

A Minimally Invasive Technique Using Cortical Bone Trajectory Screws Assisted by 3D-Printed Navigation Templates in Lumbar Adjacent Segment Degeneration

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Abstract

Background: Revision surgery of adjacent segment degeneration (ASD) commonly need to expose and remove the original fixation. In order to minimize the trauma, reduce the operation time and blood loss, we introduce a minimally invasive lumbar revision technique using cortical bone trajectory (CBT) screws assisted by three-dimensional(3D) printed navigation templates.

Methods: From April 2017 to October 2019, 18 patients with ASD underwent revision surgery with CBT screws assisted by 3D-printed templates in our hospital. All the operation data, including operation time, blood loss, incision length were recorded. We evaluated the clinical efficacy using the visual analogue scale (VAS), the Oswestry Disability Index (ODI), and the Japanese Orthopedic Association (JOA) score. X-ray and Computed Tomography (CT) scans were used to evaluate the stability of CBT screws fixation, the accuracy of screws, and the fusion rate.

Results: The mean follow-up was 22.4 ± 4.7 months (12-31m), the VAS, ODI, and JOA score were analyzed by SPSS 21.0 and showed significant improvement at 2-weeks and the last follow-up compared with preoperative data($P < 0.05$). 76 CBT screws were inserted with navigation templates, 2 screws were Grade B, other screws were all Grade 0 or A. Changes of intervertebral height showed good stability of CBT screws fixation($P > 0.05$). All the patients had satisfactory fusion results.

Conclusion: Revision surgery of ASD with CBT screws assisted by 3D-printed navigation templates has satisfactory clinical efficacy with advantages of the short operation time, small incision, and less blood loss.

Background

Lumbar fusion with pedicle screw fixation is widely used in lumbar degenerative diseases due to its definite clinic efficacy. However, because of the local biomechanical structure changes caused by exposure, iatrogenic injury to facet joints, and fusion, adjacent segment degeneration(ASD) is regarded as common long-term complication of fusion surgery [1]. Recently, a meta-analysis reported that the incidence of radiological adjacent segment disease (R-ASD) was 36.4%, the incidence of symptomatic adjacent segment disease (S-ASD) was 7.6%, and the revision surgery rate was 4.6% [2].

For patients with obvious clinical symptoms and requiring revision surgery, we routinely need to remove the original connecting rod and reinstall the rod after inserting the new screws in the adjacent vertebra. The operation needs to expose the original surgical incision, which is more traumatic, bleeding, and takes a long time. The incidence of postoperative pain and infection is relatively high. Some scholars respectively reported that the cortical bone trajectory (CBT) screws could be inserted into the segment which has been inserted original pedicle screw before by free-hand technique or using the intraoperative navigation system, in this way, they did the revision surgery without removing the original connecting rods, and satisfactory clinical results were achieved [3, 4]. However, because the original pedicle screw occupies the space of the pedicle, inserting CBT screws in the same pedicle requires high accuracy. The

free-hand technique is likely to cause complications related to internal fixation, including nerves and blood vessel damage, etc. Intraoperative navigation technology requires high costs, increasing the operation time and the patient's radiation exposure. Considering that 3D printing technology is very mature and widely used in spine surgery, we used 3D printing technology to make screw navigation templates to assist CBT screws placement and achieved satisfactory clinical effects. The report is as follows.

Methods

Patients

This study reviewed a total of 18 patients (M: F=7:11) with an average age of 67.1 years (range from 54 to 79 years old) of ASD from April 2017 to October 2019 in our hospital that underwent revision surgery using CBT screws and 3D-printed navigation templates. One patient had ASD combined with thoracic spinal stenosis and underwent ASD revision combined with thoracic spinal canal decompression and fixation; Another patient had ASD both on cephalad and caudal sides of the original operation segments; the rest of the patients had unilateral (cephalad or caudal) ASD and received one segment revision surgery (**Table 1**).

Preoperative planning & 3D printing

All patients underwent a thin-slice CT scan (1mm) before the operation, and imported the data into Mimics 20.0 (Materialistic, Belgium) software for three-dimensional reconstruction. Drawing a 4.75mm diameter cylinder simulating the CBT screw, and planning the trajectory through the axial, sagittal, and coronal perspectives to make sure that the CBT screw is not in contact with the original pedicle screw as well as to stay close to the pedicle cortex (**Figure 1**). Making a 2.7mm diameter drill guide hole in the 4.75mm-cylinder, and using the spinous process, the lamina and the original pedicle screw as the contact point to make the contact surface of the navigation template. Combining the drill guide hole and the contact surface, and making a connect bridge between the contact surface on both sides, so that the navigation template was completed. Printing and sterilizing the template before surgery.

Surgical Procedure & Postoperative care

After general anesthesia, the patient lay prone on the spine operating table, exposed the lamina isthmus and the inner edge of the facet joint. Carefully cleaned the soft tissue to ensure that the screw navigation template is fully attached to the bone surface and the original screws. Drilled and tapped along the pilot hole, carefully probed the screw path with a ball-tip probe to confirm that the four walls of the pedicle are complete and inserted a 4.75mm diameter CBT screw. The posterior decompression, intervertebral bone grafting were continued conventionally, and one cage was inserted (if the CBT screw affects the cage implantation, the cage was implanted first, then the screw was inserted). The position of the screw and cage was satisfied by fluoroscopy. After flushing, the drainage tube was inserted and the wound was sutured. On the second day after the operation, the drainage tube was pulled out. On the third day, the

patients would get off the bed with the waist brace protecting. Typical cases are shown in Figure 2, 3, 4 (Figure 2-4).

Evaluation

All operative data including operation time, incision length, estimated bleeding volume, etc. were recorded. The visual analogue scale (VAS), the Oswestry Disability Index (ODI), and the Japanese Orthopedic Association (JOA) score were assessed before the surgery, 2 weeks after the surgery and the last follow-up to evaluate the clinical efficacy. Intervertebral heights were measured as the average height of the anterior and posterior intervertebral space by lateral X-ray before the surgery, 2 weeks after the surgery and the last follow-up to evaluate the stability of fixation [5, 6]. CT scans were taken at the last follow-up to evaluate the position of the screws and the fusion of the surgical segment.

Statistical analysis

Statistical analysis was performed with SPSS 21.0 (SPSS, Inc. Chicago, IL, USA). All the general information and operative data were expressed as the mean \pm standard deviation (SD). Measurement data were compared using paired t-test. Wilcoxon Signed Ranks test was used for nonparametric comparisons. $P < 0.05$ was considered statistically significant.

Result And Follow-up

A total of 76 CBT screws were inserted in 18 patients by the same surgical team (average surgery experience more than 10 years) using 3D-printed navigation templates. The average operation time was 154 ± 58 min, the blood loss was 144 ± 176 ml, and the incision length was 6.8 ± 4.2 cm (**Table 1**). According to the standard proposed by Gertzbein [7], 54 screws were classified into Grade 0, 20 screws were classified into Grade A, 2 screws were classified into Grade B, and no screw was classified into Grade C. One patient had left radicular pain after surgery. CT scan showed that one CBT screw broke through the inferior wall of the pedicle. The symptoms were relieved after the second operation to adjust the screw position. One patient had a rupture of the spine dura mater and leakage of cerebrospinal fluid due to scar adhesion during the operation. The dura mater was repaired, and the drainage tube was removed after lying in bed for a week after the operation. One patient had a postoperative fever and painful urination, and the urine routine test suggested the urinary system infection. The infection improved after levofloxacin anti-infective treatment. The remaining patients had no perioperative complications.

The mean follow-up time was 22.4 ± 4.7 months (12-31m). The VAS(score) was 6.6 ± 1.2 before the operation, 3.3 ± 2.0 2-week after the operation, and 1.6 ± 1.0 at the last follow-up. The ODI(%) was 43.9 ± 9.4 before the operation, 24.6 ± 5.1 at 2-week after the operation, and 12.8 ± 3.9 at the last follow-up. The JOA score was 14.6 ± 2.9 before the operation, 20.5 ± 5.1 at 2-week after the operation, and 23.8 ± 1.5 at the last follow-up. The VAS, ODI, and JOA score were statistically significant at 2-week after the operation and the last follow-up compared with the data before the operation ($P < 0.05$). The intervertebral height(mm) before the operation, 2-week after the operation, and the last follow-up were 7.8 ± 2.3 , 10.8 ± 1.3 , 10.5 ± 1.4 ,

respectively. Compared with pre-operation, the intervertebral height was statistically different at 2 weeks and the last follow-up ($P < 0.05$), but there was no statistical difference between the 2-week and the last follow-up ($P > 0.05$). (**Figure 5**). All patients achieved satisfactory fusion at the last follow-up.

Discussion

CBT screw was first used for posterior spinal fixation in patients with osteoporosis reported by Santoni et al., which has the characteristics of maximizing contact with cortical bone [8]. Because it has a medial-to-lateral direction and a caudocephalad trajectory, the CBT screw can reduce soft tissue separation, minimize trauma and blood loss, shorten the operation time [9]. Sakaura et al. found that CBT can reduce the incidence of radiological adjacent segment disease changes (R-ASD) and symptomatic adjacent segment disease (S-ASD) by protecting cephalic facet joints [10]. Biomechanical studies have shown that CBT screws have 1.7 times the pull-out resistance of traditional pedicle screws [11], and the clinical efficacy in posterior lumbar fusion is equivalent to that of traditional pedicle screws [12], as an alternative technique of internal fixation of the spine, the CBT screw has been highly concerned by orthopedic surgeons.

In recent years, some scholars have adopted the method of simultaneously inserting pedicle screws and CBT screws in the same pedicle to solve some complicated spinal diseases. Ueno used the double-trajectory technique in a patient with severe osteoporosis and achieved satisfaction fixed effects [13]. Analiz Rodriguez et al. used a navigation system to insert CBT screws in the same pedicle with pedicle screw to procedure the revision surgery of ASD, as well as Chen et al. used free-hand technique, they both achieved satisfactory results [3, 4]. Obviously, the CBT screw used for ASD revision surgery does not need to remove the original fixation, which has many advantages such as small surgical incision, more minor trauma, short operation time, and less blood loss, etc. The longer the original surgical segment, the more apparent these advantages.

However, the difficulty of this procedure was that the pedicle screw and CBT screw were placed in the same pedicle at the same time. Although the pedicle screw and CBT screw have different start points and trajectories, in many cases, these two screw placement channels still will be a certain degree of overlap, and the double screws will collide in the pedicle (**Figure 6**). After radiological measurements and research, Mullin found that the success rate of inserting the pedicle screw and CBT screw in the same pedicle is about 50% [14], so it is essential to analyze CT carefully before surgery and plan a feasible screw placement trajectory. Intraoperative navigation system had been used to improve the accuracy of screw placement [3]. However, the navigation system is expensive and complicated to operate, it generally requires special operating room layout and technical personnel to assist operations, and the use of navigation system is reported to have higher radiation exposure [15]. More importantly, even if the preoperative CT scan is confirmed to have a feasible screw trajectory, it is still challenging to find the trajectory again during the operation. Due to the influence of factors such as the surgical position and the positioning of the navigation system, the trajectory may be different from the preoperative planning, and

the optimal trajectory may deviate. When the optimal trajectory has been selected with preoperative CT, the production of navigation templates is a very mature technology with low cost.

The use of individual templates in orthopedic was first reported by Radermacher in 1998 [16]. With the improvement of 3D printing technology, it has been used more widely nowadays, especially in spine surgery. The technology of making screw navigation templates is mature and relatively economical. Many researchers use 3D printing technology to make navigation templates to assist the placement of cervical pedicle screws, thoracic pedicle screws, CBT screws, or assist screw placement in special cases such as severe spinal deformity and complex revision surgery, which have been proven to have higher accuracy and safety and help reduce the radiation exposure of both the patients and operating room staff [17-20]. In this study, we used 3D printed navigation templates to assist the placement of CBT screws in the vertebral body which has been inserted pedicle screw in 18 cases, and the rest of the surgical procedures were the same as conventional techniques. Compared with the navigation technology, our operation time is shorter (154 ± 58 min), and the blood loss during the operation is less (144 ± 176 ml) [3]. The cost of making the navigation template is relatively low. We estimate that the cost of making the navigation template is 400 dollars per segment, and the cost of using CT navigation equipment may be as high as 1500-2000 dollars. The work of making the navigation template is completed before the operation. Although the workload is slightly increased, there are almost no extra steps during the operation. In addition, this technique doesn't have any extra learning curves, and 3D-printing devices are easy to get (or print the navigation templates by a cooperation company). Considering factors such as difficulty and cost. We believe that screw placement assisted by the 3D-printed navigation template has certain advantages compared with the intraoperative CT navigation system, and it is easier to be promoted and applied, especially in primary hospitals.

In this study, the newly inserted CBT screws run along the superior or inferior of the original pedicle screw from the inner to the outer side, mainly based on preoperative CT planning, the space that allows the new CBT screw to be inserted (**Figure 6**). In the preoperative planning, some of the CBT screws could not reach the cortical bone of the superior endplate because of the original pedicle screws blocking. We increased the abduction angle of the screw so that the screw just reached or penetrated the pedicle and the outer edge of the vertebral cortex, considering that there are no essential nerves, blood vessels and other anatomical structures, the screw fixation strength can be increased to prevent internal fixation failure. This increases the number of screws which is classified into Grade A-B when we evaluate the accuracy of the screw after surgery, but because most of our screws slightly break through the outer wall of the pedicle at the end, except for one Grade B screw, which had nerve root stimulation after breaking through the inferior wall of the pedicle, none of the other screws have caused postoperative complications related to internal fixation. Ueno reported that the starting point of the newly inserted CBT screw based on the original pedicle screw should be located above of the conventional CBT screws, so the CBT screws will run along the superior of the original pedicle screw [13], but in this way the CBT screw cannot interact with the inner and inferior wall of the pedicle, which may weaken the fixation strength of the screw. It is also reported in the literature that the CBT screw should be run obliquely from the inner and inferior of the pedicle screw to the outer and superior so that the screw has a stronger fixation strength [21]. However,

this may be limited by the size of the pedicle and the position of the original pedicle screw, and because the nerve root is often close to the inner and inferior wall of the pedicle, this method of screw placement is more likely to cause nerve injury. One of our patients had right pedicle pain after surgery. Considering that the CBT screw broke through the inner and inferior wall of the pedicle. In our study, we evaluated the stability of fixation by measured the intervertebral height pre-and postoperative, the result showed that the postoperative and the last follow-up intervertebral height were significantly greater than that before the operation. Meanwhile, the postoperative data and the last follow-up data had no statistical difference. The CT scan also showed good fusion at the last follow-up, so we considered that the fixation using CBT screws had satisfactory stability. But this method should be testified by biomechanics test in the future.

The accurate attachment of the navigation template is the key to the accuracy of the screw position. In an RCT study of 3D-printed navigation template assisted screw placement in patients with spinal deformity, Riccardo et al. reported that 9.8% of the screws in the 3D printed navigation template group were graded as Grade B or C [17], Evan D. Sheha believes that this situation is mainly due to the poor fit between the navigation template and the bone surface [22]. According to this study, we summarize the experience in the process of making the navigation template: Because the facet joints of the revision surgery are mostly damaged during the first operation, and the surrounding soft tissues and scars are severely proliferated, it is difficult to clean the surface of the facet joint during the revision process, so it is not suitable as a navigation template attachment point, in contrast, the original internal fixation screws fixed in position and the surface soft tissue is easy to clean and remove. In Mimics modeling, due to the high Hounsfield Unit(HU) of original screws on CT, the density of the surrounding soft tissue and bone tissue differs, the boundary is clear and the modeling accuracy is high. Therefore, we used the inner edge of the original fixation screw and the spinous process bone surface as the main contact surface of the screw navigation template. Meanwhile, a connect bridge was necessary because it could also increase the stability of the navigation template.

Limitation

There have been some limitations of this study. Firstly, this study is a retrospective study, and there is no control group, and the total number of cases is only 18. Although 18 patients achieved satisfactory fusion at the last follow-up, future studies with larger sample sizes are needed to validate the fusion rate due to the small number of cases. Secondly, the CBT screws cannot always be used for the revision surgery of adjacent segments because of its anatomical limitations. Despite that, we still recommend this technique for clinical application because multiple studies including us have confirmed the good clinical results [3,4]. Once the screws were inserted by the above-mentioned technique successfully, the patient will benefit greatly. Thirdly, due to the existence of the original pedicle screw, the trajectory of the CBT needs to be compromised, which may cause some CBT screws to fail to achieve the maximum cortical contact as it was said that the "4-point cortical contact" [23], systematic biomechanical stability research of this fixation method is required in the future.

Conclusion

CBT screw revision ASD greatly optimizes the operation plan because it does not need to remove the original fixation. The application of 3D-printed navigation template to assist the placement of CBT screws can be planned before surgery and accurately placed during surgery. The 3D printing technology is mature and low in cost. It is worth being promoted and applied in ASD revision surgery. As a new type of internal fixation with a different insertion point and trajectory from traditional pedicle screws, CBT screws may co-exist with the pedicle screw in the same pedicle, it greatly expands the internal fixation and its connection. The method can play a variety of roles in complex spinal diseases and should be further explored and applied.

Abbreviations

ASD: adjacent segment degeneration; CBT: cortical bone trajectory; 3D: three-dimensional; VAS: visual analogue scale; ODI: Oswestry Disability Index; JOA: Japanese Orthopedic Association; CT: Computed Tomography; MRI: Magnetic Resonance Imaging; R-ASD: radiological adjacent segment disease; S-ASD: symptomatic adjacent segment disease

Declarations

Ethics approval and Consent to participate: This retrospective study was approved by the institutional ethics committee of the China-Japan Friendship Hospital. Informed consent was obtained from patient included in the study.

Consent for publication: This study has obtained the consent for publication from all participations.

Availability of data and material: The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no conflict of interest.

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Author's contributions: Kun He, Chunke Dong and Hongyu Wei participated in concept development, data generation, quality control of the data, data analysis and interpretation, and writing of the manuscript, they contributed equally to this study and should be considered co-first authors. Feng Yang, Haoning Ma and Xiangsheng Tang participated in data collection and analysis. Mingsheng Tan and Ping Yi were involved in the concept development, quality control of the data, and data analysis and interpretation of the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1 General information and operative data of 18 patients

Case No.	Age(years)/Sex	Previous Fusion Levels	Surgery Levels	Operative Time(min)	Estimated blood loss(ml)	Incision Length(cm)	Hospital Days(d)
1	67/M	L4-S1	L3-4	140	50	6	15
2	63/F	L4-5	L3-4	110	50	5	13
3	72/F	L4-5	L3-4	120	50	5	33
4	58/F	L5-S1	L4-5	120	75	6	7
5	66/F	L3-4	L2-S1	240	350	14	19
6	59/M	L3-5	L2-3	150	200	8	12
7	62/F	L2-S1	T9-L1	360	800	22	36
8	65/M	L4-S1	L3-4	160	100	6	14
9	79/M	L4-5	L5-S1	120	20	5	9
10	54/F	L3-4	L4-5	120	75	5	9
11	76/M	L3-5	L5-S1	170	200	6	13
12	66/M	L5-S1	L4-5	150	100	6	12
13	71/F	L2-5	L5-S1	140	50	4	8
14	60/F	L4-S1	L3-4	130	50	4	10
15	76/F	L4-5	L5-S1	160	75	5	9
16	70/F	L3-S1	L2-3	120	150	4	9
17	67/M	L2-5	L5-S1	140	100	6	11
18	69/F	L3-5	L5-S1	130	100	6	11

Figures

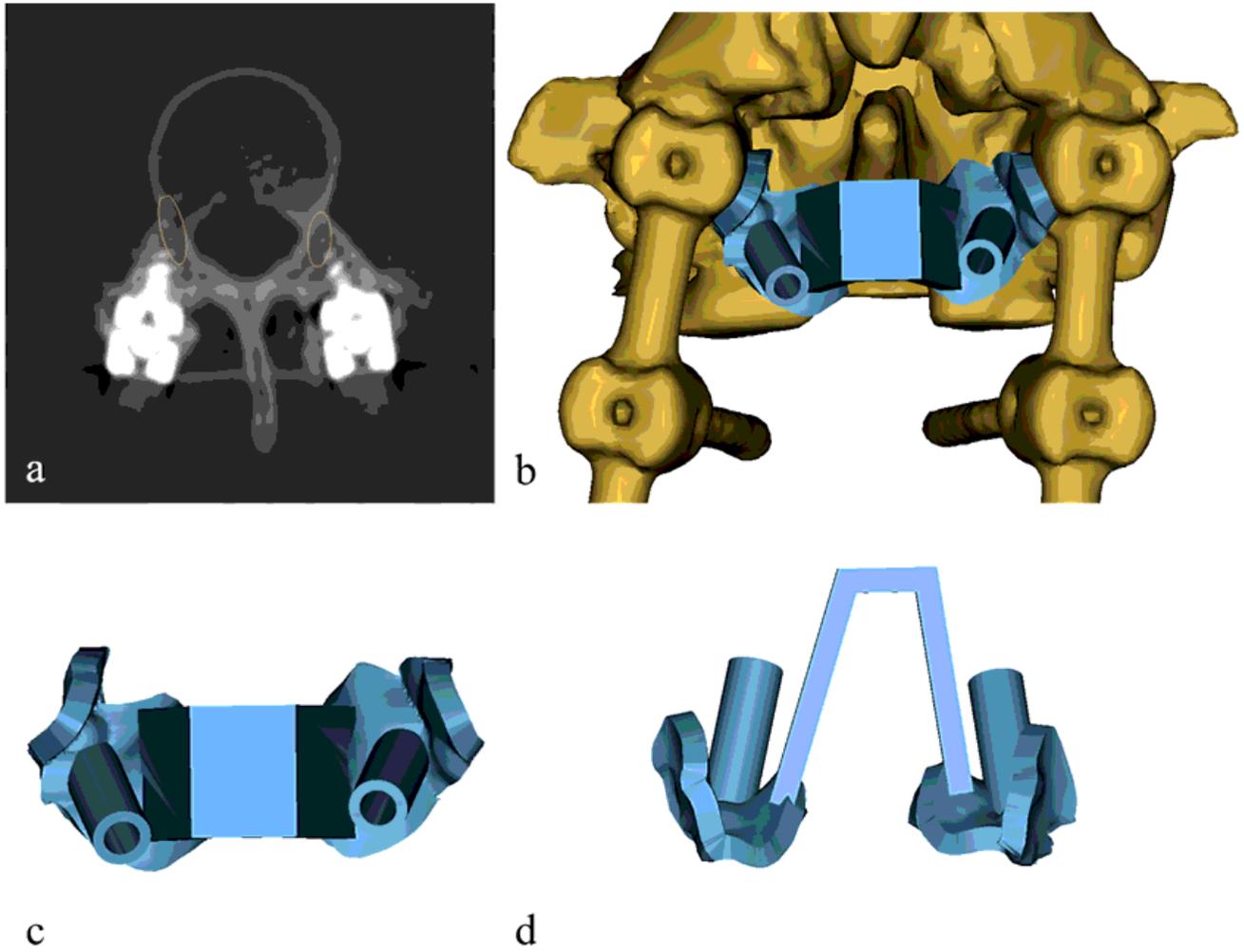


Figure 1

Preoperative planning and the 3D model of the navigation template. (a) The yellow ellipses indicated the CBT screws trajectory planned before the surgery. (b) The navigation template with the segment with original pedicle screw reconstructed by Mimics. (c, d) The top and back view of the navigation template

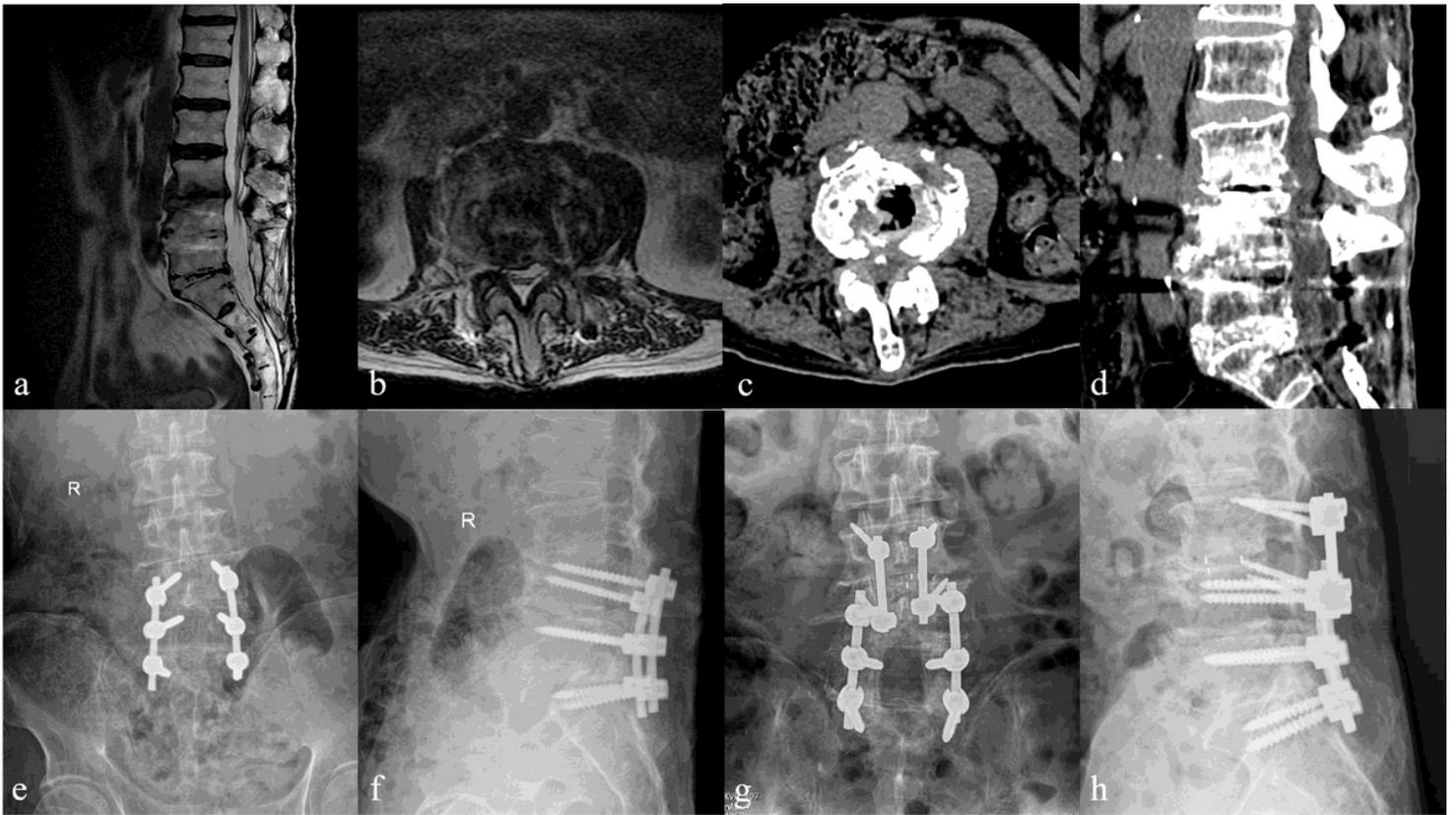


Figure 2

Case 1. A 77-year-old man with ASD of L3-4, and underwent the revision surgery with CBT screws assisted by navigation template. (a-d) Preoperative MRI and CT scan show L3/4 intervertebral disc herniation and calcification. (e-h) His pre-and the last follow-up X-ray showed the CBT screws as the fixation method of L3/4

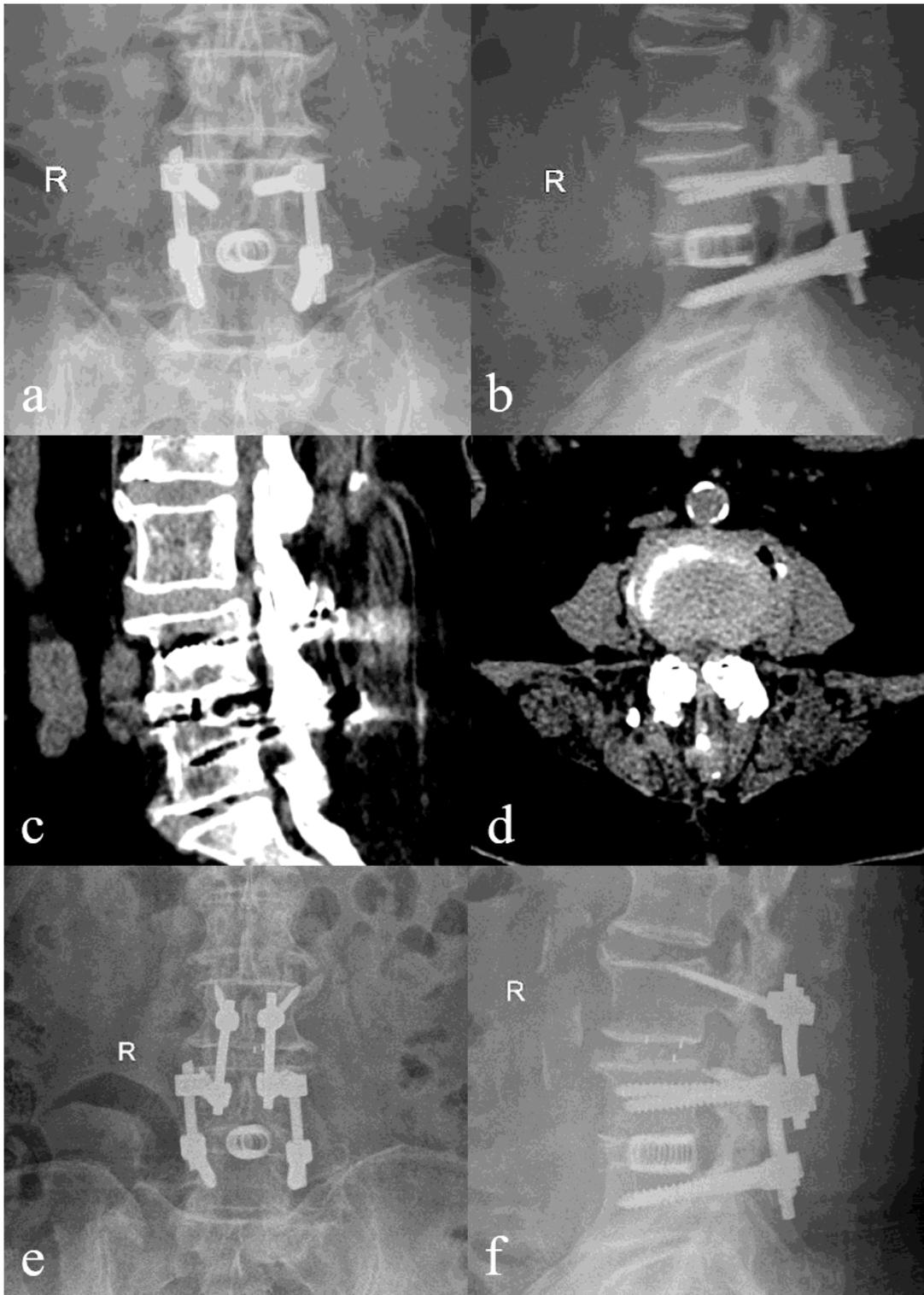


Figure 3

Case 2. A 63-year-old female underwent L4/5 fusion 5 years ago. She had radiation pain of left lower limb for half a year and diagnosed as ASD of L3/4. (a, b) Preoperative X-ray showed the original pedicle screws and cage in L4/5. (c, d) Preoperative CT showed L3/4 intervertebral disc herniation. (e, f) X-ray at the last follow-up showed the good position of CBT screws



Figure 4

Case 3. A 58-year-old female underwent L5/S1 fusion before. She had ASD of L4/5 this time. (a) Preoperative X-ray showed original fixation of L5/S1. (b) Preoperative MRI showed a herniated disc into the spinal canal. (c, d) X-ray at the last follow-up showed the good position of CBT screws

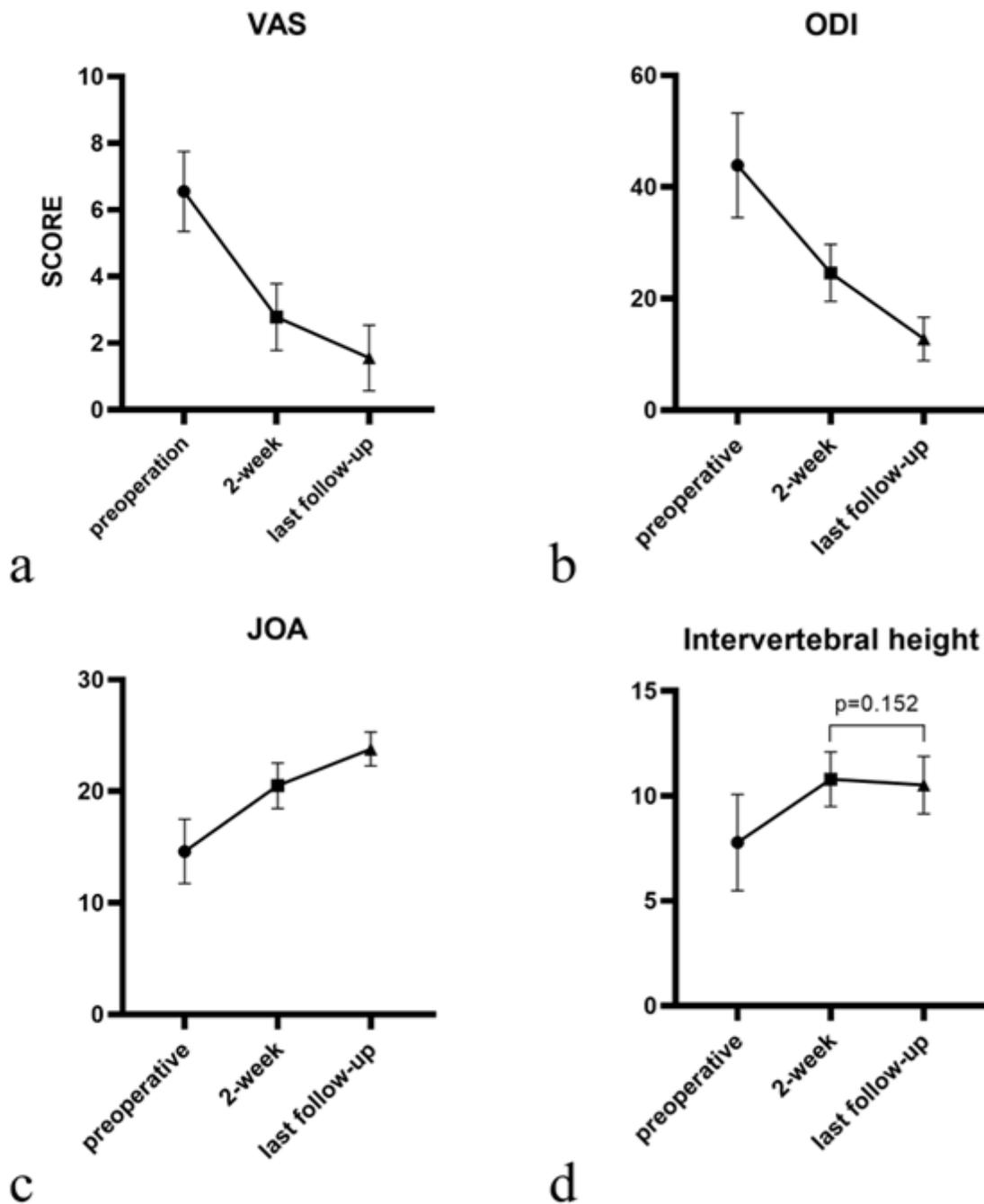


Figure 5

The VAS, ODI, JOA score, and intervertebral height in different assessments. (a) TVAS before the operation, 2-week after the operation, and the last follow-up were 6.6 ± 1.2 , 3.3 ± 2.0 , 1.6 ± 1.0 , respectively; (b) ODI before the operation, 2-week after the operation, and the last follow-up were 43.9 ± 9.4 , 24.6 ± 5.1 , 12.8 ± 3.9 , respectively; (c) JOA score before the operation, 2-week after the operation, and the last follow-up were 14.6 ± 2.9 , 20.5 ± 5.1 , 23.8 ± 1.5 , respectively. They are all statistically significant ($P < 0.05$). (d) The intervertebral height (mm) before the operation, 2-week after the operation, and the last follow-up were

7.8±2.3, 10.8±1.3, 10.5±1.4, respectively. There was no statistical difference between 2-week and the last follow-up(P>0.05)

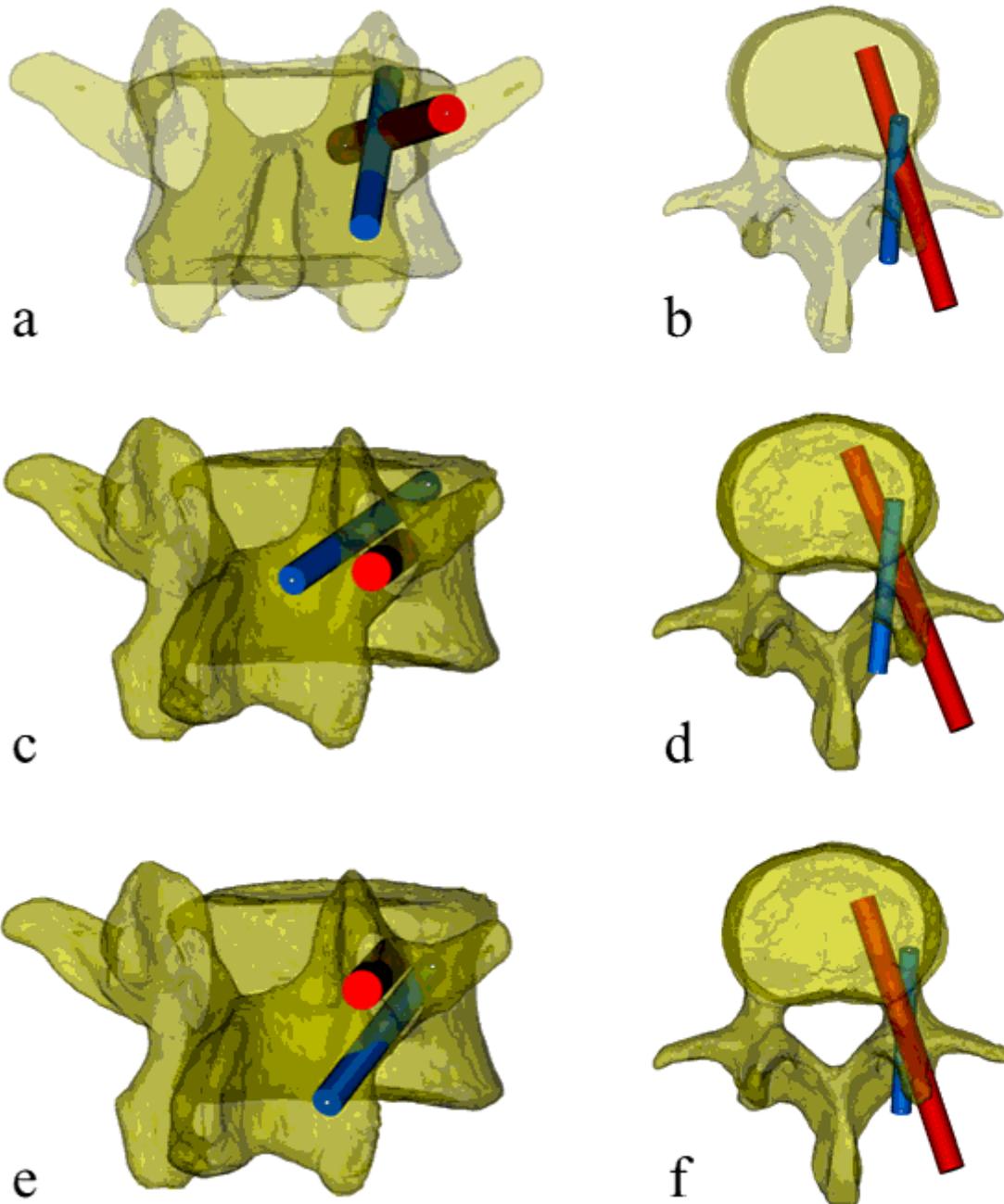


Figure 6

The trajectory relationship between pedicle screw and CBT screw, the red cylinder represents the pedicle screw, and the blue cylinder represents the CBT screw. (a, b) Using standard screw placement technique, the trajectories of pedicle screws and CBT screws partially overlap in the pedicle. (c, d) The original pedicle is closed to the inferior wall of the pedicle, the new CBT screw will walk along superior of the

original pedicle screw. (e, f) The original pedicle is closed to the superior wall of the pedicle, and the new CBT screw will walk under the original pedicle screw