigation templates of occipital screws and axial pedicle screws.

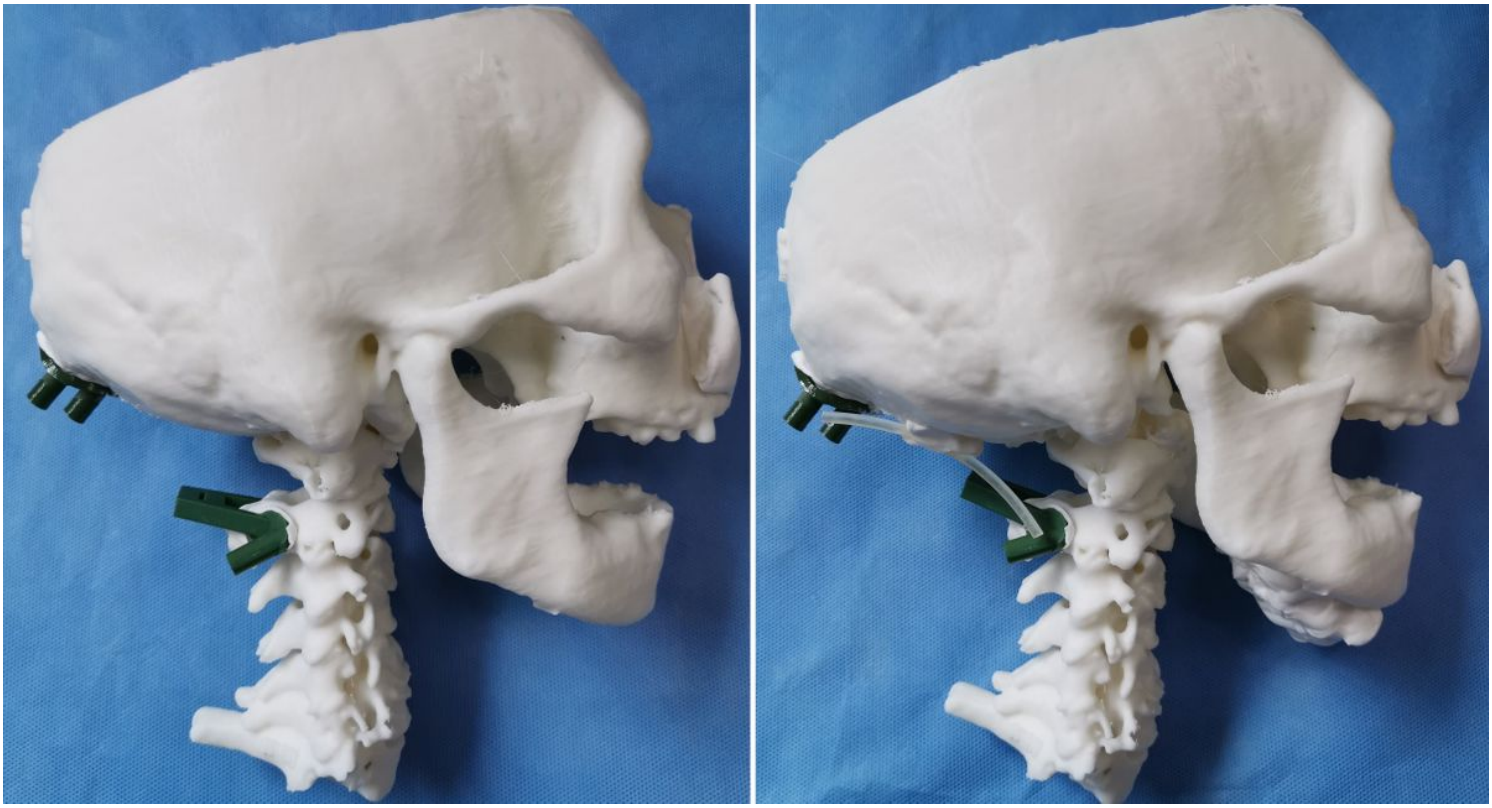

Figure 2

Simulated surgery based on the 3D-printed model a. Simulated screw placement assisted by the 3D-printed navigation template; b. The reference model of the occipitocervical angle was placed to verify its effectiveness.

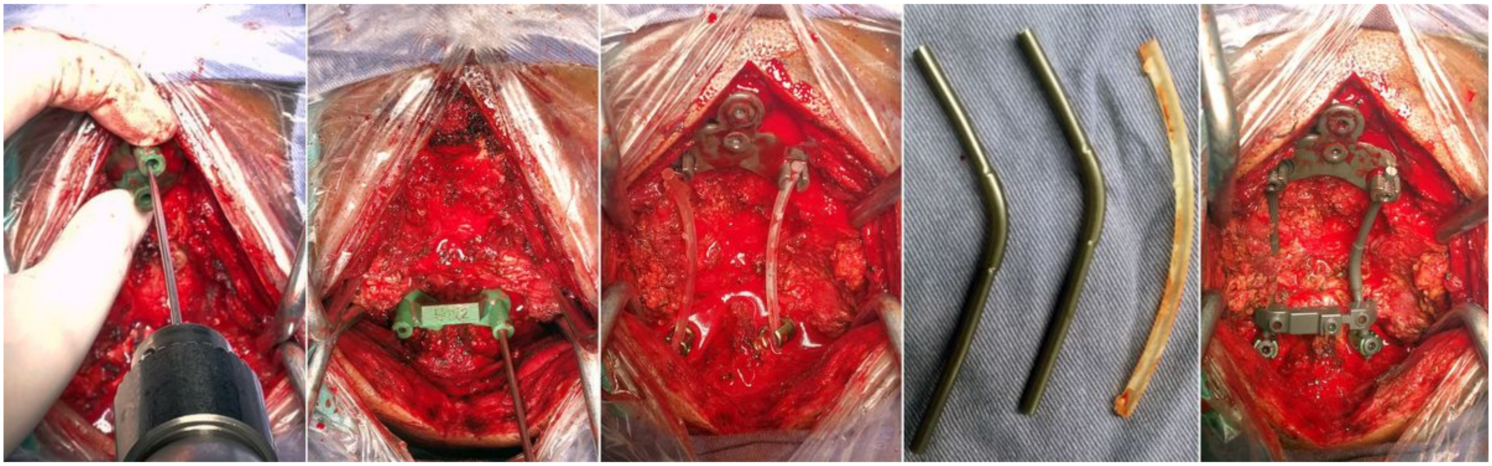

Figure 3

Surgical procedure a. Occipital screws were inserted, assisted by the navigation template; b. Axial pedicle screws were inserted, assisted by the navigation template; c. The occipitocervical angle was adjusted according to the reference model of the occipitocervical angle; d. According to the occipitocervical angle reference model, the connecting rod with an appropriate length was applied and then bent; e. Completed occipitocervical fusion.

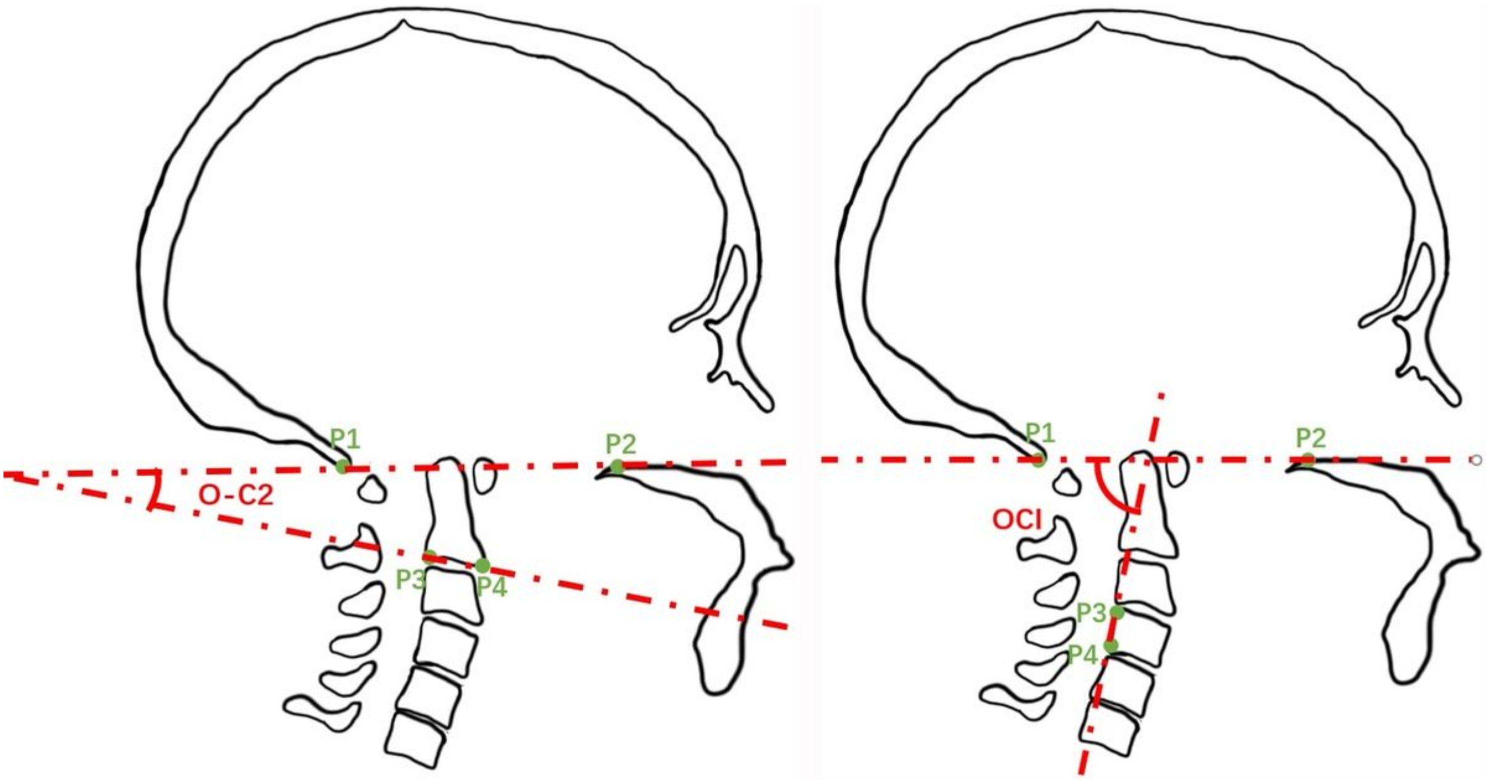

Figure 4

a. Measurement of the O-C2 angle. Point 1 is the most caudal point on the midline occipital curve, point 2 is located in the posterosuperior aspect of the hard palate, and points 3 and 4 are located in the inferior endplate of the axis. The O-C2 angle is defined as the angle between McGregor's line and the inferior endplate line of C2. b. Measurement of the OCI angle. Point 3 and point 4 are located in the vertebral body edge of C4. The OCI angle is defined as the angle between McGregor's line and the vertebral body edge of C4.

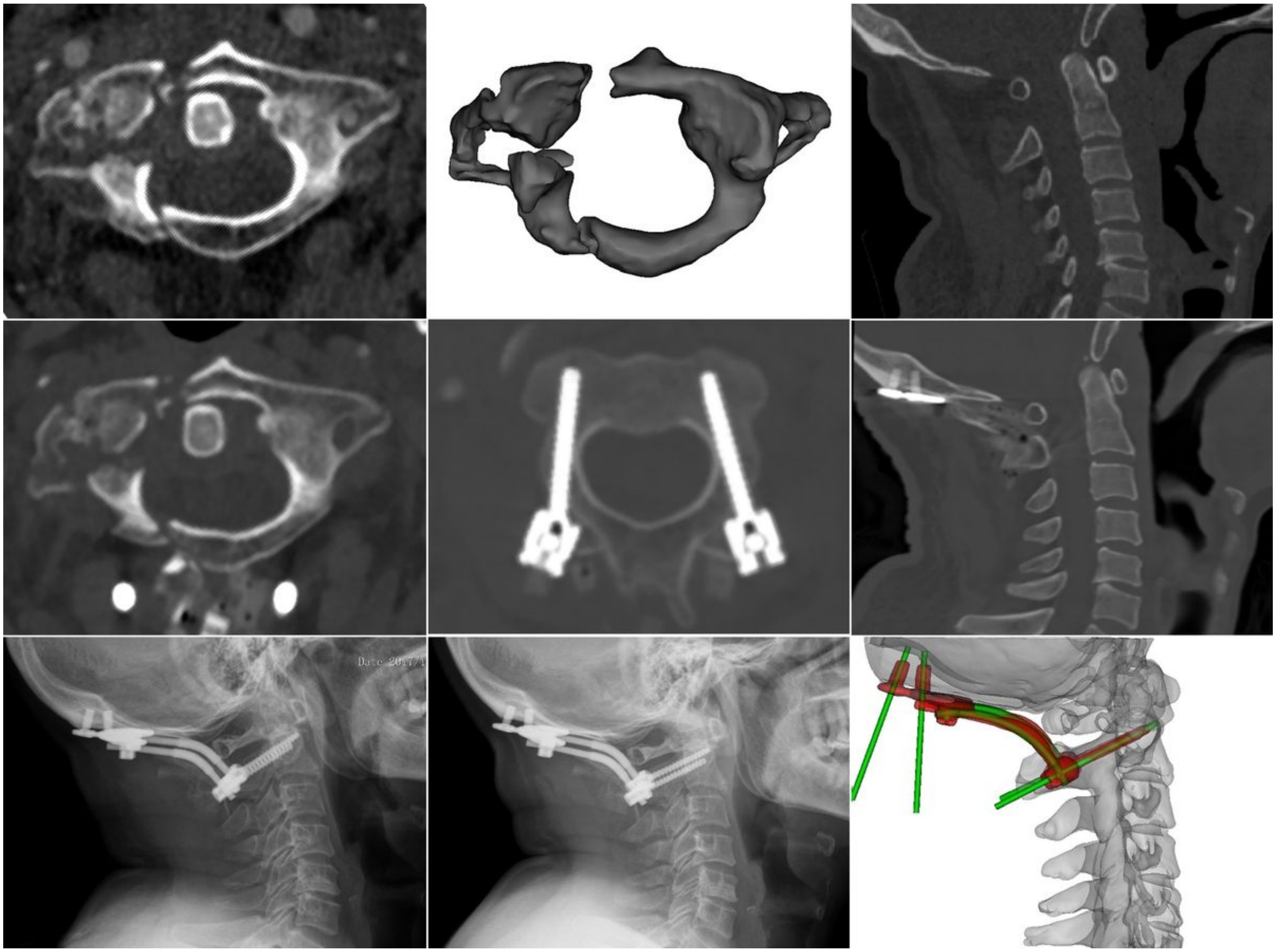

Figure 5

The imaging of patient NO. 10, male, diagnosed with a fracture of the lateral mass of C1, type 4 a. Axial CT of C2; b. 3D imaging of C2; c. Pre-operation O-C2 angle of 6.71°; d. Postoperative atlas reduction; e. C2 pedicle screw with grade 0; f. Occipital screw with grade 0; g. OCI angle of 79.56° and O-C2 angle of 14.12° immediately post-operation; h. OCI angle of 77.45° and O-C2 angle of 14.79° at the last follow-up; i. Registration of post- and pre-operation CT, screw placement and occipitocervical angle consistent with the preoperative design.