RESEARCH ARTICLE

Biomechanical Properties of Novel Lateral Hole Pedicle Screws and Solid Pedicle Screws: A Comparative Study in the Beagle Dogs

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Objective: Although pedicle screws are widely used to reconstruct the stability of the spine, screw loosening is a common complication after spine surgery. The main objective of this study was to investigate whether the application of the hollow lateral hole structure had the potential to improve the stability of the pedicle screw by comparing the biomechanical properties of the novel lateral hole pedicle screws (LHPSs) with those of the solid pedicle screws (SPSs) in beagle dogs.

Methods: The cancellous bone of the distal femur, proximal femur, distal tibia, and proximal tibia were chosen as implantation sites in beagle dogs. In each of 12 dogs, four LHPSs, and four SPSs were implanted into both lower limbs. At 1, 2, and 3 months after surgery, four dogs were randomly sampled and sacrificed. The LHPS group and SPS group were subdivided into four subgroups according to the length of their duration of implantation (0, 1, 2, 3 months). The biomechanical properties of both pedicle screws were evaluated by pull-out and the cyclic bending tests.

Results: The results of the study showed that no significant difference was found between LHPSs (276.62 ± 50.11 N) and SPSs (282.47 ± 42.98 N) in pull-out tests at time 0 ($P > 0.05$). At the same time point after implantations, LHPSs exhibited significantly higher maximal pullout strength than SPSs (month 1: 360.51 ± 25.63 *vs* 325.87 ± 28.11 N; month 2: 416.59 ± 23.78 *vs* 362.12 ± 29.27 N; month 3: 447.05 ± 38.26 *vs* 376.63 ± 32.36 N) ($P < 0.05$). Moreover, compared with SPSs, LHPSs withstood more loading cycles (month 2: 592 ± 21 *vs* 534 ± 48 times; month 3: 596 ± 10 *vs* 543 ± 59 times), and exhibiting less displacement before loosening at month 2 (1.70 ± 0.17 *vs* 1.96 ± 0.10 mm) and 3 (1.69 ± 0.19 *vs* 1.92 ± 0.14 mm) ($P < 0.05$), but no significant difference in time 0 and month 1 ($P > 0.05$).

Conclusions: The pedicle screw with the hollow lateral hole structure could allow bone to grow into the inner architecture, which improved biomechanical properties by extending the contact area between screw and bone tissue after implantation into the cancellous bone. It indicated that LHPS could reduce loosening of the pedicle screws in long term after surgery.

Key words: Animal model; Cyclic bending test; Pedicle screw; Pull-out test; Screw loosening

Introduction

The pedicle screw fixation technique was first described by Boucher in 1950s.[1] Pedicle screws have long been regarded as the gold standard of treating various spinal disorders, such as fixing fractures and dislocations of the spine, spinal deformity, spinal instability, and other congenital diseases, because they stabilize the anterior, middle, and posterior columns of the spine.[2,3] However, loosening of the screws occurs in cases of insufficient strength of the screw fixation or mechanical overload of the reconstructed spine. Excessive bone loss or osteoporosis has been proven in numerous studies to weaken the long-term anchoring strength of screws, resulting in screw displacement.[4–6] The incidence of screw loosening is between 0.6% and 11% in

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normal bone mineral density (BMD).[7] The postoperative screw loosening incidence is up to 60% in patients with osteoporosis.[5] One of the critical elements impacting screw stability is the contact area with bone tissue following screw implantation.[8–10]

To our knowledge, the most straightforward method to enhance the anchorage strength is to optimize the diameter or length of pedicle screw insertion.[11–13] According to a study by Lai *et al.*,[12] the pull-out strength of diameter 5.00 mm screws was superior than that of diameter 4.35 mm screws in osteoporotic vertebrae. Liu *et al.*[3] discovered that long screws had significant influence on fracture vertebral restoration and lumbar spinal sagittal stabilities. However, it has been observed that inserting the pedicle screw into around 80% of the vertebral body would provide adequate fixation in most cases.[14] Increasing the diameter or length of the screw is not always feasible due to the constraints of the anatomical structure of the pedicle and the adjacent important blood vessels and nerves. A larger screw diameter is at risk of fracturing the pedicle and leading to nerve injury,[12] whereas a longer screw length could penetrate the anterior vertebral body and cause resultant visceral and vascular injury.[15] In addition, the surface of screws was applied with hydroxyapatite coating to provide good integration of the bone and enhance the fixation strength.[16] However, this approach limits the depth and range of bone and implant combinations. Several studies had demonstrated that a lateral hole structure can efficiently increase the contact area between the implant and bone, resulting in the stability of implants, which has been validated in several experiments.[17–19] Kim *et al.*[20] implanted the dental implants with side holes connected to hollow inner channel into mandibles of dogs. The bone was found to successfully regenerate through the lateral openings and hollow inner channel of the implant after implantation. This similar design concept has been applied to several studies in spinal instrumentation. According to Goldhahn *et al.*,[17] a hollow cylinder-based implant was applied to the lumbar vertebrae of sheep to achieve adequate anchorage. They discovered that the bone tissue could not just bind at the interface of the implant but also grow through the lateral holes into the interior of the implant, where it tightly bound with the internal sidewalls of the implant, achieving secondary reinforcement and promoting bone fusion. Zhang *et al.*[21] designed a novel atlantoaxial anterior transarticular screw with enlarged thread structures at both ends and a porous cylinder in the middle. The finite element analysis confirmed that the novel screw could provide improved biomechanical stability. However, the author only examined the anchoring effect at the time of immediate implantation, the long-term investigations were not performed.

The hollow lateral hole structure may be a promising solution to improve the stability of screws without changing the pedicle screw size. According to this characteristic, we developed a novel lateral hole pedicle screw (LHPS) to enlarge the implant-bone interface and augment the long-term stability with more bone contacts of implant. The fenestrated pedicle screw is similar to the hollow, lateral hole-based implant in terms of design, but it is designed to inject bone cement through perforation to increase the postoperative immediate anchoring force.[22,23] The use of bone cement prolongs the surgery time and exposes patients to additional risks such as cement leakage and cement embolism. Bone cement, as a foreign body, prevents direct contact between the bone and the screw. The main purposes of this study were as follows: (i) to investigate the effectiveness of the LHPSs in preventing loosening after instant and long-term implantation; (ii) to compare the maximum pullout force and anti-bending performance of LHPSs with that of solid pedicle screws (SPSs) *in vivo*; and (iii) on the basis of the results, to provide further theoretical support for the design improvement and clinical application of LHPSs. We hypothesized that the LHPSs would provide greater resistance to screw loosening in the cancellous bone compared with the SPSs, because of their increased surface contact with bone.

Methods

Study Design

This study is a randomized control animal trial. All experiments were licensed and approved by the Animal Ethics and Welfare Committee of Zhejiang Chinese Medical University (Approval No.: IACUC-20200928-07). This study followed the "Principles of Laboratory Animal Care" (NIH Publication Vol 25, No. 28 revised 1996; http://grants.nih.gov/grants/guide/notice-files/not96-208.html).

Design and Preparation of the Implanted Screws

LHPSs (Sanyou, Shanghai, China) and SPSs (Sanyou, Shanghai, China) were designed by our team for use in this study and commissioned to be produced by Sanyou Medical Device Co. Ltd. There were 48 screws of each type. LHPSs were made of titanium alloy and consisted of an outer diameter of 3.5 mm and were 24 mm long. SPSs used the same shape and size as the control (Fig. 1). A 1.5 mm hole was made at the top part of the screw for the pull-out tests. Unlike the SPS, lateral holes were made in the LHPS, with the hollow part at the center of the screw (diameter = 1.0 mm). The thread section was 21 mm long. Each upper and lower thread contained a lateral hole (diameter = 1.2 mm). Each LHPS contained 36 lateral holes. Before implantation, all screws were sterilized beforehand by autoclave.

Animal Surgery

A total of 12 mature beagle dogs (five females and seven males), provided by the Experimental Animal Center of the Zhejiang Chinese Medical University (Hangzhou, China), with a mean weight of 12.2 ± 0.7 kg was used in the experiment. The BMD was measured using dual-energy X-ray absorptiometry (Lunar, Madison, WI, USA) at g/cm^2.

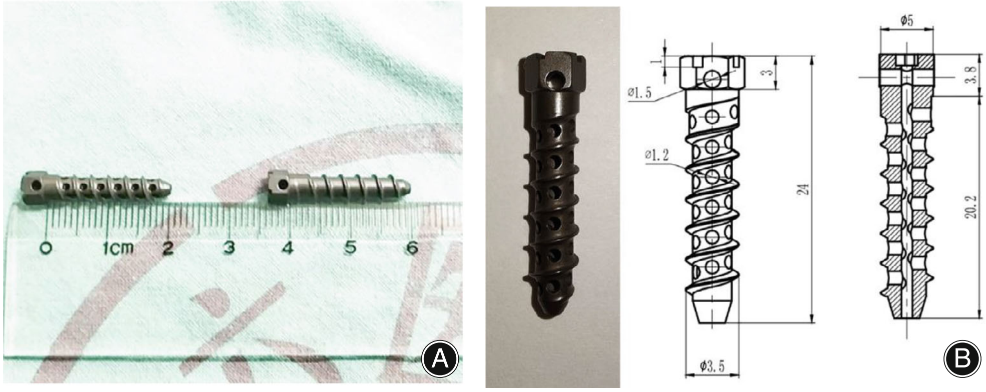

Fig. 1 The structure of the novel lateral hole pedicle screw (LHPS) and the solid pedicle screw (SPS). (A) The LHPS and the SPS. (B) The diagram of the LHPS (Dimension: mm)

After the dogs were anesthetized with pentobarbital (1%, 80 mg/kg), skin preparation and disinfection were conducted on the lateral sides of both hips and knee joints. A straight incision was made on the skin, the muscles were dissected to expose the distal and proximal metaphysis of the femur as well as the proximal metaphysis of the tibia. The aforementioned three sites were randomly implanted with LHPSs and SPSs (Fig. 2A). The postoperative positions of the screws were examined using the C-arm to ensure that they were located in the cancellous bone (Fig. 2B). Screws which were not in the appropriate place were removed. Then isotype screws were then implanted in the humeral metaphysis to maintain an equal number of LHPSs and SPSs. A total of 72 screws were utilized (six screws in each dog). The incisions were sutured layer by layer. After the operation, all dogs were put on penicillin for 5 days to prevent infection. The dogs were fed the same type and an equal amount of food. Twelve dogs, randomly allocated to three groups ($n = 4$ per each group) were randomly sacrificed with an overdose of pentobarbital (100 mg/kg injected intravenously) at the end of months 1, 2, and 3. Intact femurs and tibiae were removed and dissected free of soft tissue. Then SPSs and LHPSs were randomly inserted into the untreated metaphysis of distal tibia as time 0 controls. The samples were wrapped in a saline gauze and stored at −20°C. Half of the specimens underwent cyclic bending tests, while the other half were subjected to pull-out tests. The distribution of the two types of screws in above two tests is shown in Table 1.

Pull-out Tests

The samples were removed from the refrigerator 24 h before the experiment and thawed naturally at room temperature. The samples contained bone with screws implanted were embedded in denture base resin. Denture powder was carefully used to avoid penetrating into the interface of exposed prosthesis and bone, as this could enhance biomechanical strength and impact the reliability of the data. A high-strength steel wire was crossed into a hole pre-prepared on the screw for pulling out, and it was fixed into the clamp of the testing machine (Instron 5966, Instron, Norwood, MA, USA). And ensured that the direction of the pulling force was in the same straight line as the longitudinal axis of the screw. Each screw was pulled out at a constant rate of 5 mm/min until the failure of fixation. The displacement force curve was continuously captured and the peak force before failure was recorded as the maximal pull-out force (Fmax).

Cyclic Bending Tests

Cyclic bending tests on LHPSs and SPSs at different time points were performed using the same testing machine as the

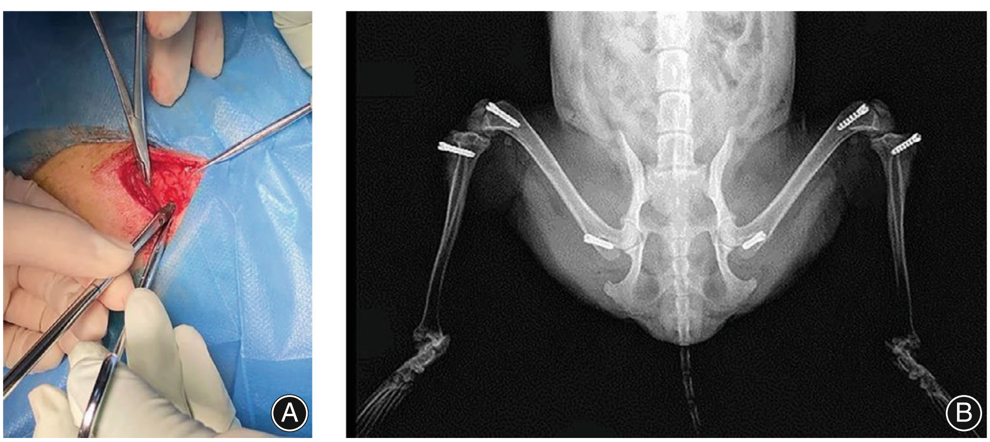

Fig. 2 (A) Lateral hole pedicle screw (LHPS) in the cancellous bone of the right lower extremities in the beagle dog. (B) X-ray photos of lower extremities implanted with LHPSs and solid pedicle screws (SPSs). The two screws on the upper end of the femur were removed because they were mispositioned

TABLE 1 The distribution of biomechanical test of the samples in each experimental group

		Number of tests performed	
Time (month)	Screw type	Pull-out test	Cyclic bending test
0	LHPS	6	6
	SPS	6	6
1	LHPS	6	6
	SPS	6	6
2	LHPS	6	6
	SPS	6	6
3	LHPS	6	6
	SPS	6	6

Abbreviations: LHPS, lateral hole pedicle screw; SPS, solid pedicle screw.

pull-out tests (Fig. 3). Each sample was fixed on the test platform with the screw aligned parallel to the horizontal plane of the platform. A perpendicular pressure was then applied to the longitudinal axis at the head of the screw through a rod. Based on previous research[10,24] and the normal physiological load (150 N) on pedicle screws, while walking in individuals,[25] the cyclic load was applied in the sinusoidal form at a frequency of 5 Hz, beginning at 10 and increasing gradually to 25 N, before reducing to 10 N (10 N → 25 N → 10 N). This process was performed 100 times. Then the load was raised by 25 N. This was followed by the 10 N → 50 N → 10 N, …, 10 N → 150 N → 10 N cycles. A total of 600 cycles were performed at each test. If the loading cycles did not reach 600 times, the displacement of the screw ≥2 mm was deemed to have loosened. The load and cycles were then recorded. After 600 cycles, the screw was regarded to have remained an anchor if the displacement was <2 mm and the displacement was recorded, and the load was recorded as 150 N at the end of the test.

Fig. 3 Cyclic bending test. Loading was applied to the head of the screw through the rod in a vertical direction to the screw axis

Statistical Analysis

Data were analyzed using SPSS software version 21.0 (IBM, Armonk, NY, USA). Variables were expressed as mean ± standard deviation (means ± SD). Depending if the results were normally distributed or not, parametric or non-parametric were used, respectively. Comparisons the data of the pull-out tests were performed using the two-way analysis of variance (ANOVA). When the ANOVA showed a significant interaction, simple effects analyses were conducted. For cyclic bending test results, the difference in the rates of the screw loosening at the same time point was analyzed using Fisher's exact test. The displacement and cycle results of LHPSs and SPSs at the same time point were compared using the Mann–Whitney *U* test. Comparisons of values between different time points for the same type of screws were performed using the Friedman test. Statistical significance was set at $P < 0.05$.

Results

The Characteristics of the Specimens

The dual-energy X-ray absorptiometry showed that the mean bone density of all the dogs was 0.63 ± 0.13 g/cm^2. There was no significant difference in BMD between the experimental groups ($P > 0.05$).

Analysis of Pull-Out Tests

The maximum pull-out force can be measured from the load–displacement curve (Fig. 4). During the pull-out of LHPS, the cancellous bone adhered to the screw surface through the lateral holes (Fig. 5A and B). After carefully removing the bone on the surface of the LHPS, the lateral holes and internal spaces of the screw were filled with bone (Fig. 5C). The average maximum pull-out force in the LHPS group and SPS group at time 0, and months 1, 2, and 3 are shown in Table 2. There was no significant difference at time 0 on peak pull-out force between LHPSs and SPSs ($P = 0.768$). At 1, 2, and 3 months, the average maximum pull-out force for LHPS group was greater than that for SPS group ($P = 0.087$, $P = 0.012$, $P = 0.003$, respectively). At the same time point, LHPSs provided a 10.63%, 15.04%, and 18.70% increase in pull-out strength over the SPSs, respectively. Compared with time 0, the maximal pull-out force of LHPSs increased by 30.32%, 51.60%, and 61.61%, at months 1, 2, and 3 respectively, after implantation. For SPSs, the

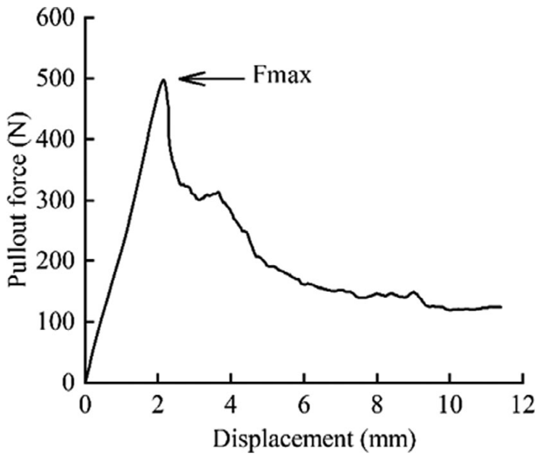

Fig. 4 The force-displacement curve after the axial pull-out test of the lateral hole pedicle screw (LHPS). The maximum pullout strength (Fmax) was defined as the inflection point at which the load hits its peak and drops sharply as displacement increases

pull-out force increased by 15.36%, 28.19%, and 33.34%. By 2 months, the maximum pull-out force of the LHPSs and SPSs increased significantly compared with time 0 ($P < 0.001$, $P = 0.001$, respectively), but the pull-out force between months 2 and 3 had no significant difference ($P = 0.553$, $P = 0.977$, respectively) (Fig. 6).

Analysis of Cyclic Bending Tests

The ratio of screw loosening, load, and displacement results for the LHPSs and SPSs are shown in Table 3. The loosening rates of the LHPSs in 1, 2, and 3 months were 66.7% (4/6), 33.3% (2/6), 16.7% (1/6), lower than the rates of SPSs, which were 83.3% (5/6), 66.7% (4/6), 66.7% (4/6). However, no significant difference was observed at those time points ($P > 0.05$). At time 0, similar results in cycles and displacement were found in two types of screws. Two and three months after implantation, there was a significant difference in displacement between the LHPSs and SPSs ($P = 0.043$, $P = 0.043$, respectively), and the LHPSs could bear greater ultimate loads. Significant improvement in displacement was detected in the LHPSs after implantation ($P < 0.05$), however, *post hoc* comparisons using the Bonferroni posttest were not statistically significant. While the displacement in SPS group showed no significant advance ($P > 0.05$). Furthermore, the loading cycles for LHPSs were significantly higher at months 2 and 3 ($P = 0.022$, $P = 0.010$, respectively). However, for SPSs, a significant difference was only observed at month 3 ($P = 0.031$) (Fig. 7).

Discussion

In the current study, we investigated the biomechanical properties of LHPSs in preventing postoperative loosening using pull-out tests and cyclic bending tests. The findings indicated that LHPSs provided comparable fixation stability to SPSs at the initial stage of implantation. Furthermore, we found that the strength of the bond between the bone and LHPSs increased larger over time than it did with SPSs, resulting in LHPSs having better long-term post-operative resistance.

The Reason for Selecting the Metaphysis of Dog Limbs as Implant Sites

In this study, we used a novel pedicle screw design with a hollow lateral hole structure to improve the long-term stability of the screws in the dog models. This screw design offers potential advantages because of larger contact area with the

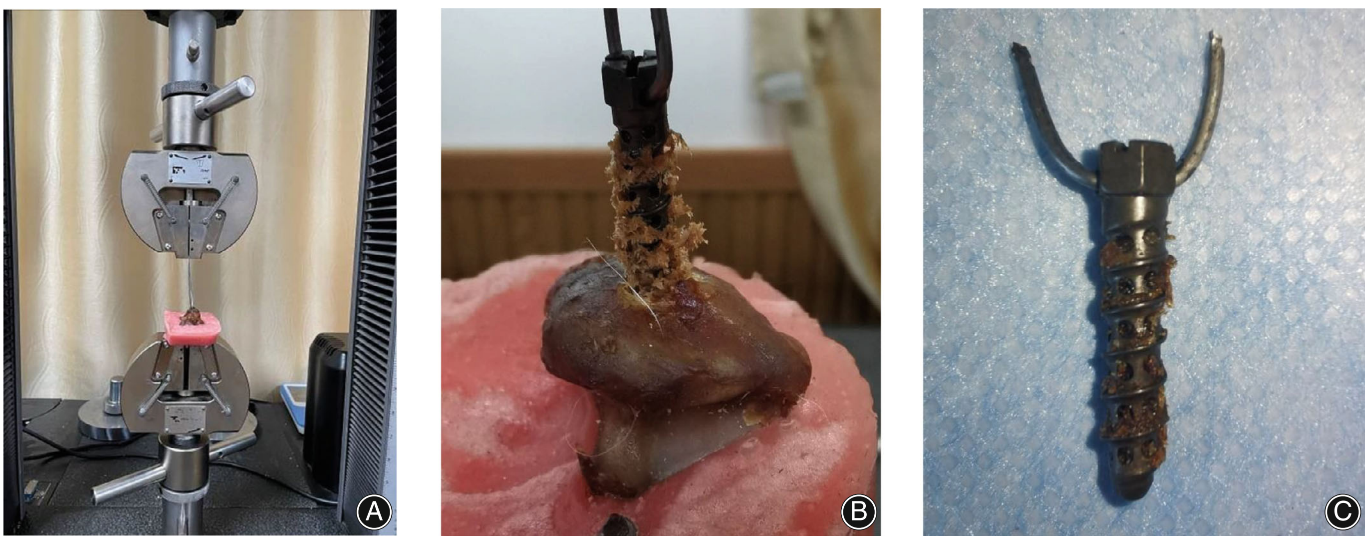

Fig. 5 (A) The pull-out test for the lateral hole pedicle screw (LHPS). (B) LHPS was pulled out with part of the bone adhere. (C) Lateral holes and inner spaces were filled with cancellous bone

TABLE 2 Results of LHPSs and SPSs in pullout tests ($n = 6$, means ± SD)

Study periods (Month)	LHPSs' Fmax (*N*)	SPSs' Fmax (*N*)	*F*	*P* value
0	276.62 ± 50.11	282.47 ± 42.98	0.088	0.768
1 month	360.51 ± 25.63	325.87 ± 28.11	3.094	0.087
2 months	416.59 ± 23.78*	362.12 ± 29.27	7.062	0.012
3 months	447.05 ± 38.26*	376.63 ± 32.36	9.868	0.003

Notes: Fmax represents the maximum pull-out strength.; * The difference in Fmax between SPS and LHPSs at the same time point, $P < 0.05$ (two-way ANOVA, effect of the type of screw).; Abbreviations: LHPS, lateral hole pedicle screw; SPS, solid pedicle screw.

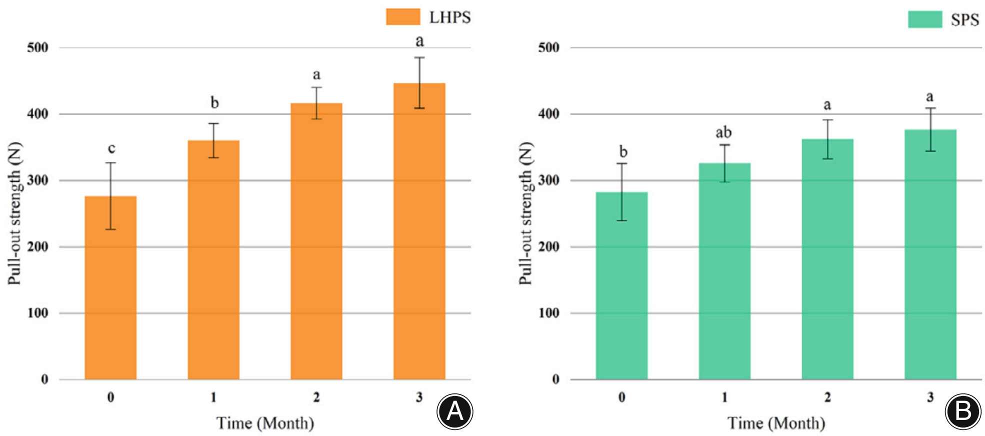

Fig. 6 The pullout force of lateral hole pedicle screws (LHPSs) and solid pedicle screws (SPSs) at different time points. Error bars represented mean ± SD. Same letter indicates a lack of significant difference, whereas different letters indicate a significant difference, $P < 0.05$. (two-way ANOVA, effect of time)

TABLE 3 Findings of the cyclic bending tests ($n = 6$, means ± SD)

Evaluation	LHPS	SPS	*Z*	*P* value
Loosening rate				
time 0	100%	100%	-	-
1 month	66.7%	83.3%	-	1.000
2 months	33.3%	66.7%	-	0.567
3 months	16.7%	66.7%	-	0.242
Cycle				
time 0	311 ± 34	317 ± 35	−0.314	0.753
1 month	508 ± 73	478 ± 85	−1.214	0.225
2 months	592 ± 21*	534 ± 48	−2.023	0.043
3 months	596 ± 10	543 ± 59	−1.841	0.066
Displacement (mm)				
time 0	2.00 ± 0.00	2.00 ± 0.00	0.000	1.000
1 month	1.92 ± 0.15	1.99 ± 0.04	−1.342	0.180
2 months	1.70 ± 0.17**	1.96 ± 0.10	−2.023	0.043
3 months	1.69 ± 0.19***	1.92 ± 0.14	−2.023	0.043
Load (*N*)				
time 0	88 ± 14	88 ± 14	0.000	1.000
1 month	133 ± 13	129 ± 19	−0.577	0.564
2 months	150 ± 0	141 ± 13	−1.414	0.157
3 months	150 ± 0	141 ± 13	−1.414	0.157

Abbreviations: LHPS, lateral hole pedicle screw; SPS, solid pedicle screw.; *Notes*: * Cycle comparison at month 2, $P < 0.05$.; ** Compared with SPSs' displacement at month 2, $P < 0.05$.; *** Compared with SPSs' displacement at month 3, $P < 0.05$ (Mann–Whitney *U* test).

surrounding trabecular bone. The results confirmed our hypothesis that the LHPSs performed superiorly to the SPSs after operation. Beagle dogs were used in the biomechanical tests to simulate the performance of the screws *in vivo* in a more realistic manner, as their bone tissue structure and bone metabolism are similar to those of humans.[26,27]

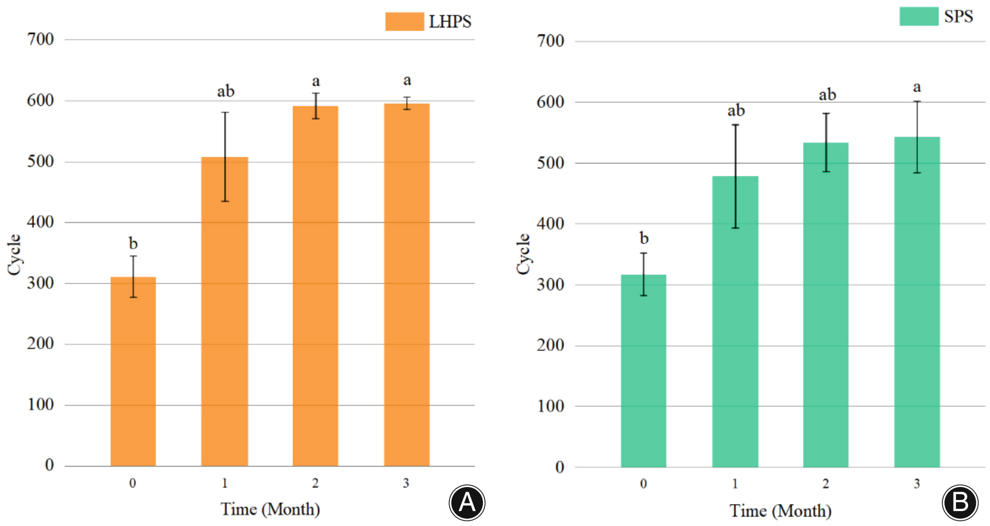

Fig. 7 The average number of cycles for lateral hole pedicle screws (LHPSs) and solid pedicle screws (SPSs) at different time points in the cyclic bending tests. Error bars represented mean ± SD. The difference between groups was analyzed using the Friedman and the *post hoc* multiple comparisons test. A significant difference is indicated by different letters, $P < 0.05$

The implantation path of the pedicle screw includes the pedicle and the anterior vertebral body. Because the threads of the pedicle screw engage in the denser subcortical bone of the pedicle, the cancellous bone within the pedicle segment is not decisive for screw fixation.[28] The diameter of the two experimental screws utilized in this study was the same, so their anchoring performance at the pedicle segment would be little difference. Instead, a large amount of cancellous bone with regenerative ability in the vertebral body had the greatest impact on the comparison of the biomechanical characteristics of LHPSs and SPSs. Selecting the metaphyseal cancellous bone of the dog limbs as the screw implantation sites was equivalent to simulating the performance of LHPSs in the vertebral body. This choice was similar to that made by Chen *et al.*[29] and Fu *et al.*,[30] who investigated the biomechanical characteristics of reinforced pedicle screws by simulating the vertebral cancellous bone structure using synthetic bone modules. The lower extremity metaphysis performed the same role as synthetic bone modules, but it also simulated bone tissue healing and remodeling. Furthermore, implanting screws in the dog limbs could reduce the difficulty of operation and surgical trauma.

Axial Pull-out Tests Outcomes

In pull-out tests, the peak pull-out force, which represents the maximal screw-bone interfacial strength, was higher in LHPSs compared with the SPSs at the same time point, particularly at months 2 and 3. The bonding strength is largely determined by the combined area of bone-screw contact.[31] After the LHPSs were pulled out, we found that bone tissues regenerated through the lateral holes and bridged across the internal hollow structure. Due to this, LHPSs display superior stability by providing mechanical interlocking at the bone-screw interface. Pull-out tests can directly and objectively reflect the screw fixation strength and longitudinal stability by measuring the pull-out resistance of the pedicle screw.[7,32] This method provides valuable comparison data, while screw pullout is not a typical clinical failure method.

Cyclic Bending Tests Outcomes

Axial compression, anteroposterior shear, and flexion/extension are the main cyclic loads that are given to pedicle screws during daily activities after surgery. The flexion and extension movements are the major factors leading to the loosening of the pedicle screws.[13] When subjected to cyclic loading, pedicle screws experience a "teeter-totter effect," in which the outer cortical bone acts as a fulcrum, and the distal end of the screw swings and pushes away from the surrounding cancellous bone in the vertebral body, resulting in pedicle screw loosening.[33] Given that the pull-out force tests cannot simulate human flexion and extension on pedicle screws, these events were simulated using cyclic bending tests in order to more closely approximate the clinical model of pedicle screw loosening.[34,35] Subjected to the cyclic loading in the present model, the LHPSs proved to be more effective at resisting screw loosening. Except for the immediate postoperative, we discovered that the vertical loosening displacement was less for LHPSs, relative to SPSs. These tests showed that LHPSs could withstand more cycles and greater load before loosening. As a result, there was lower tendency to failure of LHPSs.

Main Findings Analysis of this Study

In this study, we decided to standardize the length and diameter of testing screws, and chose the length (24 mm) and outer diameter (3.5 mm) of SPS to match the length and outer diameter of LHPS. Previous literature has shown that increasing the screw length and diameter increased fixation strength.[3,12] Axial pull-out tests and cyclic bending tests have been proven to be reliable indicators for evaluating the strength of pedicle screw fixation, including in cadaveric spine specimens, animal models, and synthetic models.[33,36]

Biomechanical tests revealed that LHPSs could achieve the similar fixation strength as SPSs at the initial stage of implantation, allowing them to meet the initial stability requirements. After insertion of screw, the screw formed an immediate "screw-bone" interface through direct contact with the surrounding bone, which laid a foundation for the long-term stability of screws.[37,38] The interface experienced a healing process of micro-fracture. Moreover, these biomechanical findings demonstrated that the strength of bonding between the bone and LHPSs was increased with implantation time, and the magnitude of the increase was larger than that of the SPSs. This may be associated with the continuous growth of the bone into the screw through the lateral holes, and the integration of the internal and external surface of the screw as a whole, potentially improving anchorage of the LHPSs within trabecular bone. While SPSs with non-lateral holes allow bone to grow on the surface only. Clinically, the fixation device must provide strong enough fixation in the initial first 6 months with minimal movement of the pedicle screw until fusion is complete. Thus, LHPSs had a good impact on the overall fixation and longevity after surgery. However, the strength of bonding for LHPSs and bone did not improve significantly in the third month, relative to the second. We speculated that the healing time of testing screws ranged from 2 months to 3 months in beagle dogs. This finding was consistent with the duration of bone remodeling cycle in dogs reported in the literature.[39]

Limitations and Strength of the Study

There were still some limitations of this study. First, our sample size of only 12 dogs was relatively small. Second, studies utilizing synthetic bone modules, due to anatomical differences in the vertebrae and limb metaphysis, the experimental results might deviate. The results of this experiment were similar with the long-term performance of screws in the vertebral body but not in vertebrae. However, the results of this study were nevertheless instructive. Additionally, it was worth noting that the screws were implanted at the proximal and distal end of femur and tibia. The thickness of cortical bone at the above locations were not the same, and this variation may change the performance of screw fixation. Finally, LHPS was designed with evenly spaced lateral holes to maximize the ingrowth of new bone tissue, but this ignored the variation of cancellous bone content in various regions of the vertebra. In following study, the design of the lateral hole structure should be improved based on the proportion of cancellous bone content in the pedicle and vertebral body. The relationship between screw stability and hollow lateral hole structure should be examined by correlation tests in the vertebrae.

Conclusions

In summary, the lateral holes and hollow inner channel of the LHPS could conduct bone ingrowth during post-implantation healing and achieve the purpose of increasing the contact area between screw and bone in cancellous bone. The LHPSs retained the ability of the pedicle screw to immediately anchor strength, effectively increased purchase after implantation, and lowered the risk of loosening.

Acknowledgments

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Authors' Contributions

All authors had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Yong Hu designed the study and provided a critical review of the manuscript. Yong Hu and Zhen-tao Chu collected and analyzed the data and wrote the main manuscript. Shu-feng Shen provided conceptual advice and the statistical analyses and critically revised the article. Wei-xin Dong, Jian-bin Zhong and Bing-ke Zhu performed the surgeries and collected the data. Jia-da Wu and Zhen-shan Yuan prepared Figures and tables and revised the initial manuscript. All authors have read and approved the final submitted manuscript.

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