







# The Role of Pedicle Screw Surface on Insertion Torque and Pullout Strength\*

## *Influência da superfície dos parafusos pediculares no torque de inserção e resistência ao arrancamento*

Rodrigo Barra Caiado Fleury<sup>1</sup> Antônio Carlos Shimano<sup>2</sup> Thiago Dantas Matos<sup>1</sup>  
Kelsen de Oliveira Teixeira<sup>1</sup> Valéria Romero<sup>3</sup> Helton Luiz Aparecido Defino<sup>4</sup>

<sup>1</sup> Postgraduate Course, Department of Biomechanics, Medicine and Rehabilitation of the Locomotor System, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, SP, Brazil

<sup>2</sup> Department of Biomechanics, Medicine and Rehabilitation of the Locomotor System, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, SP, Brazil

<sup>3</sup> Department of Internal Medicine, Faculty of Medical Sciences, Universidade Estadual de Campinas, Campinas, SP, Brazil

<sup>4</sup> Department of Biomechanics, Medicine and Rehabilitation of the Locomotor System, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, SP, Brazil

Address for correspondence Rodrigo Barra Caiado Fleury, MD, Faculdade de Medicina de Ribeirão Preto, Departamento de Cirurgia Ortopedia e Traumatologia, Universidade de São Paulo, Avenida Bandeirantes, 3900, Monte Alegre, Ribeirão Preto, SP, 14049900, Brazil (e-mail: caiadomed@hotmail.com).

Rev Bras Ortop 2020;55(6):695–701.

### Abstract

**Objective** Compare by mechanical tests the pullout resistance and the insertion torque of rough and smooth pedicle screws.

**Methods** Pedicle screws with rough surface and smooth surface, with diameters of 4.8; 5.5 and 6.5 mm, were inserted in polyurethane blocks with density of 10 PCF (0.16 g/cm<sup>3</sup>). Insertion torque and pullout strength were assessed.

**Results** The pullout strength of the rough surface and smooth surface screws did not differ, except in the group of 4.8 mm diameter screws. In this group, the rough surface screws showed greater resistance to pullout.

**Conclusion** Pedicle screws with a rough surface did not show increased pullout resistance in the acute phase of their insertion in polyurethane blocks compared to smooth surface screws. The rough surface screws had a higher insertion torque than the smooth surface screws, depending on the diameter of the screw and the preparation of the pilot hole.

### Keywords

- ▶ spine
- ▶ bone screws
- ▶ biomechanical phenomena

### Resumo

**Objetivo** Comparar por testes mecânicos a resistência ao arrancamento e o torque de inserção do parafuso pedicular jateado e liso.

**Métodos** Parafusos pediculares de superfície áspera e de superfície lisa com diâmetros de 4,8; 5,5 e 6,5 mm foram inseridos em blocos de poliuretano com densidade de 10 PCF (0,16 g/cm<sup>3</sup>). O torque de inserção e a força de arrancamento foram avaliados.

\* Work developed in the Department of Biomechanics, Medicine and Rehabilitation of the Locomotor System, Ribeirão Preto Medical School, Universidade de São Paulo, Ribeirão Preto, SP, Brazil.

**Palavras-chave**

- ▶ coluna vertebral
- ▶ parafusos ósseos
- ▶ fenômenos biomecânicos

**Resultados** A força de arrancamento dos parafusos de superfície áspera e de superfície lisa não diferiu, exceto no grupo de parafusos com 4,8 mm de diâmetro. Nesse grupo, os parafusos de superfície áspera apresentaram maior resistência ao arrancamento.

**Conclusão** Os parafusos pediculares de superfície áspera não apresentaram aumento da resistência ao arrancamento na fase aguda de sua inserção em blocos de poliuretano em relação aos parafusos de superfície lisa. Os parafusos de superfície áspera apresentaram maior torque de inserção que os parafusos de superfície lisa, dependendo do diâmetro do parafuso e da preparação do furo piloto.

**Introduction**

Spinal fixation systems using pedicle screws are currently the most used in spinal surgery.<sup>1</sup> Although this fixation modality has mechanical advantages over other spinal fixation systems, loosening of pedicle screws remains a frequent complication.<sup>2</sup> The mechanical resistance of this type of fixing system is related to the intrinsic properties of the components of the fixing system (diameter, type of material, design), the type and quality of bone tissue (spongy, cortical, bone density), the way of preparing the pilot hole and the interface between the anchoring component of the fixation system and the bone tissue.<sup>3</sup> Osteointegration at the implant and bone tissue interface promotes increased stability of the fixation system and a consequent reduction in the percentage of loosening of the implants.<sup>4,5</sup>

Changes in the implant thread design and surface are made to improve the anchoring of the implants in bone tissue.<sup>6</sup> The alteration of the screw surface in contact with bone tissue has been one of the strategies developed to improve the fixation of the implant by increasing the connection of the bone tissue with the implant.<sup>7</sup> The resistance of the implant to pullout is proportional to the contact surface of the thread with the bone tissue, which prevents loosening and classifies it as a stability property of the screw.<sup>8,9</sup> Alteration of the implant surface has been carried out by coating the implant surface or altering the surface roughness, which can stimulate bone growth and osteointegration, with the consequent increase in implant fixation.<sup>5,10,11</sup> It was observed in histological studies that implants with a rough and porous surface have an effective surface area increased up to 12 times in relation to the same smooth surface area, which produces an osteoinductive effect, and increases the anchoring of the implant in the bone.<sup>12</sup> Implants with textured surfaces are indicated for low bone quality, grafted areas, immediate implant installation protocols and immediate loading. The influence of the implant surface on osteointegration has induced the production of implants with a rough surface, which can be obtained by different processes.<sup>6</sup>

Considering reports of the influence of the implant surface on anchoring in bone tissue,<sup>6,9</sup> the objective of the present study was to compare the insertion torque and the pullout resistance of the screws of the vertebral fixation system with rough or smooth surface, in the acute phase of its placement.

**Material and Methods**

Polyurethane blocks with density of 10 PCF or 0.16 g/cm<sup>3</sup> were used, with a dimension of 5cmx8cmx5cm (Nacional Ltda, São Paulo, SP, Brazil). The pilot hole was drilled in the center of the upper face of each polyurethane block with a 2.7 mm drill. The 40 mm long screws and 4.8 mm, 5.5 mm and 6.5 mm outside diameter of the pedicular fixation system (SAFE Víncula, Rio Claro, SP, Brazil), which have a rough surface, and the screws of the pedicular fixation system Pedicol Plus (Víncula, Rio Claro, SP, Brasil), which present a smooth surface, were used in the study (▶ **Figures 1** and **2**). The screws of both systems are made of Titanium F136 and have a conical internal diameter. The rough surface screws (SAFE) are produced by means of mechanical blasting. Smooth surface screws (Pedicol Plus) are produced using the tumble finishing technique.

The experimental groups were formed according to the screw type (rough or smooth surface), screw diameter and pilot hole preparation. Each experimental group consisted of five blocks of polyurethane, in which the screws were inserted to measure the insertion torque and pullout resistance, after the pilot hole was prepared. In the 4.8 mm group of rough surface screws (SAFE), the screws were at first inserted into the polyurethane blocks without tapping the pilot hole, and after tapping the pilot hole, with 4.3 mm taps. The 5.5 mm screws were at first inserted without tapping the pilot hole, and after the tapping, with 4.3 mm and 5.0 mm in diameter. The 6.5 mm diameter screws were inserted without tapping the pilot hole, and after the tapping with diameters of 4.3 mm, 5.0 mm and 6.0 mm. The taps used had a thread design similar to the pedicle screws of the fixation system.

In the group of smooth surface screws (PedicolPlus) with 4.8 mm, the screws were inserted without the pilot hole tapping, and after the tapping with 4.0 mm in diameter. The 5.5 mm screws were inserted without tapping the pilot hole, and after tapping, with 4.3 mm and 5.0 mm in diameter. The 6.5 mm screws were inserted without tapping the pilot hole, and after tapping, with 4.3 mm, 5.0 mm and 6.0 mm in diameter. The taps used had a thread design similar to the pedicle screw of the fixation system. During the insertion of the screws in the polyurethane blocks, the insertion torque was measured by means of a switch coupled to the digital electronic torque wrench TL-500/MKT-1 (Mackena Corporation, São Paulo, SP, Brazil) the highest value of the insertion



**Fig. 1** 5,5 mm SAFE Screw (A) and Pedicol Screw (B).

torque measured during the insertion of the screw in the polyurethane block was registered.

The pullout resistance of the screws was assessed by means of mechanical tests using an EMIC universal testing machine (► **Figure 3**) (DL 10000; EMIC, São José dos Pinhais, PR, Brazil), Tesc 3.13 software for analysis of the results, load cell with 2000N capacity and speed of application of the force of 2 mm/min. A 50N preload and a 10 second accommodation time were used. A rod was attached to the screw head and the pullout force was applied vertically. The maximum pullout force was the property evaluated in the tests. The comparison of the values of insertion torque and pullout force was performed by means of statistical analysis using the nonparametric Mood test, in which the comparison between the medians was performed, having been established  $p < 0.05$  as statistical significance.

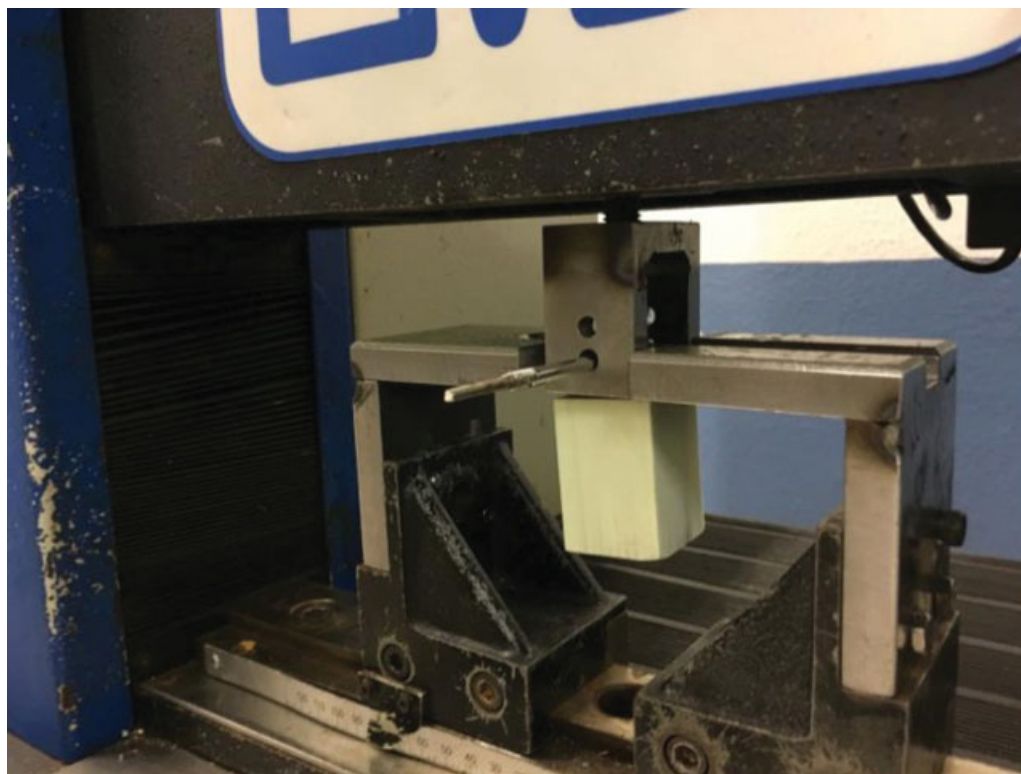
## Results

The values of the insertion torque and pullout resistance of the screws with rough surface (SAFE) and smooth surface (Pedicol Plus) are presented in ► **Tables 1** and **2**. The comparison of the insertion torque of the rough and smooth surface screws is shown in ► **Table 3**. The 4.8 mm rough surface screws showed greater insertion torque with the pilot hole tapping, with a smaller diameter than the outer diameter of the screw (non-



**Fig. 2** 5, 0 mm Pedicol Tap (A) and SAFE Tap(B).

parametric Mood test [ $p = 0.002$ ]). The 5.5 mm rough surface screws showed higher insertion torque compared with the smooth surface screws in all tapping modes (nonparametric Mood test [ $p = 0.002$ ]). The 6.5 mm rough surface screws showed higher insertion torque when compared to the smooth surface screws and the experimental group where was done the 5.0 mm tapping (non parametric Mood Test [ $p = 0.002$ ]) (► **Table 3**).



**Fig. 3** Universal testing machine.

**Table 1** Insertion torque values

INSERTION TORQUE								
GROUP	Screw Diameter	Pilot hole tapping	n	Mean	Standard Deviation	Minimum	Median	Maximum
Smooth surface (Pedicol)	4.8 mm	4,0 mm	5	0.16	0.03	0.11	0.16	0.20
		Without tapping	5	0.32	0.04	0.27	0.32	0.37
	5.5 mm	4,0 mm	5	0.20	0.05	0.14	0.20	0.28
		5,0 mm	5	0.14	0.01	0.13	0.14	0.16
		Without tapping	5	0.23	0.05	0.15	0.24	0.26
	6.5 mm	4,0 mm	5	0.38	0.09	0.28	0.39	0.48
		5,0 mm	5	0.41	0.05	0.33	0.40	0.48
		6,0 mm	5	0.29	0.04	0.25	0.29	0.33
Without tapping		5	0.39	0.03	0.37	0.37	0.44	
Rough surface (SAFE)	4.8 mm	4,3 mm	5	0.30	0.04	0.27	0.29	0.36
		Without tapping	5	0.30	0.05	0.24	0.28	0.37
	5.5 mm	4,3 mm	5	0.43	0.02	0.40	0.42	0.45
		5,0 mm	5	0.34	0.07	0.24	0.34	0.41
		Without tapping	5	0.35	0.12	0.15	0.37	0.47
	6.5 mm	4,3 mm	5	0.56	0.11	0.44	0.54	0.73
		5,0 mm	5	0.60	0.06	0.50	0.63	0.64
		6,0 mm	5	0.35	0.06	0.28	0.33	0.42
Without tapping		5	0.62	0.02	0.59	0.63	0.65	

**Table 2** Values of the mechanical pullout resistance test

PULLOUT STRENGTH								
GROUP	Screw Diameter	Pilot hole tapping	n	Mean	Standard Deviation	Minimum	Median	Maximum
Smooth surface (Pedicol)	4.8 mm	4,0 mm	5	262.13	35.72	235.73	251.10	322.90
		Without tapping	5	456.17	19.71	429.44	454.94	483.83
	5.5 mm	4,0 mm	5	525.47	35.16	489.89	522.25	575.42
		5,0 mm	5	384.39	22.19	362.13	382.59	420.26
		Without tapping	5	524.36	14.87	505.80	532.18	537.21
	6.5 mm	4,0 mm	5	685.39	32.05	642.60	678.09	729.08
		5,0 mm	5	653.99	60.10	591.74	648.58	742.48
		6,0 mm	5	451.65	45.41	402.72	445.83	513.00
		Without tapping	5	622.73	29.40	582.42	617.10	657.01
	Rough surface (SAFE)	4.8 mm	4,3 mm	5	427.51	29.99	396.33	429.98
Without tapping			5	434.70	25.29	401.70	433.25	465.48
5.5 mm		4,3 mm	5	486.46	13.09	468.88	490.63	498.72
		5,0 mm	5	476.81	46.80	408.77	474.54	534.22
		Without tapping	5	536.35	48.56	468.67	538.09	602.41
6.5 mm		4,3 mm	5	648.15	38.56	600.92	671.02	679.38
		5,0 mm	5	625.84	19.62	598.54	626.01	653.88
		6,0 mm	5	518.33	49.86	439.37	528.98	576.58
		Without tapping	5	599.44	17.31	581.34	600.71	624.92

**Table 3** Comparison of insertion torque values

Screw Diameter	Pilot hole tapping	Type of surface	Median	95% CI	p-value
4,8 mm	Without tapping	Smooth (Pedicol)	0,323	-0,103; 0,130	0,527
4,8 mm	Without tapping	Rough (SAFE)	0,284		
4,8 mm	4,0 mm Pedicol	Smooth (Pedicol)	0,160	-0,244; -0,071	*0,002
4,8 mm	4,3 mm (SAFE)	Rough (SAFE)	0,289		
5,5 mm	Without tapping	Smooth (Pedicol)	0,240	-0,262; 0,103	0,099
5,5 mm	Without tapping	Rough (SAFE)	0,370		
5,5 mm	4,0 mm Pedicol	Smooth (Pedicol)	0,204	-0,309; -0,116	*0,002
5,5 mm	4,3 mm (SAFE)	Rough (SAFE)	0,422		
5,5 mm	5,0 mm Pedicol	Smooth (Pedicol)	0,136	-0,278; -0,085	*0,002
5,5 mm	5,0 mm (SAFE)	Rough (SAFE)	0,338		
6,5 mm	Without tapping	Smooth (Pedicol)	0,372	-0,287; -0,151	*0,002
6,5 mm	Without tapping	Rough (SAFE)	0,626		
6,5 mm	4,0 mm Pedicol	Smooth (Pedicol)	0,392	-0,444; 0,045	0,058
6,5 mm	4,3 mm(SAFE)	Rough (SAFE)	0,536		
6,5 mm	5,0 mm Pedicol	Smooth (Pedicol)	0,403	-0,305; -0,018	*0,002
6,5 mm	5,0 mm (SAFE)	Rough (SAFE)	0,626		
6,5 mm	6,0 mm Pedicol	Smooth (Pedicol)	0,290	-0,173; 0,054	0,058
6,5 mm	6,0 mm (SAFE)	Rough (SAFE)	0,327		

Abbreviation: CI, confidence interval.

The asterisk (\*) indicates statistical difference (non-parametric Mood test [ $p < 0.05$ ]).

**Table 4** Comparison of the resistance force to pullout

Screw Diameter	Pilot hole tapping	Type of surface	Median	95% CI	p-Value
4,8 mm	Without tapping	Smooth (Pedicol)	454,90	-36,0; 82,1	0,527
4,8 mm	Without tapping	Rough (SAFE)	433,30		
4,8 mm	4,0 mm (Pedicol)	Smooth (Pedicol)	251,0	-231,0; -73,0	*0,002
4,8 mm	4,3 mm (SAFE)	Rough (SAFE)	430,0		
5,5 mm	Without tapping	Smooth (Pedicol)	532,0	-97,0; 69,0	0,527
5,5 mm	Without tapping	Rough (SAFE)	538,0		
5,5 mm	4,5 mm (Pedicol)	Smooth (Pedicol)	522,0	-9,0; 107,0	0,527
5,5 mm	4,5 mm (SAFE)	Rough (SAFE)	491,0		
5,5 mm	5,0 mm (Pedicol)	Smooth (Pedicol)	383,0	-172,0; 11,0	0,058
5,5 mm	5,0 mm (SAFE)	Rough (SAFE)	475,0		
6,5 mm	Without tapping	Smooth (Pedicol)	617,1	-42,5; 75,7	0,058
6,5 mm	Without tapping	Rough (SAFE)	600,7		
6,5 mm	4,5 mm (Pedicol)	Smooth (Pedicol)	678,0	-37,0; 128,0	0,527
6,5 mm	4,5 mm (SAFE)	Rough (SAFE)	671,0		
6,5 mm	5,0 mm (Pedicol)	Smooth (Pedicol)	649,0	-62,0; 144,0	0,527
6,5 mm	5,0 mm (SAFE)	Rough (SAFE)	626,0		
6,5 mm	6,0 mm (Pedicol)	Smooth (Pedicol)	446,0	-174,0; 74,0	0,058
6,5 mm	6,0 mm (SAFE)	Rough (SAFE)	529,0		

Abbreviations: CI, confidence interval.

The asterisk (\*) indicates statistical difference (non-parametric Mood test [ $p < 0.05$ ]).

The comparison of the pullout resistance values of the screws is illustrated in ► **Table 4**. Only 4.8 mm rough surface screws with a pilot hole of smaller diameter than the outer diameter of the screw showed greater pullout resistance compared to smooth surface screws (nonparametric Mood test [ $p = 0.002$ ]) (► **Table 4**).

## Discussion

In the tests performed, no statistically significant differences were observed in the biomechanical properties of smooth or rough pedicle screws. With the exception of the insertion torque of most of the rough surface screws used in the present study, and the pullout resistance of the rough surface screws of 4.8 mm, there was no statistical difference in the comparison of the other mechanical tests performed. The increase in the insertion torque during the insertion of the rough surface screws can be explained by the greater friction of the rough surface of the implant with the specimen interface, although it was not observed in all tests. The insertion torque does not correlate with the pullout resistance of the pedicle screws,<sup>6</sup> and the results observed in the trials of the present study corroborate these reports.

The pullout resistance of the rough surface screws was not superior to the smooth surface screws in the mechanical tests performed in our study, except for the 4.8 mm screws inserted after tapping using the taps of the referred fixation systems. Probably other factors, with emphasis on the smaller diameter of the pilot hole tapping, participated in this isolated result of the tests.<sup>1</sup>

Loosening of pedicle screws is an “in vivo” indicator of failure of implant fixation and has been observed in ~ 0.6 to 11% of patients.<sup>13</sup> In order to increase the anchorage of the implants and reduce the index of loosening of the pedicle screws, some strategies have been applied to the implants, the surface treatment of the implants has been one of the alternatives presented with good clinical and experimental results.<sup>14</sup> Increased implant surface roughness stimulates bone growth, increases the rate of osteointegration and reduces implant failure.<sup>5</sup> The beneficial effects of implant surface roughness on osteointegration have been experimentally observed.<sup>11</sup>

The greater resistance to pull-out of screws with a rough surface compared to screws with a smooth surface was observed in the acute and chronic phase, after insertion in sheep's vertebrae.<sup>7</sup> The results of the present study do not corroborate these reports, but the experimental model used should be taken into account. In our study, the tests were performed with screws inserted in polyurethane, which despite being widely used in this type of mechanical test, should be recognized as a limitation. The real benefits and limitations can only be noticed through clinical observation. However, the performance of mechanical tests is the initial step for investigating the biomechanical properties of implants. This test modality, using synthetic materials and pullout tests, is easy to perform, reproducible, and represents the initial stage of this experimental investigation modality.

The rough surface screws were not superior to the smooth surface screws in the pullout tests carried out in the acute phase of screw insertion. However, it must be considered

that the increased resistance to the pullout of the implants is related to the osteointegration that occurs at the interface between the implant and the bone. The effect of osteointegration cannot be observed in the experimental model used due to the use of a synthetic specimen and the realization of the experiment in the acute phase of implant insertion. Additional “in vivo” studies should be performed, allowing osteointegration to occur so that its effect can be observed on the pullout resistance of the implants, since in our experimental observation the rough surface of the implant alone did not increase its resistance to pullout.

## Conclusion

Pedicle screws with a rough surface did not show increased pullout resistance in the acute phase of their insertion in polyurethane blocks, when compared with smooth surface screws. The screws with a rough surface showed higher insertion torque compared to the smooth surface screws, depending on the diameter of the screw and on the preparation of the pilot hole.

### Authors' Declaration of Contribution

Each author contributed individually and significantly to the development of this article. Fleury R. B. C. (0000-0001-7643-6466)\*: Substantial contributions to the conception and design of the work, acquisition and interpretation of data for the work and final approval of the version to be published; Shimano A. C. (0000-0002-3119-2362)\*: contribution to data collection, analysis and final approval; Matos T. D. (0000-0003-3853-502X)\*: contribution to data collection and analysis; Teixeira K. O. (0000-0002-8165-2427)\*: contribution to data collection and analysis; Romero V (0000-0002-3278-5223)\*: review for important intellectual content; Defino H. L. A. (0000-0003-4274-0130)\*: Substantial contributions to the conception and design of the work, contributions to the analysis and interpretation of data for the work and final approval of the version to be published.

### Conflict of Interests

The authors have no conflict of interests to declare.

## References

- 1 Shea TM, Laun J, Gonzalez-Blohm SA, et al. Designs and techniques that improve the pullout strength of pedicle screws in osteoporotic vertebrae: current status. *Biomed Res Int* 2014;2014:748393
- 2 De lure F, Bosco G, Cappuccio M, Paderni S, Amendola L. Posterior lumbar fusion by peek rods in degenerative spine: preliminary report on 30 cases. *Eur Spine J* 2012;21(Suppl 1):S50-S54
- 3 Zhang QH, Tan SH, Chou SM. Effects of bone materials on the screw pull-out strength in human spine. *Med Eng Phys* 2006;28(08):795-801
- 4 Hasegawa T, Inufusa A, Imai Y, Mikawa Y, Lim TH, An HS. Hydroxyapatite-coating of pedicle screws improves resistance against pull-out force in the osteoporotic canine lumbar spine model: a pilot study. *Spine J* 2005;5(03):239-243
- 5 Ong JL, Carnes DL, Bessho K. Evaluation of titanium plasma-sprayed and plasma-sprayed hydroxyapatite implants in vivo. *Biomaterials* 2004;25(19):4601-4606
- 6 Wiendieck K, Müller H, Buchfelder M, Sommer B. Mechanical stability of a novel screw design after repeated insertion: can the double-thread screw serve as a back up? *J Neurosurg Sci* 2018;62(03):271-278
- 7 Wang WT, Guo CH, Duan K, et al. Dual pitch titanium-coated pedicle screws improve initial and early fixation in a polyetheretherketone rod semi-rigid fixation system in sheep. *Chin Med J (Engl)* 2019;132(21):2594-2600
- 8 Hsu CC, Chao CK, Wang JL, et al. Increase of pullout strength of spinal pedicle screws with conical core: biomechanical tests and finite element analyses. *J Orthop Res.* 2005;23:788-794
- 9 Rosa RC, Silva P, Shimano AC, et al. Análise biomecânica de variáveis relacionadas à resistência ao arrancamento dos parafusos do sistema de fixação vertebral. *Rev Bras Ortop* 2008;43(07):293-299
- 10 Kueny RA, Kolb JP, Lehmann W, Püschel K, Morlock MM, Huber G. Influence of the screw augmentation technique and a diameter increase on pedicle screw fixation in the osteoporotic spine: pullout versus fatigue testing. *Eur Spine J* 2014;23(10):2196-2202
- 11 Kim YY, Choi WS, Rhyu KW. Assessment of pedicle screw pullout strength based on various screw designs and bone densities-an ex vivo biomechanical study. *Spine J* 2012;12(02):164-168
- 12 Schroeder A, van der Zypen E, Stich H, Sutter F. The reactions of bone, connective tissue, and epithelium to endosteal implants with titanium-sprayed surfaces. *J Maxillofac Surg* 1981;9(01):15-25
- 13 Esses SI, Sachs BL, Dreyzin V. Complications associated with the technique of pedicle screw fixation. A selected survey of ABS members. *Spine* 1993;18(15):2231-2238
- 14 Upasani VV, Farnsworth CL, Tomlinson T, et al. Pedicle screw surface coatings improve fixation in nonfusion spinal constructs. *Spine (Phila Pa 1976)* 2009;34(04):335-343