Clinical effect of individualized 3D printing guide assisted placement of upper cervical pedicle screw

Guoqi Niu (ssngq2888@163.com)
The Second affiliated hospital of medical college
Chao Li
The second affiliated hospital of bengbu medical college
Jianzhong Bai
The second affiliated hospital of bengbu medical college
Gong Zhou
The second affiliated hospital of bengbu medical college
Lutan Liu
The second affiliated hospital of bengbu medical college
Qiankun Zhou
The second affiliated hospital of Bengbu medical college
Hui Chen
The second affiliated hospital of bengbu medical college
Hu Nie
The second affiliated hospital of bengbu medical college
Tao Liu
The second affiliated hospital of bengbu medical college
Weili Jiang
The second affiliated hospital of bengbu medical college
Jiawei Cheng
The second affiliated hospital of bengbu medical college
Baoyin Zhao
The second affiliated hospital of bengbu medical college
Jun Zhu
The second affiliated hospital of bengbu medical college
Ruochen Yu
The second affiliated hospital of bengbu medical college

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Abstract

Objective

To investigate the clinical effect of individualized 3D printing guide assisted upper cervical pedicle screw placement.

Methods

Eighteen patients with upper cervical spine injury requiring surgical treatment were included in our hospital from May 2010 to May 2019. These patients were divided into guide plate assisted screw implantation group (Group A, N = 10) and traditional operation group (Group B, N = 8). All patients were followed up for more than 6 months. Screw implant accuracy, cervical spine JOA score, ASIA score, VAS score, operation time, intraoperative blood loss were compared between the two groups.

Result

A total of 72 atlantoaxial pedicle screws were implanted, 40 in group A and 32 in group B. The accuracy rate of nail implantation was 97.50% in group A and 81.25% in group B ($P < 0.05$). The operation time in group A (189.7 ± 16.1 mins) and group B (242.1 ± 23.2 mins), $P < 0.05$. The intraoperative blood loss in group A (216.0 ± 49.7 ml) and group B (385.0 ± 23.5 ml), $P < 0.05$. The intraoperative fluoroscopic times was 8.7 ± 1.1 in group A and 30.0 ± 3.3 in group B ($P < 0.05$). Besides, the JOA, Asia and VAS scores of the two groups at one week after operation and the last follow-up were significantly different from those before operation. One week after operation, the JOA, Asia and VAS scores of group A were significantly better than those of group B, but there was no significant difference between the two groups at the last follow-up.

Conclusions

individualized 3D printing guide assisted placement of upper cervical pedicle screw can significantly improve the accuracy of screw implantation and postoperative function of patients, reduce the times of X-ray fluoroscopy, operation time, and intraoperative blood loss, which is a safe and effective approach and worthy of clinical promotion.

Introduction

The upper cervical spine is adjacent to important anatomical structures, such as vertebral artery, medulla oblongata and cerebellum, which is an important transition area of craniocervical function[1]. Thus, upper cervical spine injury can significantly increase the morbidity and mortality of patients. The upper cervical spine deformity mainly caused by the occipital, atlantoaxial physiological spatial position or anatomical structure abnormalities[2], which makes it difficult to accurately implant the screws even for experienced spine surgeons. Once the implant position deviates, it may lead to disability and even life-threatening risk[3]. Therefore, the accuracy of nail implantation is critical to the success of the operation.

The method of pedicle screw placement in the upper cervical spine is usually combined with traditional freehand placement of X-ray fluoroscopy during the operation. This procedure has a long operation time, a large amount of bleeding during the operation, a lot of radiation exposure to doctors and patients, and the accuracy of pedicle screw placement is difficult to achieve the desired expectations, which reduces the overall success rate of the operation. 3D printing technology develops rapidly and is widely used in the field of orthopedics [4–6], significantly improves the efficiency, accuracy and success rate of the operation. However, 3D printing technology is less used in upper cervical spine surgery. Therefore, we did this retrospective study, and through long-term follow-up, to study the accuracy and safety of individualized 3D printing guide assisted upper cervical pedicle screw placement.

Materials And Methods

Eighteen patients underwent upper cervical pedicle screws placement and internal fixation in our hospital, were enrolled in this retrospective study from May 2010 to May 2019. These patients were divided into guide plate assisted screw implantation group (Group A, N=10) and traditional operation group (Group B, N=8). In group A, there are 6 males and 4 females, with an average age of 47.3 (30 to 65) years. All patients had spinal cord compression with neurological symptoms, 2 cases of atlantoaxial subluxation, 3 cases of atlantoaxial joint dislocation, 5 patients have symptoms of incomplete paralysis. In group B, there are 3 males and 4 females, with an average age of 40.4 (25 to 45) years. All patients have significant neurological symptoms, 4 cases with atlantoaxial dislocation, and 4 cases of incomplete paralysis. All included patients have complete follow-up data. The operation method has been approved by the ethics committee of our hospital, and all patients have signed the operation consent form.

Selection criteria

Inclusion criteria: (1) diagnosis of upper cervical spine deformity is clear, accompanied by obvious neurological symptoms; (2) the patient is older than 18 years old.

Exclusion criteria: (1) old fractures cause acquired deformities; (2) the degree of pedicle variability is too large to be fixed with pedicle screws; (3) the underlying disease cannot tolerate surgery; (4) follow-up information is incomplete.

Orientation template design

The patients in group A underwent spiral CT scan (Siemens, Germany) before the operation. The CT data of the upper cervical spine after the scan was converted into DICOM format for storage, and the stored data was transferred to Mimics 17.0 (Materialise, Belgium) to build a model. Select the target vertebral body in the Mimics virtual software, extract the anatomical structure of the atlantoaxial pedicle on the back of the deformed vertebral body, generate a virtual pedicle screw, and fit the best pedicle screw entry point, screw channel, and the length of screw to ensure that none of the virtual screws penetrate the four walls of the pedicle. In the software, design a guide tube with an inner diameter of 0.4cm, an outer diameter of 0.8cm, and a length of about 1.5 to 2.0cm. Combined with the anatomical shape of the back of the atlantoaxial vertebral body, a reverse 3D guide plate matching its anatomical characteristics is designed behind the vertebral body, and the final individualized atlantoaxial pedicle screw placement is fitted through the "Boolean calculation" in the software orientation template (shown in **Figure 1**).

Model, guide plate printing

Import the saved STL data into ideaMaker (China, Jiangsu) to verify the integrity of the model printing. Save the completed model in .gcode format and import it into a 3D printer (raise 3d N2 plus, Shanghai Maiditu Company). Use PLA as the printing material to print the upper cervical spine model at a ratio of 1:1. The printing parameters are: single layer Height: 0.25mm, filling rate 10.0%, printing speed 70.0mm/s, print out the model base, internal and external support and upper cervical spine model. In addition, print out 40 guide templates, 10 upper cervical spine models, and perform simulated surgery. The surgeon uses a 0.2cm Kirschner wire to drill holes under the protection of the sleeve. When the Kirschner wire drills into the same length as the length of the screw generated in the preoperative software. Observe the trajectory of the Kirschner wires in the pedicle of the model. If the Kirschner wires are in the pedicle, it is confirmed that the guide template is usable. Record the depth of the Kirschner wires into the pedicle at this time, which is the choice of intraoperative screws (shown in **Figure 2**).

Surgical approach

Group A

After the patient's general anesthesia was completed, the patient was routinely indwelled with urinary catheterization. First, the patient was placed in a supine position, the neck was hyper-extensive, and the treatment weight was 3KG. Then use the prone position, take a median longitudinal incision on the back of the neck, cut the skin and other subcutaneous tissues in turn to expose the C1 posterior arch and C2 lamina, and use the periosteal device to peel off the suboccipital muscles and the posterior atlantoaxial muscles for periosteal dissection. The lamina and spinous processes are fully exposed with the assistance of the laminar spreader, and the intervertebral and paravertebral soft tissues are fully cleaned. Attach the sterilized 3D guide template to the back of the atlas, and when the matching degree is confirmed and stable, the assistant will help to fix the guide plate, and put a protective sleeve in the guide pin sleeve of the guide plate. The surgeon uses a diameter of 2.0mm. The needle is drilled under the protection of the sleeve, and the depth of drilling refers to the length recorded before and after the simulation operation. After removing the guide plate, the probe looks at the four walls of the pedicle to ensure that the nail path is completely in the pedicle cortex. Then the tap is slowly tapped, Re-measure the depth and select the appropriate length of screw to slowly screw in, and the nail is completed after the position is good under the perspective. The same method is used to insert the screw in the axis. The occipital plate is drilled and fixed, the pedicle screw is fixed with the shaped titanium rod, and the transverse connection is inserted. The ultrasonic bone knife sharpening head is used to polish and implant to treat the completed ilium. After washing, suture layer by layer incision (shown in **Figure 3**).

Group B

The surgical procedure is basically similar to that of group A, except that during the process of screw implantation, the surgeon performs the screw implantation based on the imaging examination and experience.

Postoperative treatment

(1) underwent cervical collar after fixation, cervical neutral position as far as possible, to avoid over extending through flexion; (2) dexamethasone and intravenous omeprazole in 2-3 days , prevention of surgery Spinal cord edema and stress ulcers caused by the operation, conventional anti-infection, nutritional nerve, analgesic drugs and other supportive treatment; (3) anterior surgery to strengthen oral care, surgical incisions are regularly cleaned and changed dressing, beware of oropharynx and Infection of the incision at the back of the neck; (4) Drainage is routinely placed, and the drainage volume is less than 50ml within 24 hours to remove, to avoid prolonged placement to increase the risk of infection.

Outcome evaluation index

All patients underwent cervical three-dimensional CT after operation, and based on the results of postoperative CT imaging Kawaguch method evaluates the accuracy of screw placement [7]. Grade 0 screws are defined as those without piercing the pedicle, grade 1 screws are defined as piercing the pedicle wall less than 2 mm without complications, and grade 2 screws are defined as piercing the pedicle wall more than 2 mm without complications occurrence, grade 3 screws are defined as the occurrence of related complications. This study classified grade 0 and 1 screws as high-quality screws. JOA (Japanese Orthopaedic Association Scores) score, ASIA score and VAS (Visual Analogue Scale) are commonly used evaluation indicators for evaluating patients after cervical spine surgery.

Statistical analysis

SPSS 20.0 statistical software was used to process the data. T test was used for measurement data, chi square test was used for counting data, $P < 0.05$ was considered to have statistical difference.

Clinical Outcomes

A total of 72 atlantoaxial pedicle screws were implanted, 40 in group A and 32 in group B. The accuracy rate of nail implantation was 97.50% in group A and 81.25% in group B ($P<0.05$) (shown in **Table 1**). The operation time in group A (189.7 ± 16.1 mins) and group B (242.1 ± 23.2 mins), $P<0.05$. The intraoperative blood loss in group A (216.0 ± 49.7) and group B (385.0 ± 23.5), $P<0.05$. The intraoperative fluoroscopic times was 8.7 ± 1.1 in group A and 30.0 ± 3.3 in group B ($P<0.05$) (shown in **Table 2**). Besides, the JOA, Asia and VAS scores of the two groups at one week after operation and the last follow-up were significantly different from those before operation. One week after operation, the JOA, Asia and VAS scores of group A were significantly better than those of group B, but there was no significant difference between the two groups at the last follow-up (shown in **Table 3**).

Postoperative complications

In group A, one patient experienced postoperative breathing difficulties and was transferred to the ICU for symptomatic treatment such as tracheostomy device ventilation and lumbar drainage, and was discharged after recovery; one patient developed posterior occipital skin necrosis, and healed after regular disinfection for 1 month. In group B, one patient developed fever after operation and recovered after active anti infection and dressing change; one patient developed limb weakness 5 months after operation, and imaging examination showed atlantoaxial dislocation again after admission. After improving the preoperative preparation, posterior occipitocervical fusion was performed. Cerebrospinal fluid leakage occurred after operation, and the symptoms disappeared after intensive dressing change.

Discussion

The upper cervical spine has a relatively large range of motion and assumes important functions such as rotation and flexion of the cervical spine, but due to its own anatomical specificity, the stability is relatively poor [8]. The deformity of the upper cervical spine is more likely to cause instability and abnormal development of the skeletal structure, which often leads to disturbance of the atlantoaxial joint alignment and atlantoaxial dislocation [8, 9]. Variations in these anatomical structures may cause the compression of the spinal cord to weaken the muscle strength of the limbs. In severe cases, it may cause paralysis or even death due to respiratory depression. Traditional conservative treatment methods are not effective, and long-term conservative treatment even delays the course of the disease, causing the patient to endure continuous pain and pressure. Therefore, once a patient is clinically diagnosed with an upper cervical spine deformity, it is particularly important to have an appropriate and effective treatment method as soon as possible. Clinically, active surgical interventions are taken to correct and maintain the unstable upper cervical spine sequence, and relieve the compression and invasion of the surrounding important tissues. Maintain the normal anatomical relationship of the vertebral body.

The use of the cervical spine posterior internal fixation system has become the most effective way to further maintain the normal anatomical relationship of the vertebral body after the atlantoaxial reduction. Initially, Gallie proposed the use of wire binding combined with autogenous iliac bone graft fusion, but this surgical method has many shortcomings[10], such as the biomechanical stability of internal fixation is poor, wire injury to the spinal cord, and high postoperative complications. In recent years, with the development of the medical device industry, pedicle screw technology has gradually become the main method of posterior cervical internal fixation[11]. However, the particularity of the anatomical structure of the pedicle of the atlantoaxial vertebra itself has higher requirements for pedicle fixation technology.

The traditional freehand method of nail placement is mainly based on the two-dimensional plane imaging data of the patient before the operation, and the relevant anatomical landmarks during the operation. The advantage is that it does not require expensive and sophisticated equipment to assist, even if the low-level hospital has mature technology can also be used. However, this method is difficult to place nails, the learning curve is steep, the operation process requires careful operation, and it has high requirements for the surgeon, and it relies too much on the previous experience of surgeon, so the accuracy of the nail placement is difficult to guarantee. In addition, a large number of X-ray fluoroscopy aids are required during the operation, which increases the number of radiation exposures of the patient and the surgical team[12]. Besides, the technique of freehand nail placement is highly subjective, and it takes a long time for the maturity of the technology. The computer-assisted nail placement method mainly relies on obtaining three-dimensional CT imaging data of the patient's upper cervical spine during the operation, importing it into the virtual software that comes with the computer navigation system for real-time reconstruction, avoiding important tissues such as nerves and blood vessels under computer guidance, select the best insertion point, and complete the screw insertion after the angle is adjusted. Richer et al. used computer technology to assist cervical pedicle screw placement, and the results showed that the failure rate of navigation screw placement was only 3% [13]. Shin et al. found that the application of navigation technology can reduce the probability of screw penetration of the pedicle, and reduce the nerve and blood vessel damage caused by screw placement [14]. However, computer-aided nail placement also has disadvantages. For example, the instrument is expensive and complicated, and the learning curve is steep[15]. Besides, the patient's posture cannot be changed during the operation, otherwise it needs to be re-positioned. 3D printing technology is to obtain three-dimensional CT data of the patient's upper cervical spine before surgery, reconstruct it in virtual software and use a 3D printer to make a model. Meanwhile, according to the anatomical characteristics of the posterior vertebral body of the upper cervical spine, a guide template for screw placement was designed to guide the precise and rapid placement of the screw during the operation.

Experience of upper cervical spine surgery

The 3D solid cervical spine model provides a visual aid very similar to the surgical object, which can eliminate individual differences in the understanding of two-dimensional images. The anatomical structure of the upper cervical spine deformity is complicated, and the surgical nail placement is difficult. A reasonable plan before the operation and simulated nail placement can increase the confidence of the surgical team and reduce the operation time.

Conclusions

Individualized 3D printing guide assisted placement of upper cervical pedicle screw can significantly improve the accuracy of screw implantation and postoperative function of patients, reduce the times of X-ray fluoroscopy, operation time, and intraoperative blood loss, which is a safe and effective approach and worthy of clinical promotion.

Abbreviations

JOA scores: Japanese Orthopaedic Association Scores; VAS: Visual Analogue Scale; Group A: Guide plate assisted screw implantation group; Group B: Traditional operation group.

Declarations

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Availability of data and materials

All data are fully available without restriction.

Author contribution

GQN and CL conceived of the design of the study. GQN, CL, GZ, HN, HC and TL participated in the operation. CL, LTL, JWZ, BYZ, JZ, RCY, and QKZ performed the data collection and statistical analysis. GQN, JZB, and CL finished the manuscript. GQN and JZB participated in the revision of the article. All authors read and approved the final manuscript.

Authors' information

The author information can be found in the title page.

Ethics approval and consent to participate

The study was approved by the ethics committee of our hospital

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Salunke P, Sahoo SK, Deepak AN, Ghuman MS, Khandelwal NK. Comprehensive drilling of the C1-2 facets to achieve direct posterior reduction in irreducible atlantoaxial dislocation. Journal of Neurosurgery-Spine. 2015;23(3):294–302.
2. Yun D-J, Hwang B-W, Kim DJ, Lee S-H. An Upper and Middle Cervical Spine Posterior Arch Defect Leading to Myelopathy and a Thoracic Spine Posterior Arch Defect, World Neurosurgery 93 (2016).
3. Bredow J, Meyer C, Siedek F, Neiss WF, Loehrer L, Mueller LP, Eysel P, Stein G. Accuracy of 3D fluoro-navigated anterior transpedicular screws in the subaxial cervical spine: an experimental study on human specimens. Eur Spine J. 2017;26(11):2934–40.
4. Wang J, Cai L, Xie L, Chen H, Guo X, Yu K. 3D printing-based Ganz approach for treatment of femoral head fractures: a prospective analysis, Journal of Orthopaedic Surgery and Research 14(1) (2019).
5. Cai L, Zhang Y, Chen C, Lou Y, Guo X, Wang J. 3D printing-based minimally invasive cannulated screw treatment of unstable pelvic fracture, Journal of Orthopaedic Surgery and Research 13 (2018).
6. Michalski MH, Ross JS. The Shape of Things to Come 3D Printing in Medicine. Jama-Journal of the American Medical Association. 2014;312(21):2213–4.
7. Kawaguchi Y, Nakano M, Yasuda T, Seki S, Hori T, Kimura T. Development of a New Technique for Pedicle Screw and Magerl Screw Insertion Using a 3-Dimensional Image Guide. Spine. 2012;37(23):1983–8.
8. Goel A, Patil A, Shah A, More S, Vutha R, Ranjan S. Alternative technique of C1-2-3 stabilization-sectioning of muscles attached to C2 spinous process and C2-3 fixation. Journal of craniovertebral junction spine. 2020;11(3):193–7.
9. Finn MA, Bishop FS, Dailey AT, SURGICAL TREATMENT OF OCCIPITOCERVICAL INSTABILITY, Neurosurgery 63(5) (2008) 961–968.
10. Coyne TJ, Fehlings GM, Wallace MC, Bernstein M, Tator CH. C1-C2 POSTERIOR CERVICAL FUSION - LONG-TERM EVALUATION OF RESULTS AND EFFICACY. Neurosurgery. 1995;37(4):688–92.
11. Ringel F, Reinke A, Stueer C, Meyer B, Stoffel M. Posterior C1-2 fusion with C1 lateral mass and C2 isthmic screws: accuracy of screw position, alignment and patient outcome. Acta Neurochir. 2012;154(2):305–12.
12. Zhou L-P, Zhang R-J, Sun Y-W, Zhang L, Shen C-L. Accuracy of Pedicle Screw Placement and Four Other Clinical Outcomes of Robotic Guidance Technique versus Computer-Assisted Navigation in Thoracolumbar Surgery: A Meta-Analysis. World Neurosurgery. 2021;146:E139–50.
13. Richter M, Cakir B, Schmidt R. Cervical pedicle screws: Conventional versus computer-assisted placement of cannulated screws. Spine. 2005;30(20):2280–7.
14. Shin BJ, James AR, Njoku IU, Haertl R. Pedicle screw navigation: a systematic review and meta-analysis of perforation risk for computer-navigated versus freehand insertion A review. Journal of Neurosurgery-Spine. 2012;17(2):113–22.
15. Sugawara T, Kaneyama S, Higashiyama N, Tamura S, Endo T, Takabatake M, Sumi M. Prospective Multicenter Study of a Multistep Screw Insertion Technique Using Patient-Specific Screw Guide Templates for the Cervical and Thoracic Spine. Spine. 2018;43(23):1685–94.

Tables

Table 1. Comparison of intraoperative outcomes between the two groups.

Group	Operation time (mins)	intraoperative blood loss (ml)	intraoperative fluoroscopic times (N)
Group A	189.7±16.1	216.0±49.7	8.7±1.1
Group B	242.1±23.2	385 .0±23.5	30.0±3.3
t value	-5.661	-8.823	-17.362
P value	0.001	0.001	0.001

Table 2. Comparison of the accuracy of implant screws between two groups.

Group	N	Grade 0 (%)	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	c_2 value	*P* value
Group A	40	34 □85.00 □	5□12.50 □	1□2.50 □	0	5.349	0.04
Group B	32	21 □65 .60 □	5□15.63 □	6□18.75 □	0		
N	72	55	10	7	0		

N: Total number of screws

Table 3. Comparison of JOA, Asia and VAS scores between the two groups.

Evaluating Indicator	Group A	Group B	*t* value	*P* value
Preoperative JOA score	9.70±1.57	8.75±0.89	1.525	0.147
Postoperative JOA score(one week)	12.10±2.33	10.13±1.25	2.154	0.047
Postoperative JOA score(last follow up)	15.30±1.57	14.75±1.49	0.756	0.46
Preoperative ASIA sensory score	197.20±18.07	194.00±13.82	0.413	0.685
Postoperative ASIA sensory score(one week)	215.40±6.95	207.00±6.32	2.65	0.017
Postoperative ASIA sensory score(last follow up)	220.80±5.85	220.00±4.90	0.316	0.756
Preoperative ASIA motor score	86.60±9.72	86.88±4.79	-0.073	0.943
Postoperative ASIA motor score(one week)	95.90±6.03	90.00±4.87	2.241	0.04
Postoperative ASIA motor score(last follow up)	98.70±2.00	98.63±1.77	0.083	0.935
Preoperative VAS score	5.30±1.50	6.125±1.36	-1.212	0.243
Postoperative VAS score(one week)	2.00±0.67	3.00±0.756	-2.981	0.009
Postoperative VAS score(last follow up)	0.70±0.82	1.00±0.76	-0.796	0.438

Figures

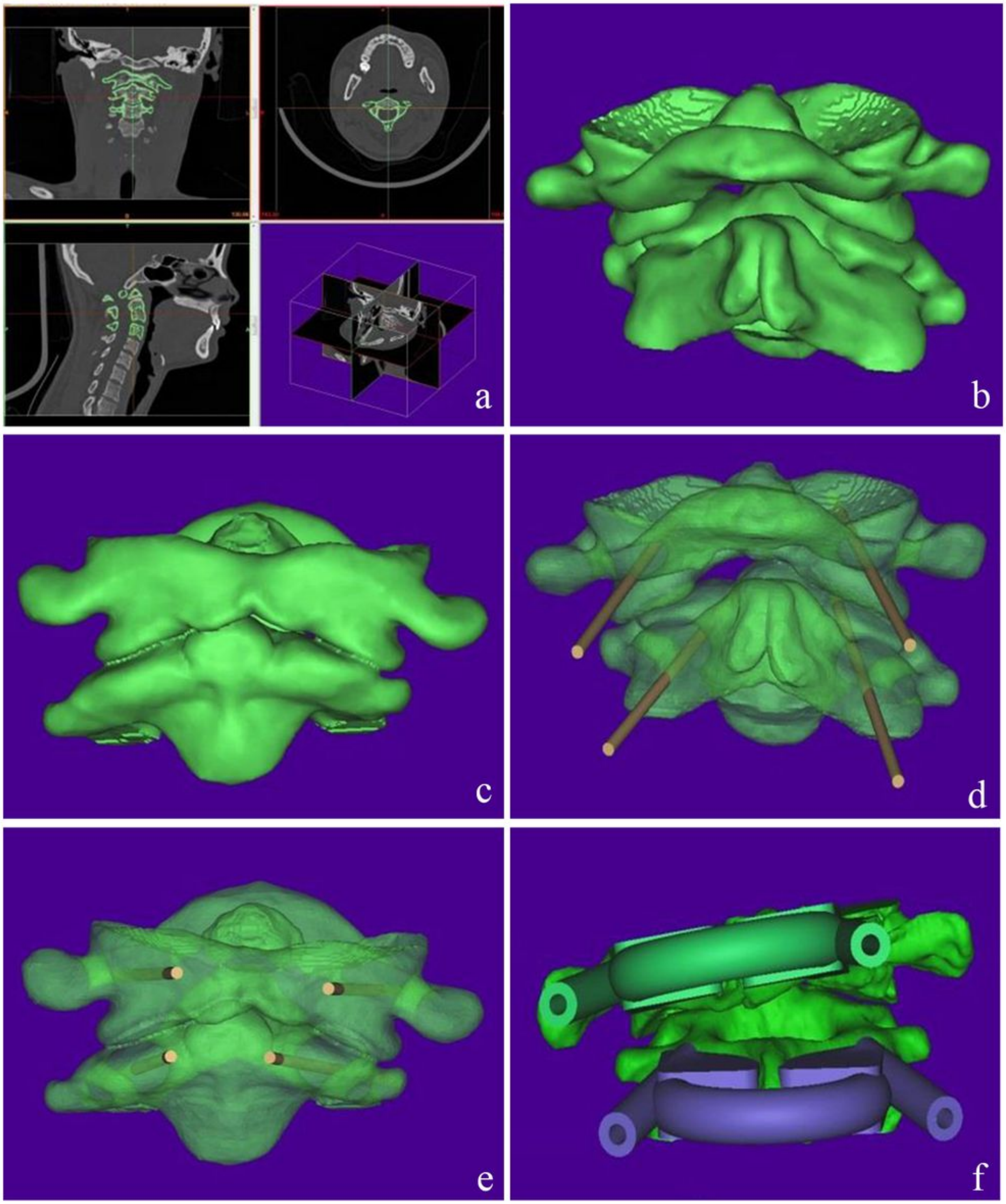

Figure 1

Import of CT data and manufacture of guide plate (a: import of CT data; bc: select the segments that need to be reconstructed; de: generation of virtual screws based on anatomical characteristics of atlantoaxial arch; f: design oriented template).

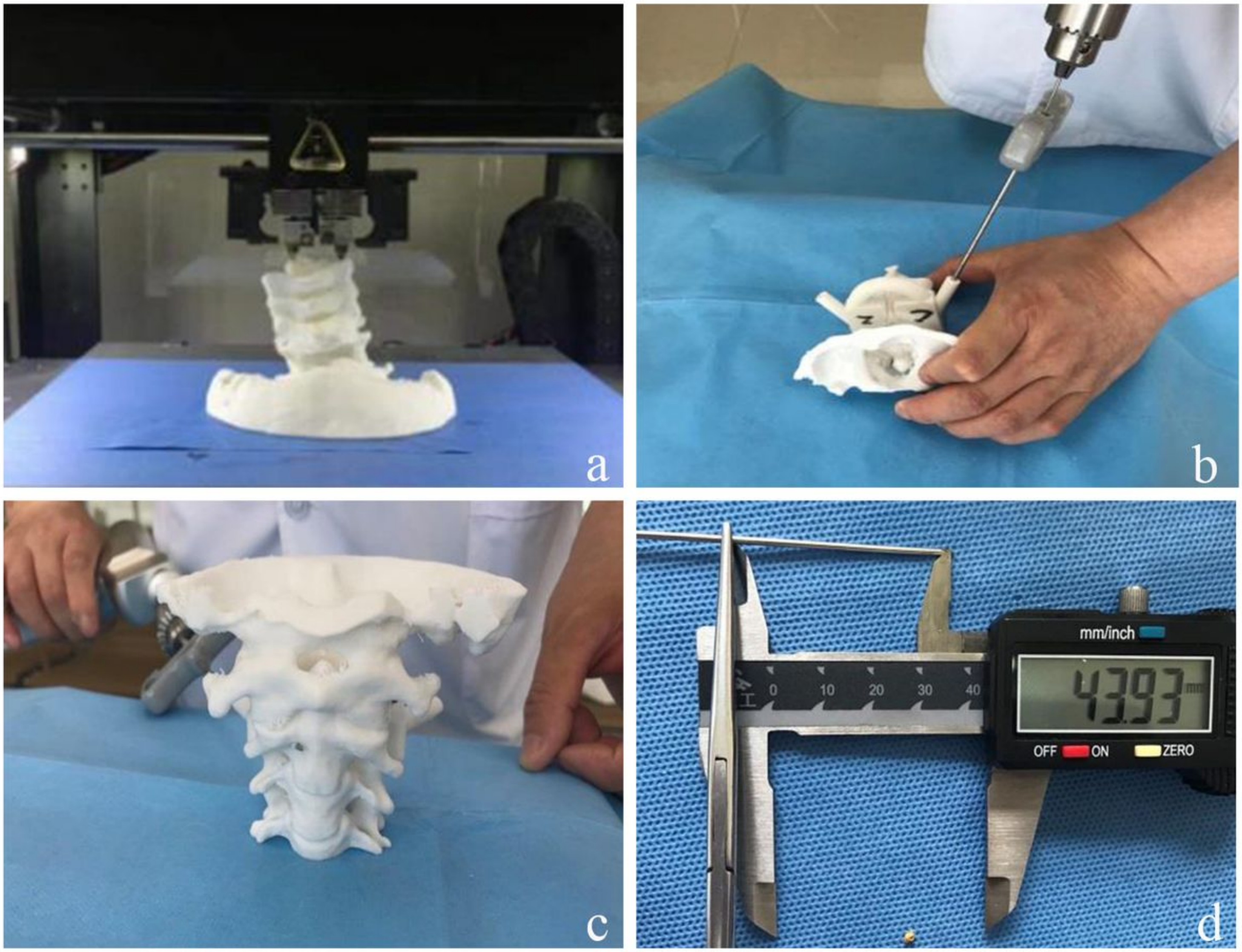

Figure 2

Preoperative simulation surgery (a: model making; b: use electric drilling under the protective sleeve; c: the Kirschner wires were all in the pedicle, indicating that the screw track was good; d: the length of Kirschner wire was recorded to provide reference for the selection of screws).

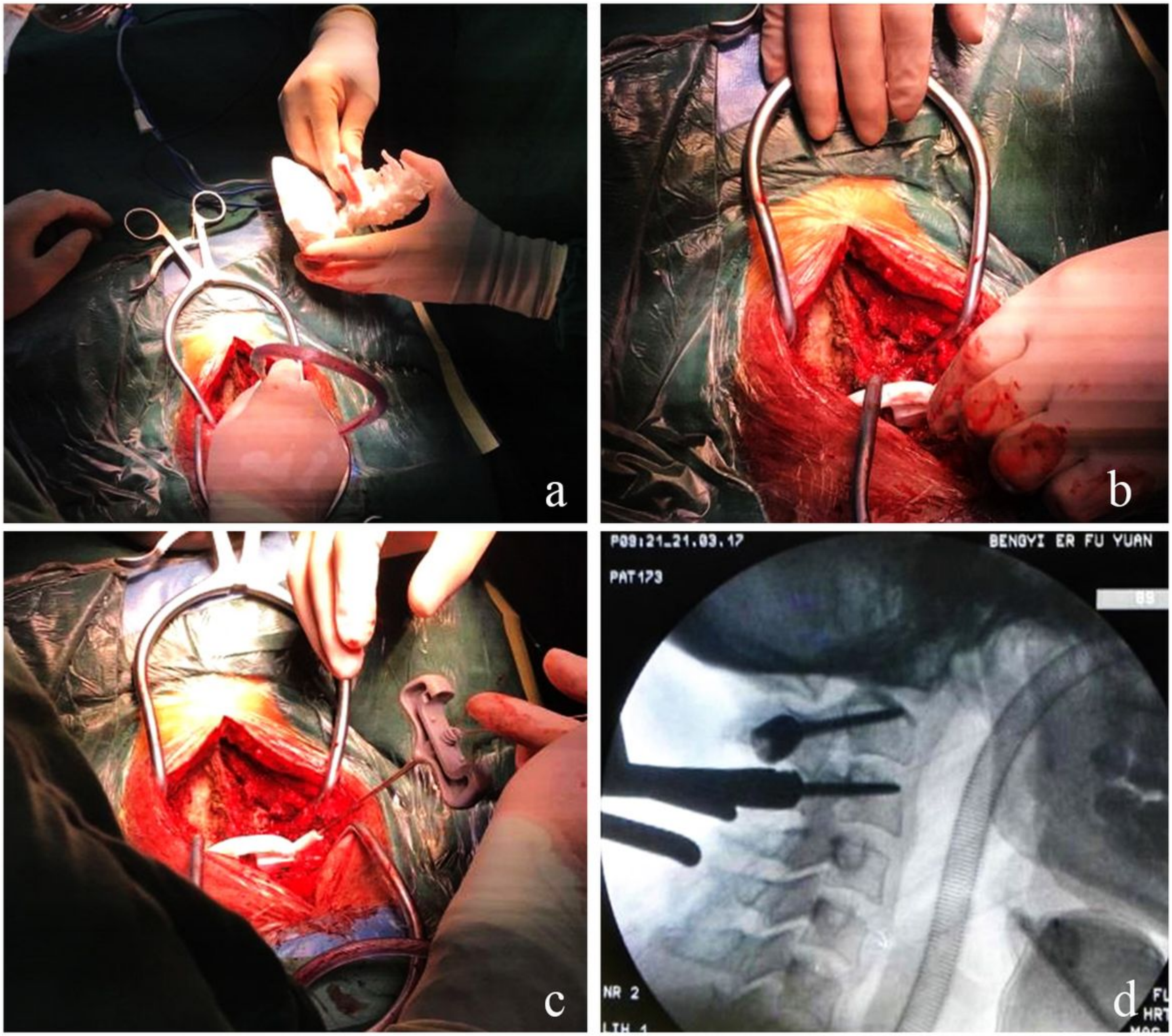

Figure 3

Operation process (a: the matching degree of guide plate was tested again before nailing; b: the corresponding segment guide template was attached after exposure of atlantoaxial vertebrae; c: drill the hole with Kirschner wire under the protective sleeve, and tap after the four walls are complete; d: intraoperative fluoroscopy was used to verify the accuracy of nail placement).