The Influence of Thread Tap Mismatch on Pedicle Screw Pullout Strength*

A influência da incompatibilidade do macho de rosca na resistência à extração do parafuso pedicular

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Abstract

Objective We aimed to study the "in vitro" pullout strength of SpineGuard/Zavation Dynamic Surgical Guidance Z-Direct Screw (DSG Screw, SpineGuard Inc, Boulder, Colorado, USA), a screw designed to be inserted using a direct insertion technique.

Methods Dynamic Surgical Guidance Screws of 5.5 and 6.5 mm were introduced into polyurethane blocks with a density of 10 PCF (0,16g/cm^3). According to the experimental group, screws were inserted without pilot hole, with pilot without tapping, undertapping and line-to-line tapping. Screw pullout tests were performed using a universal test machine after screw insertion into polyurethane blocks.

Results Screws inserted directly into the polyurethane blocks without pilot hole and tapping showed a statistically higher pullout strength. Insertion of the screw without tapping or with undertapping increases the pullout screw strength compared with line-to-line tapping.

Conclusion Dynamic Surgical Guidance Screw showed the highest pullout strength after its insertion without pilot hole and tapping.

Keywords
- spinal fusion
- pedicle screw
- bone screws
- biomechanical phenomena/ physiology

Resumo

Objetivo Nosso objetivo foi estudar a resistência à extração "in vitro" do parafuso SpineGuard/Zavation Dynamic Surgical Guidance Z-Direct (Parafuso DSG Guia

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Cirúrgico Dinâmico SpineGuard Inc, Boulder, Colorado, USA), um parafuso projetado para ser inserido utilizando a técnica de inserção direta.

Métodos Os parafusos DSG de 5,5 e 6,5 mm foram introduzidos em blocos de poliuretano com densidade de 10 PCF (0,16g/cm^3). De acordo com o grupo experimental, os parafusos foram inseridos sem um orifício piloto, com um orifício piloto sem o macheamento, com macheamento e com macheamento linha a linha. Os testes de extração do parafuso foram realizados em uma máquina de teste universal, após a inserção do parafuso em blocos de poliuretano.

Resultados Os parafusos inseridos diretamente nos blocos de poliuretano sem o orifício piloto e o macheamento mostraram uma resistência à extração estatisticamente maior. A inserção do parafuso sem o macheamento ou com o macho de menor diâmetro aumenta a resistência à extração do parafuso em comparação com o macheamento linha a linha.

Conclusão O parafuso DSG apresentou a maior resistência à extração após a inserção sem o orifício piloto e o macheamento.

Palavras-chave
- fusão vertebral
- parafusos pediculares
- parafusos ósseos
- fenômenos biomecânicos/fisiologia

Introduction

Pedicle screw-based construction is currently the most used method for fixation of the thoracic and lumbar spine.[1,2] The clinical usefulness of pedicle screw-based construction is supported by the high rate of fusion, deformity correction and clinical outcomes.[1–3] The average accuracy for pedicle screws inserted with free-hand or fluoroscopy is of 85,1%, and of 95% for pedicle screws using navigation.[4] The main problems related to pedicle fixations include the mechanical properties of pedicle screws, their accuracy and the use of intraoperative radiation for placement. Failures such as screw loosening still occur despite technological advances, at rates reported to as being between 0.6 and 11%.[5,6] The placement and radiation exposure to the surgeon, mainly in minimally invasive procedures, are drawbacks of pedicle screw fixation.[3–5] The exposure of the surgeon to radiation during a fluoroscopic assisted thoracolumbar pedicle screw surgery is 10 to 12 times greater when compared with other nonspinal procedures assisted by the fluoroscopic technique.[2,7,8]

The Pediguard Threaded Device (PDT) was developed to prepare the pilot hole into the vertebra and to overcome the problems related to pedicle screw insertion. The PTD is a drilling instrument with a thread design and a sensor at the tip that can be used to drill the pilot hole, directly followed by the screw insertion, reducing surgical steps and radiation exposure, and with increased accuracy.[9–11]

The PTD is a drilling instrument with a threaded tip available in various sizes (4.0, 4,5, 5.5 mm) with different thread designs, that is used to streamline surgical steps while maintaining the accuracy for pedicle preparation for screw placement. The use of PDT allows to prepare the pilot hole of the pedicle to provide adequate mechanical purchase of the screw, improving the pedicle screw accuracy using the impedance at its tip.

Tapping the pilot hole is currently performed by spinal surgeons before pedicle screw insertion.[10] Pilot hole tapping allows the inspection of the pedicle walls before screw insertion and guides the insertion of the screw into the pedicle.[11] A thread on the inner surface of the pilot hole is produced by the tap, creating a female surface for the pedicle screw. Although the use of a tap with the same diameter of the pedicle screw results in a perfect match, it reduces the screw pullout strength, mainly in osteoporotic bone, and it is not recommended.[3,4,12] Screw pullout strength is related to screw purchase and to the biomechanical stability of the pedicle fixation system. The use of a tap 1 mm smaller than the diameter of the screw (undertapping) increases pedicle screw pullout strength, and undertapping is commonly used for pedicle screw placement.[10]

It was reported that undertapping with incongruent pitch (longitudinal distance between thread crest) reduces the pedicle screw pullout strength.[10] Using a tap with a different pitch from that of the pedicle screw does not allow the screw thread to fit the precut groove by the tap. A concerned raised with the use of PDT for the introduction of pedicle screws with different pitch was the motivation for the study.

The aim of the present study was to experimentally evaluate the influence of the pilot hole tapping using PTD and a screw with a different pitch from that of the tap. We tested the hypothesis that undertapping with congruent and incongruent threads will have similar effect on screw pullout strength.

Methods

One hundred and five polyurethane blocks of 8 cm height, 5 cm width and 5 cm length, with a density of 10 PCF (0.16g/cm^3) (National Ltda., Santana de Parnaíba, São Paulo, Brasil) were used as test bodies to introduce screws and to perform the mechanical pullout tests. A pre-hole of 40 mm depth was made in the center of the polyurethane block using a 2.7mm drill. The screws were inserted straight into the foam after tapping according to the experimental group. Three types of tapping were performed: 1–Line-to-line tapping (tap with same pitch and external diameter of the screw), 2–

Fig. 1 PediGuard Threaded Drill used in the study.

Fig. 2 Screws of 5.5 mm and 6.5 mm in external diameter.

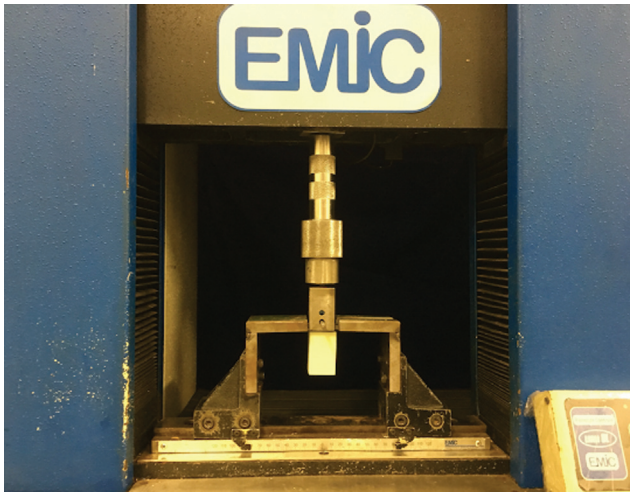

Fig. 3 Universal test machine EMIC.

Table 1 Pullout strength for Legacy pedicle screw 5.5mm

Tap	Pullout Strength (N)
Tap Legacy 5.5	587.9 ± 18.19 (*) (**)
Tap Legacy 4.5	549.0 ± 21.92 (*)
Ped 4.5 D1TA 11	544.2 ± 3.176 (**)
Ped 4.5 D1TA 13	531.0 ± 34.03

The asterisks (*) and (**) indicate a statistical difference

Undertapping with congruent pitch (tap with the same pitch and 1 mm smaller external diameter than the screw) and 3 - Undertapping with incongruent pitch (tap with different pitch and/or different number of lead and 1 mm smaller external diameter than the screw).

Tap with congruent pitch was a tap provided by companies as part of the instrumentation set. A congruent pitch means that the thread pitch of the tap is the same as that of the screw. Congruent taps of the same external diameter of the screw (5.5 and 6.5 mm) (line-to-line tap) or 1 mm smaller (4.5 and 5.5 mm) (undertapping) were used according to the experimental group.

Pediguard Threaded Devices of different diameters and pitches were used in the experimental group of undertapping with incongruent pitch. Two PDTs of 4.5mm (Ped D1TA0011 and Ped D1TA0013) were used as undertapping with incongruent pitch for 5.5 mm screws. The D1TA0011 tap has a pitch of 2. 9mm with a double lead design, and the D1TA0013 has a pitch of 2.5 mm with a double lead design. One PDT of 5.5mm (D1TA0001) was used as undertapping with incongruent pitch for a 6.5 mm screw. The D1TA0001 tap has a pitch of 2.8mm with a single lead design. Compared with the respective manufacturer taps, the Pediguard threaded devices also have a tip with a nonthreaded portion ($\sim$ 10 mm) for redirection (►**Figure 1**).

Three different types of pedicle screws of 5.5 and 6.5 mm in external diameter, and with different types or design with different diameters and pitches were used. Screws with diameter-tapered and homogeneous pitch (Legacy-Medtronic, Minneapolis, MN, USA), with core and threads of two types (Solera-Medtronic, Minneapolis, MN, USA), and with conical core homogeneous threads (Revere-Globus, Audubon, PA, USA) (►**Figure 2**) were used.

The experimental group was formed according to the type of the screw (external diameter and manufacturer) and preparation of the pilot hole. Each experimental group was formed by five polyurethane blocks.

After screw insertion, pullout strength was evaluated using a universal test machine (EMIC-DL10000, São José dos Pinhais, PR, Brazil). A rod was attached to the head of the screw and pullout force was applied vertically (►**Figure 3**). The pullout force was applied at a speed of 2.0 mm/min until the screw was pulled out of the polyurethane block (►**Figure 1**).

Statistical Methods

The nonparametric Kruskal-Wallis test was used to compare the pullout strength among the different screws. The level of significance was set at 5% ($p \leq 0.05$). To further define these differences, the Dunn multiple comparison post-test was performed, and comparisons with a p-value below the adopted level of significance (0.05) were indicative of a difference between groups.

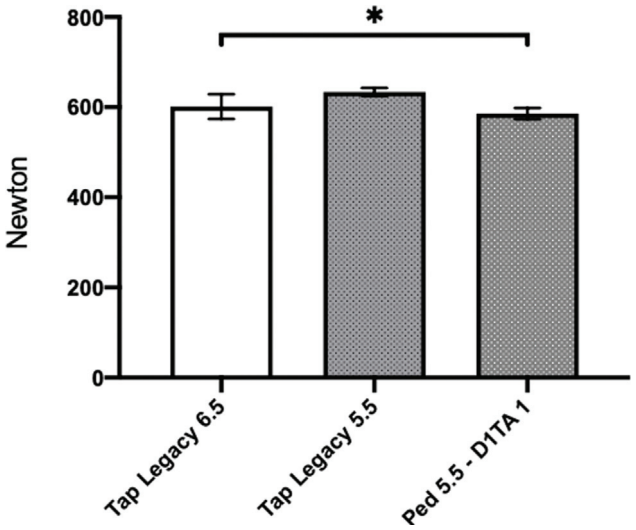

Fig. 4 Pullout strength for Legacy pedicle screw 6.5mm.

Table 2 Pullout strength for Legacy pedicle screw 6.5mm

Tap	Pullout Strength (N)
Tap Legacy 6.5	601.5 ± 27.40 (*)
Tap Legacy 5.5	633.6 ± 9.311
Ped 5.5 - D1TA 1	585.8 ± 12.43 (*)

The (*) asterisks indicate a statistical difference

Results

The results of screw pullout strength in the experimental groups according to the tapping are illustrated in Tables and Figures.

There was no statistical difference between pullout strength of 5.5 and 6.5 mm Legacy screws (►**Table 1** and ►**Figure 4**) using undertapping with congruent pitch or undertapping with incongruent pitch. Undertapping with incongruent screw showed a statistically lower pullout strength compared with line-to-line tapping ($p = 0.0089$).

The Legacy 5.5 mm screw presented lower pullout strength using line-to-line tap compared with undertapping with congruent and incongruent pitch. A statistical difference was observed between undertapping with congruent and incongruent pitch using the D1TA0011 tap ($p < 0.05$) compared with line-to-line tapping. No statistical difference was observed between undertapping using incongruent pitch with the D1TA0013 tap. (►**Table 2** and ►**Figure 5**)

There was no statistical difference between the pullout strength of 5.5 and 6.5 mm Solera screws (►**Tables 3**, **4** and ►**Figure 6**, **7**) using undertapping with congruent pitch or undertapping with incongruent pitch.

There was no statistical difference between the pullout strength of 5.5 and 6.5 mm Revere (Globus) (►**Tables 5**, **6** and ►**Figure 8**,**9**) using undertapping with congruent pitch or undertapping with incongruent pitch.

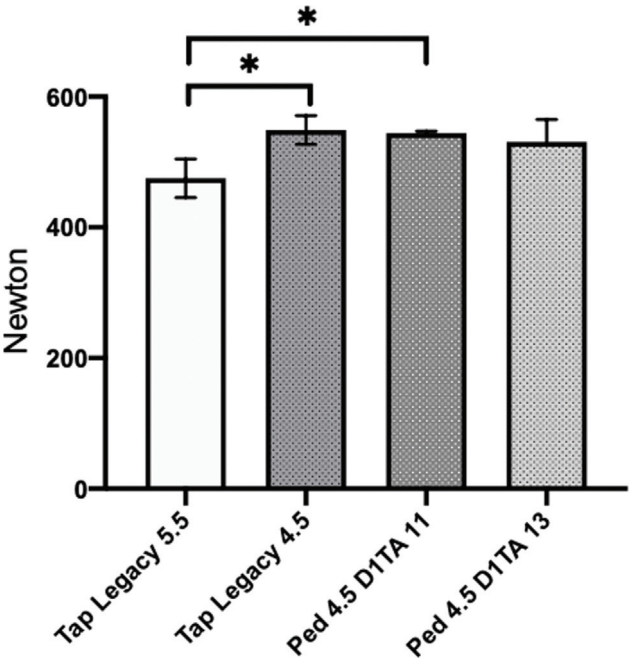

Fig. 5 Pullout strength for Legacy pedicle screw 5.5mm.

Table 3 Pullout strength for Solera pedicle screw 5.5mm

Tap	Pullout Strength (N)
Tap Solera 5.5	541.3 ± 18.19
Tap Solera 4.5	546.6 ± 42.46
Ped 4.5 D1TA 11	501.1 ± 29.16
Ped 4.5 D1TA 13	513.8 ± 14.56

Table 4 Pullout strength for Solera pedicle screw 6.5mm

Tap	Pullout Strength (N)
Tap solera 6.5	581.3 ± 42.10 (*)
Tap Solera 5.5	662.8 ± 48.32 (*)
Ped 5.5 - D1TA 1	607.8 ± 20.27

The (*) asterisks indicate a statistical difference

Discussion

Our findings support the hypothesis that undertapping of the pilot hole with incongruent pitch does not reduce screw pullout strength compared with undertapping with congruent pitch in every modality of pedicle screw tested. The effect of undertapping was not uniform on the three pedicle screw types used in the study.

Although pedicle screws are largely used in spinal surgery, problems still occur due to insufficient fixation of the interface between the screws and the bone.[13] The reported rate of pedicle screw loosening is of between 0.6 and 11%.[14,15] It is important to avoid screw loosening from the viewpoint of

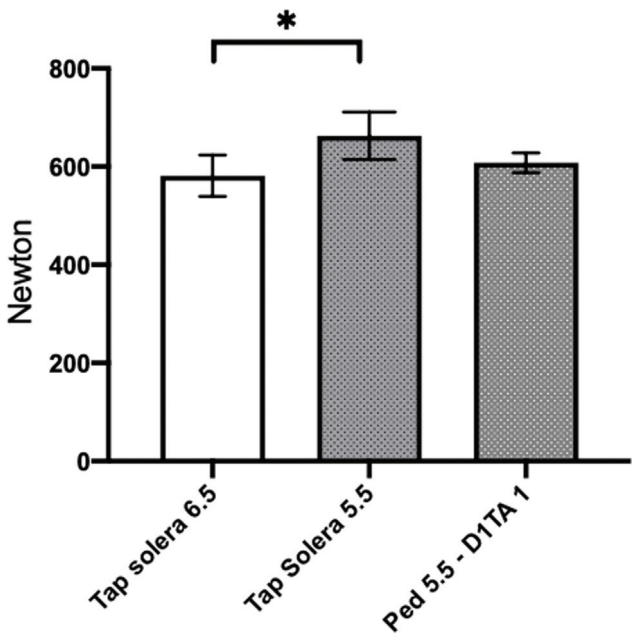

Fig. 6 Pullout strength for Solera pedicle screw 6.5mm.

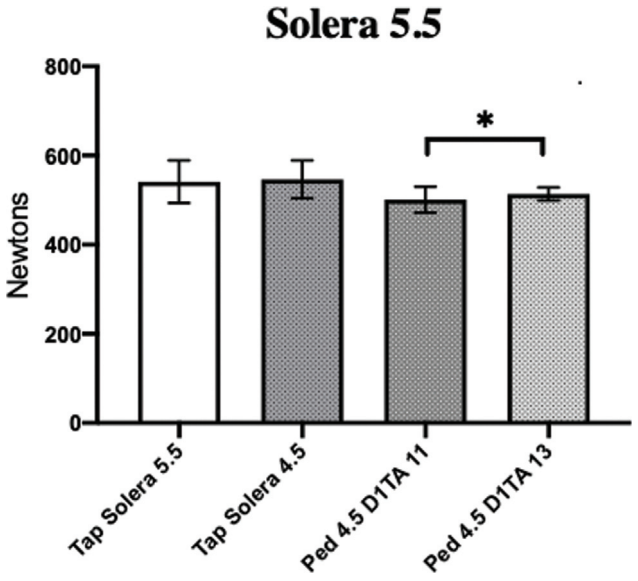

Fig. 7 Pullout strength for Solera pedicle screw 5.5mm.

Table 5 Pullout strength for Globus pedicle screw 5.5mm

Tap	Pullout Strength (N)
Tap Globus 5.5	587.9 ± 18.19
Tap Globus 4.5	607.2 ± 21.88
Ped 4.5 D1TA 11	625.7 ± 24.54 (*)
Ped 4.5 D1TA 13	581.6 ± 9.776 (*)

The (*) asterisks indicate a statistical difference

biomechanics and to secure mechanical stability in the vertebrae. Several strategies have been made on implant design and pilot hole preparation to improve fixation on the bone screw interface to improve screw loosening.[10,16]

Table 6 Pullout strength for Globus pedicle screw 6.5mm

Tap	Pullout Strength (N)
Tap Globus 6.5	667.3 ± 14.36
Tap Globus 5.5	678.0 ± 21.03
Ped 5.5 - D1TA 1	652.9 ± 16.17

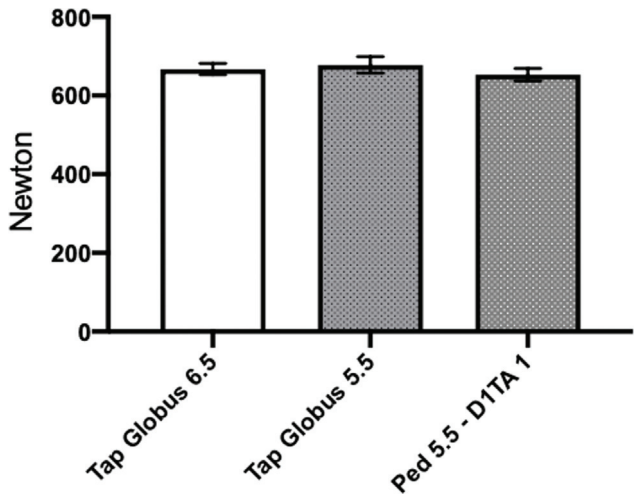

Fig. 8-Pullout strength for Globus pedicle screw 6.5mm.

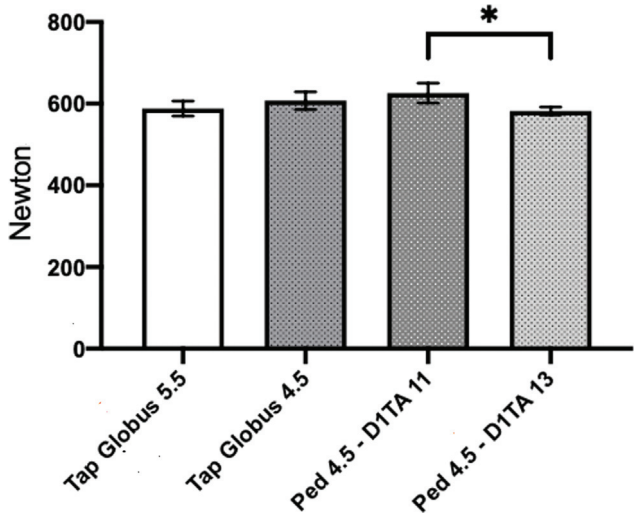

Fig. 9 Pullout strength for Globus pedicle screw 5.5mm.

Pilot hole preparation is the only variable that can be controlled by the surgeons during the operation. Parameters related to the preparation of the pilot hole, such as diameter, mode of preparation, tapping and repetitive insertion of screw have been reported,[10,17–19] and optimization of the pilot hole has been performed to enhance the mechanical anchorage of the screws into the vertebrae.[20]

The use of PTD with a different pitch compared with the screw designs used in the present study did not reduce the pullout strength of all types of screws used in the study. The effect of undertapping with incongruent pitch observed in

our study does not correlate with the results reported by Bohl et al.,[10] who reported the decrease of screw pullout strength of undertapping with incongruent pitch compared with undertapping with congruent pitch. Undertapping has a smaller minor diameter and major diameter than the screw and, even though it is incongruent, it allows the radial displacement and compaction of the cancellous bone by the core of the screws. The design of the screw could interfere with the ultimate amount of bone compacted and contained inside the screw thread that act on screw pullout strength. If undertapped, incongruent tap pitch alone would not be able to change the screw pullout strength, and other factors like screw design could play a role in it.[19–22]

Tapping the pilot hole is currently performed by spinal surgeons before pedicle screw insertion.[10] However, same-size pretapped pedicle screws reduce the screw pullout strength, mainly in osteoporotic bone, and they are not recommended.[3,12,19] The undertapped pilot hole promotes a radial displacement and compaction of cancellous bone by the core of the screw during its insertion, resulting in greater bone-screw contact and in a larger amount of bone inside the screw thread.[23]

Undertapping by 1 mm is considered safe and achieves the same screw pullout strength compared with an untapped screw, which has the highest pullout strength.[19]

In the field of spinal surgery, tapping was also introduced to allow the inspection of the pilot hole walls before screw insertion and to guide the insertion of the screw into the pedicle.[19] The accuracy of the trajectory of the pedicle screw is improved by tapping the pilot hole before screw insertion.[23] In clinical practice, it should also be considered that the use of PTD reduces the number surgical steps for pedicle screw insertion, increases the accuracy and reduces the radiation exposure to the surgeon.[20,24] The PTD combines the need to make a pilot hole and do a tap into one step without a decrease in screw pullout strength.[25]

The limitation of the experimental model used in the present study should be considered. Insertional torque, which has been used in many experimental studies related to pedicle screws, was not performed. There is no correlation between insertional torque and pullout strength,[20] and this was the reason for not including this type of evaluation in the present study.

Another limitation of the experimental model used in the present study is the fact that only pure axial force was applied, and no radial force. The test was performed on a single screw setup and not on a complete construct with rods or plates. The screws were not submitted to side load, which influences the mechanics of the bone-screw interface.

Finally, the tests have been performed in soft foam blocks, representative of osteoporotic bone. A harder model could give higher and different pullout values.

The pullout strength test may not be commonly seen in a clinical setting, but its simplicity and reproducibility allow it to be considered as the most efficient method to compare screw anchorage within the bone. It is accepted as a good predictor of the mechanical performance of the screw. However, pedicle screws are subjected to a complex mechanically demanding situation represented by an association of twisting, bending and pullout force.[24,25]

The simplification of force studied here may not represent a realistic clinical condition, but it may provide useful information when comparisons are made under controlled conditions.[24,25] Screw pullout strength does not represent the only mechanism of screw failure, but it reflects the magnitude of screw purchase.[25]

The PTD is a drilling instrument with a threaded tip available in various sizes (4.0, 4,5, 5.5mm) with different thread designs that is used to streamline surgical steps while maintaining the accuracy for pedicle preparation for screw placement. This device has an impedance measurement capability at the tip. A change in the pitch and cadence of the audio feedback indicates a change in the tissue around the tip of the PTD. A mid-range-pitch and medium-cadence audio signal can be heard as the probe is being advanced into the cancellous bone. A low-pitch and low-cadence audio signal can be heard as the probe approaches the pedicle cortical wall, and is the first indication of the potential breach.[26] The ability of the probe with impedance capability at the tip (Pediguard probe) has been experimentally and clinically shown to improve accuracy and to reduce surgeon radiation exposure.[6,9–12]

As the surgeon cannot change the bone quality, improvement in screw design and insertional techniques are made to improve screw fixation, and undertapping of the pilot hole should be included among them.[25,27] Although PDT has an incongruent pitch compared with the pedicle screws used in the present study, undertapping the pilot hole with incongruent pitch showed no statistical difference compared to undertapping with congruent pitch.

Conclusion

Undertapping of the pilot hole with congruent or incongruent pitch does not affect the pedicle screw pullout strength. The pedicle screw pullout strength may be influenced by many factors, such as screw thread design, and the use of an incongruent pitch alone has no effect.

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Conflict of interests
The authors have no conflict of interests to declare.

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