ORIGINAL ARTICLE

BIOMECHANICAL EVALUATION OF THE INFLUENCE OF CERVICAL SCREWS TAPPING AND DESIGN

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ABSTRACT

Objective: To assess if the screw design (self-drilling/self-tapping) and the pilot hole tapping could affect the insertion torque and screw pullout strength of the screw used in anterior fixation of the cervical spine. Methods: Forty self-tapping screws and 20 self-drilling screws were inserted into 10 models of artificial bone and 10 cervical vertebrae of sheep. The studied parameters were the insertion torque and pullout strength. The following groups were created: Group I – self-tapping screw insertion after pilot hole drilling and tapping; Group II – self-tapping screw insertion after pilot hole drilling without tapping; Group III – self-drilling screw insertion without drilling and tapping. In Groups I and II, the pilot hole had 14.0 mm in depth and was made with a 3mmn drill, while tapping was made with a 4mm tap. The insertion torque was measured and the pullout test was performed. The comparison between groups was made considering the mean insertion torque and the maximum mean pullout strength with the variance analysis (ANOVA; p≤ 0.05). Results: Previous drilling and tapping of pilot hole significantly decreased the insertion torque and the pullout strength. Conclusion: The insertion torque and pullout strength of self-drilling screws were significantly higher when compared to self-tapping screws inserted after pilot hole tapping.

Keywords – *Spine; Bone screw; Orthopedic fixation devices; Biomechanics*

INTRODUCTION

Anterior plates for the fixation of the cervical spine have been used to stabilize the cervical segment during the process of bone graft consolidation in arthrodesis[1]. The additional benefits of using a plate and screws are well-established[2,3].

The mechanical stabilization provided by the plate system is related to several factors, foremost among them the anchoring of the screws in bone tissue[3]. Bone mineral density is the main factor that interferes with the mechanical stability of the implant. However, this is one of the parameters that cannot be controlled by the surgeon, so that the new screw designs have been developed to improve the quality of fixation.

Bicortical or unicortical fixation screws of the anterior cervical plate have been designed to be inserted into pre-drilled and tapped pilot holes. The use of unicortical screws has become the simplest surgical procedure and reduced risk compared with bicortical fixation[5,6].

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However, the perforation and tapping of the pilot holes result in additional trauma and increased operative time for the completion of the procedures. For this reason, changes in the designs of the screws were performed in order to eliminate the tapping and drilling of the pilot hole. Self-drilling and self-tapping screws have been developed. The advantage of these screws is that they can be inserted without prior tapping and can be attached directly to the bone, simplifying the surgical procedure.

However, changes in the screw design can cause repercussions in their mechanical performance, requiring studies to compare the performance of new screw designs to establish the real advantages and disadvantages of each model.

Tapping of the pilot hole has been a controversial topic in the literature that addresses this issue. This procedure is used to prepare the adjacent bone tissue for the introduction of the screw.

The acute mechanical development of screws can be evaluated by the torque and pullout strength of the implants. The insertion torque is defined as the angular momentum of force required to move the screw inside the fixation material and is directly related to the quality of the fixation system.

The aim was to study the influence of screw design (self-drilling and self-tapping) and pilot hole tapping on the insertion torque and pullout strength of screws used for anterior fixation of the cervical spine.

METHOD

Forty self-tapping screws and 10 self-drilling screws were used in the study, both made of titanium, for fixation of cervical plates (CSLP – Synthes®). The screws had expanding heads, with a 4-mm outer diameter and 14 mm in length (Figure 1).

The insertion torque and pullout strength were measured through the insertion of screws into the body of the anterior cervical vertebrae of sheep. We used ten cervical vertebrae (C3-C6) of Santa Ines Deslanadados sheep with a mean age of 12 ± 3 months. After their removal, muscle tissue was removed, examined, and bone mineral density was measured by dual-energy X-ray absorptiometry (DEXA®) using QDR system software version 11 – 2:5 (Hologic 4500 W®, Waltham, MA, USA). Vertebrae with bone mineral density averaging 0.33 ± 0.01 g/cm3 (from 0.32 to 0.34 g/cm3) were selected for study.

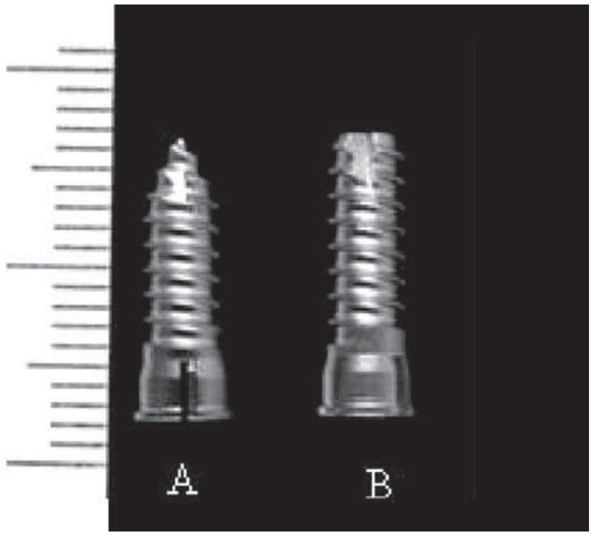

Figure 1 – Screws used in the study. A) self-drilling screw and B) self-tapping screw (CSLP Synthes®).

Three screws were tested in each cervical vertebra, each corresponding to an experimental group. The screws were inserted with approximately 5 mm of distance between them to avoid possible interference in the measurement of insertion torque and pullout strength.

The experimental groups were formed according to the technique used to prepare the pilot hole and the screw type used in the study (self-drilling and self-tapping): group I – self-tapping screw inserted after drilling and tapping a pilot hole, group II – self-tapping screw inserted after drilling the pilot hole without tapping, group III – self-drilling screw inserted directly into the vertebral bodies without drilling or tapping.

The pilot hole (groups I and II) was made with a 3.0-mm diameter drill and drilled 14 mm deep. The screws were inserted in the anterior body of the cervical vertebra simulating its clinical use.

In group II, tapping was performed using a tap with 4 mm in diameter to cut and prepare the bone tissue for the insertion of the screw.

The insertion torque of the implants was measured using a TI-500/MKMT-1, 1N.m model MK® digital microtorquemeter, with a resolution of 0.001 Nm and Graphic III® software was used for data analysis.

The mechanical tests were carried out using an

Emic® universal testing machine with load cells capable of 1.000N and data were analyzed using Tesc® 3.13 software.

To perform mechanical pullout testing, the screw head was fixed to the test machine by means of connectors that allowed for multidirectional movement and application of axial tensile load without torque. A pre-load of 5N was applied for a period of 10 seconds to accommodate the system; the axial load was then applied with a constant pull of 0.2 mm/min until the implant pulled out (Figure 2).

Ten mechanical tests and 10 insertion torque measurements were performed for each experimental group. In total, 30 tests of torque and 30 mechanical tests were performed.

The results underwent multifactorial analysis of variance (ANOVA) and the Tukey-Kramer multiple comparison test with the significance level set at 5% ($p \leq 0.05$).

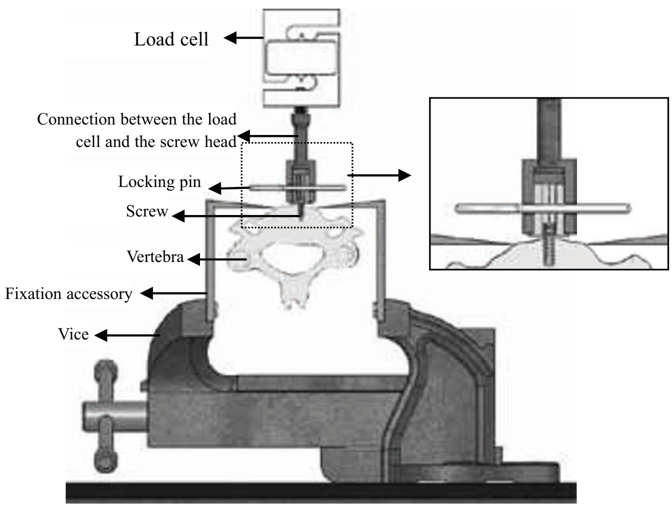

Figure 2 – Schematic drawing of the accessories used in the mechanical tests. Close-up: a clearer view of the screw and the accessories used for fixation.

RESULTS

Insertion torque

The mean maximum insertion torque of the screws implanted in sheep cervical vertebra and in the artificial bone model in the compared groups are presented in Table 1 and Figure 3.

Table 1 – Mean values and standard deviations of the average maximum torque in the three experimental groups in the artificial bone model and in the cervical vertebrae and comparison between groups.

	Experimental groups	Insertion torque (N.m)	Comparison between groups (p value)
Artificial bone model (polyurethane blocks)	*I – Drilled and tapped (CSLP self-tapping)*	*0.04 ± 0.01*	*I x II p < 0.001*
	II – Drilled and not tapped (CSLP self-tapping)	*0.08 ± 0.01*	*II x III p < 0.001*
	III – Not drilled and not tapped (CSLP selfdrilling)	*0.27 ± 0.03*	*III x I p < 0.001*
Cervical vertebrae	*I – Drilled and tapped (CSLP self-tapping)*	*0.05 ± 0.01*	*I x II p < 0.001*
	II – Drilled and not tapped (CSLP self-tapping)	*0.16 ± 0.02*	*II x III p < 0,001*
	III – Not drilled and not tapped (CSLP self-drilling)	*0.33 ± 0.03*	*III x I p < 0.001*

Pullout strength

The average maximum pullout strength of the screws implanted in sheep cervical vertebrae and in the artificial bone model in the comparison groups is shown in Table 2 and Figure 4.

Table 2 – Mean values and standard deviations of the average maximum pullout strength in the three experimental groups in the artificial bone model and the cervical vertebrae and comparisons between groups.

	Experimental groups	Insertion torque (N.m)	Comparison between groups (p value)
Artificial bone model (polyurethane blocks)	*I – Drilled and tapped (CSLP self-tapping)*	*368.90 ± 23.48*	*I x II p < 0.05*
	II – Drilled and not tapped (CSLP self-tapping)	*393.16 ± 18.71*	*II x III p < 0.001*
	III – Not drilled and not tapped (CSLP self-drilling)	*449.12 ± 14.79*	*III x I p < 0.001*
Cervical vertebrae	*I – Drilled and tapped (CSLP self-tapping)*	*237.12 ± 24.97*	*I x II p < 0.05*
	II – Drilled and not tapped (CSLP self-tapping)	*308.89 ± 80.63*	*II x III p < 0.05*
	III – Not drilled and not tapped (CSLP self-drilling)	*381.95 ± 53.46*	*III x I p < 0.001*

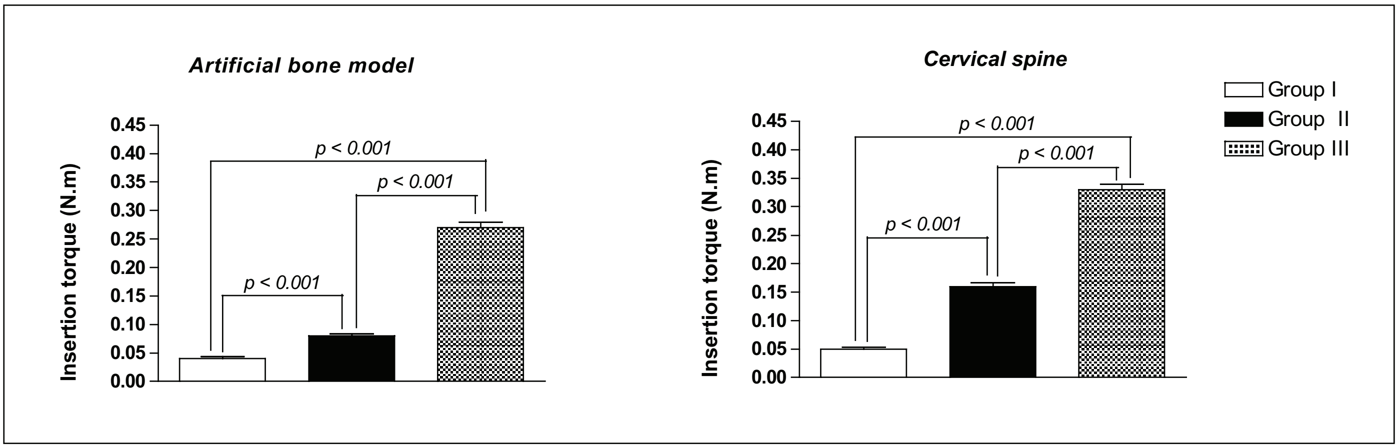

Figure 3 – Comparison between the mean values of the maximum insertion torque in the three experimental groups of the screws inserted into the artificial bone model and cervical vertebrae and comparisons between groups.

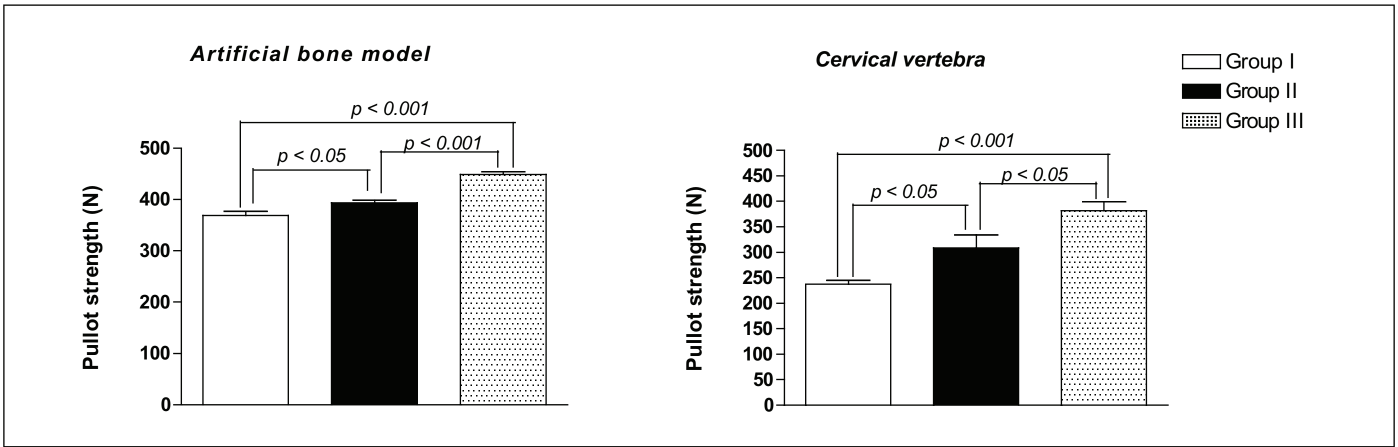

Figure 4 – Comparison between the mean values of the maximum pullout strength in the three experimental groups of the screws inserted in the artificial bone model and cervical vertebrae and comparisons between groups.

DISCUSSION

This study sought to investigate and answer questions regarding the biomechanical characteristics of new screw designs that were especially designed for cervical fixation[8,9]. Our study was designed to biomechanically compare self-drilling and self-tapping screws. In addition, we included another group in which the self-tapping screw was inserted into a previously tapped pilot hole. This last group was created based on practical clinical circumstances. In some surgical situations, after inserting the screw into a previously tapped pilot hole, the implant may need to be replaced, a principle applied to the salvage screw. Is it possible to insert a self-tapping screw into the previously tapped pilot hole and get good quality of fixation? This event can also occur with the use of the hole caused by the application of temporary cervical plate fixation.

The results showed that insertion torque and pullout strength have significantly different clinical relevance for the three groups. The best quality of fixation was obtained with the use of self-drilling screws and the worst results were observed when the self-tapping screw was inserted into the previously tapped pilot hole. This clearly shows the negative effect of pilot hole tapping. In the comparison of tapped and untapped pilot holes, we observed reduced insertion torque and pullout strength when the pilot hole was previously tapped, which corroborates findings by other authors[10,11].

The study demonstrated that the use of self-drilling screws in clinical practice provides greater system fixation when inserted into bone tissue that is not osteopenic or osteoporotic, and reduces the surgical time and number of surgical procedures. The bone mineral density of normal human vertebrae has been well reported in the literature and ranges on average from 0.30 to 0.34

g/cm3[12,13]. The cervical vertebrae of the sheep used in the present study correspond to the density of non-osteoporotic human vertebrae, with an average density of 0.33 ± 0.01 g/cm3 (0.32 to 0.34 g/cm3).

However, Hitchon *et al*.[14] found no difference in pullout strength when comparing self-drilling and self-tapping screws with the same geometries as those used in our study. In this study, the group of self-drilling screws had higher pullout resistance when compared with that of the similar self-tapping screws, but this difference was not statistically significant. The authors used human cervical vertebrae in the study in situations that do not reflect the real conditions of human bone, by presenting a wide range and quality of bone mineral density. However, the advantages found in our study favor the use of self-drilling or self-tapping screws, which can be counterbalanced in situations where the bone is osteoporotic. We believe that this hypothesis should be investigated in the future, but the study of Conrad *et al*.[15] noticed no difference in pullout strength of self-drilling and self-tapping screws using polyurethane blocks with a density comparable to that of osteoporotic bones.

The increase in pullout strength of self-drilling screws is supported by the fact that the pullout strength is proportional to the volume of bone between the threads[16]. It has been experimentally observed that the screw/bone interface of self-drilling screws was superior to that of self-tapping screws and that they would not cause damage to bone tissue adjacent to the implant[17].

CONCLUSION

We observed a difference in the insertion torque and pullout strength in comparisons between the self-drilling and self-tapping screws inserted into the artificial bone model and the cervical vertebrae of sheep.

The self-drilling screws had higher mean insertion torque values and pullout strength when compared with self-tapping screws.

The pilot hole tapping promotes significant reduction in insertion torque and pullout strength.

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REFERENCES

1. Dvorak MF, Pitzen T, Zhu Q, Gordon JD, Fisher CG, Oxland TR. Anterior cervical plate fixation: a biomechanical study to evaluate the effects of plate design, endplate preparation, and bone mineral density. Spine. 2005;30(3):294-301.
2. Wang JC, McDonough PW, Endow KK, Delamarter RB. Increased fusion rates with cervical plating for two-level anterior cervical discectomy and fusion. Spine. 2000;25(1):41-5.
3. Wang JC, McDonough PW, Kanim LE, Endow KK, Delamarter RB. Increased fusion rates with cervical plating for three-level anterior cervical discectomy and fusion. Spine. 2001;26(6):643-6.
4. Öktenoglu BT, Ferrara LA, Andalkar N, Özer AF, Sarioglu AC, Benzel EC. Effects of hole preparation on screw pullout resistance and insertional torque: a biomechanical study. J Neurosurg. 2001;94(1 Suppl):91-6.
5. Kostuik JP, Connolly PJ, Esses SI, Suh P. Anterior cervical plate fixation with the titanium hollow screw plate system. Spine. 1993;18(10):1273-8.
6. Suh PB, Kostuik JP, Esses SI. Anterior cervical plate fixation with the titanium hollow screw plate system. A preliminary report. Spine. 1990;15(10):1079-81.
7. Yang S, Wang LW. Biomechanical comparison of the stable efficacy of two anterior plating systems. Clin Biomech.(Bristol, Avon). 2003;18(6):S59-S66.
8. Conrad BP, Cordista AG, Horodyski M, Rechtine GR. Biomechanical evaluation of the pullout strength of cervical screws. J Spinal Disord Tech. 2005;18(6):506-10.
9. Hitchon PW, Brenton MD, Coppes JK, From AM, Torner JC. Factors affecting the pullout strength of self-drilling and self-tapping anterior cervical screws. Spine. 2003;28(1):9-13.
10. Chapman JR, Harrington RM, Lee KM, Anderson PA, Tencer AF, Kowalski D. Factors affecting the pullout strength of cancellous bone screws. J Biomech Eng. 1996;118(3):391-8.
11. Reitman CA, Nguyen L, Fogel GR. Biomechanical evaluation of relationship of screw pullout strength, insertional torque, and bone mineral density in the cervical spine. J Spinal Disord Tech. 2004;17(4):306-11.
12. Hsu CC, Chao CK, Wang JL, Hou SM, Tsai YT, Lin J. Increase of pullout strength of spinal pedicle screws with conical core: biomechanical tests and finite element analyses. J Orthop Res. 2005;23(4):788-94.
13. Kandziora F, Pflugmacher R, Scholz M, Schnake K, Lucke M, Schroder R, *et al*. Comparison between sheep and human cervical spines: an anatomic, radiographic, bone mineral density, and biomechanical study. Spine. 2001;26(9):1028-37.
14. Hitchon PW, Brenton MD, Coppes JK, From AM, Torner JC. Factors affecting the pullout strength of self-drilling and self-tapping anterior cervical screws. Spine. 2003;28(1):9-13.
15. Conrad BP, Cordista AG, Horodyski M, Rechtine GR. Biomechanical evaluation of the pullout strength of cervical screws. J Spinal Disord Tech. 2005;18(6):506-10.
16. Benzel EC. Implant-bone interfaces. In: Benzel EC, editor. Biomechanics of spinal stabilization. New York: Thieme; 2001. p.155-70.
17. Reitman CA, Nguyen L, Fogel GR. Biomechanical evaluation of relationship of screw pullout strength, insertional torque, and bone mineral density in the cervical spine. J Spinal Disord Tech. 2004;17(4):306-11.