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ORIGINAL ARTICLE

Effect of pilot hole on biomechanical and in vivo pedicle screw–bone interface

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Abstract

Purpose To experimentally study the influence of pilot hole diameter (smaller than or equal to the internal (core) diameter of the screw) on biomechanical (insertion torque and pullout strength) and histomorphometric parameters of screw–bone interface in the acute phase and 8 weeks after pedicle screw insertion.

Methods Fifteen sheep were operated upon and pedicle screws inserted in the L1–L3 pedicles bilaterally. The pilot hole was smaller (2.0 mm) than the internal diameter (core) of the screw on the left side pedicle and equal (2.8 mm) to the internal diameter (core) of the screw on the right side pedicle. Ten animals were sacrificed immediately (five animals were assigned to pullout strength tests and five animals were used for histomorphometric bone–screw interface evaluation). Five animals were sacrificed 8 weeks after pedicle screw insertion for histomorphometric bone–screw interface evaluation.

Results The insertion torque and pullout strength were significantly greater in pedicle screws inserted into pilot holes smaller than internal (core) diameter of the screw. Histomorphometric evaluation of bone–screw interface showed that the percentage of bone-implant contact, the area of bone inside the screw thread and the area of bone outside the screw thread were significantly higher for pilot holes smaller than the internal (core) diameter of the screw immediately after insertion and after 8 weeks.

Conclusion A pilot diameter smaller than the internal (core) diameter of the screw improved the insertion torque and pullout strength immediately after screw insertion as well the pedicle screw–bone interface contact immediately and 8 weeks after screw placement in sheep with good bone mineral density.

Keywords Biomechanics · Bone screws · Histology · Spine

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Introduction

Pedicle screw-based construction has been extensively used to provide mechanical stability in the treatment of various diseases including tumors, traumas, deformities, or degeneration [2]. The anchorage system relies on the holding capacity of screws placed in bone, which in turn is directly dependent on the purchase capacity of the screw. Despite technological advances, implant failures, such as screw bending, breakage, and loosening still occur [2, 10, 40]. It is well established in the literature that the holding power of the pedicle screw is influenced by bone mineral density [5], geometry of the screw [1, 20, 25–27] and the screw insertion technique employed by the surgeon [5, 14, 33, 38]. It has been reported that the holding power of the pedicle screw is significantly influenced by the size and technique of the pilot hole [5, 7, 14, 15, 33]. For self-tapping cylindrical pedicle screws, reduction of the pilot hole diameter in relation to the screw outer diameter increases screw pullout force; however, the correlation of the pilot hole with screw internal (core) diameter was not mentioned [4, 6, 12, 15, 16].

Most published studies concerning pedicle screw pullout strength have used autopsied bone [11, 13, 17] or synthetic materials [9, 14, 21], whereas living bone has rarely been evaluated [37]. In living bone, the holding power of the screw is related to the bone adjacent to the screw, which is the weakest element in the bone–screw component [36]. Screw pullout strength is proportional to the quantity and quality of bone between the threads. Holding power will be dependent not only on screw design, but also on the changes induced in bone by insertion trauma, bone reaction around the implant, and resorption and remodeling as a result of healing [10, 36].

The purpose of the present study was to experimentally study the influence of pilot hole on insertion torque, pullout strength and in vivo bone–screw interface of lumbar pedicle screws in the acute and chronic phase after screw insertion. We addressed the following research questions: (a) does the diameter of the pilot hole in relation to the screw core diameter influence screw insertion torque, pullout strength, and bone–screw contact? (b) What are the features of the bone interface contact in the acute and chronic phase of screw insertion? (c) Does compaction alter bone outside the screw thread? We tested the hypothesis that changes of the pedicle pilot hole diameter should be followed by biomechanical and histomorphometric alterations at the pedicle screw–bone interface in the acute and chronic phase after screw insertion.

Materials and methods

All experiments were strictly conducted in accordance with National Institute of Health Guidelines for the Welfare of Experimental Animals, with the methodology reviewed and approved by the local Animal Care Use Committee (protocol number 011/2005). Lumbar vertebrae from L1 to L3 segments of 15 healthy male Santa Inês sheep, body weight 35.7 ± 4.8 kg, were used ($n = 45$ vertebrae).

The screws used in the study were cylindrical self-tapping pedicle screws (4.0-mm outer diameter, 2.8-mm internal diameter, 30 mm in length) composed of commercial titanium (USSI®-Synthes, Paoli, PA, USA).

Surgical protocol

In all surgical procedures, animals were anesthetized with an intramuscular solution consisting of 0.5 mg/kg xylazine (Dopaser®; Calier, Barcelona, Catalunya, Spain), 0.1 mg/kg acepromazine (Acepram®; Univet, São Paulo, São Paulo, Brazil), and 2 mg/kg ketamine (Ketamina®; Agener União Saúde Animal, São Paulo, São Paulo, Brazil) for induction followed by a maintenance solution of 1 g ketamine, 100 g xylazine, and 50 g guaiacol glyceryl ether (Quimibrás, Rio de Janeiro, Rio de Janeiro, Brazil) in saline infused through a venous line (3 mL/kg/h) during the procedure. Postoperative analgesia was obtained using intramuscular tramadol hydrochloride (União Quimica Farmaceutica Nacional; Porto Alegre, Minas Gerais, Brazil). Animals of the acute group ($n = 10$) were euthanized immediately after screw placement (acute phase) and animals of the chronic group ($n = 5$) were euthanized 8 weeks after surgery (chronic phase). Euthanasia was performed under general anesthesia with intravenous ketamine (10 mg) and xylazine (10 mg).

The lumbar spine was exposed through a posterior approach and lumbar vertebrae (L1–L3) were exposed after skin incision, sectioning of the fascia, and muscle retraction.

For every pedicle (L1–L3), the pilot hole was prepared coaxial with the pedicle under direct vision using a pilot hole smaller (2.0 mm) or equal (2.8 mm) to the internal diameter (core) of the pedicle screw. On the left side, the pilot hole was smaller than the internal diameter of the pedicle screw (2.0 mm) and on the right side the pilot hole was the same as the internal diameter (2.8 mm) of the pedicle screw. A starter awl was used to create the entry point and the pilot holes were created under direct vision using drills at the L1–L3 levels. All screws were manually inserted into the pedicle under direct visualization according to the manufacturer's specification.

Ten animals were randomly sacrificed immediately after screw placement (acute phase) and five animals were sacrificed 8 weeks after surgery (chronic phase). In the animals of the acute group, the vertebrae (L1–L3) were removed after screw placement. The individual vertebral bodies were separated from one another using a scalpel and prepared for mechanical (five animals) and histological (five animals) study.

Bone mineral density was assessed in the group of five animals prepared for mechanical study. The mineral bone density of each vertebra was assessed by dual-energy X-ray absorptiometry (DEXA) using the QDR system with version 11-2:5 software (Hologic 4,500 W, Watham, MA, USA). The results showed that the mean bone mineral density of the specimens was 0.62 ± 0.12 g/cm^3 (mean ± standard deviation).

In the animals of the chronic group ($n = 5$), the wounds were closed in layers using degradable atraumatic 3.0 polyglycan suture material (Vycril 2.0; Ethicon, Somerville, NJ, USA) and the skin was sutured using Nylon 3.0 suture (Mononylon 3.0; Ethicon). The animals were sacrificed after 8 weeks under general anesthesia with ketamine (10 mg) and xylazine (10 mg) and the lumbar vertebrae (L1 and L3) were removed.

Biomechanical assessment (insertion torque and pullout test)

The pedicle screws were driven through the pilot hole with a screwdriver coupled to a torque device (TL-500/MKMT-1;Mackena Corporation, São Pailo, SP, Brazil) and the maximum torque reached during screw insertion was recorded.

A mechanical pullout test was carried out using a universal testing machine EMIC® (DL 10,000; EMIC, São José dos Pinhais, PR, Brazil) working with a load cell capacity of 2,000 N, at room temperature. The pullout force was applied longitudinally in relation to the screw position, at a rate of 2.0 mm/min until the screw came out. The pullout strength was determined by the computer software Tesc 3.13 (EMIC®, São José dos Pinhais, PR, Brazil).

Histomorphometric analysis

Individual vertebral bodies were separated from one another with a scalpel and prepared for histological study. The screws together with 5 mm surrounding bone were separated from the lumbar vertebrae and fixed in 10 % neutral buffered formalin. The specimens were subsequently dehydrated in an ascending series of ethyl alcohols and infiltrated with methyl methacrylate (LR White®, London Resin Company, Berkshire, Inglaterra). The hardened blocks were sectioned with a microtome (Microslice 2-Ultratec®, Santa Ana, CA, EUA) along the long axis of each screw to obtain sections of ~100 µm, and passed again through the process of grinding and polishing until reaching a thickness of about 70 µm. Sections were then stained with Alizarin red and Stevenel′s blue for light microscopy analysis.

Blind quantitative histomorphometric analysis was performed with a Leica DM LB2 light microscope using images acquired at 25× and 100× magnification with a Leica camera (Leica DC300 F; Leica Microsystems GmbH, Wetzlar, Germany) coupled to the light microscope. For the analysis of images, software Quiuin Leica (Leica Microsystems GmbH Nussloch, Germany) was used. The program quantifies the bone tissue in the blade, setting the amount bone in relation to bone density. The values were given in percentage e μm^2. Histomorphometric measurements included bone-implant contact (percentage of linear measurement along the axial wall of the sectioned implant), area of bone inside the screw thread in a measuring frame, and area of bone outside the screw thread (rectangular area adjacent to the screw thread) with a length equivalent to the number of screw threads in the measuring frame and a height equal to the height of the screw thread. The measurement frame was the same for both screw modalities, covering the length of three threads of the pedicular screw (Fig. 1).

Statistical analysis

Analysis of variance (ANOVA) was used for the biomechanical assessment of the different groups. Then, insertion torque and pullout strength were compared for the diameter of the pilot hole using the Wilcoxon test. The level of significance was set at 5 % ($p < 0.05$). The Mixed Effects Linear Model using SAS® 9.0 (SAS Institute Inc., Cary, NC, USA) software was used to compare the histomorphometric measurements, with the level of significance set at $p < 0.05$.

Results

Insertion torque

The insertion torque was measured during screw insertion (L1–L3) in five animals ($n = 30$) in the acute phase. The mean insertion torque required for screws inserted into the pilot hole (2.0 mm) smaller than the internal diameter (core) of the screw was significantly greater than that of the pilot hole equal to the internal diameter (core) of the screw ($p = 0.006$) (Table 1).

Pullout strength

The screw pullout strength test was applied to the pedicle screws ($n = 30$) of five animals in the acute phase (15 screws inserted with a pilot hole smaller than the internal diameter of the screw and 15 screws inserted with a pilot

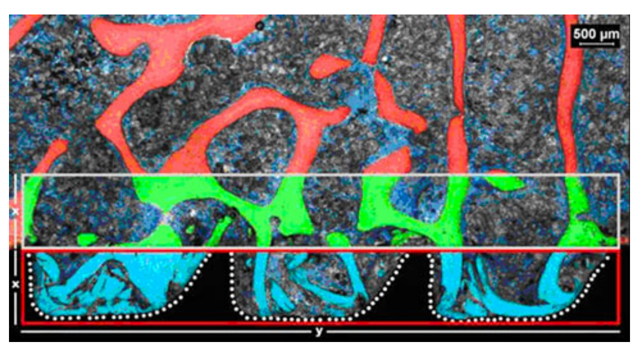

Fig. 1 Micrograph of the bone-implant interface illustrating the histomorphometric measurement. Bone-implant contact is indicated by the *dotted line*. The *red rectangle* delimits the area selected for evaluation of the area of bone inside the screw thread. The length (*y*) is equivalent to the number of screw threads in the measuring frame. The height (*x*) is equal to the height of the screw thread. The *white rectangle* delimits the area of bone outside the screw thread. Staining: alizarin *red* and Stevenel′s *blue*; ×25 magnification

Table 1 Screw insertion torque and pullout strength (mean and standard deviation) of screws inserted into pilot holes of 2.0 and 2.8 mm of five animals

Pilot hole diameter (mm)	Insertion torque (Nm)	Pullout strength (N)
2.0	3.7 ± 0.5	2196.9 ± 420.9
2.8	3.2 ± 0.5	1926.8 ± 259.11
	*$p = 0.006$	*$p = 0.027$

* indicates a statistically significant difference ($p = 0.006$ and $p = 0.027$)

hole diameter equal to the internal diameter of the screw). The mean pullout strength was significantly greater for the screws in the pilot hole smaller than the core of the screw ($p = 0.027$) (Table 1).

Histomorphometry

Results were analyzed considering the diameter of the pilot hole (smaller than or equal to the internal diameter of the screw) and period of sacrifice (acute phase—immediately after screw placement; chronic phase—8 weeks after screw placement). A total of three histomorphometric analyses were performed for each screw in the acute (5 animals) and chronic (5 animals) groups.

The pullout resistance of the screw is proportional to the volume of bone between the threads. To evaluate the impact of the pilot diameter on screw–bone interface, we measured the percentage of bone-implant contact and the area of bone inside the screw thread.

The percentage of bone-implant contact was significantly higher for pilot hole smaller than the internal diameter (core) of the screw in the acute (40.81 ± 12.87 vs. 6.15 ± 2.69; $p < 0.01$) and chronic phase (62.49 ± 19.73 vs. 16.38 ± 9.42; $p < 0.01$) (Figs. 2, 5, 6).

The percentage of bone inside the screw thread area was significantly higher for a pilot hole smaller than internal (core) screw diameter in the acute (37.40 ± 5.68 vs. 14.22 ± 3.85 µm^2; $p < 0.01$) and chronic phases (58.47 ± 4.68 vs. 41.33 ± 9.84 µm^2; $p < 0.01$) (Figs. 3, 5).

The area of bone outside the screw thread was significantly greater for pilot holes smaller than the internal (core) screw diameter in the acute (33.67 ± 7.59 vs. 23.51 ± 5.97 µm^2; $p < 0.01$) and chronic phases (61.67 ± 9.85 vs. 45.15 ± 6.52 µm^2; $p < 0.01$) Figs. 4, 5).

Discussion

Our findings support the hypothesis that the diameter of the pilot hole in relation to the screw core diameter influences screw–bone contact, insertion torque, and pullout strength. Pedicle screw insertion torque and pullout strength in the acute phase were higher in screws inserted into pilot holes smaller than internal (core) diameter of the screw as also was screw–bone contact in both the acute and chronic phases. The use of a pilot hole smaller than the internal diameter of the screw promoted greater bone-implant contact, increased area of bone inside the thread of the screw, and a larger area of bone outside the thread of the screw immediately and 8 weeks after screw insertion.

Most published data concerning pedicle screw pullout strength are based on autopsied bone [11, 14, 17] or synthetic materials [9, 15, 21]. Despite numerous reports on screw pullout strength, there are only limited data on the histomorphometric analysis of the pedicle screw–bone interface [10, 34, 35, 41]. Histomorphometric evaluation is more frequently reported for coated or expandable pedicle screws. Although the quantity and quality of bone between screw threads are important factors concerning screw pullout strength [10] and screw pullout strength is reportedly proportional to the volume of bone between the screw threads [3], the pullout test is the standard and more commonly used method to evaluate the mechanical properties of the bone–screw interface [22, 23]. The need to use living animals in the acute phase of the study for

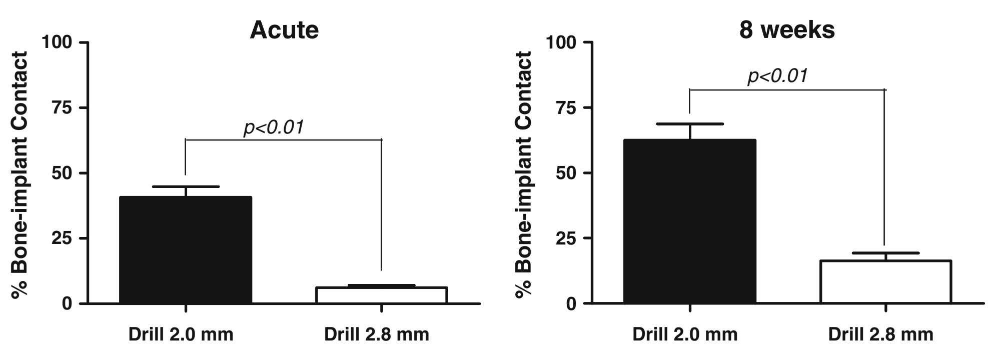

Fig. 2 Graph showing the percentage of bone-implant contact (mean and standard deviation) comparing pilot holes of 2.0 and 2.8 mm immediately (acute) and 8 weeks (chronic) after screw insertion. A significant difference ($p < 0.01$) was observed in the acute and chronic phases

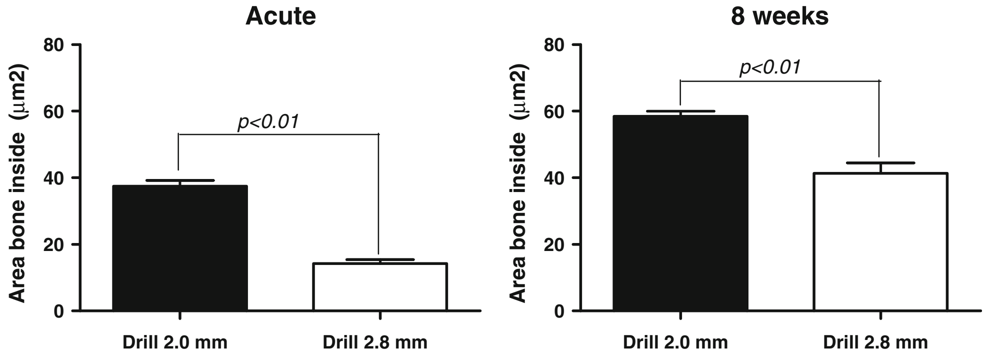

Fig. 3 Graph showing the area of bone inside the screw thread (mean and standard deviation) comparing pilot holes of 2.0 and 2.8 mm immediately (acute) and 8 weeks (chronic) after screw insertion. A significant difference ($p < 0.01$) was observed in the acute and chronic phases

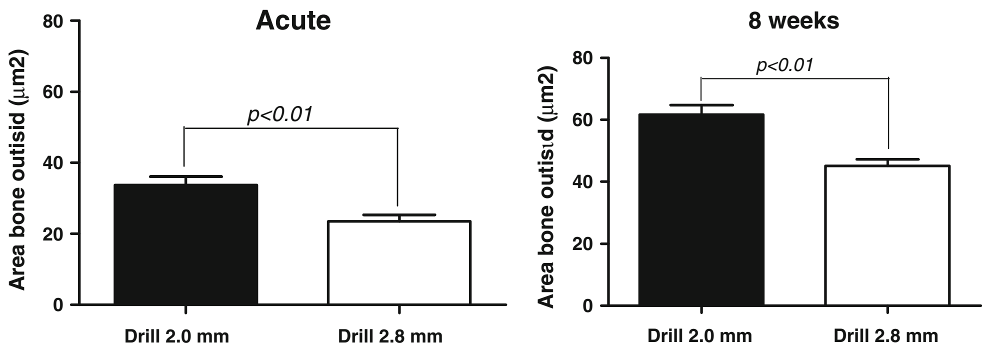

Fig. 4 Graph showing the area of bone outside the screw thread (mean and standard deviation) comparing pilot holes of 2.0 and 2.8 mm immediately (acute) and 8 weeks (chronic) after screw insertion. A significant difference ($p < 0.01$) was observed in the acute and chronic phases

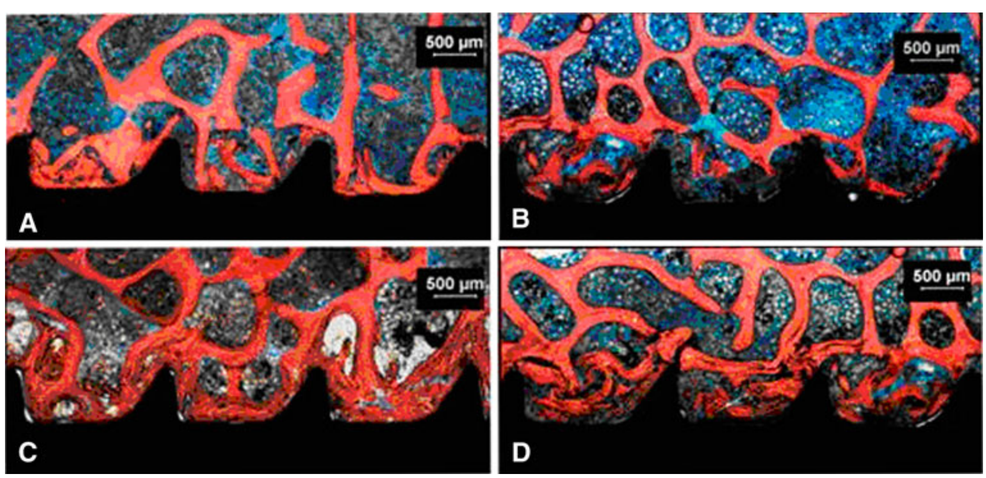

Fig. 5 Micrographs of the trabecular bone-implant interface illustrating the histomorphometric results of drilling different diameters in the acute and chronic phases. Alizarin *red* staining represents the bone in contact with implant interface (**a**) Drilling of 2.0 mm in the acute phase; (**b**) drilling of 2.8 mm in the acute phase; (**c**) drilling of 2 mm in the chronic phase; (**d**) drilling of 2.8 mm in the chronic phase. Staining: Alizarin *red* and Stevenel′s *blue*; magnification ×25

histomorphometric investigation of the screw–bone interface was based on the results of the pilot study. On pilot study spines from the butcher showed considerable changes of the bone histological architecture.

As stated above, screw pullout strength is related to the screw–bone interface and the quantity and quality of bone between the threads. In living bone, the holding power of a screw is a function of the weakest element in the

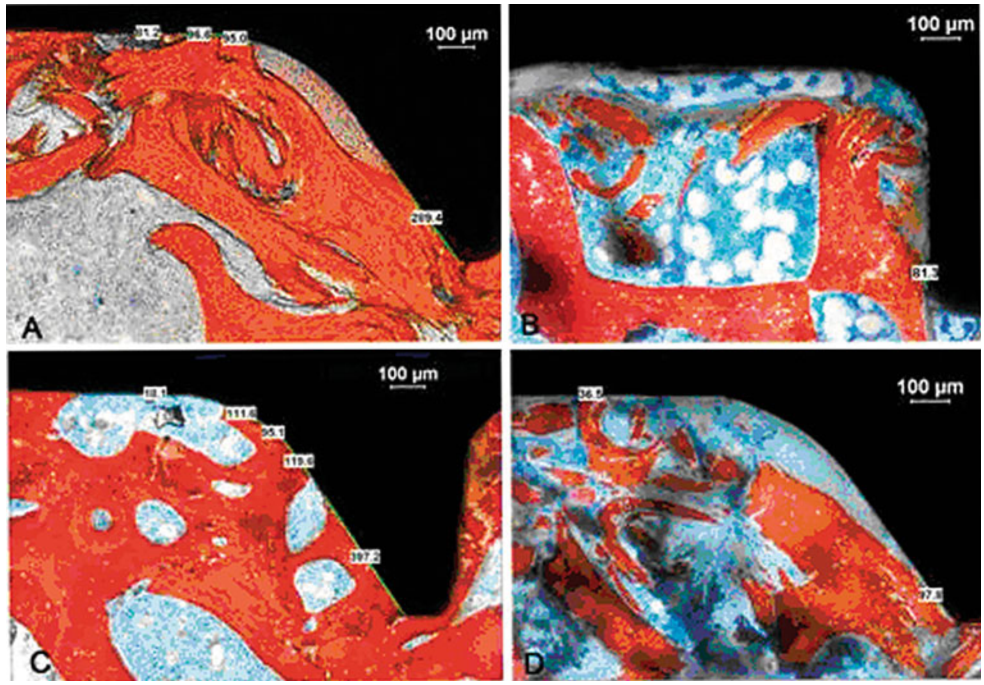

Fig. 6 Micrographs of the trabecular bone-implant interface contact illustrating the histomorphometric results of drilling different diameters in the acute and chronic phases. Alizarin *red* staining represents the bone in contact with implant interface. (**a**) Drilling of 2.0 mm in the acute phase; (**b**) drilling of 2.8 mm in the acute phase; (**c**) drilling of 2.0 mm in the chronic phase; (**d**) drilling of 2.8 mm in the chronic phase. Staining: Alizarin *red* and Stevenel′s *blue*; magnification ×100

bone–screw composite, the bone adjacent to the screw. Holding power will not only be dependent on the screw design but also on changes induced in bone by insertion trauma, reaction of bone to the implant, and resorption and remodeling as a result of healing [36]. According to our findings, the simple use of a pilot hole diameter smaller than the inner diameter of the screw increases pedicle screw fixation that provides immediate stability to the spinal fixation system. Our results of the study are statistically significant and may reflect the clinical application. Coating of pedicle screws, bisphosphonate treatment, and expandable screws have also been used to improve the holding power of pedicle screws by acting on the screw–bone interface and increasing the contact and volume of the bone surrounding the screw thread [35, 41].

The insertion torque has been considered the best predictor of ultimate screw interface failure and is correlated with pullout strength [42]. The use of a pilot hole smaller than the internal diameter (core) of the screw promotes a radial displacement and impaction of cancellous bone by the core of the screw during its insertion, resulting in greater bone–screw contact and a larger area of bone inside the screw thread. There are limited reports on the histomorphometric analysis of the pedicle screw–bone interface; compression of the cancellous bone by the screw during its insertion is considered to increase its density and pullout strength, which is thought to explain the higher pullout strength observed in the conical pedicle screw [10, 37] and pedicle screw implanted without tapping [10, 34]. The holding power of cancellous screws inserted into a cadaveric femur through pilot holes smaller than those proposed by the manufacturer increased significantly the pullout strength. Unlike the vertebral cancellous bone, the use of a pilot hole smaller than the internal (core) screw diameter should be avoided in cortical bone because it causes cortical bone fissures and microcraks that lead to bone fixation failure [39]. The increased pullout strength effect of cancellous bone compression around the pedicle screw was also observed using a tap smaller than the screw diameter or untapped screw pedicle screw insertion [7]. In our study, the pilot hole smaller (2.0 mm) than the internal diameter of the screw (2.8 mm) was randomly chosen. So far the threshold diameter of the pilot hole to promote mechanical and histomorphometric changes in bone tissue adjacent to the screw is not known.

Pilot hole preparation and pedicle screw insertion promote mechanical and environment changes in bone tissue adjacent to the screw. After screw insertion, initial healing involves bone remodeling in the vicinity of the screw, resembling the repair of bone fractures [19, 39]. The screw–bone interface was more active in screws inserted into smaller pilot holes. It is likely that the amount of compacted bone, microfractures, and bleeding influence bone remodeling and explain the larger amount of bone surrounding the screw after 8 weeks, even in the area outside the screw thread. A greater number of inflammatory cells was observed when high insertional torque was applied to screws inserted into bone [28, 29]. Studies on mechanical tension of metallic implants over bone tissue consider microtension over bone to be a favorable stimulus for healing and improvement of bone density. However, excessive force can cause necrosis and ischemia at the screw–bone interface [32].

While animal models may closely represent the mechanical and physiological human clinical situation and allow the evaluation of materials in loaded and unloaded situations and the study of the implant-bone interface, it should be remembered that this is only an approximation, since each animal model has unique advantages and disadvantages [24]. Sheep spines have been accepted and used as a model, but they have smaller pedicle and vertebral body size than human spines, and screws of smaller diameter were used in the study. Although differences in bone density exist between humans and sheep, sheep bone dimensions are suitable for the study of human implants. Sheep and humans have similar patterns of bone growth; thus, sheep remain a valuable model for human bone turnover and remodeling activity [8, 18, 30, 31].

There are some limitations of the present study. The first is related to the lack of an associated rod or plate attached to the screws, which would closely simulate the clinical situation. The second factor to be considered is that the screws were not submitted to load, so the adjacent bone healed undisturbed. If the cantilever effect on the screw promotes more or less remodeling of bone around the screw is another question to be answered. The screw loading rate influences the mechanics of the bone–screw interface. The zone of histology within the pedicle and within the vertebral body could be differentiated in the study. The pedicle of the spine is more important in resisting pullout than the vertebral body. A pullout test in the chronic phase would have added value to the study and would correlate with the histomorphometric outcomes.

In our study, the use of a pilot hole smaller than the internal (core) diameter of the screw improved insertion torque and screw pullout strength in the acute phase. The screw–bone contact—immediately and 8 weeks after pedicle screw insertion, according to histomorphometric parameters—indicates that the use of a pilot hole smaller than internal diameter of the screw in sheep with good bone mineral density is a useful method for improving the holding capacity of the pedicle screw. The clinical application of the results would be the recommendation of undersizing the pilot hole and not to use taps of the same size of the screw for pedicle screw insertion. However, the results cannot be extrapolated to bone conditions like osteoporotic bone.

Conflict of interest None.

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