TAPPING PILOT HOLE: MECHANICAL ANALYSIS OF SHEEP VERTEBRA AND THE ARTIFICIAL BONE MODEL

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ABSTRACT

Objective: To determine the effect of pilot hole tapping, together with other variables such as pilot hole diameter, in relation to inner screw diameter and preparation method, on the insertion torque and pullout resistance of the screws used for anterior fixation of the cervical spine. Method: Twenty polyurethane test bodies and 30 thoracic vertebrae (T1-T5) were tested. Four holes were drilled into each test body: two of them with a diameter of 2.0 mm and two with a diameter of 2.5 mm. The holes were drilled using a bit or probe, according to the experimental group. Each experimental group was divided into two equal subgroups, with and without pilot hole tapping. In all, there were eight experimental groups: four using polyurethane specimens and four using sheep vertebrae. Cortical screws of 3.5 mm in outer diameter and 14 mm in length were inserted into the pilot holes. The insertion torque was measured during screw implantation and mechanical pullout tests were then performed using an Emic® universal testing machine, with the Tesc 3.13 software, load cells of 1000 N, force application rate of 0.2 mm/min, preloading of 5 N and accommodation time of 10 seconds. The property evaluated in the mechanical tests was the maximum pullout force. Results and Conclusion: Pilot hole tapping significantly decreased the insertion torque and pullout force of the screws in all the experimental groups.

Keywords – *Spine; Bone screws; Biomechanics; Torque; Orthopedic fixation devices*

INTRODUCTION

Fixation of the cervical spine is used to provide mechanical stability to this vertebral segment during the process of arthrodesis consolidation(1). The stability of the cervical fixation depends on several factors such as the bone mineral density, screw insertion torque and screw pullout resistance(26).

The insertion torque and pullout resistance of screws may be influenced by tapping the pilot hole, although there are divergences in the literature on this topic(710). The negative effects of pilot hole tapping on pullout resistance have been demonstrated especially on low-hardness test bodies and on trabecular bone(7,11). In the lumbar spine, pilot hole tapping significantly reduced the resistance to pulling out pedicle screws(12,13). However, Ronderos *et al*(9) observed that tapping the pilot hole did not increase the axial pullout force when the anterior cervical screws were anchored in the posterior cortical bone of the vertebral body. Carmouche *et al*(14) observed that tapping reduced the resistance to pulling out pedicle screws fixed in the human lumbar spine and did not change the resistance to pulling out implants in the thoracic spine.

The aim of this study was to evaluate the influence of tapping the pilot hole, along with other variables such as the hole diameter, in relation to the inner diameter of the screw and the pilot hole preparation method, on the insertion torque and pullout resistance of screws used for anterior fixation of the cervical spine.

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We declare that there is no conflict of interests in this article

METHOD

This study was conducted on polyurethane test bodies that formed an artificial bone model, and on vertebrae from shorn Santa Inês sheep of mean weight 38 ± 5 kg and mean age 12 ± 3 months. Twenty test bodies of the artificial bone model were used, of length 40 mm, width 40 mm and height 40 mm, with a density of 0.32 g/cm^3 (Nacional Ltda.), and 30 sheep vertebrae from the T1-T5 segment, with a density of 0.6 ± 0.03 g/cm^2. The density of the vertebrae was obtained by means of dual-energy X-ray absorptiometry (DXA) and the QDR system with software version 11 – 2:5 (Hologic 4500 W, Waltham, MA, USA).

Four holes were made in each test body: two with a diameter of 2.0 mm and two with a diameter of 2.5 mm. These holes were made with a bit or a probe, according to the experimental group. In each experimental group, half of the holes of the same diameter were tapped, using a tapping device of 3.5 mm in diameter (Synthes®). In the other holes, the screws were inserted without prior tapping.

Cortical screws of outer diameter 3.5 mm, inner diameter 2.5 mm and length 14 mm (Synthes®) were inserted in the pilot holes (Figure 1).

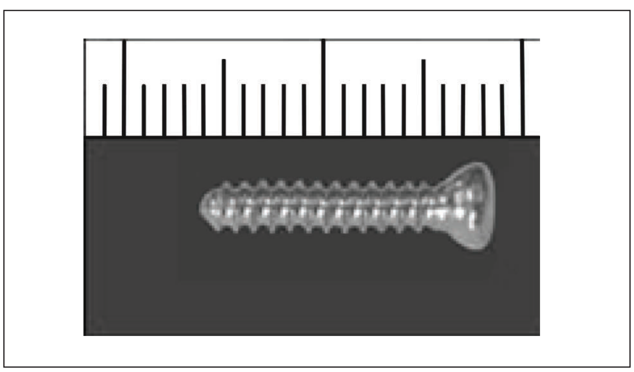

Figure 1 – Screw used in the study

Eight experimental groups were formed: four using the artificial bone model and four using sheep vertebrae. The groups using the artificial bone model were as follows: I (hole drilled with a bit of 2.0 mm in diameter); II (hole drilled with a bit of 2.5 mm in diameter); III (hole drilled with a probe of 2.0 mm in diameter); and IV (hole drilled with a probe of 2.5 mm in diameter). The groups using the vertebrae were as follows: V (hole drilled with a bit of 2.0 mm in diameter); VI (hole drilled with a bit of 2.5 mm in diameter); VII (hole drilled with a probe of 2.0 mm in diameter); and VIII (hole drilled with a probe of 2.5 mm in diameter).

The insertion torque of the implants was measured using an MK digital micro-torque meter (model TI-500/MK-MT-1), 1 N.m, with a resolution capacity of 0.001 N.m. The Graphic III software was used for the data analysis.

The mechanical tests were performed using an Emic® universal testing machine with a load cell capacity of 1,000 N, and the data were analyzed by means of the Tesc 3.13 software.

To perform the pullout mechanical tests, the screw head was fixed to the test machine by means of connectors that allowed multidirectional movements and an axial load was applied without applying any torque. Preloading of 5 N was applied for a 10-second period in order to accommodate the system. The axial traction force was then applied at a constant 0.2 mm/min until the implant had been pulled out (Figure 2).

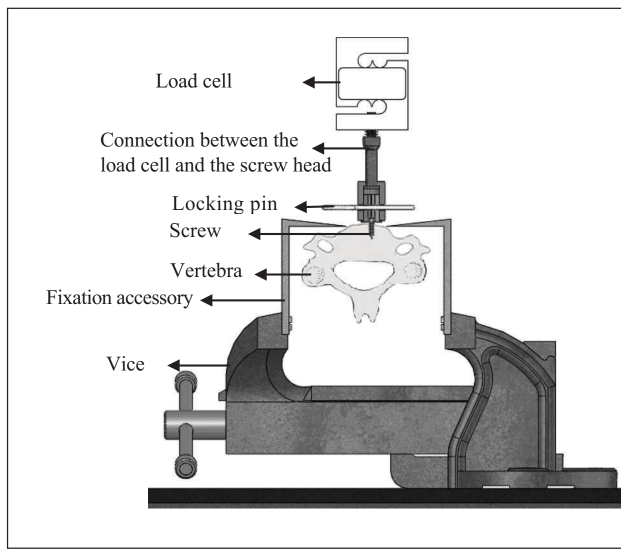

Figure 2 – Layout of the accessories used in the mechanical tests

Ten mechanical tests and ten insertion torque measurements were made on each experimental group using the artificial bone model (10 tapped and 10 non-tapped). In total, 80 mechanical tests and 80 insertion torque measurements were made. For the experimental groups using the vertebral body, 15 mechanical tests and 15 insertion torque measurements were made (15 tapped and 15 non-tapped), making a total of 120 mechanical tests and 120 insertion torque measurements. The mechanical property evaluated in the mechanical tests was the maximum pullout force.

The results were subjected to the multifactorial analysis of variance (Anova) test, using the PROC GLM SAS software version 9. The significance level of 5% was established ($p \leq 0.05$).

RESULTS

Insertion torque

The mean insertion torque of the screws implanted in the artificial bone model and the vertebral body is shown in Table 1 and Figure 3.

Table 1 – Mean values and standard deviations for the insertion torque of the screws implanted in the tapped and non-tapped pilot holes in the artificial bone model and vertebral bodies. The significance level established was p < 0.05

Material	Experimental groups	Insertion torque		P value
		Non-tapped (N.m)	Tapped (N.m)	
Artificial bone model	I (Bit – 2.0 mm)	0.15 ± 0.027	0.03 ± 0.006	< 0.001
	II (Bit – 2.5 mm)	0.15 ± 0.018	0.03 ± 0.008	< 0.001
	III (Probe – 2.0 mm)	0.16 ± 0.017	0.03 ± 0.007	< 0.001
	IV (Probe – 2.5 mm)	0.17 ± 0.028	0.03 ± 0.005	< 0.001
Vertebral body	V (Bit – 2.0 mm)	0.22 ± 0.053	0.07 ± 0.048	< 0.001
	VI (Bit – 2.5 mm)	0.18 ± 0.051	0.07 ± 0.035	< 0.001
	VII (Probe – 2.0 mm)	0.25 ± 0.061	0.06 ± 0.027	< 0.001
	VIII (Probe – 2.5 mm)	0.21 ± 0.038	0.05 ± 0.016	< 0.001

It was observed that the insertion torque values for the implants fixed in pilot holes with prior tapping were significantly lower than the values for the implants in holes without prior tapping, for all the experimental groups.

Pullout force

The mean pullout force for the screws implanted in the artificial bone model and vertebral body is shown in Table 2 and Figure 4.

It was observed that the maximum pullout force values for the implants fixed in pilot holes with prior tapping were significantly lower than the values for the implants in holes without prior tapping, for all the experimental groups.

Table 2 – Mean values and standard deviations for the pullout force of the screws implanted in the tapped and non-tapped pilot holes in the artificial bone model and vertebral bodies. The significance level established was p < 0.05

Material	Experimental group	Pullout force		P value
		Non-tapped (N)	Tapped (N)	
Artificial bone model	I (Bit – 2.0 mm)	411.85 ± 14.69	369.58 ± 11.98	< 0.001
	II (Bit – 2.5 mm)	406.04 ± 12.95	356.40± 7.96	< 0.001
	III (Probe – 2.0 mm)	451.48 ± 18.67	384.94 ± 15.72	< 0.001
	IV (Probe – 2.5 mm)	412.29 ± 33.33	339.85 ± 44.92	< 0.001
Vertebral body	V (Bit – 2.0 mm)	374.43 ± 83.10	277.98 ± 72.33	= 0.001
	VI (Bit – 2.5 mm)	379.71 ± 76.52	259.30 ± 42.29	< 0.001
	VII (Probe – 2.0 mm)	515.08 ± 101.23	338.07 ± 77.61	< 0.001
	VIII (Probe – 2.5 mm)	372.55 ± 98.36	254.68 ± 52.93	< 0.001

DISCUSSION

The 3.5 mm cortical screws used in this study were the type of screw initially used for fixation of the cervical spine[14]. This type of screw is still used for posterior fixation of the cervical spine and, to a lesser extent,

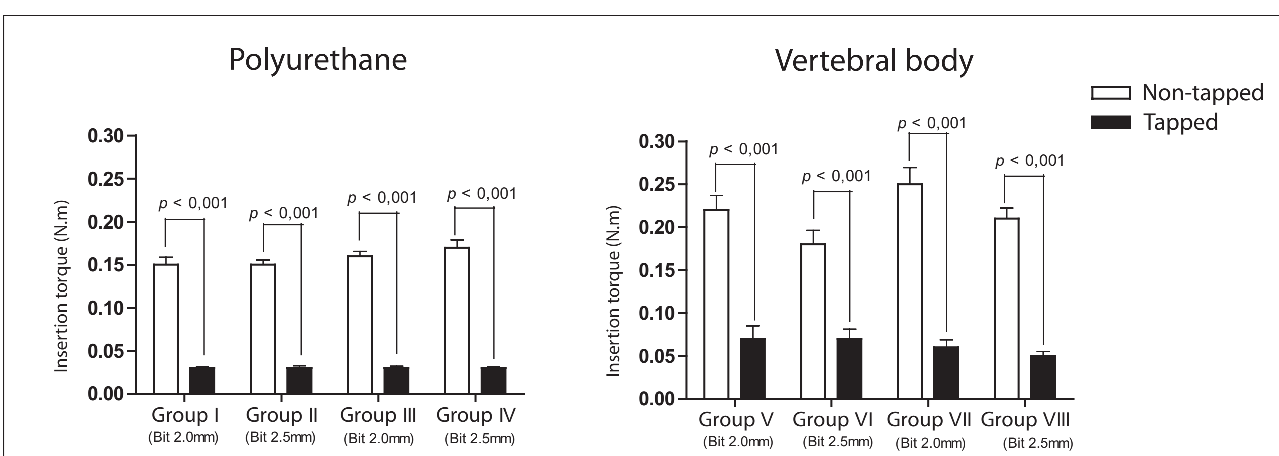

Figure 3 – Mean values for the insertion torque of the screws implanted in the tapped and non-tapped pilot holes in the artificial bone model and vertebral bodies. The significance level established was p < 0.05

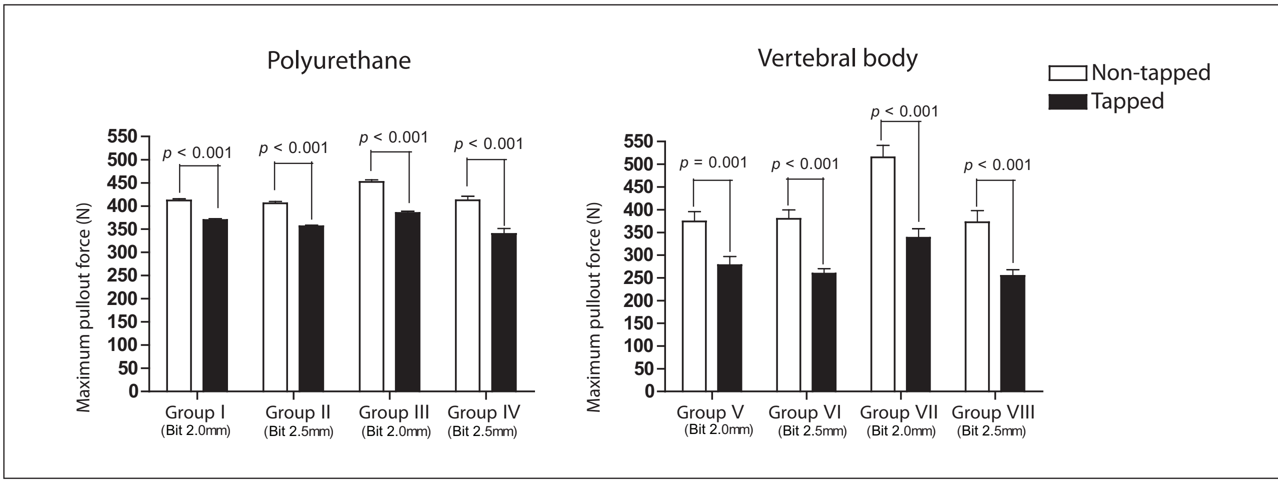

Figure 4 – Mean values for the pullout force of the screws implanted in the tapped and non-tapped pilot holes in the artificial bone model and vertebral bodies. The significance level established was $p < 0.05$

for anterior fixation, since other screws with designs and diameters better adapted to the spongy bone of the vertebral body have been developed[2]. For the most recent screws developed, the pilot hole does not need to be tapped (self-tapping screws) and/or drilled (self-drilling screws), thereby reducing the additional trauma for patients and also the duration of the operation[3,8].

Screw taps were designed to cut the bone tissue and exactly reproduce the pitch of the corresponding screws. Tapping of the pilot hole modifies the internal composition of the bone and produces fractures of the spongy bone tissue matrix, thereby favoring the formation of dead spaces and reducing the bone components at the bone-implant interface, which makes it more difficult to anchor the implant[7]. Other studies have reported that although pilot hole tapping removes bone material, this process does not reduce the pullout force when applied to cortical bone but, rather, facilitates implant fixation[9,15]. However, in less dense or osteoporotic bone reductions of up to 30% in the maximum force needed to pull the implant out have been observed[15].

The results obtained in the present study showed that pilot hole tapping statistically reduced the implant insertion torque and pullout force in all the experimental groups, independent of the way in which the pilot hole was prepared and the drilled diameter, in relation to the inner diameter of the screw. The impaction of the bone tissue adjacent to the implant caused by using a probe or drilling the pilot hole with a diameter smaller than the inner diameter of the screw[7] was insufficient to prevent the negative effects from tapping. However, non-tapping of the pilot hole not only diminishes the duration of the operation but also is associated with better anchorage for implants.

The disadvantages of pilot hole tapping with regard to the force needed to pull the screws out have been well demonstrated, especially in soft materials or spongy bones[7,9,11]. The normal densitometric values for the cervical column have been well reported in the literature, covering a range from 0.304 to 0.343 g/cm^3[2]. The vertebrae used in the present study, like the test bodies of the artificial bone model, had bone mineral values within the normal limits, with the absence of osteoporosis[2]. Nonetheless, the results obtained showed that there were reductions in the implant insertion torque and pullout force when the pilot hole had previously been tapped, even though the densitometric parameters were within the normal limits. However, in a study in which cortical screws were used for anterior fixation of the cervical spine, Ronderos *et al*[9] observed that tapping did not debilitate or increase the pullout force when the screws were fixed bicortically. In the thoracic spine, they did not observe any significant reduction in resistance to pulling the implant out with a variety of tapping techniques[9].

The insertion torque is the angular moment of the force required for the screw to advance on its thread inside the fixation material[3]. Tapping reduces the force required to achieve the insertion torque, for cutting and preparing the site for implantation of the screw; this reduction has been observed in the thoracic and lumbar spine[8,9].

The aim of the present experiment was not to exactly simulate clinical conditions, but to furnish reliable measurements relating to implant anchorage. The mechanical tests performed are static in nature, and have the purpose of evaluating the mechanical resistance to pulling implants out by means of applying an axial load along the implant and enabling simple and safe comparisons[9]. Failure of implant anchorages may be related to a variety of factors, such as the implant geometry, bone mineral density and pilot hole preparation technique[7,9,14].

The stability of the fixation system is dependent on the anchorage strength of the implants in the bone. Failure of this fixation may result in loosening of the implant and consequent loss of stability. Pilot hole tapping for cortical screws implanted in the spine is not advantageous because, in addition to increasing the duration of the operation, it diminishes the resistance of the implant to being pulled out.

CONCLUSION

Pilot hole tapping reduced the insertion torque and pullout force of screws fixed in different test bodies (bone and an artificial bone model), independent of the drilled diameter of the pilot hole (less than or equal to the inner diameter of the screw) and its preparation method (bit or probe).

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