Clinical Efficacy Analysis of the New PRUNUS Spine Plate System for Anterior Cervical Spine Surgery

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Objective: Although the role of anterior cervical titanium plate system in stabilizing the spine sequence and promoting bone graft fusion has been widely recognized, more and more attention has been paid to the design of the plate itself and the complications caused by it. In order to solve the problems of poor stability of internal fixation, plate displacement and screw looseness, we designed the new PRUNUS spine plate system. Hence, the present study was conducted to describe observe and evaluate the clinical efficacy of a new type of three-leaf reinforced cervical anterior screw plate system (PRUNUS nailing system) developed for anterior cervical surgery.

Methods: A retrospective analysis of 56 patients from June 2018 to October 2019 was used. Twenty-seven patients with cervical spine disease treated with new PRUNUS nail plate internal fixation were selected as the observation group, and 29 patients with cervical spine disease treated with conventional cervical anterior screw fixation were selected as the control group. Postoperative follow-up was performed. Cervical stability, internal fixation position and bone graft fusion were evaluated according to imaging data. The operative time, intraoperative blood loss, cervical Cobb angle, pain visual analogue scale (VAS), and Japanese orthopaedic association (JOA) 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: The patients were followed up for 5–18 months, with an average of 7.33 months. The average operative time of the observation group was 98.4 ± 9.2 min, and the mean intraoperative blood loss was 65.3 ± 10.6 ml, which were significant different from the control group’s 109.7 ± 9.4 minutes (P < 0.05), 72.9 ± 15.6 ml (P < 0.05). Comparison between the two groups in postoperative and final follow-up of cervical Cobb angle, JOA score and improvement rate, VAS score and preoperative comparison showed no significant differences (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 suitable for the surgical treatment of anterior cervical revision and osteoporosis patients.

Key words: Anterior cervical spine plate; Anterior cervical surgery; Clinical efficacy; Nailing system; New type

Introduction

With the transformation of people’s living habits and working methods, cervical-vertebral-related diseases such as cervical spondylosis and cervical trauma 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 and Ganderhak first used the screw-plate system for anterior cervical fixation, the anterior cervical plate system has been improved in...
research and application over the following years. This operation can directly relieve the compression of the spinal cord, which greatly improves the symptoms of the patient. The anterior cervical spine screw plate system has been used as a routine internal fixation method in cervical spine disease surgery because it can stabilize cervical spine sequence, promote bone graft fusion, and correct spinal deformity.

Although the application of the screw-plate system for anterior cervical fixation showed good clinical results, 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. For elderly patients with cervical spondylosis complicated by osteoporosis, the cervical vertebral body is obviously osteoporotic, and improper selection of internal fixation will often lead to higher risks of plate displacement, screw loosening, and non-fusion of bone grafts, increasing the risk of anterior surgery renovation rate. To solve the technical issues associated with plate displacement and screw loosening, our team has provided a new type of PRUNUS screw-plate system that is used for the anterior cervical vertebral surgery. The PRUNUS nail plate system has a better anatomical surface than the traditional nail plate system. At the same time, there are three screw holes at both ends of the nail plate and are arranged as an isosceles triangle and the middle of the nail plate has a larger perspective window to facilitate bone grafting. This study aims to: (i) evaluate the clinical efficacy of the self-designed PRUNUS nail plate system; (ii) analyze the advantages and limitations of the PRUNUS nail plate system; and (iii) discuss the indications of the PRUNUS nail plate system in anterior cervical surgery. Early non locking and non solid nail plate system (AO Orozco steel plate) has no locking device, which increases the risk of screw loosening and nail withdrawal. The screws of the locking solid nail plate system (CSLP steel plate) form an appropriate angle with the vertebral body. The screws and steel plate are designed as a whole and cannot be moved. The firm fixation of such steel plates may cause stress shielding of the bone graft, reduce the appropriate pressure stimulation on the bone graft area, and affect the fusion of the bone graft area after surgery.

Materials and Methods

Design and Related Parameters of PRUNUS Nail Plate System

The PRUNUS nail plate system (Wuxi BOTEC Co. Ltd., Suzhou, China) is made of medical titanium alloy, including titanium plate, fixing screws and locked plates. Titanium plate had a width of 17 mm, length ranging 25–75 mm, and increment of 3 mm. Screw length ranging 25–75 mm, and diameter of 4 mm. 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 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 plate 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 (Fig. 1).

Clinical Materials

This study conducted a retrospective control study on the clinical data of patients with cervical spondylosis who used PRUNUS or traditional nail plate system for internal fixation.

The current clinical research protocol meets the requirements of the Helsinki Declaration and has been approved by the Ethics Review Committee of 2nd Hospital of Shanxi Medical University (2018LL039). And the participants voluntarily signed informed consent prior to participating.

Twenty-seven 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 2018 to October 2019. Of these, 15 were male and 12 were female, with mean age of 63.6 years, ranging 42–82 years. 9 patients had cervical spine fracture or dislocation (Frankel grade A, four cases; B grade, two cases; and D grade, four cases), 13 patients had cervical spondylosis, four patients had postoperative revision surgery and one had cervical vertebral metastatic tumors. 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, ranging 39–85 years old. Eight patients had cervical spine fracture or dislocation (Frankel grade A, two cases; B grade, two cases; and D grade, four cases), 18 patients had cervical spondylosis, two patients had postoperative revision surgery and one had cervical vertebral metastatic tumors. The duration of the disease ranged from 3 days to 21 years with an average of 25.32 months. There were no statistically significant differences between the two groups. Traditional cervical anterior plate for anterior cervical discectomy and fusion (ACDF) was performed on 21 patients. Single-level cervical spondylotic myelopathy was performed in two cases at C3–4; four cases at C4–5; seven cases at C5–6, and two cases at C6–7. Two-level cervical spondylotic myelopathy was performed in 4 cases at C4–5 and C5–6, 2 cases at C5–6 and C6–7, and traditional cervical anterior plate for anterior cervical corpectomy decompression and fusion (ACCF) was performed on 8 patients. The new type PRUNUS cervical anterior plate for anterior cervical discectomy and fusion (ACDF) was performed on 22 patients. Single-level cervical spondylotic myelopathy was performed in two cases at C3–4; six cases at C4–5; five cases at C5–6; and three cases at C6–7. Two-level cervical spondylotic myelopathy was performed in three cases at C4–5 and C5–6; three cases at C5–6 and C6–7, and the traditional cervical anterior plate for ACCF was performed on 5 patients. The preoperative and postoperative follow-up data of all patients were complete and clear.

**Inclusion and Exclusion Criteria**

The inclusion criteria were as follows: (i) patients met the symptoms and signs of cervical spondylosis, cervical fracture, cervical disc herniation, cervical spondylitis or brucellosis, confirmed by imaging and neurophysiological examinations; (ii) patients treated with anterior cervical surgery using the conventional cervical- and new PRUNUS nail plates; and (iii) patients who completed preoperative and postoperative imaging examinations and follow-up.

The exclusion criteria were as follows: (i) patients with heart, brain, kidney, and other important organ diseases; (ii) combined with acute infection of cervical spine and severe deformity; and (iii) patients unable to cooperate with surgical treatment.

**Surgery**

The patient was placed in supine position, and a transverse incision was made in front of the right neck. Followed by 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 end plate, 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. A drainage tube was used 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 scale (VAS) and Japanese Orthopedic Association (JOA) scores, 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 (version 21.0; SPSS; Chicago, IL, USA). The measured values were presented as means (±). A paired-sample t-test was performed for comparing the preoperative and the postoperative results, and control group with observation group. The test level was α = 0.05. The statistical significance was considered as P < 0.05.
Table 1: The demographic and clinical characteristics data of the patients of two Groups

|                     | Observation Group | Control Group | P Value |
|---------------------|-------------------|---------------|---------|
| Number              | 27                | 29            | -       |
| Sex (M/F)           | 15/12             | 17/12         | 0.974   |
| Age, yr             | 63.6 ± 6.2        | 65.9 ± 5.3    | 0.392   |
| Preoperative diagnosis |                  |               |         |
| Cervical spondylosis| 13                | 18            | -       |
| Cervical spine fracture |               |               |         |
| or dislocation       | 9                 | 8             | -       |
| Postoperative revision |               |               |         |
| Cervical vertebral metastatic tumors | 4 | 2 | - |
| Operation segment    | 0.766             |               |         |
| ACDF                | 22                | 21            | -       |
| C3-4                | 2                 | 2             | -       |
| C4-5                | 6                 | 4             | -       |
| C5-6                | 5                 | 7             | -       |
| C6-7                | 3                 | 2             | -       |
| Two-level           | 6                 | 6             | -       |
| ACCF                | 5                 | 8             | -       |

Note. The difference was not significant (P > 0.05).

Results

Operative Time and Intraoperative Blood Loss

The observation group demonstrated an average operative time of 98.4 ± 9.2 min (range 80–180 min), while the mean intraoperative blood loss was 65.3 ± 10.6 ml (range 50–120 ml). The control group showed an average operative time of 109.7 ± 9.4 min (range 70–200 min), while the mean intraoperative blood loss was 72.9 ± 15.6 ml (range 50–130 ml). The differences of the operative time and intraoperative blood loss between the two groups showed statistically significant differences (P < 0.05) (Table 2).

Clinical Score

In the two groups, the preoperative, 1 week postoperation, and the last follow-up of cervical cobb angle, JOA scores and VAS are shown in Table 3. 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 postoperative and the last follow-up cervical cobb angle, JOA scores and VAS scores in control group and in 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) (Figs. 2–4).

Postoperative Conditions

Postoperative drainage volume was less than 30 ml 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. The average follow-up time was 7.33 months (5–18 months). In the control group, four patients with cervical spine fracture and dislocation in Frankel A and B demonstrated no feeling and movement, while other patients were relieved of the symptoms. After 1 month, two of them began to recover from sensation and movement. During the last follow-up, the body movement function of these four patients had different degrees of recovery. In the observation group, five patients with cervical spine fracture and dislocation had no feeling and movement, while other patients were relieved of the symptoms. Two of them began to recover feeling and movement at 7 days after surgery, and two of them had a recovery of sensation and movement after 1 month. During the last follow-up, the body movement function of these four patients showed different degrees of recovery, and only one patient had dyskinesia in double limbs. (Fig. 5).

Complications

In the control group, there were nine patients with the complaint of hoarseness and six patients with dysphagia after surgery. In the observation group, 11 patients suffered from postoperative hoarseness, and five patients suffered dysphagia, and began to relieve at 3 days after surgery and disappeared within 1 month. No loosening, fracture, and break out of the plate and screws occurred in both the groups.

Discussion

Design Significance of the New PRUNUS Nail Plate System

In daily clinical work, we often see some patients with cervical fracture due to severe trauma, or some patients with severe osteoporosis, who need a more reliable nail plate system to fix the cervical spine. However, the traditional design of anterior cervical nail plate system does not consider how much stress the two ends of the nail plate need to bear and its stress distribution, which often leads to the risk of broken nails and plates. This is the original intention of the design of the new PRUNUS nail plate system. The unique structural design and stress distribution will make the cervical spine more stable and fixed.
Development and Limitations of Traditional Cervical Anterior Plate

In 1952, Abbott has first proposed anterior cervical surgery. Later on, Robinson and Smith 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 and Ganderhak 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.

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 results in the failure of 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 esophagus, and even cause vascular damage, trachea or esophageal damage. Due to low bone mass, bone microstructure is destroyed in patients with

| TABLE 3 Preoperative and postoperative scores in the control group and observation group (x ± S) |
|---------------------------------------------------------------|
| Control group Cobb angle                                      | Observation group Cobb angle |
| Preoperative        | Postoperative 1 week       | Last follow-up |
| t value and p value | t value and p value         | t value and p value         |
| Control group JOA scores                                     | Observation group JOA scores |
| Preoperative        | Postoperative 1 week       | Last follow-up |
| t value and p value | t value and p value         | t value and p value         |
| Control group VAS scores                                     | Observation group VAS scores |
| Preoperative        | Postoperative 1 week       | Last follow-up |
| t value and p value | t value and p value         | t value and p value         |

Abbreviations: t1, Postoperative 1 week and preoperative data comparison results; t2, Last follow-up and preoperative data comparison results.; a One week post-operative and the last follow-up compared with preoperative (P < 0.01); b Compared with control group, (P > 0.05).
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.

Advantages of the New PRUNUS Nail Plate System
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 resistance. At the same time, through 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

![Fig. 4 Preoperative and postoperative VAS scores in the control group and observation group](image)

![Fig. 5 A 57-year-old female patient with spinal stenosis due to cervical swan neck deformity came to our hospital for treatment. (A and B) Preoperative cervical dynamic position X-ray showed there was no relief of deformity on anterior flexion and posterior extension; (C) Preoperative CT showed kyphotropic deformity Cobb angle 102° and bone bridge was formed in front of C2-4; (D) MRI showed compression degeneration of the spinal cord; (E and F) were Schematic diagram of osteotomy orthopedic surgery; (G and H) were anterior and posterior combined cervical osteotomy orthopedic vertebral fusion. PRUNS steel plate system was applied during anterior cervical spine surgery to achieve secure fixation of the cervical spine after vertebral orthopedics. To protect the spinal cord, a linear steel plate was used at the back of the cervical spine. After the operation, the symptoms of limb weakness were significantly alleviated, and swan neck deformity was significantly corrected](image)
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.

**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 statistical significance. And there are four patients 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 to the same level as conventional anterior cervical surgery. Meanwhile, it can also simplify the surgical procedures, reduce operative time and blood loss to enhance the surgical safety. One week after post-operation and the last follow-up demonstrated that the cervical cobb angle, JOA scores and VAS scores in the control group and in the observation group 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.

**Indications and Deficiencies of the New PRUNUS Screw-Plate System**

Indications of the new PRUNUS screw-plate system include: (i) degenerative conditions of cervical spine, such as cervical spondylosis, posterior longitudinal ligament ossification, etc.; (ii) cervical traumatic injuries such as cervical spine fracture and dislocation, cervical instability; (iii) a variety of benign, malignant cervical tumors and thoracic vertebral body (T1, T2) tumors; (iv) patients who require revision surgery after anterior cervical surgery; (v) cervical vertebral infections (tuberculosis, brucellosis); and (vi) osteoporosis with cervical spine-related diseases.

**Strengths and Limitations**

There are some strengths in our study. First, we have innovated a new nail plate system, and found that its clinical effect is accurate after clinical surgery. Second, the nail plate system can be used for surgical treatment of patients with osteoporosis and cervical deformity, because the structure of the nail plate is more stable.

This study also has several limitations. The current clinical efficacy analysis showed that the new PRUNUS screw-plate system has definite effect in the anterior cervical surgery, due to the short clinical application time and insufficient case data, further follow-up is needed to improve the long-term efficacy analysis.

**Conclusions**

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.

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**Author Contributions**

Xiao-feng Zhao contributed to the conception and design. Bin Zhao and Yi-bo Zhao contributed to the acquisition, analysis, and visualization of the data. Xiao-nan Wang, De-tai Qi, Zhi-feng Fan, Run-tian Zhou and Yuan-zhang Jin wrote the main manuscript text. Xiang-dong Lu contributed to the supervision and review.

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