

# Pull-out strength of patient-specific template-guided vs. free-hand fluoroscopically controlled thoracolumbar pedicle screws: a biomechanical analysis of a randomized cadaveric study

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## Abstract

**Purpose** To assess the pull-out strength of thoracolumbar pedicle screws implanted via either a patient-specific template-guided or conventional free-hand fluoroscopically controlled technique in a randomized cadaveric study, and to evaluate the influence of local vertebral bone density, quantified by Hounsfield units (HU), on pedicle screw pull-out strength.

**Methods** Thoracolumbar pedicles of three spine cadavers were instrumented using either a free-hand fluoroscopically controlled or a patient-specific template-guided technique. Preoperative bone density was quantified by HU measured on CT. Pedicle perforation was evaluated on postoperative CT scans by an independent and blinded radiologist. After dissected vertebrae were embedded in aluminum fixation devices, pull-out testing was initiated with a preload of 50 N and a constant displacement rate of 0.5 mm/s. Subgroup analyses were performed excluding pedicle screws with a pedicle breach ( $n = 47$ ).

**Results** Pull-out strength was significantly different with  $549 \pm 278$  and  $441 \pm 289$  N in the template-guided ( $n = 50$ ) versus fluoroscopically controlled ( $n = 48$ ) subgroups ( $p = 0.031$ ), respectively. Subgroup analysis limited to screws with an intrapedicular trajectory revealed a tendency toward a higher pull-out strength in the template-

guided ( $n = 30$ ) versus fluoroscopically controlled screws ( $n = 21$ ) with  $587 \pm 309$  and  $454 \pm 269$  N ( $p = 0.118$ ), respectively. There was a trend toward a higher pull-out strength ( $709 \pm 418$  versus  $420 \pm 149$  N) in vertebrae with a bone density of ( $>171$  HU) versus ( $<133$  HU), respectively ( $p = 0.061$ ).

**Conclusions** There was a significantly higher pull-out strength of thoracolumbar pedicle screws when inserted via a patient-specific template-guided versus conventional free-hand fluoroscopically controlled technique, potentially associated with screw trajectory.

**Keywords** Pedicle screw · Pedicle perforation · Bone density · Hounsfield units · Patient-specific · Template-guided · Biomechanical analysis · Pull-out strength

## Introduction

Screw purchase in the vertebral pedicle, which is crucial for a successful spinal fusion, is challenged by several parameters, with a reported incidence of pedicle screw loosening of up to 60 percent in patients with osteoporosis [1, 2]. Besides the influence of bone mineral density on the biomechanical strength of pedicle screw fixation [1–4], a plethora of variables has been identified to potentially influence pedicle screw failure. While previous analyses have reported an increased fixation strength for screws with a supero-lateral trajectory [5] with a resulting cortical bone anchorage [6], others have emphasized potential disadvantages, such as posteromedial bony impingement of the screw head [7], as well as a potentially increased risk of pseudoarthrosis and caudal adjacent segment failure [8]. In addition to the screw trajectory within the pedicle [5–13], parameters such as the screw diameter and screw design,

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the depth of screw insertion, and cement augmentation have been underlined as influencing factors [14–28]. In fact, the requirement of screw redirection after a pedicle wall breach is associated with significant decreases in resistance to screw loosening and axial pull-out force [12].

As opposed to the conventional free-hand technique of pedicle screw instrumentation under fluoroscopic control, template-guided techniques have been developed [29–39]. The implantation of thoracolumbar pedicle screws via a patient-specific template-guided versus conventional technique has previously been associated with a higher accuracy and thereby reduced incidence of dangerously misplaced pedicle screws, a lesser extent of intraoperative radiation exposure, as well as a reduced intraoperative instrumentation time [29–39].

However, the question whether such template-guided techniques are also associated with potential biomechanical advantages has not yet been answered and was subject of the present study. We hypothesized that pull-out strength of pedicle screws implanted via a patient-specific template-guided technique is superior when compared to implantation via the conventional free-hand fluoroscopically controlled technique. We further aimed to evaluate whether Hounsfield units (HU)—as a quantification of the local vertebral bone density—directly correlate with the pull-out strength of thoracolumbar pedicle screws. We combined these two research questions as one parameter can potentially influence the other, and only consideration of both aspects can add valuable information.

## Materials and methods

### Specimens and surgical technique

The surgical technique as well as the experimental setup for insertion of the pedicle screws has previously been described [29] and is summarized shortly: Instrumentation was conducted via either a free-hand fluoroscopically controlled versus patient-specific template-guided (MySpine®, Medacta SA International, Switzerland) technique by three surgeons in three cadavers without prior spinal surgery, in a randomized order (intravertebral computerized randomization). For patient-specific instrumentation, a three-dimensional reconstruction and digital surgical plan as well as drill guides were developed based on preoperative 0.64-mm spiral CT scans. Pedicle screws (MUST®—Medacta Unconstrained Screw Technology) with a diameter ranging between 5 and 6 mm and a length ranging between 25 and 55 mm were utilized (Table 1), depending on the pedicle size and diameter. Vertebral columns were dissected into separate vertebrae and stored at  $-20^{\circ}\text{C}$ .

**Table 1** Vertebral bone density, screw diameter, and screw trajectory for each level

Level	HU	Diameter (mm)		Angle (axial) (°)	
		Right	Left	Right	Left
Cadaver #1					
Th1	194.7	5	5	28.0	29.2
Th2	158.6	5	5	20.9	27.8
Th3	144.0	5	5	14.8	17.8
Th4	141.9	5	5	11.7	13.2
Th5	150.1	5	5	19.0	11.9
Th6	161.5	5	5	19.8	13.1
Th7	147.2	5	5	12.1	15.1
Th8	147.8	5	5	8.0	12.3
Th9	165.5	5	5	5.4	14.6
Th10	188.2	5	5	22.0	2.9
Th11	155.9	6	6	25.5	6.3
Th12	144.4	6	6	12.5	13.2
L1	138.8	6	6	21.5	6.4
L2	136.5	6	6	14.2	15.8
L3	146.4	6	6	22.6	5.9
L4	173.8	5	6	23.8	7.5
L5	185.9	6	6	15.7	22.1
Cadaver #2					
Th1	Bilateral screw exclusion				
Th2	174.4	5	5	18.4	11.0
Th3	167.2	5	5	20.0	22.0
Th4	Unilateral screw exclusion				
Th5	170.2	5	5	15.4	12.4
Th6	166.6	5	5	18.5	13.8
Th7	162.9	5	5	15.4	6.4
Th8	154.4	5	5	10.4	23.8
Th9	144.1	5	5	12.2	6.7
Th10	134.2	5	6	10.0	5.6
Th11	149.4	6	6	8.8	13.6
Th12	124.9	6	6	11.4	7.9
L1	114.7	6	6	13.1	10.5
L2	116.2	6	6	24.2	14.1
L3	118.5	6	6	16.8	22.8
L4	104.4	6	6	25.0	25.1
L5	107.9	6	6	25.1	19.2
Cadaver #3					
Th1	Unilateral screw exclusion				
Th2	172.7	5	5	18.4	16.8
Th3	168.8	5	5	21.3	15.5
Th4	178.0	5	5	13.7	27.4
Th5	158.0	5	5	15.0	27.0
Th6	144.3	5	5	13.7	26.7
Th7	146.9	5	5	25.4	11.2
Th8	209.1	5	5	16.9	8.6
Th9	216.0	5	5	18.0	9.5

**Table 1** continued

Level	HU	Diameter (mm)		Angle (axial) (°)	
		Right	Left	Right	Left
Th10	133.0	5	5	18.8	10.5
Th11	145.3	6	6	10.6	20.4
Th12	139.1	6	5	18.2	25.2
L1	132.5	6	6	32.9	14.3
L2	144.9	5	6	15.4	29.2
L3	143.9	6	6	29.6	13.6
L4	129.8	6	6	28.7	11.6
L5	326.9	6	5	12.9	29.2

### Radiographic evaluation

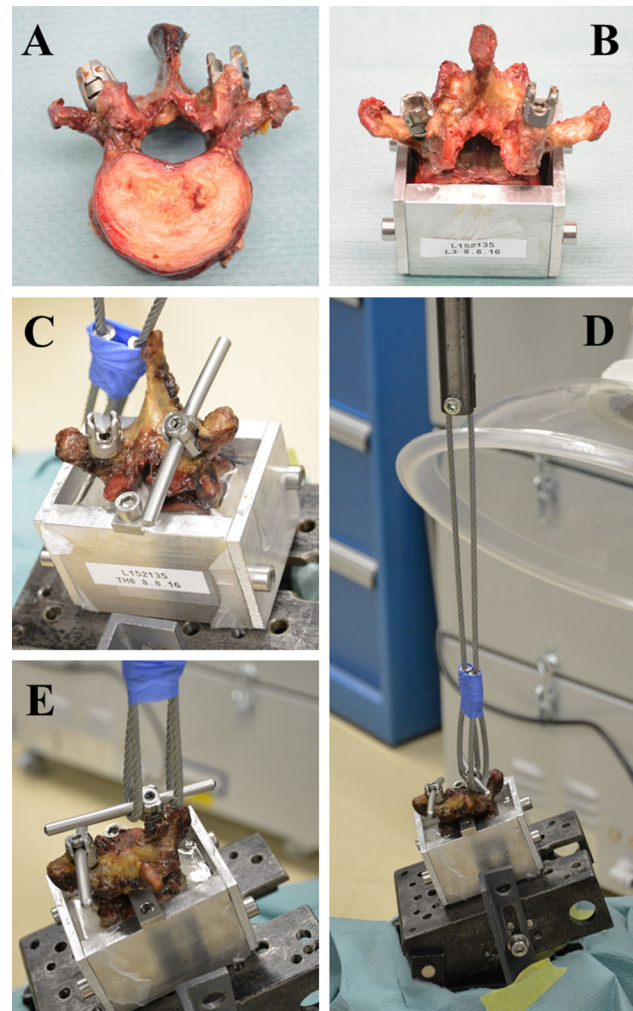
A 0.64-mm spiral CT scan was available both pre- and postoperatively for each specimen. HU were measured preoperatively on axial CT scans by two independent readers, according to the technique described by Schreiber et al. [40] using the picture archiving and communication system (IMPAX 6.4, AGFA HealthCare, Germany). The mean of both measurements was calculated for each vertebra and used for analysis. The presence of pedicle perforation [29] was evaluated by a board-certified radiologist, blinded to the performed technique, based on postoperative CT scans. The trajectory was evaluated for each screw on axial CT scans, and the transverse angulation was measured.

### Specimen preparation and fixation

Dissected vertebrae were de-frozen over 12 h in a 4 °C fridge after removal from a –20 °C freezer. Specimens were then embedded in aluminum u-shaped fixation devices (blocks, Fig. 1) and rigidly fixed using high-strength epoxy adhesive EA 3430 (Loctite, Henkel). For additional support, a traverse metal rod was placed through the vertebral foramen and fixed with screws to the fixation device. Epoxy was hardened for 4 h at room temperature before testing.

### Biomechanical analysis: pull-out strength

Aluminum blocks were mounted on a universal material testing machine (Zwick 1456, Zwick GmbH, Ulm, Germany). A *xy*-table allowed unconstrained travel in horizontal plane and angle adjustment of the aluminum fixation device. This allowed a coaxial position of the pedicle screws and the tensile axis of the universal testing machine. The head of the pedicle screw was connected to



**Fig. 1** Illustration of the biomechanical analysis setup. Dissected vertebrae with pedicle screws (MUST®—Medacta Unconstrained Screw Technology) with a diameter ranging between 5 and 6 mm and a length ranging between 25 and 55 mm (a) were embedded and fixed in aluminum u-shaped fixation devices (b, c). Pull-out testing was initiated with a preload of 50 N and a constant displacement rate of 0.5 mm/s (d), until screw failure was noted (e)

rods at which a steel wire was enlaced. The upper end of the steel wire was connected to a 20-kN load cell (Gassmann Theiss, Bickenbach, Germany) (Fig. 1). Pull-out testing was initiated with a preload of 50 N and a constant displacement rate of 0.5 mm/s. Data were recorded using TestXpert 10 software (Zwick-Roell, Zwick GmbH, Ulm, Germany), and maximum pull-out force was quantified. Since randomization had already been conducted preoperatively for each specimen, biomechanical testing was initiated for the right screw per vertebra to also perform pull-out analysis in a randomized order. Pull-out data of screws with a failure during the preload cycle were not considered in further analysis (template-guided: 1; fluoroscopically controlled: 3).

## Statistical analysis

Categorical variables are reported as frequencies with the according percentages, and continuous variables as mean  $\pm$  standard deviation with the corresponding range, unless otherwise stated. The Kolmogorov–Smirnov test was used for testing normal distribution. In case of a normal distribution, continuous variables were compared between groups via a Student *t* test, as opposed to a non-parametric Mann–Whitney *U* test in case of a non-normal distribution. Categorical variables were compared using the Pearson’s Chi-squared test. A one-way analysis of variance (ANOVA) was performed to compare the pull-out strength of pedicle screw subgroups instrumented within vertebrae with a bone density of (<133 HU), (133–171 HU), and (>171 HU). The first threshold was set at 133 HU, as this was the previously reported [40] average HU value in patients with a *T* score of  $-1.0$  or greater ( $133 \pm 38$  HU). The second threshold (171 HU) represents the HU value one standard deviation above the mean in patients with a *T* score of  $-1.0$  or greater, as reported by Schreiber et al. [40]. Statistical significance was defined by *p* values  $p < 0.05$ . Data analysis was performed using IBM SPSS Statistics, Version 21.0 (IBM Corp., Armonk, NY, USA).

## Results

Out of a total of 98 thoracolumbar pedicle screws being available for analysis, 50 had been instrumented via the utilization of patient-specific template guides, compared to 48 via the free-hand fluoroscopically controlled technique. For the comparison of the accuracy of both techniques and the details of pedicle perforation, please refer to Ref. [29].

## Radiographic evaluation

Overall ( $n = 98$ ), preoperative HU assessment revealed an average local vertebral bone density of  $157 \pm 35$  versus  $156 \pm 35$  HU in subgroups of pedicle screws with (1) the utilization of template guides compared to screws instrumented via, (2) the conventional free-hand technique ( $p = 0.815$ ), respectively. Those values were above the previously reported average HU levels in the setting of both osteopenia ( $101 \pm 25$  HU) and osteoporosis ( $79 \pm 32$  HU) [40].

Postoperative CT analysis identified 47 screws with a pedicle perforation, resulting in a total number of 51 pedicle screws with an intrapedicular trajectory (52%). When evaluating the average local vertebral bone density for screws with an intrapedicular trajectory only, values were  $155 \pm 40$  versus  $145 \pm 24$  HU in the template-guided ( $n = 30$ ) versus the fluoroscopically controlled

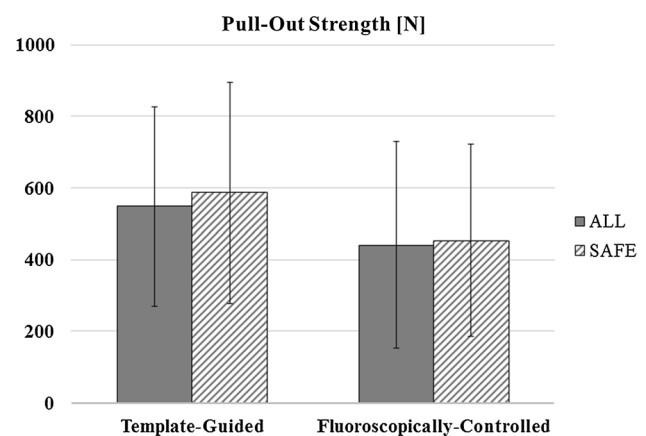
( $n = 21$ ) subgroups ( $p = 0.527$ ), respectively. There was a thoracic-to-lumbar screw ratio of 1.3:1 and 1.1:1 in the reported subgroups ( $p = 0.762$ ), respectively.

## Biomechanical analysis: pull-out strength

Overall, biomechanical analysis in the entire set of included thoracolumbar screws revealed a significantly higher pull-out strength of  $549 \pm 278$  versus  $441 \pm 289$  N in the template-guided ( $n = 50$ ) compared to the fluoroscopically controlled ( $n = 48$ ) subgroups ( $p = 0.031$ ), respectively. When solely evaluating screws with an intrapedicular trajectory, pull-out strength was identified as  $587 \pm 309$  and  $454 \pm 269$  N, in the template-guided ( $n = 30$ ) versus the fluoroscopically controlled ( $n = 21$ ) subgroups ( $p = 0.118$ ), respectively (Fig. 2). In both the overall analysis ( $n = 98$ ) and the subanalysis including intrapedicular screws only ( $n = 51$ ), the axial screw trajectory was found to be less convergent in the template-guided versus the fluoroscopically controlled cohort. In fact, the axial angulation was  $13 \pm 5^\circ$  versus  $21 \pm 6^\circ$  in the template-guided versus fluoroscopically controlled cohort, when including all screws ( $p < 0.001$ ), and  $13 \pm 6^\circ$  versus  $22 \pm 6^\circ$  when including screws with an intrapedicular trajectory only ( $p < 0.001$ ).

## Subanalysis: influence of Hounsfield units on pull-out strength

In order to evaluate the influence of local vertebral bone density on pull-out strength, as assessed by HU



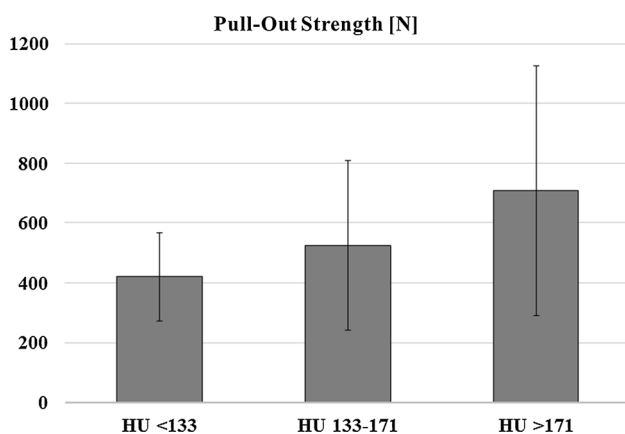
**Fig. 2** Biomechanical analysis in the entire set of included thoracolumbar screws revealed a pull-out strength of  $549 \pm 278$  and  $441 \pm 289$  N in the template-guided ( $n = 50$ ) versus the fluoroscopically controlled ( $n = 48$ ) subgroups ( $p = 0.031$ ), respectively. When solely evaluating screws with an intrapedicular trajectory, pull-out strength was identified as  $587 \pm 309$  and  $454 \pm 269$  N, in the template-guided ( $n = 30$ ) versus the fluoroscopically controlled ( $n = 21$ ) subgroups ( $p = 0.118$ ), respectively

measurements [40], vertebrae were divided into three subgroups. For this subanalysis, only screws with an intrapedicular trajectory were evaluated ( $n = 51$ ). There were 14, 27, and 10 screws instrumented within vertebrae with a bone density of ( $<133$  HU), (133–171 HU), and ( $>171$  HU), respectively. There was no statistically significant difference regarding the distribution of template-guided versus fluoroscopically controlled screws between the three subgroups ( $p = 0.616$ ).

There was a trend toward a higher pull-out strength when pedicle screws were inserted into vertebrae with a higher local bone density: The average pull-out strength for screws inserted into vertebrae with an average bone density of ( $<133$  HU), (133–171 HU), and ( $>171$  HU) was  $420 \pm 149$ ,  $525 \pm 283$ , and  $709 \pm 418$  N, respectively ( $p = 0.060$ ). We observed a mean difference of 289 N of axial pull-out strength between the averages measured for vertebrae with a high ( $>171$  HU) versus low ( $<133$  HU) local vertebral bone density ( $p = 0.061$ ) (Fig. 3).

## Discussion

Use of patient-specific individual templates for insertion of pedicle screws can reduce intraoperative use of fluoroscopy and therefore radiation exposure of both the patient and the surgical team. Instrumentation via this technique seems to reach a higher accuracy, being less dependent on the surgeon's experience [29–39]. As described in a previous study using the same surgical technique, experimental setup and cadavers for insertion of the pedicle screws, the



**Fig. 3** Illustration of the pull-out strength of pedicle screw subgroups instrumented within vertebrae with a bone density of ( $<133$  HU), (133–171 HU), and ( $>171$  HU). There was no statistically significant difference regarding the distribution of template-guided versus the fluoroscopically controlled screws between the three subgroups ( $p = 0.616$ ). There was a tendency toward a higher pull-out strength when pedicle screws were inserted into vertebrae with a higher local bone density [ $>171$  HU]:  $709 \pm 418$  N versus ( $<133$  HU):  $420 \pm 149$  N;  $p = 0.061$ ]

proportion of screws being fully within the pedicle was 58% in the template-guided group, compared to 44% in the fluoroscopically controlled group ( $p = 0.153$ ). Approximately 98 versus 81% of screws were within the “safe” zone in the template-guided versus the fluoroscopically controlled groups ( $p = 0.008$ ). Furthermore, implantation of screws was significantly faster when performed via the template-guided compared to the fluoroscopically controlled technique ( $01:14 \pm 00:37$  versus  $01:40 \pm 00:59$  min per level;  $p = 0.013$ ) [29].

As an alternative option to implanting pedicle screws via a template-guided technique, intraoperative image-guidance and navigation has been reported to result in a higher accuracy when compared to the conventional two-dimensional fluoroscopically controlled technique [41–45]. In a meta-analysis on the accuracy of thoracic pedicle screw placement including 9019 screws, the reported malposition rate was significantly lower in the computer navigation group, compared to the fluoroscopy-guided navigation group. While the time of screw insertion was reported to be significantly shorter when using the computer navigation technique, the overall operative time was reported to be significantly longer [42]. With regard to pedicle instrumentation in the setting of congenital spine deformity and altered anatomy, the accuracy rate was even reported at 99.3% [43]. This concurs with the findings of another meta-analysis evaluating 130 studies with a total of 37,337 screws, with a reported accuracy of 95.2 versus 90.3% with or without the use of an intraoperative navigation technique [44].

In a previous porcine cadaveric study, an increasing degree of cortical violation was associated with decreasing axial pull-out forces of lumbar pedicle screws [46]. Considering that pedicle wall breach and the need of screw redirection are associated with significant decreases in resistance to screw loosening and axial pull-out force [12], we hypothesized that screws inserted with patient-specific individual templates would have better biomechanical pull-out characteristics compared to conventionally implanted screws.

According to the results of the present randomized biomechanical cadaver study, there was a significantly higher pull-out strength of thoracolumbar pedicle screws when inserted via a patient-specific template-guided versus conventional free-hand fluoroscopically controlled technique. Although not statistically significant, a similar trend was also observed when solely analyzing screws with an intrapedicular trajectory. We observed a mean difference of 133 N of axial pull-out strength between the averages measured for the template-guided versus the conventional free-hand fluoroscopically controlled technique, after excluding screws with a pedicle perforation ( $p = 0.118$ ). This observation might be related to several aspects. In

addition to a reduced rate of pedicle wall perforation, the pedicle screw insertion site is not violated but precisely drilled instead. The latter allows an optimal cortical grip of the screw at the insertion site. Furthermore, the trajectory of the screw is assumed to be optimally planned, based on a preoperative three-dimensional reconstruction and digital surgical plan. Interestingly, the axial trajectory of template-guided screws was found to be less convergent compared to fluoroscopically controlled screws. As previously described, more laterally pointing screws [5] and a cortical bone trajectory [6] were reported to be associated with an increased fixation strength, which also concurs with the results of the present study.

In a subanalysis we further aimed at evaluating the influence of local vertebral bone density, quantified by Hounsfield units (HU), on pedicle screw pull-out strength. This association was previously observed in a retrospective study by Bredow et al., involving 365 patients after implantation of an average of 5.6 pedicle screws per patient. The authors reported a postoperative incidence of screw loosening of 12.3%, with a significant difference in mean preoperative bone density between patients with and without screw loosening. Preoperative CT analysis revealed a mean bone density of 116 versus 133 HU in cases with or without screw loosening ( $p = 0.003$ ), respectively [2]. To further elucidate the influence of local vertebral bone density, as quantified on CT scans, we analyzed the average pull-out strength for screws inserted into vertebrae with a differing average bone density and found a tendency toward a difference between groups ( $p = 0.060$ ). Although not statistically significant, we observed a mean difference of 289 N of axial pull-out strength between the averages measured for vertebrae with a high ( $>171$  HU) versus low ( $<133$  HU) local vertebral bone density ( $p = 0.061$ ), supporting the recently published findings by Bredow et al. [2].

To the authors' best of knowledge, this study represents the first of its kind published in the English literature, by comparing the pull-out strength of pedicle screws implanted via either a patient-specific template-guided or the conventional free-hand fluoroscopically controlled technique in a randomized biomechanical cadaver study. Furthermore, our results support the previously suggested influence of vertebral HU levels on postoperative occurrence of screw loosening [2].

Limitations need to be considered when interpreting the reported findings. The herein reported results are based on the biomechanical analysis of three fresh-frozen adult cadaver samples, without any information of comorbidities. However, since this fact applies to both instrumentation techniques, in addition to the randomized study design on the vertebral level, we believe that this limitation does not reduce the validity of our assumptions.

Furthermore, to the best of our knowledge, no previous study has evaluated the correlation of in vivo versus postmortem HU measurements. Potential influences of the freezing and thawing processes on the postmortem HU values cannot be excluded. Again, this limitation applied to both instrumentation techniques in the present study. Nevertheless, HU threshold values regarding an increased risk for postoperative screw loosening need to be defined based on prospective clinical studies, rather than observations during biomechanical cadaver studies. Moreover, the observed differences between subgroups did not reach a level of statistical significance due to a potentially underpowered study. Finally, the alignment of the pedicle screw with the pull-out vector was aligned by eye, thereby potentially introducing minimal inaccuracy or bias, which, however, again applied to both groups of instrumentation techniques.

We believe that the main advantage of assessing bone density via HU, as opposed to dual-energy X-ray absorptiometry (DEXA), is the fact that an estimation can be made regarding the regional bone density at the specific level of instrumentation. HU measurements may therefore serve as an easily accessible additional parameter in the process of surgical planning regarding the extent and technique of fusion. Also, with the technology of patient-specific templates allowing accurate execution of the preoperative planning, regions with a better bone density within the vertebra could be aimed for. Follow-up studies are warranted to confirm such findings in the clinical setting.

## Conclusions

There was a significantly higher pull-out strength of thoracolumbar pedicle screws when inserted via a patient-specific template-guided versus conventional free-hand fluoroscopically controlled technique, potentially associated with screw trajectory. Although not statistically significant, subgroup analysis revealed a tendency toward a higher pull-out strength when pedicle screws were inserted into vertebrae with a higher bone density, as quantified by HU on CT scans.

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## Compliance with ethical standards

This study was conducted in accordance with Swiss and international law requirements. Ethical board's approval was obtained from the Ethical Committee of Northwestern and Central Switzerland (ID: EKNZ BASEC 2016-00204).

**Conflict of interest** None.

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