Clinical efficacy analysis of the new PRUNUS spine plate system for anterior cervical spine surgery

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Abstract

BACKGROUND To observed and evaluated the clinical efficacy of a new type cervical anterior screw plate system development for anterior cervical surgery.

Methods 27 patients with cervical spine disease treated with new PRUNUS nail plate internal fixation were selected as observation group, and 29 patients treated with conventional cervical anterior screw fixation were selected as the control group. Cervical stability, internal fixation position and bone graft fusion were evaluated according to imaging data. The operative time, intraoperative blood loss, cervical Cobb angle, VAS scores, and JOA scores were compared between the two groups. Spinal function scores and neurological improvement rates were used to evaluate the clinical efficacy of the new PRUNUS spine plate.

Results There were statistical differences in operation time and blood loss between the two groups ($P<0.05$). The difference in Cobb angle, JOA score and improvement rate, VAS score before and after surgery in two groups were statistically significant ($P<0.05$), but no significant differences between two groups ($P>0.05$).

Conclusion The new PRUNUS spine plate system can be applied to the anterior cervical spine surgery, and its clinical efficacy was similar to the traditional cervical anterior plate. But PRUNUS simplified the operation process, especially for the osteoporosis patients.

Background

With the transformation of people's living habits and working methods, cervical-vertebral-related diseases such as cervical spondylosis and cervical trauma fractures have gradually become common clinical diseases. Surgical treatment is recommended as the therapeutic choice for patients with cervical spondylotic myelopathy who were unresponsive to regular conservative treatment. Since Bohler [1] first used the screw-plate system for anterior cervical fixation, and so the anterior cervical plate system has been improved in research and application in the following years.

Although the application of the screw-plate system for anterior cervical fixation showed good clinical results [2-3], other postoperative complications may occur, including spinal injury, plate displacement, screw loosening and plate or screw fracture. Hence, the revision of the surgeries has been increased [4-5]. To solve the technical issues associated with plate displacement and screw loosening, scientific research has provided a new type of PRUNUS screw-plate system that is used for the anterior cervical vertebral surgery. Our study aimed to observe its clinical efficacy and explore the clinical application of the PRUNUS screw-plate system and its advantages.

Methods

Clinical materials

27 patients with cervical spine disease treated with anterior cervical decompression, cage or titanium mesh graft fusion, and new PRUNUS nail plate internal fixation were selected (observation group) from the Department of Orthopedics in our hospital from June 2016 to October 2017. Of these, 15 were male and 12 were female, with a mean age of 63.6 years, range 42-82 years. Nine patients had cervical spine fracture or dislocation (Frankel grade A 4 cases, B grade 2 cases, and D grade 4 cases), 11 patients had cervical spondylosis, 5 patients had postoperative revision surgery and 2 patients had a cervical vertebral metastatic tumour. The disease duration ranged from 2 days to 19 years with an average of 39.37 months. At the same time, 29 patients with cervical spine disease treated with cervical anterior decompression, cage or titanium mesh graft fusion, and conventional cervical anterior screw fixation were selected as the control group. Of these, 17 were male and 12 were female, with an average age of 65.9 years, range 39-85 years old. Eight patients had cervical spine fracture or dislocation (Frankel grade A 2 cases, B grade 2 cases, and D grade 4 cases), 19 patients had cervical spondylosis, 1 patient had postoperative revision surgery and 1 patient had cervical tuberculosis. The duration of the disease ranged from 3 days to 21 years with an average of 25.32 months. The inclusion criteria were as follows: (1) patients met the symptoms and signs of cervical spondylosis, cervical fracture, cervical disc herniation, cervical spondylitis or brucellosis, confirmed by imaging and neurophysiological examinations. (2) patients treated with anterior cervical surgery using the conventional cervical- and new PRUNUS nail plates. (3) patients who completed preoperative and postoperative imaging examinations and follow-up. (4) the main evaluation indicators included operation time, intraoperative blood loss, cervical vertebra Cobb angles, VAS scores and the Japanese Orthopedic Association (JOA) scores. (5) a retrospective comparative study. The exclusion criteria were as follows: (1) patients with heart, brain, kidney, and other important organ diseases. (2) Cervical diseases caused by infection or tumour. (3) patients unable to cooperate with surgical treatment.

Surgical method

The patient was placed in supine position, and a transverse incision was made in front of the right neck. Followed by the incision of the skin, subcutaneous tissues, platysma and superficial cervical fascia to bluntly separate till the target vertebral body, and determine the vertebral body clearance of the lesion, and confirm the segment under the C-arm X-ray. Using the distractor, the adjacent vertebral body of the surgical lesion intervertebral space was distracted, and then the intervertebral disc or vertebral body subtotal excision of the intervertebral space was scraped. After decompression, the spinal cord should be inspected for no pressure, handle the cartilage endplate, and put it into a suitable size cage or a suitable length of titanium mesh. The C-arm perspective determines the position of the cage or titanium mesh accurately and well. The appropriate size of the new type of open dynamic nail plate that was close to the front edge of the vertebral body was selected, and locked in place after a good position. Rinse, place a negative pressure drainage tube after complete hemostasis, sew up the layers, and close the surgical incision. Drainage tube was indwelled for 1~3 days according to the drainage condition. After 3 days of operation, proper function exercise was allowed to get out of bed and under the brake.

Efficacy evaluation

Fifty-six patients were reviewed postoperatively, and routine cervical X-ray and MRI examinations were performed. The stability of the cervical spine, the position of the internal fixation, and the fusion of the bone graft were observed according to the imaging data. The cervical Cobb angle, visual analogue scores of pain (VAS) and Japanese Orthopedic Association (JOA) scores[6], neurological recovery rate [recovery rate = (final follow-up score - preoperative score) / (17-preoperative score) × 100%], the neurological function of patients before and after surgery was evaluated using Frankel grading were recorded to comprehensively evaluate the clinical efficacy of the new type of three-leaf reinforced cervical anterior screw-plate system.

Statistical analysis

The data were analyzed using SPSS, version21.0 for windows. The measured values were presented as means (±). A paired-sample t-test was performed for comparing the preoperative and the postoperative results, and the control group with the observation group. The test level was $\alpha=0.05$. The statistical significance was considered as $P<0.05$.

Results

The observation group demonstrated an average operative time of 98.4±9.2 minutes (range 80-160minutes), while the mean intraoperative blood loss was 65.3±10.6ml (rang 50-100ml). The control group showed an average operative time of 109.7±9.4 minutes (range 70-170minutes), while the mean intraoperative blood loss was 72.9±15.6ml (rang 50-130ml). The difference in operative time and intraoperative blood loss between the two groups was statistically significant($P<0.05$). In the two groups, the preoperative, one week postoperative, and the last follow-up of cervical cobb angle, JOA scores and VAS are shown in Table. The recovery rate in the control group was 89.74%±6.12%, and the recovery rate in the observation group was 88.69%±7.33%. The last follow-up cervical cobb angle, JOA scores and VAS scores in the control group and the observation group showed significant differences from their respective preoperative cervical cobb angle, JOA scores and VAS scores. But the values showed no statistical significance between the two groups ($P>0.05$) (Table 1-4; Fig 1-3).

Postoperative drainage volume was less than 30ml and then the drainage tube was removed. On the second day after surgery, the patients with a cervical collar were moved down to the ground. In the control group, there were 9 patients with the complaint of hoarseness and 6 patients with dysphagia after surgery. In the observation group, 11 patients suffered from postoperative hoarseness, and 5 patients suffered dysphagia and began to relieve at 3 days after surgery and disappeared within one month. The average follow-up time was 7.33 months (5-18 months). In the control group, 4 patients with cervical spine fracture and dislocation in Frankel A and B demonstrated no sense and movement, while other patients were relieved of the symptoms. After one month, 2 of them began to recover from sensation and movement. During the last follow-up, the body movement function of these 4 patients had different degrees of recovery. In the observation group, 5 patients with cervical spine fracture and dislocation had no sense and movement, while other patients were relieved of the symptoms. Two of them began to

recover from sensation and movement at 7 days after surgery, and 2 of them had a recovery of sensation and movement after one month. During the last follow-up, the body movement function of these 4 patients showed different degrees of recovery, and only one patient had dyskinesia in double limbs. No loosening, fracture, and break out of the plate and screws occurred in both the groups.

Discussion

Development and limitations of traditional cervical anterior plate

In 1952, Abbott [7] has first proposed anterior cervical surgery. Later on, Robinson [8] and Smith [9] improved the technique in 1958 and proposed that anterior cervical discectomy and fusion with bone grafting using autologous bone grafting can promote the fusion rate. The surgery can directly remove the compressive elements, and ensure adequate decompression of the spinal cord. This subsequently improved the patient's symptoms. But this anterior decompression with bone grafting alone, without using plate and screw fixation can easily cause cervical instability. This instability also caused serious problems such as non-fusion of bone grafting and prolapse of bone grafting. So, Bohler [1] proposed the use of steel plate and screws in the anterior cervical surgery in 1964. In the following years, a variety of cervical anterior plate systems were developed, including non-locking non-robust type, locking firm type, variable angle semi-restricted type, and slip semi-limited type [10].

During the process of anterior cervical surgery, it is necessary to select an appropriate vertebral fixation device due to different bone qualities of the patient. After the surgery is completed, the implant is under a micro-motion state in the patient body, which causes displacement of the steel plate, loosening and fracture of the screw in the long-term micro-motion state. This finally fails the internal implant. Especially in patients with osteoporosis, there is a higher risk of plate displacement and screw loosening. Severe plate displacement and screw loosening can stress the blood vessels, trachea or oesophagus, and even cause vascular damage, trachea or oesophagal damage. Due to low bone mass, the bone microstructure is destroyed in patients with osteoporosis, causing increased bone fragility and easy fracture. It is more difficult to locate the steel plate in patients undergoing anterior cervical spine surgery for osteoporosis. Clinically, when patients with osteoporosis had accepted anterior cervical surgery, the incidence of internal fixation plates revision surgery was significantly increased.

Design and advantages of the new PRUNUS nail plate system

The PRUNUS nail plate system is made of medical titanium alloy, including titanium plate, fixing screws and locked plates. Titanium plate had a width of 17mm, length ranging 25-75mm, and increment of 3mm. Screw length ranged 25-75mm, and diameter of 4mm. The two ends of the titanium plate are designed as a curved surface, which can fix the surface of the actual anatomical bone. This, in turn, makes it suitable for the physiological curvature of the cervical spine, avoids the problem of uneven stress load effectively, and there are three screw holes are arranged in an isosceles triangle at the two ends. After the screws are fixed, they are fixed triangularly, and the screw nails cross each other, significantly enhancing the anti-rotation ability of the titanium plate system, and also reducing the risk of

screw backing and screw fracture. A locked plate is provided in the middle of the screw hole to prevent screw loosening effectively. The middle part of the titanium place is provided with a large perspective window to facilitate bone grafting and the observation during and after surgery. The screws are designed with self-tapping screws, which reduces the usage of wiretapping. The screw diameters and colors can be distinguished, and at the same time, can be divided into fixed angles and adjustable angles, which are used for different indications (figure 5).

Based on the recent biomechanical studies on the stability, fatigue life and pull-out strength, the PRUNUS plate system demonstrated good biomechanical properties, effective stability on the cervical spine and maintained the acute stability of the cervical spine, while it has a better anti-pull out strength and figure resistance. At the same time, through a biomechanical test and practical application in clinical surgery, we believed that the new PRUNUS nail plate system can achieve the fixation of cervical vertebrae more effectively, especially in patients with osteoporosis and multilevel cervical fusion. It can also reduce the risk of revision surgery due to screw loosening and plate displacement. Otherwise, it is particularly suitable for revision surgery. In the revision surgery, screws holes have already been drilled in the cervical vertebrae. Therefore, if the screws are placed in the original hole, the screws can be easily loosened and the plate can be displaced. If the new PRUNUS nail plate was used in the revision surgery, it affords a new position for the screws and disperses the screw force significantly. The geometrical principle of the three-point stable can be used to enhance the holding force of the plate, achieving a good fixed effect greatly and improving the success rate of revision surgery.

The efficacy analysis of the new PRUNUS screw-plate system

Through the follow-up data of the control and the observation groups, we found that the operative time and blood loss of the observation group were higher than the control group, but the differences between the two groups showed no statistical significance. Nevertheless, 5 patients are undergoing anterior cervical revision surgery in the observation group. The operations of these patients were generally more complex, had longer operation time and more bleeding. The use of the new type of PRUNUS screw-plate system can reduce the operative time and the amount of bleeding compared to conventional anterior cervical surgery. Meanwhile, it can also simplify the surgical procedures, reduce operative time and blood loss to enhance surgical safety. One week after postoperatively and the last follow-up demonstrated that the cervical cobb angle, JOA scores and VAS scores in the control group and the observation group was significantly differed from their respective preoperative cervical cobb angle, JOA scores and VAS scores. But there was no statistically significant difference between the two groups. These data indicated that the new PRUNUS nail plate system can maintain the stability and restore the physiological curvature of the cervical spine, significantly improving the patient's symptoms, and achieving similar clinical results compared with the traditional cervical spine plate. The new PRUNUS screw-plate system can simplify the surgical procedures, reduce operating time and surgical risk, particularly in cases of cervical fractures, cervical revision surgery, and osteoporosis. It also can reduce the patient's physical and mental pain and economic burden.

The indications and deficiencies of the new PRUNUS screw-plate system

Indications of the new PRUNUS screw-plate system include 1. degenerative conditions of cervical spine, such as cervical spondylosis, posterior longitudinal ligament ossification, etc.; 2. cervical traumatic injuries such as cervical spine fracture and dislocation, cervical instability; 3. a variety of benign, malignant cervical tumours and thoracic vertebral body (T1, T2) tumours; 4. patients who require revision surgery after anterior cervical surgery; 5. cervical vertebral infections (tuberculosis, brucellosis); 6. osteoporosis with cervical spine-related diseases.

Although recent clinical efficacy analysis showed that the new PRUNUS screw-plate system has short-term effect in the anterior cervical surgery, due to short clinical application time, no abundant case data, short follow-up time, long-term complications and efficacy requires further follow-up to study and improve.

Conclusion

Overall, the short-term efficacy of the new PRUNUS screw-plate system in anterior cervical surgery remained satisfactory. It is particularly applicable for patients undergoing anterior cervical surgery and osteoporosis. The operation is simple and convenient, safe and effective, and worthy of clinical promotion.

List Of Abbreviations

PRUNUS: CT: Computed tomography; MRI: Magnetic resonance imaging; JOA: Japanese Orthopaedic Association Scores. VAS: Visual Analogue Scale/Score

Declarations

Ethics approval and consent to participate

The study design was approved by the Ethical Committee of the second affiliated hospital of Shanxi medical university. All of the participants provided written informed consent.

Consent for publication

Not Applicable.

Availability of data and material

All data generated or analyzed during this study are included in this published article and its additional files.

Competing interest

The authors declare that they have no competing interests

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Authors' contributions

ZZF and ZB were in charge and contributed to all stages of the present study. WWX and QDT were responsible for the original data collection. LXD and ZYB contributed to interpreting the data and writing the final manuscript. ZRT, JYZ and WXN contributed to reviewing the accuracy of the data. All authors read and approved the final manuscript.

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Tables

Table 1. Operation time and blood loss in the control group and observation group (±)

	operation time	blood loss
control group	109.7±9.4	72.9±15.6
observation group	98.4±9.2	65.3±10.6
t value	2.77	2.07
p value	0.01	0.04

Note: In the two groups, the operation time and blood loss were compared ($P < 0.05$).

Table 2. Preoperative and postoperative cobb angles in the control group and observation group (±)

	preoperative	postoperative one week	Last follow-up	t value	p value
control group	4.89°±1.03°	11.47°± 1.12°	10.74°± 2.58°	20.2	0.00
observation group	5.36°±1.51°	12.15°±0.84°	11.39°±1.02°	26.28	0.00
t value	1.92	1.99	1.94		
p value	0.06	0.05	0.06		

Note: In the two groups, the improvement in Cobb angle before surgery and last follow-up ($P < 0.05$), and the improvement in Cobb angle between the two groups were compared ($P > 0.05$).

Table 3. Preoperative and postoperative JOA scores in the control group and observation group(±)

	preoperative	postoperative one week	Last follow-up	t value	p value
control group	8.43±1.26	14.21±1.09	15.17±0.89	36.34	0.00
observation group	8.14±1.16	13.63±0.97	14.72±1.17	26.25	0.00
t value	1.45	1.93	1.96		
p value	0.15	0.06	0.06		

Note: In the two groups, the improvement in JOA scores before surgery and last follow-up ($P < 0.05$), and the improvement in JOA scores between the two groups were compared ($P > 0.05$).

Table4. Preoperative and postoperative VAS scores in the control group and observation group(±)

	preoperative	postoperative one week	Last follow-up	t value	p value
control group	5.13±0.72	1.69±0.62	1.57±0.71	23.59	0.00
observation group	5.42±0.84	1.51±0.72	1.33±0.71	23.34	0.00
t value	1.51	1.44	1.82		
p value	0.14	0.16	0.08		

Note: In the two groups, the improvement in VAS scores before surgery and last follow-up ($P < 0.05$), and the improvement in VAS scores between the two groups were compared ($P > 0.05$).

Figures

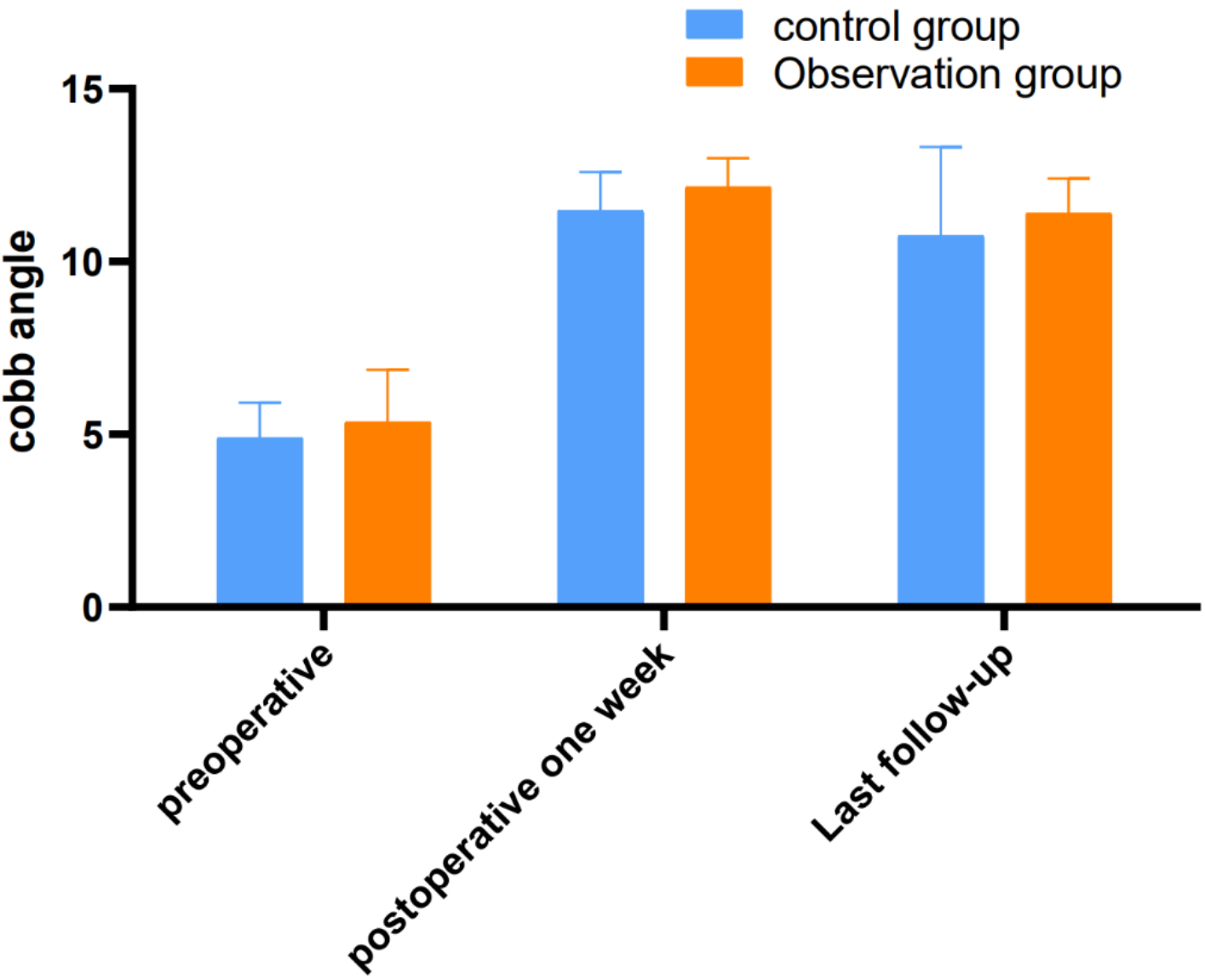

Figure 1

Preoperative and postoperative Cobb angle in the control group and observation group.

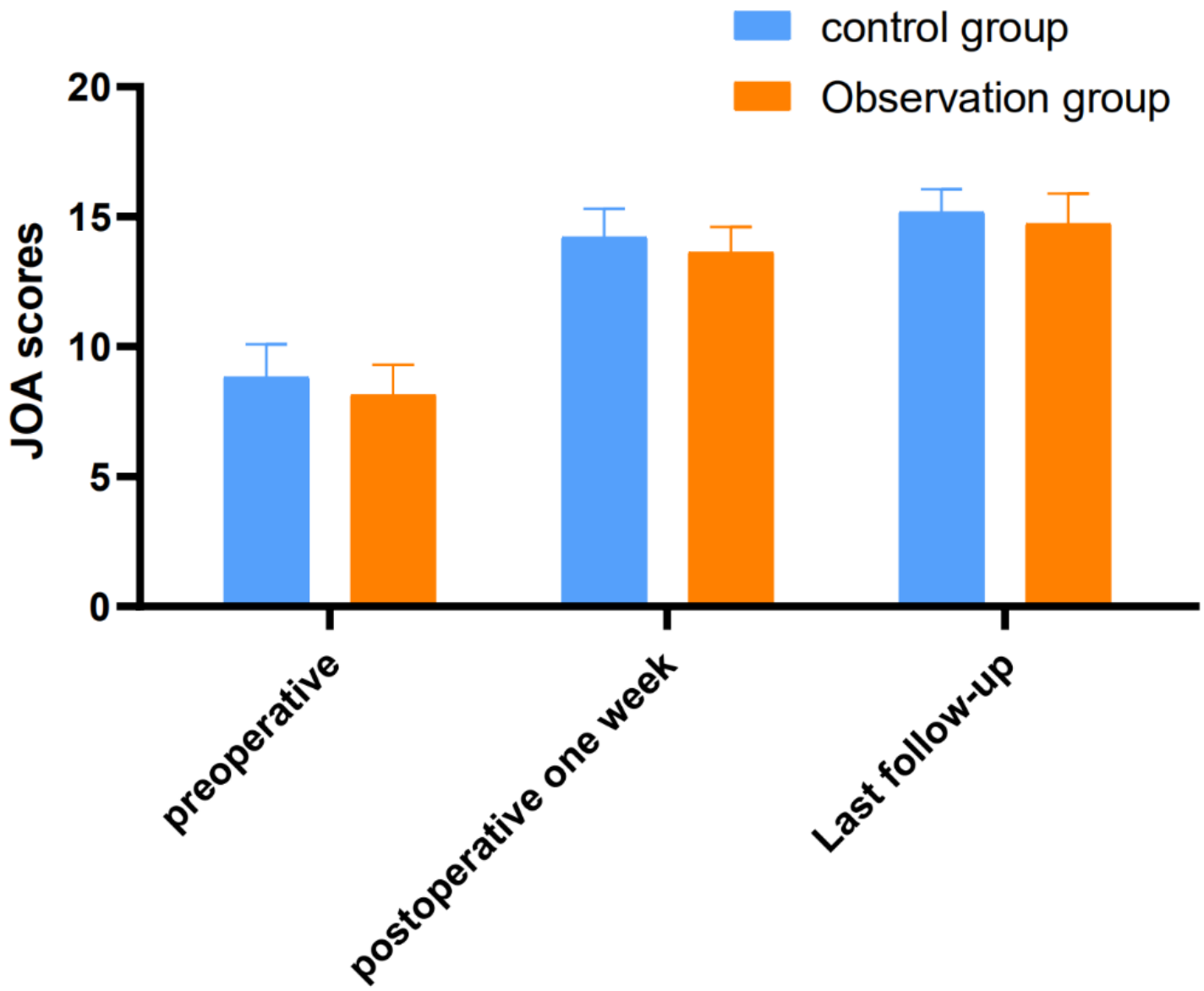

Figure 2

Preoperative and postoperative JOA scores in the control group and observation group.

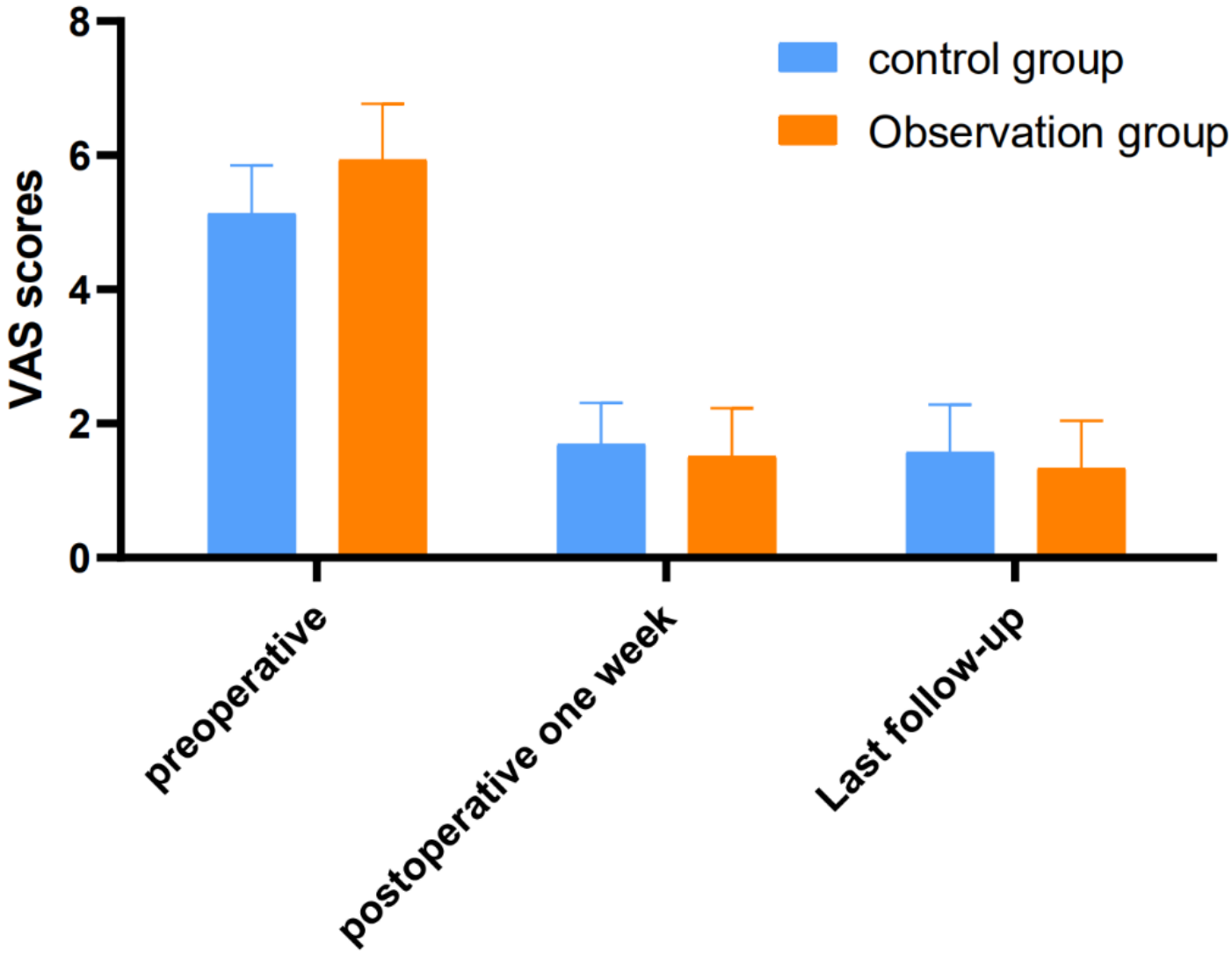

Figure 3

Preoperative and postoperative VAS scores in the control group and observation group.

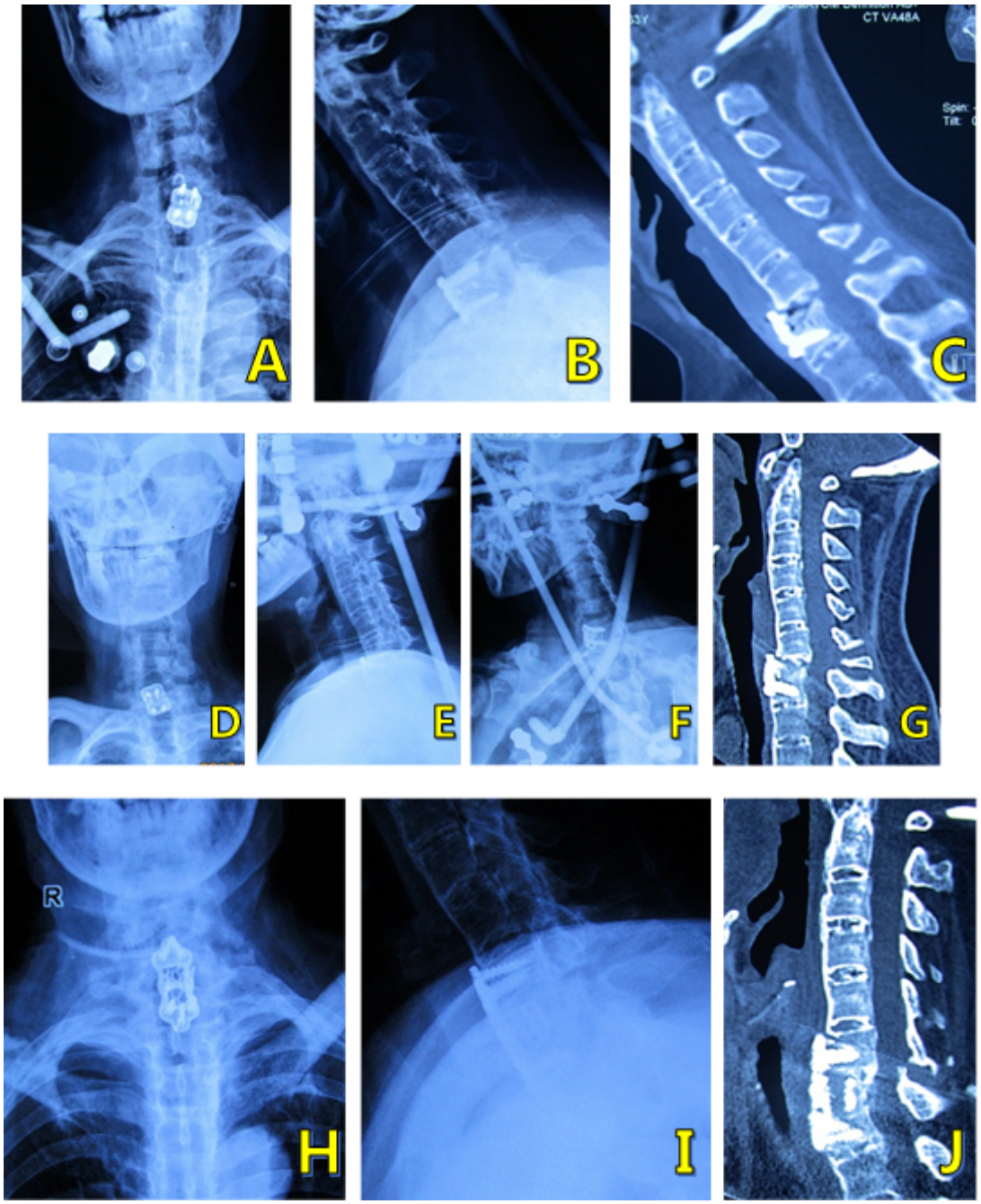

Figure 4

A 63-year-old female patient with previous ankylosing spondylitis was treated with anterior cervical ACDF for cervical fracture and dislocation of 6 vertebrae with incomplete paralysis caused by fall. Fig.4A-CX-ray and CT examination after the first operation, which showed that two screws in the upper position of titanium plate were placed into the intervertebral space of C5-6. D-G X-ray and CT examination before revision, which showed that the bone graft of C5-6 was not fused. H-JX-ray examination after revision operation with new trefoil enhanced nail plate system, which showed that the position of implant was good and the fixation was firm.

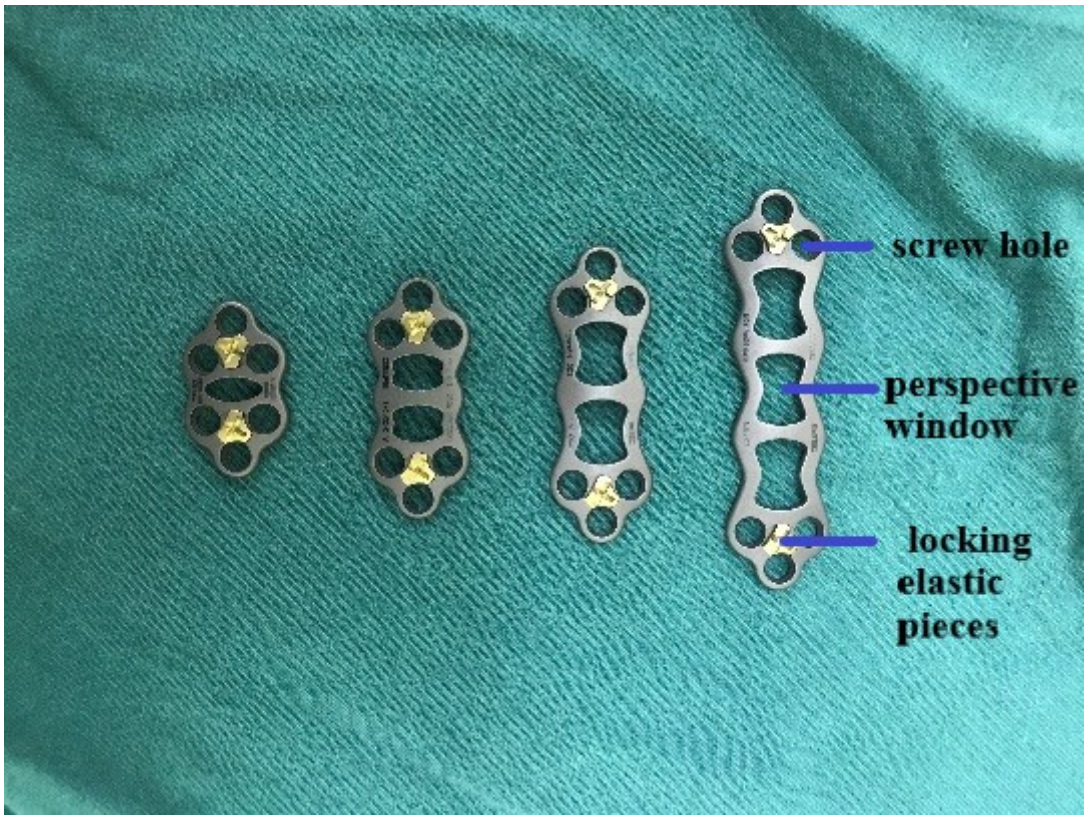

Figure 5

A variety of new type of PRUNUS titanium plates. Three screw holes are arranged in an isosceles triangle at the two ends screws are fixed triangularly, and the screw nails cross each other, significantly enhancing the anti-rotation ability of the titanium plate system; A large perspective window is easy to facilitate bone grafting and the observation during and after surgery; The locking elastic pieces are arranged above the nail holes at both ends of the titanium plate to effectively prevent the loosening of screws.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryMaterialThedateofallthepatientsl.xls