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Cutting Flute and Thread Design on Self-Tapping Pedicle Screws Influence the Insertion Torque and Pullout Strength

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Abstract: Self-tapping screws are commonly used in trauma and maxillofacial surgery and are increasingly used for pedicle screw insertions. In order to evaluate how the quantity and length of cutting flutes on self-tapping pedicle screws affect the insertion torque and pullout strength, eight different self-tapping pedicle screw designs were evaluated. All screws had a threaded length of 35 mm and featured variations in the number of leads, as well as the length and quantity of cutting flutes. Five samples of each design were inserted into pre-drilled, untapped holes (ø2.7 mm, length 35 mm) in sawbone blocks of density 20 PCF. The insertion torque and pullout strength were measured according to ASTM F543. The results showed that screws with a longer cutting flute of 9.5 mm had a lower mean maximum insertion torque than screws with shorter 2.9 mm cutting flutes. Pedicle screws with a double-lead thread design had a greater insertion torque than their single-lead counterparts, and the use of three cutting flutes produced a lower torque than two cutting flutes. The results demonstrated a greater pullout strength in screws with a single-lead thread rather than a double-lead, three cutting flutes instead of two, and a longer length for the cutting flute. In conclusion, to provide immediate stability and reduce the surgical insertion time, a single-lead, self-tapping pedicle screw incorporating three long cutting flutes is recommended because of the significantly greater pullout strength. This design could also reduce the risk of implant loosening in comparison to double-lead, self-tapping pedicle screw designs.

Keywords: self-tapping screws; pedicle screws; cutting flute; insertion torque; pullout strength

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1. Introduction

The traditional method of inserting bone screws is to drill a pilot hole and use a tapping tool to create a threaded path. For traditional pedicle screw insertion, the first step is to open the superficial cortex of the entry point with a burr and use a pedicle probe to navigate down the isthmus of the pedicle into the vertebral body. A tap is then used to create the screw threads. However, self-tapping screws are now commonly used in trauma and maxillofacial surgery and are increasingly used for pedicle screw insertions because of the simpler insertion technique without the use of a tapping tool and reduced operative time [1,2].

The fixation ability of bone screws can be gauged by the insertion torque and pullout strength, which are assessed using methods described in ASTM F543 [3]. It has been reported [4–6] that self-tapping screws have a lower insertion torque and higher pullout strength than conventional screws. The initial lower insertion torque and compression force of the bone screw could provide surgeons with the feeling of the screw driving into bone and provide a higher holding power for a more stable fixation [1]. Although screws rarely fail by pulling out of the bone in clinical applications, pullout testing is still considered a good predictor of screw fixation capability [7].

Previous studies have reported that the thread pitch, cutting flute length, and the total number of flutes can have a considerable influence on the insertion torque and pullout strength of self-tapping bone screws inserted into cortical and cancellous bone [8–10]. Although a number of manufacturers claim their screw designs are self-tapping, most commercially available pedicle screws with a self-tapping design still state that a pre-tapped hole is required. Chatzistergos et al. [11] showed that a pre-tapping technique could increase the pullout force of self-tapping pedicle screws inserted into solid rigid polyurethane foam, but this finding is not consistent with similar research [9,10]. Pedicle bone acts as a strong bridge between the dorsal spinal elements and the vertebral body, consisting of a strong shell of cortical bone and a dense core of cancellous bone [12]. Since the bone material modulus impacts the self-tapping screw design, the material properties of spine pedicle may cause the performance of self-tapping design to be different from the trauma bone screw used in long bone insertion. The insertion process of pedicle screws is different from the insertion of a small bone screw into long bone shaft, and the influence of flute design may not be comparable for small cortical/cancellous bone screws.

In most commercial pedicle screws, the conical core often narrows towards the distal aspect of the screw, and hence screws with short flutes (one to two cutting pitches) may not provide adequate fixation in cases where a pre-drilled pilot hole is used. Previous studies have shown that the quantity and design of cutting flutes are critical factors affecting the insertion torque and resulting holding strength of traditional pedicle screws in bone [10]. Pedicle screws with a double-lead design (screw thread with a lead equal to twice the pitch) have recently been brought to market and have reported a higher driving torque compared to the standard pedicle screws [13]. However, the authors are not aware of any previous research into the influence of cutting flute design on the insertion of double-lead pedicle screws. The aim of this study was to evaluate how the quantity and length of cutting flutes on a self-tapping double-lead pedicle screw affect the torque and pullout strength, and to compare the results against those from a self-tapping single-lead pedicle screw.

2. Materials and Methods

This study assessed eight different screw designs (Table 1, Figure 1). All screws were made of a titanium alloy (Ti6Al4V ELI) and had a solid and conical core, full-length threaded shaft, 6.0 mm major diameter, 4.4 mm minor diameter, 35 mm shaft length, and a V-shaped thread with a 2.5 mm pitch for single-lead screws and 5.0 mm pitch for double-lead screws. The control screws (Groups A and E) were commercially available pedicle screws commonly used in spinal surgery (OCTOPODA, Bricon GmbH, Wurmlingen, Germany) and included two full-length flutes spaced at 2.9 mm. The six other screws (Groups B to D and F to H) were experimental prototypes designed explicitly for use in this study by the investigators and manufactured by Bricon GmbH.

Table 1. Design features of eight pedicle screws evaluated in this study.

Screw Group	Lead of Thread	Number of Cutting Flutes	Length of Flutes (mm)
A	single-lead	2	2.9
B		3	
C		2	9.5
D		3	
E	double-lead	2	2.9
F		3	
G		2	9.5
H		3	

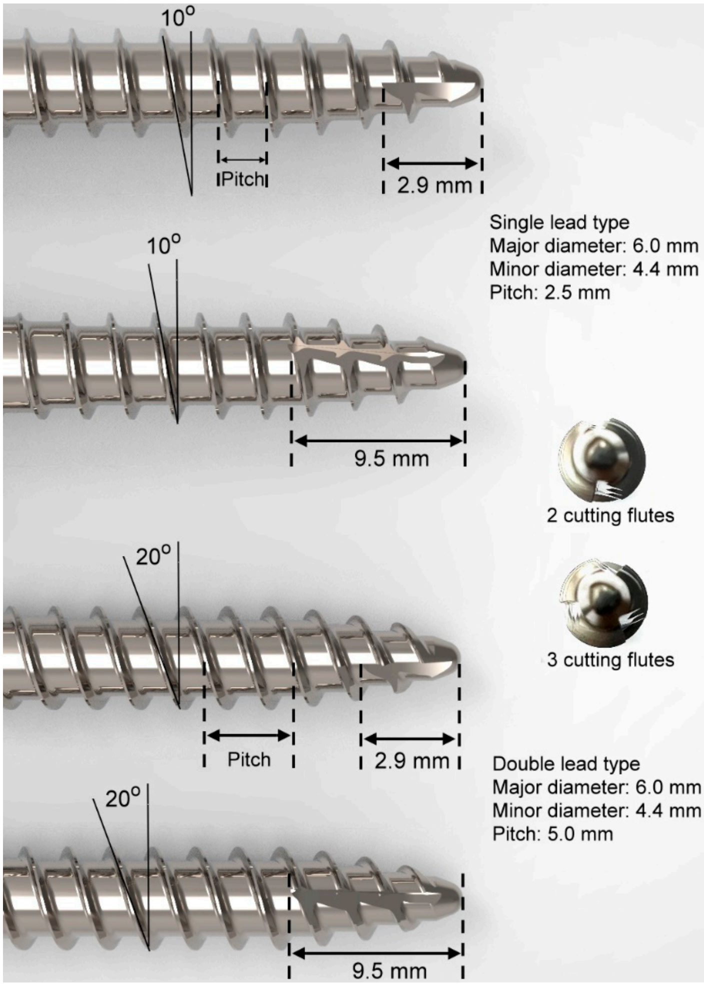

Figure 1. Screws with varying leads of thread and cutting flute length. A differential screw uses a spindle with two screw threads of differing leads, a single-lead means equal to the thread pitch and double-lead means twice the thread pitch. Major diameter is the diameter at the thickest part of the thread. Minor diameter is the thickness at the base of the screw.

This study aimed to replicate implantation in a healthy human vertebra. To achieve this, synthetic sawbones (Sawbones, Pacific Research Laboratories, Vashon, WA, USA) were used which had a similar density (0.32 g/cm^3, 20 PCF, solid polyurethane foam) to the pedicles of vertebrae [14]. The sawbones were shaped into sample blocks of size 60 mm × 40 mm × 40 mm (width × depth × height). Each insertion site was pre-drilled using a 2.7 mm drill bit to a depth of 35 mm to prepare the trajectory of the pedicle probe according to the surgical procedure recommended by Bricon GmbH.

A universal testing machine (eXpert 8602, ADMET, Norwood, MA, USA) equipped with a custom-made pulling jig was used to perform the insertion torque and pullout strength tests in accordance with ASTM F543 [3] (Figure 2). The machine had an axial force capability of 2.2 kN and torque capacity of 20 Nm. To insert the screws into the test block, each screw was rotated at a rate of 5 rev/min under an axial load of 11.18 N and inserted to a depth of 35 mm. The insertion torque was recorded during insertion from the initial to final revolution of the screw. Once fully inserted, the pullout test was performed by pulling the screw away from the test block at a loading rate of 1 mm/s. The fixation strength of each screw was defined by the maximum load recorded prior to failure by any means. Each test setup was performed five times with separate screws and separate sawbone samples.

Fisher's post hoc test with a level of significance of 0.05 was used to ascertain significant differences between individual means when the analysis of variance resulted in significant differences.

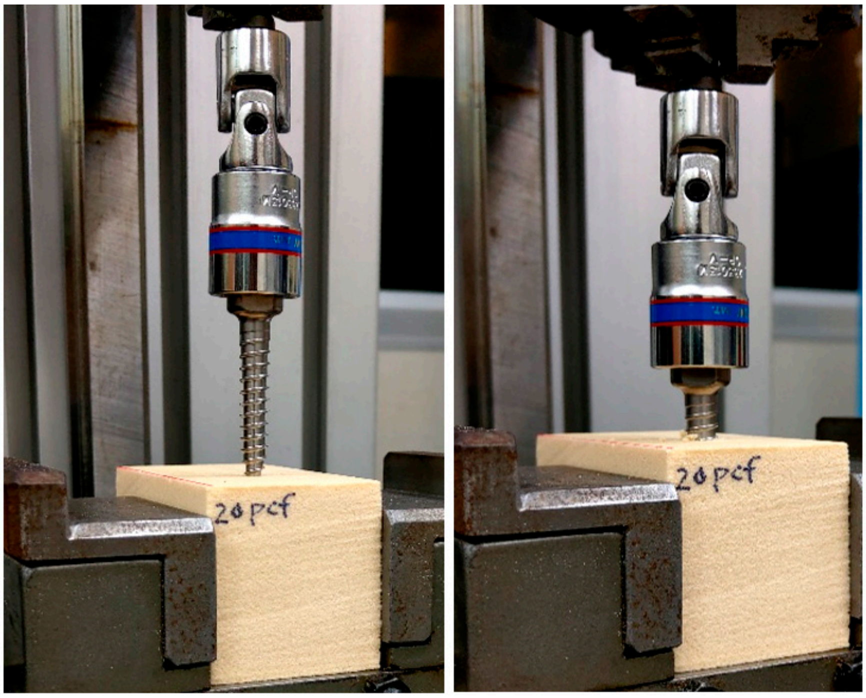

Figure 2. A custom-made pulling jig was used to perform the insertion torque and pullout strength tests.

3. Results

The length of the cutting flute was found to significantly influence ($p < 0.05$) the screw insertion torque, with significant differences observed between groups with the same number of flutes but different flute lengths: A and C, B and D, E and G, and F, and H. A lower mean maximum insertion torque was observed for the screws with a longer cutting flute and with three cutting flutes instead of two (Figure 3). The double-lead thread design produced a larger mean maximum insertion torque than the single-lead thread ($p < 0.05$), but was able to reach specific depths using half the number of revolutions (Figure 4). The number of cutting flutes on the screw was also found to significantly influence ($p < 0.05$) the insertion torque, but only in Groups G and H (Figure 3).

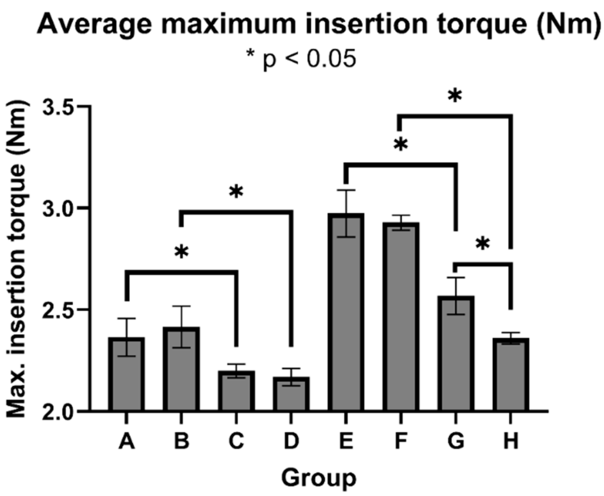

Figure 3. Bar chart of the mean insertion torque for each screw design. Error bars represent plus or minus one standard deviation.

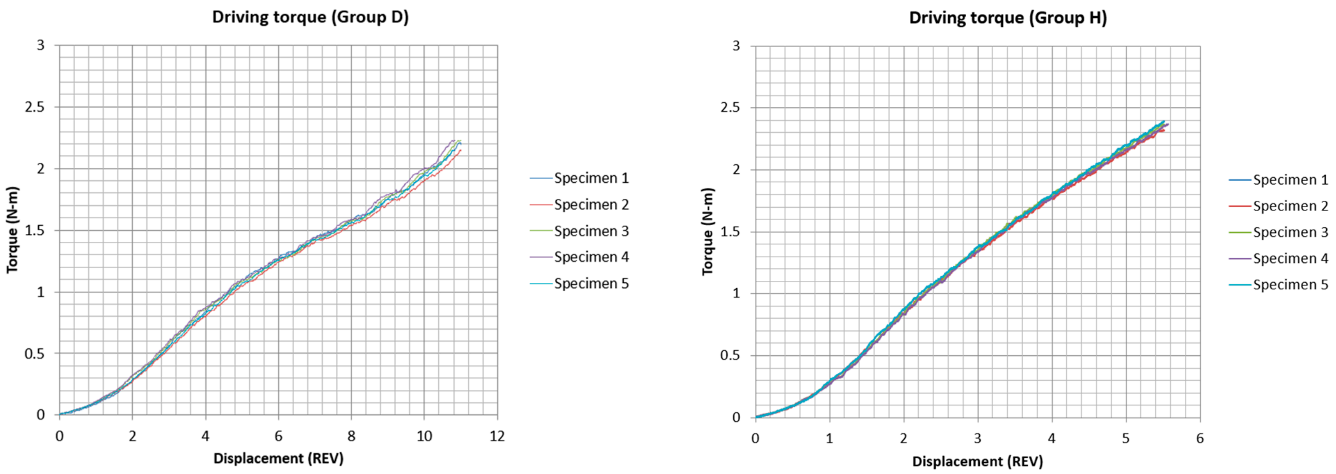

Figure 4. Plot of screw insertion torque and displacement for Groups D and H.

The mean pullout strength of Group D was significantly ($p < 0.05$) greater than all other screw designs (Table 2, Figure 5). The cutting flute length, cutting flute quantity, and number of thread leads were found to significantly influence the pullout strength ($p < 0.05$). Incorporating three cutting flutes into the screw design increased the pullout strength over the screw with two flutes when using the same cutting flute length and lead thread. The groups with a single-lead threaded screw were also found to produce a greater pullout strength than the double-lead screws.

Table 2. Mean results of insertion torque and pullout strength in each group.

Group	Average Insertion Torque (Nm) during Initial Screw Revolutions				Average Max. Insertion Torque (Nm)	STD	Average Pullout Strength (N)	STD
	1st Rev.	2nd Rev.	3rd Rev.	4th Rev.				
A	0.100	0.294	0.586	0.902	2.365	0.093	1766	15.8
B	0.110	0.323	0.610	0.923	2.415	0.103	1809	20.7
C	0.100	0.294	0.561	0.833	2.2	0.034	1919	33.2
D	0.103	0.317	0.589	0.858	2.17	0.042	1967	34.0
E	0.299	0.928	1.605	2.143	2.974	0.115	1606	14.3
F	0.300	0.895	1.566	2.101	2.929	0.037	1645	18.8
G	0.259	0.847	1.415	1.906	2.568	0.091	1747	30.4
H	0.282	0.849	1.360	1.790	2.36	0.028	1791	35.5

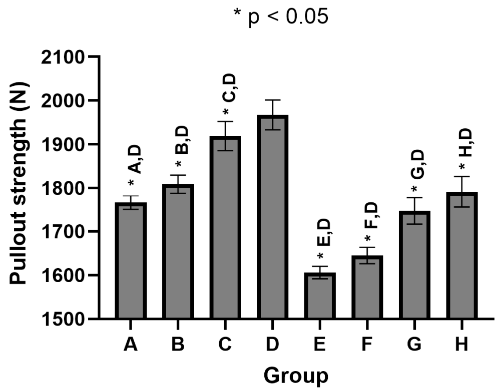

Figure 5. A bar chart of the pullout strength for each screw design. Error bars represent plus or minus one standard deviation.

4. Discussion

The initial stability of pedicle screws has been shown to be positively associated with long-term fixation, stabilizing the bone until fusion occurs [15]. The stability of the initial fixation is typically evaluated using a pullout test, and is heavily influenced by factors such as bone quality, screw design, surgical technique, and insertion torque [8–10]. In practice, surgeons have found that double-lead pedicle screws can be inserted quicker and with greater stability than their single-lead counterparts. However, there is little experimental data available to support this. The present study used torque analysis to determine the effects of different thread designs on pullout capability.

During the initial revolution (1st revolution), the insertion torque of the double-lead screws was nearly three times that of the single-lead screws with the same number of flutes and same cutting length, but the average final maximum torque of the double-lead screw was only slightly higher than that of the single-lead screw. Similarly, Yamaguchi et al. reported a greater insertion torque with double-lead dental implants [16]. For surgeons placing pedicle screws in clinical settings, the torque required to insert the screws is believed to be a good predictor of initial stability and pullout strength [17]. An in vitro biomechanical test by Jacob et al. [13] showed that double-lead pedicle screws could reduce insertion time, but did not improve the pullout strength. This result is similar to the findings of this study, where the double-lead designs had a lower pullout strength than their single-lead counterparts (Figure 5). There are two main reasons for this. First, the single- and double-lead screws had helical angles, with the high helical angle of the double-lead screws producing a lower helical cross-sectional area, leading to a reduction in axial force resistance. Ma et al. [18] indicated that the thread helix angle affects the stability of vertically and horizontally loaded implants, and as the helix angle is increased, the implant's resistance to loading is reduced. Second, an analysis of the contact interfaces was performed using the method described by Yamaguchi et al. [16] and showed that the double-lead screws had a higher level of defects. However, quantifying the defects is difficult, especially for small caves on the contact interfaces (Figure 6).

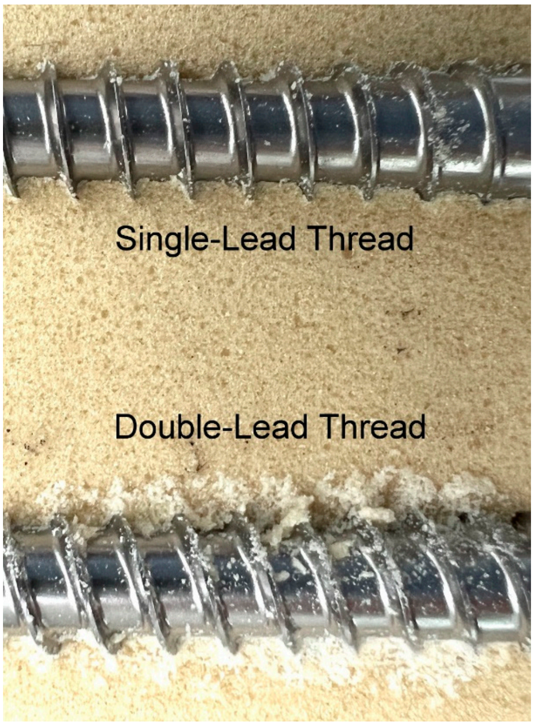

Figure 6. Observations of the artificial bone implant for Screw D (single-lead) and Screw H (double-lead).

In this study, the number of cutting flutes was not found to significantly affect the screw torque in any of the single-lead screw groups (A/B and C/D) or in the short flute double-lead screws (E/F). In addition, the maximum insertion torque of the 9.5 mm double-lead screw with three cutting flutes was less than the same screw with two cutting flutes. In terms of insertion torque, this result indicates that there would be negligible benefit from increasing the number of cutting flutes in single-lead screws when using a pre-drilled hole. However, increasing the number of cutting flutes in the double-lead design provided a significant reduction in insertion torque. Group H, which had the largest cutting surface area of all groups with three cutting flutes, recorded a maximum insertion torque that was 7.81% lower than Group G with two cutting flutes. The greater cutting area offset the additional resistance from the double-lead design as the screw advanced through the test block. Theoretically, cutting flutes can facilitate insertion, and Yerby et al. [10] indicated that screws with fewer than three cutting flutes had difficulty cutting threads as the screw rotated into the test material. However, our study did not find any significant difference in initial insertion torque due to different numbers of cutting flutes, possibly due to a pilot hole being pre-drilled in the material before screw insertion.

The results showed a significant reduction in insertion torque in all groups with a long cutting flute in comparison to the corresponding screws with a short flute. Longer cutting flutes were also shown to increase the pullout strength. It is possible that the bone could rebound into the flutes during insertion [19], forming bone chips that accumulate around the threads of the flute and provide greater friction and resistance to pullout. The long cutting flutes could also carry more bone chips towards the proximal part of screw, creating a greater compressive force on the screw shaft.

Although double-lead screws demonstrated greater penetration into the test block with each revolution, the double-lead design and greater helix angle may cause more material damage and reduce the pullout strength. Longer cutting flutes were found to significantly increase the pullout resistance in the double-lead screw groups, but the results were still considerably lower than those of the corresponding single-lead screws. When immediate stability is required, the risk of pedicle screw pullout may be reduced by using a single-lead design.

There are some noteworthy limitations to this study. This study used an artificial bone model simulating the physical properties of real bone, but the material is distinct in that it has an entirely homogeneous structure. While not truly representative of real bone, the use of a bone model negated any variation between samples and allowed the investigation to focus on a comparison of different screw designs in terms of insertion torque and pullout strength. Artificial bone does have some notable advantages, including negligible inter-specimen variability, low cost, ready availability, and minimal specimen preparation. The use of synthetic bone complements the aim of this study to compare the pullout properties of different pedicle screws [19–21]. It should also be recognized that this study only assessed the thread design of one commercially available pedicle screw. Future studies may consider a wider range of pedicle screws. The test environment was also different than in vivo implantation in that testing was performed in a dry environment at room temperature. Similarly, the loading conditions did not accurately represent physiological loading, hence this testing did not account for the mechanical environment at a specific fixation site or when using different implantation methods.

5. Conclusions

When using a self-tapping screw for pedicle screw insertion, incorporating longer cutting flutes into the design of the pedicle screw could reduce the insertion torque and improve the pullout strength in both single-lead and double-lead designs. However, in our study, increasing the quantity of cutting flutes alone did not significantly affect the insertion torque. While double-lead screws could be inserted quicker, if immediate stability is required, single-lead screws with three long cutting flutes could provide greater pullout strength and reduce the risk of implant loosening.

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