Biomechanical analysis of detachable duet screw to resist intraoperative screw loosening.

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Abstract

Purpose

Pedicle screws are widely used in spinal fusion surgery, while screw loosening frequently occurs during spinal deformity correction. The aim of this study was to evaluate whether detachable duet screw can resist cutting or breach of pedicle walls under tensile test.

Methods

In this study, a novel duet screw was designed and developed for the purpose of spinal deformity correction. Eight spine specimens from goats were used and divided into two groups: group A (traditional insertion) and group B (combination of two detachable duet screws). Prior to biomechanical testing, the average density of the vertebrae was determined using quantitative computed tomography (QCT). To simulate the distraction or compression process during spinal deformity correction, loading was applied to the side of the screw through the rod, which was perpendicular to the pedicle screw axis. The process from initiation to the breach of the pedicle was assessed in order to determine the effectiveness of the duet screw.

Results

The quantitative computed tomography (QCT) analysis revealed that the average bone density of the entire goat population was 500.63 ± 37.88 mg/cm^3. In group A and group B, the mean maximum failure load (MFL) was determined to be 1052.38 N and 1762.25 N, respectively. Notably, the average MFL exhibited a significant increase in group B compared to group A ($P < 0.05$).

Conclusion

The implementation of detachable duet screws exhibits the potential to enhance the resistance against screw loosening by connecting two screws under tensile force. This investigation offers valuable preclinical evidence for future clinical applications.

Introduction

Pedicle screws have revolutionized the treatment of spinal conditions, serving as a crucial element in spinal instrumentation and playing a pivotal role in the correction of spinal deformities in contemporary spine surgery[1−3]. Nevertheless, clinical evidence has demonstrated a notable incidence of failures and potential complications, including screw loosening and pull-out, particularly in osteoporotic spines due to poor bone-screw contact[4, 5]. Following the surgical correction of deformities, the pedicle screws experience substantial axial and lateral forces. Furthermore, the persistence of physiological stress across the unfused segment, resulting from delayed union or pseudarthrosis, has the potential to exacerbate the loosening or failure of the instrumentation subsequent to spinal surgery[6]. Previous research has indicated that the ability of the screw to resist axial pull-out primarily relies on its holding strength within the cortical bone of the pedicle[2, 7].

There exist clinical situations wherein immediate pedicle breach or fracture may arise during the surgical intervention for scoliosis correction, attributable to compression or distraction of the spinal column. The frequency of such occurrences during surgery is not infrequent, yet remains poorly understood. Multiple studies have elucidated a correlation between the mechanical characteristics of bone and the strength of screw fixation, indicating that patients with lower bone density are at a heightened risk for screw loosening[8–10]. The mechanical characteristics of the vertebrae exhibit variability among individuals, particularly in those with osteoporosis[11]. Consequently, the utilization of screws for spinal correction surgery poses a formidable obstacle due to compromised bone quality. To address this issue, various alternatives, such as the implementation of expandable pedicle screws to enhance frictional resistance and the adoption of longer screws for bicortical fixation, have been proposed as potential substitutes for conventional pedicle screws[12, 13]. Regrettably, these methodologies were discovered to augment the likelihood of subsequent fixation loss and potential neural impairment or vascular harm, ranging from immediate hemorrhage to pseudoaneurysm formation[12, 14]. Consequently, the mitigation of immediate pedicle breach or fracture incidence holds significant importance. In this study, we propose the implementation of detachable duet screws to interconnect multiple screws during scoliosis correction surgery as a means to address this concern.

The aim of this study was to investigate whether the use of detachable duet screws can enhance tensile properties without necessitating an increase in screw diameter and length or altering the threading of the anchor. The clinical implication of this research would be to mitigate the potential risks of pedicle breach or fracture during spinal correction procedures, particularly in patients with osteoporosis.

Materials and methods

Design of duet screws

In this study, a parallel device was developed and integrated with a patented traditional pedicle screw in China (Fig. 1) [15]. More specifically, this device comprises two distinct components that can be interconnected through a specialized concave and convex design. The outer detachable U-shaped structure features a ball head nail positioned at its base, while the pedicle screw includes a corresponding aperture on its side, precisely aligning with the ball head nail. In the current study, the integration of a titanium rod into the external detachable U-shaped structure and subsequent tightening of the nut facilitates the close connection between the ball screw and the pedicle screw through insertion into the corresponding hole. It is noteworthy that the material composition of the titanium alloy employed remains consistent with the widely utilized pedicle screw in clinical settings. Specifically, titanium rods with a diameter of 5.5 mm were utilized for the purposes of this investigation.

Specimens

This study was granted ethics approval by the Third People's Hospital of Chengdu, Southwest Jiaotong University (ID SWJTU-2105-001). A total of eight spine specimens from goats aged 1–2 years, weighing 40–50 kg, were obtained from a local abattoir for the purpose of conducting biomechanical testing in our study. The isolated spine specimens were collected immediately after the goats were sacrificed, within a time frame of 2 hours, and were kept moist by means of wet gauze. Subsequently, the specimens were stored at a temperature of -20°C until the time of experimentation. To prepare for the experiment, the specimens were removed from the − 20°C freezer 24 hours prior and were allowed to thaw overnight at room temperature. The paravertebral muscles of the goat spine were excised using a scalpel, while ensuring the preservation of the supraspinous ligaments, interspinous ligaments, vertebral bodies, and intervertebral discs. In light of previous research indicating minimal disparity in width between these vertebral bodies in goats and their human counterparts, T9 to L4 vertebral bodies were selected as the definitive specimens for this experimental investigation[16]. Specimens showing pathologic changes such as spinal deformities, fractures, destructive diseases were excluded from this study.

Groups and experimental models

In this study, a total of 8 goats were chosen as subjects for experimentation. Each specimen was then divided into two groups, namely group A and group B, in order to conduct different tests. Specifically, group A represented the traditional fixation group, where pedicle screws measuring 5.5 mm in diameter and 35 mm in length were inserted into the unilateral side of the vertebral bodies. Additionally, titanium rods with a diameter of 5.5 mm were attached, with the lower nuts being tightened while the uppermost nut remained untightened to allow for sliding during stretching. On the other hand, group B involved the use of detachable duet screws measuring 5.0 mm in diameter and 35 mm in length, which were unilaterally inserted into the vertebral bodies. Similarly, titanium rods were placed in this group as well. Group B consisted of combination of two detachable duet screws, wherein the lower nuts were tightened while the upper nuts remained untightened. Additionally, a short titanium rod was inserted into the lateral groove of the second and third screws, followed by the tightening of the nuts (refer to Fig. 2).

Subsequently, all specimens underwent X-Ray and CT scan examinations to verify the optimal positioning of the screw internal fixation implant, alongside the assessment of vertebral bone density. Figure 2 displays an image of a representative specimen alongside its corresponding radiologic image.

Experimental protocol

The custom-made clamp is affixed to one end of the biomechanical test instrument (Shimadzu AG-X plus, Shimadzu Corporation, Kyoto, Japan). The opposite side of the fixture is secured to a titanium rod featuring a curved hook. A screw, positioned perpendicular to the testing machine, is suspended by a clamp with a meatal sleeve at the upper vertebra, while the other end of the clamp is fastened to the biomechanical machine (see Fig. 4). Following the successful establishment of the specimen model, a "break-in" loading procedure was conducted at a constant loading speed of 2 mm/minute. Subsequently, the loading force and displacement incurred during the loading process were meticulously documented. The failure load, denoted as the maximum force recorded, was ascertained based on the load-displacement curves that were recorded.

Statistical methods

Statistical analysis was performed using SPSS (version 22.0; IBM, Armonk, NY). Normally distributed continuous variables are reported as mean ± SD and 95% confidence intervals (CIs), while categorical variables are reported as frequencies and percentages. p-values < 0.05 were considered statistically significant. Comparisons between two groups were evaluated using paired-sample t tests.

Results

The Characteristics of the Specimens

The QCT showed that the mean bone density of all the goats was 500.63 ± 37.88 mg/cm^3. The same specimen divided into two groups was tested two times to exclude effects of different individuals.

Analysis of tensile testing

The maximum failure load can be measured from the load–displacement curve (Fig. 6). The average MFL in group A and group B are shown in Table 1. The mean MFL of groups A and B was1052.38 N and 1762.25 N, respectively. the average MFL for group B was greater than that for group B (P<0.05). Compared with group A, the MFL of group B increased by 67.45%.

Table 1
Results of group A and group B in tensile tests (n = 8, means SD)

Group A’ MFL	Group B’ MFL	*t*	*P* value
1052.38 ± 132.42	1762.25 ± 173.90*	-23.14	<0.01
Abbreviations: MFL, maximum failure load. *Compared with Group A’ MFL, P < 0.05.			

Discussion

Pedicle screw loosening remains a significant concern in clinical settings, particularly for patients with osteoporosis. The utilization of detachable duet screws has the potential to enhance the load capacity necessary for spinal orthopaedic surgery, while minimizing the risk of pedicle fracture or rupture. This study employed biomechanical testing to simulate the distraction process involved in spinal deformity correction. The analysis of the findings demonstrated a notable 1.67-fold increase in MFL during tensile tests when the connection of two detachable duet screws was applied.

In relation to the duet screw, there exist solely a few clinical reports[17, 18]. To be more specific, the implementation of the satellite rod technique, utilizing duet screws, has demonstrated potential for sequential correction, leading to enhanced orthopaedic outcomes and heightened stability in spinal deformity surgery. Diverging from the conventional duet screw, our approach incorporates a detachable design in order to enhance the screws' resistance to loosening during the distraction process in goat models, thereby facilitating the distribution of stress. To this day, there have been limited reports on the biomechanical investigation of duet screws. The findings of our study substantiate the initial hypothesis that the utilization of detachable duet screws yields superior performance compared to a single screw.

The present study also observed characteristic phenomena of toggling, which is the most commonly observed pattern of pedicle screw loosening. These findings align with previous reports[19, 20]. The presence of a crush region at the interface between the bone and screw reduces the screw's ability to securely hold in the cortical bone of the pedicle, making early postoperative screw loosening unavoidable. The utilization of detachable duet screws presents notable benefits due to their ability to connect multiple screws in an arbitrary manner and their detachability, which facilitates the completion of spinal orthopaedic surgery while minimizing the accumulation of metallic residue within the body. By employing detachable duet screws prior to reaching their maximum load capacity, a higher corrective force can be exerted, resulting in a greater degree of correction.

This study possesses certain limitations. Firstly, the utilization of goat specimens in our experiment deviates from the actual conditions of the human spine in terms of size, anatomy, and kinematics[16], which are inherent consequences of employing comparative animal data to establish clinical applicability. Nevertheless, previous studies have suggested that the width of partial vertebral bodies in goats is comparable to that of human vertebral bodies[14]. Additionally, the restricted accessibility of fresh human spines and the substantial variability in geometry and mechanical properties due to factors such as age, sex, and bone mineral density present further challenges.[21]. The specimens utilized in our investigation exhibited elevated and uniform bone density, in contrast to the comparatively lower and less uniform bone density observed in humans. Consequently, to mitigate the influence of confounding variables, the goat can be considered a relatively appropriate animal model for the specific objectives of our study. Furthermore, our experimentation involved the connection of solely two detachable duet screws, with subsequent tests conducted accordingly. The biomechanical implications of connecting three or more pedicle screws remain uncertain. Predicting the requisite number of screws for attaining adequate strength in spinal orthopaedic surgery poses a challenge. In the event of osteoporosis, additional screws may be affixed during the surgical procedure to accomplish spinal correction. Consequently, future investigations will be conducted to ascertain the optimal quantity of detachable duet screws that should be simultaneously secured, accounting for varying bone density conditions. Finally, the etiology of screw loosening appears to be influenced by multiple risk factors[22, 23]. Of these, osteoporosis is a crucial risk factor of screw loosening[24]. The density of bone at the interface between the bone and screw has been found to be closely linked to the occurrence of screw loosening[3, 25].

Notwithstanding, reducing the intraoperative fracture of pedicle as much as possible can also reduce the incidence of postoperative screw loosening to a certain extent.

Conclusions

In conclusion, the acquisition of a detachable duet screw through the implementation of a specialized concave and convex design enables an enhanced capacity to withstand screw loosening by facilitating the connection of multiple screws. This investigation offers valuable insights for addressing the issue of screw loosening in patients undergoing spinal deformity correction surgery, particularly those afflicted with osteoporosis.

Declarations

Ethics approval and consent to participate

This study protocol was granted ethics approval by the Third People's Hospital of Chengdu.

Conflict of interest

The authors have no conflicts of interest concerning this article.

Authors' contributions

Zhong Zhang and Zheng-Jun Hu designed the concept of the study and drafted the manuscript. Deng Zhao and Rui Zhong contributed to the data acquisition, statistical analysis, and interpretation. Ting Gao analyzed the image data and interpretation. Hua-Qiang Huang edited the manuscript and Deng-Xu Jiang drew the illustrated photograph. Fei Wang and Yi-Jian Liang wrote a review and edited it. All authors have read, revised, and approved the final version of the manuscript.

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Availability of data and materials

Data and materials contributing to this article may be provided by sending an e-mail to the first author.

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Figures

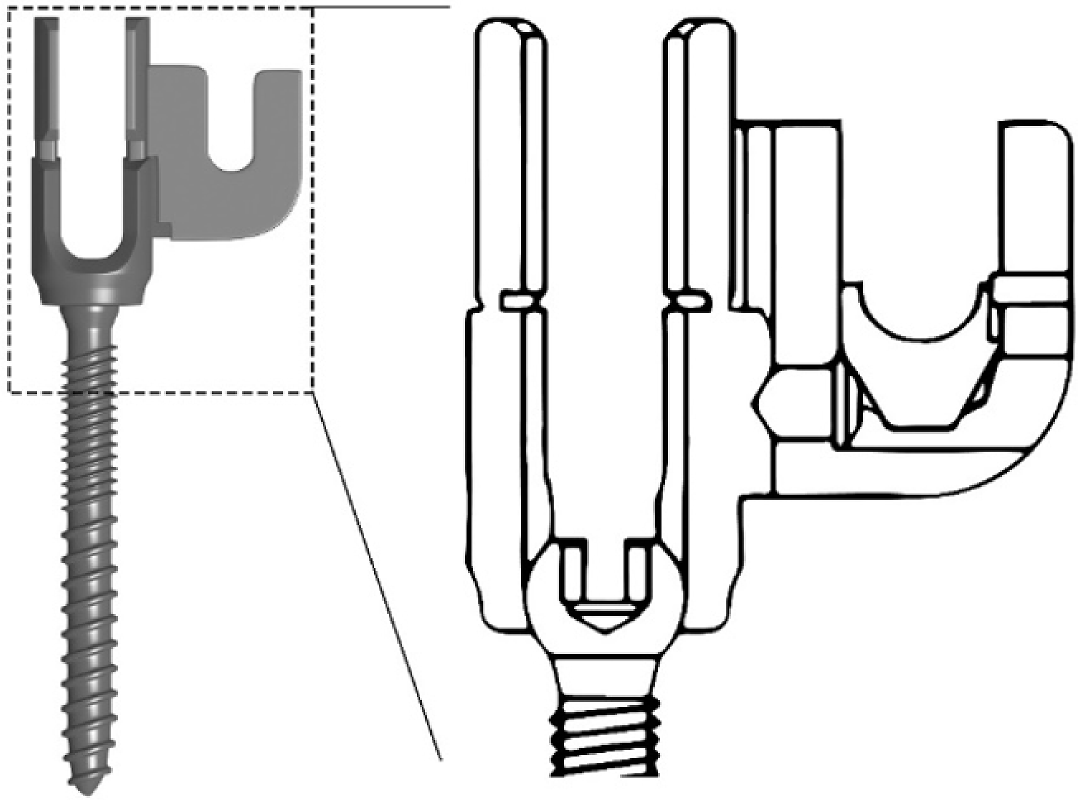

Figure 1

shows the geometry of a detachable duet screw.

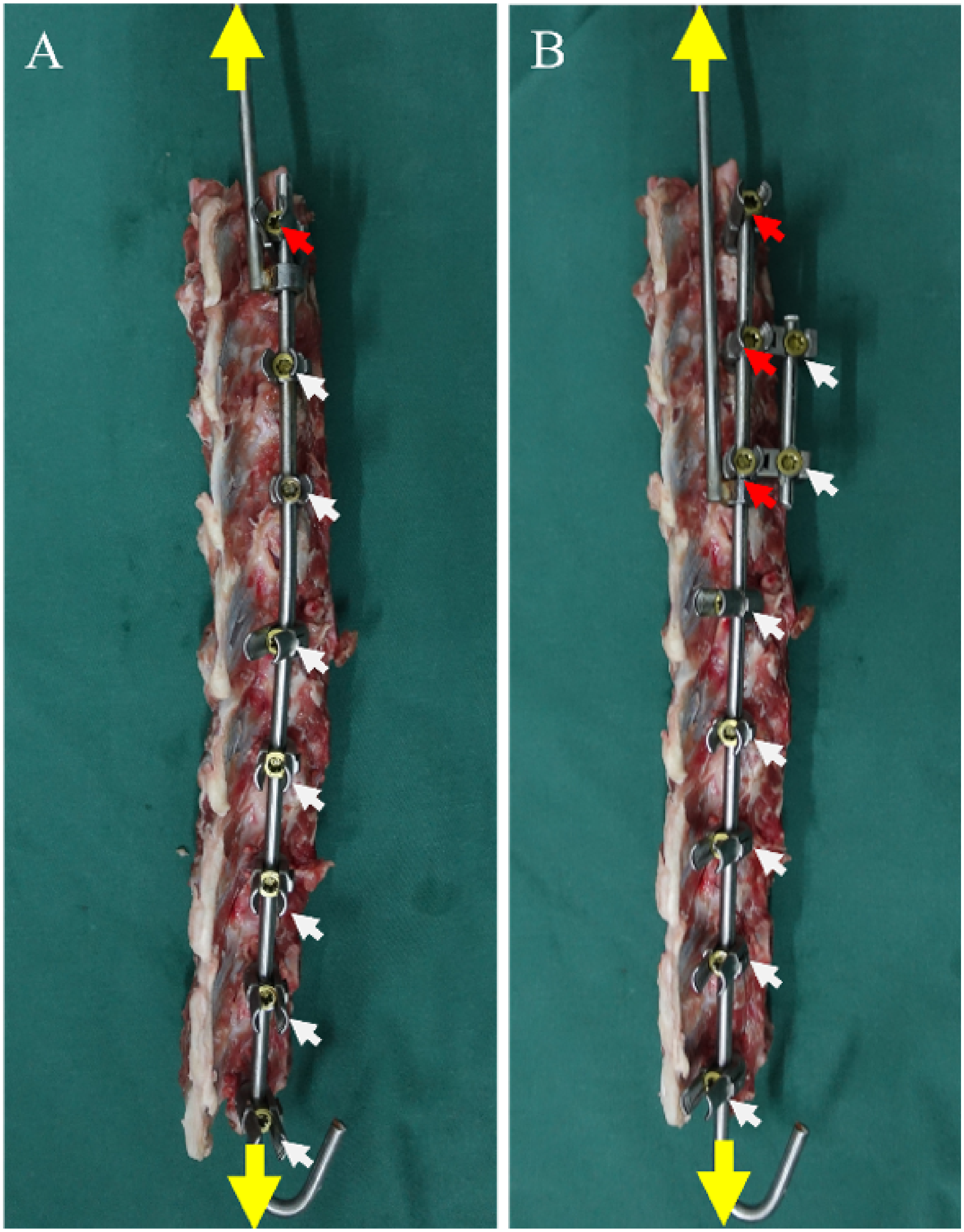

Figure 2

A for group A and B for group A (the yellow arrows represent the direction of the load, the red arrows represent untightened nuts, and the white arrows represent tightened nuts).

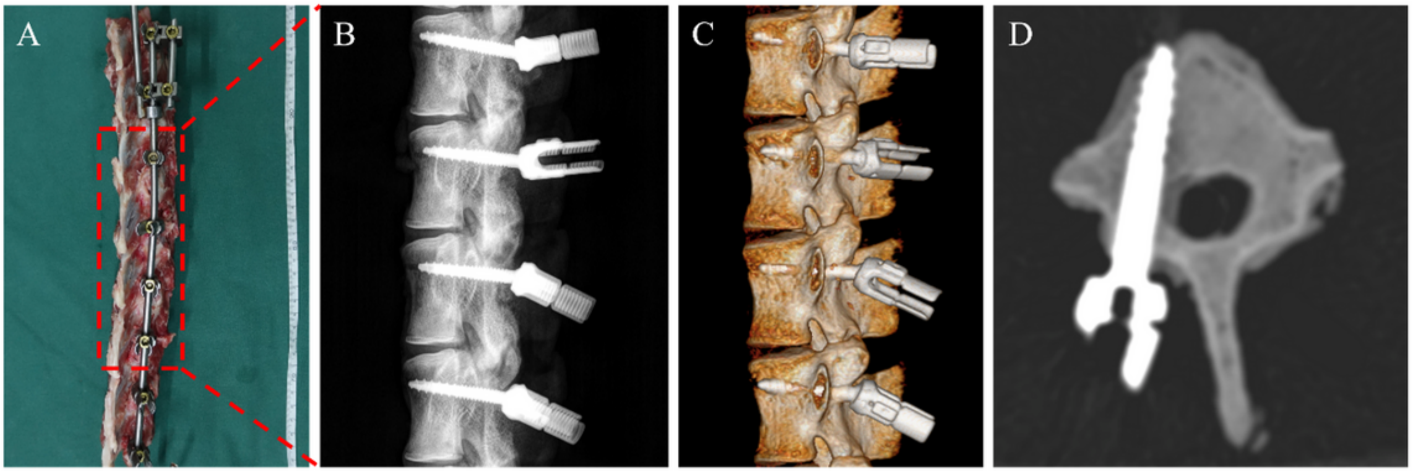

Figure 3

A specimen model and its X-ray(B), 3D CT reconstruction(C) and CT axial images(D). D shows that the pedicle screw was in a good position.

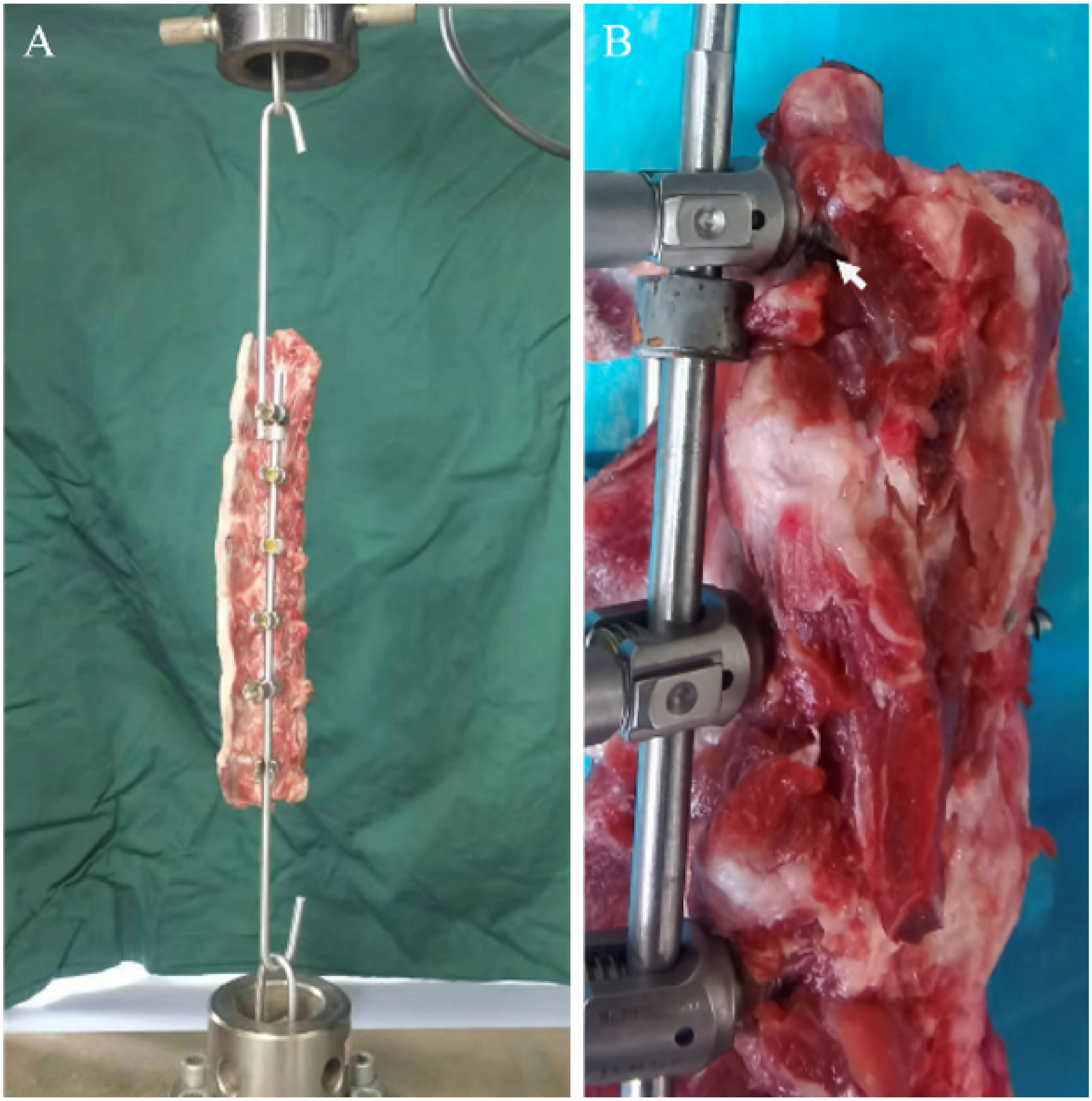

Figure 4

(A)Main experimental equipment for tensile test. Loading was applied to the side of the screw through the rod perpendicular to the pedicle screw axis. (B) Obvious gap between the pedicle screw and the bone (white arrows).

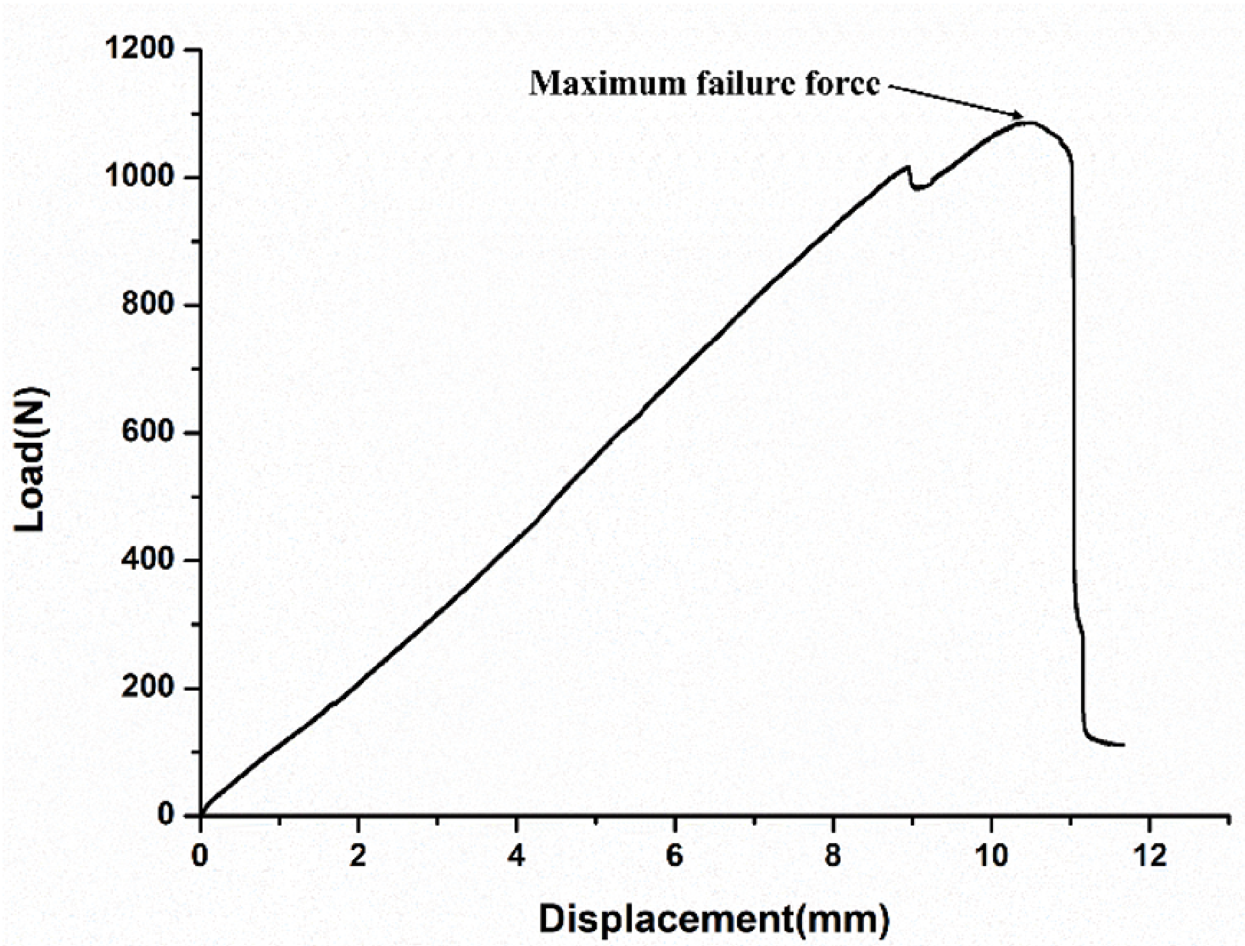

Figure 5

The load-displacement curve. The maximum failure load(MFL) was defined as the first peak of the load-displacement curve with a subsequent drop in force 10% as displacement increases.