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Research

The impact of the reduction and tightening procedure for the screw-rod assembly on pedicle screw anchorage: A biomechanical study

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Abstract

Introduction: In posterior thoracolumbar instrumentation, reduction and tightening of the rods are mechanically critical processes that may lead to overloading of the construct and surrounding tissues, possibly resulting in screw loosening, breakage, or disassembly of the implants.

Study Objective: To investigate the impact of the reduction and tightening procedure to the pedicle screw-bone anchorage.

Material and Methods: Two human cadaver specimens (T5-S1) fixed with pedicle screw-rod systems of different fixation philosophies, direct side-by-side comparison: Neo Pedicle Screw System™, controlled fixation and CD Horizon™ Solera™, standard fixation.

Insertion torques and, after assembly and locking of the construct, extraction torques are recorded. The influence of the reduction and tightening procedure is demonstrated by comparing the difference between the insertion and extraction torques. The effect of distraction forces on pedicle screws is investigated.

Results: Median torque losses are significantly higher for standard fixation (0.539 Nm) compared to controlled fixation (0.393 Nm) ($p<0.001$), with higher insertion torques for standard fixation (0.966 Nm *vs*. 0.747 Nm) but similar extraction torques (0.344 Nm *vs*. 0.301 Nm). Insertion and extraction torque correlate for controlled fixation ($r=0.792$; $p<0.001$) and standard fixation ($r=0.783$; $p<0.001$). Torque losses are higher for both groups when distraction forces are applied on pedicle screws ($p \leq 0.041$).

Conclusion: Reduction and tightening of the rod-screw interface has a relevant influence on the bone purchase of pedicle screws. Losses of biomechanical behavior appear to be greater in standard fixation surgical technique, controlled fixation techniques may result in lower forces. Clinical studies comparing both intraoperative procedures for potential benefits in screw loosening, construct failure, reoperation rates, and improved clinical outcomes are warranted.

Keywords: Spine biomechanics; Pedicle screw; Rod contouring; Rod reduction; Distraction forces; Controlled force fixation.

INTRODUCTION

Instrumented thoracolumbar surgery using pedicle screws and rods is an established procedure with increasing case numbers worldwide for the treatment of various spinal disorders such as spinal stenosis, degenerated disc disease, deformity, spinal fracture and tumor [1-5]. Numerous studies have shown that pedicle screw systems adequately stabilize the affected spinal segments and increase fusion rates when intended [1,6,7]. Despite substantial clinical success, various postoperative mechanical and pseudarthrosis complications are described in the relevant literature. Screw loosening accounts for the most frequent complications, occurring at up to 15% in good bone quality and up to 63% in osteoporotic cases [8,9]. Age and bone density, especially in the intrapedicular segment, are known risk factors that are often addressed in practice by using larger screw diameters, bone cement augmentation, expandable screws, varying insertion angles, or performing bicortical insertions [8-12].

Though the influence of screw loosening on clinical outcome is a matter of debate, several authors demonstrate clinical relevance after spine stabilization, especially in the elderly at increased risk of osteoporosis due to associated mechanical construct failures such as screw breakage, non-union, or curve progression, which usually require reoperation [8, 13, 14]. In their study, Ohba et al. showed poorer clinical outcome of patients with screw loosening and found that approximately 82% of all screws later identified as loosened were pulled out during rod connection [13]. The process of reduction and rod tightening is critical and may lead to mechanical overload that not only affects the implant construct itself, but also places stress on the surrounding tissues, potentially leading to pedicle screw loosening, construct disassembly, implant breakage, malalignment, pain, or degeneration of adjacent segments [13, 15-17].

In a previous fundamental study, Kafchitsas et al. investigated the anchorage behavior of pedicle screws in different host material densities by means of Insertion Torque (IT) and Extraction Torque (ET) [18]. The results confirmed that in a low-density environment, the IT is less than in denser material and that the ET is significantly lower compared to the IT [18]. The magnitude of the difference between IT and ET represents the amount of loss in biomechanical behavior or so-called loss of bone purchase.

The aim of this in-vitro biomechanical study is to investigate the impact of the reduction and tightening procedure during posterior instrumentation assembly to the pedicle screw-bone anchorage.

MATERIAL and METHODS

HYPOTHESIS

It is hypothesized that the influence of the reduction and tightening procedure during posterior instrumentation assembly can be demonstrated by comparing the difference between the IT and, after assembly and locking of a pedicle screw construct, the ET of the pedicle screws for two systems following different fixation philosophies. In addition, it is investigated if there is a correlation between IT and ET measures.

METHODS

Thirteen motion segments each of two human cadaver specimens (T5-S1) were fixed with two different pedicle screw–rod systems in direct side-by-side comparison. The Neo Pedicle Screw System™ (Neo; Neo Medical S.A., Villette, Switzerland) was used for controlled fixation (CF; investigational group) and the CD Horizon™ Solera™ (Solera; Medtronic plc, Dublin, Ireland) for standard fixation (SF; control group). Controlled fixation, a relatively new philosophy in surgical technique, means that the loads acting intraoperatively on the construct and thus on the spine can be better controlled by the surgeon, to reproducibly apply appropriate forces during the assembly and locking of the pedicle screw construct. To achieve this, it is mandatory to keep the applied forces under control as much as possible by respecting the following three aspects: 1) Unique physiological screw head position 2) Maintaining screw head mobility, 3) Awareness and control of mechanical loads applied. This requires lightweight, non-forcing instruments that do not inadvertently apply avoidable loads. However, the surgical technique also considers the placement of pedicle screws according to individual anatomy and biomechanics, as well as the precise bending and placement of the rods while maintaining the polyaxiality of the screws.

Per side and cadaver, fourteen polyaxial pedicle screws (CF: Ø6 mm, 45 mm: cadaver 1 = left, cadaver 2 = right); SF: Ø6.5 mm, 45 mm: cadaver 1 = right, cadaver 2 = left) were inserted under radiographic control into the torsos mounted on a table using the surgical techniques recommended by the respective manufacturer for their pedicle screw system. No tapping was used in any case. In this process, the IT was digitally recorded by the method of Kafchitsas et al. using a modified torque screwdriver covering 0.01 Nm to 4.0 Nm (accuracy of ± 0.5% F.S.) [18]. Prior to placement the rod (CF: Ø 5.5 mm x 400 mm titanium; SF: Ø 5.5 mm x 450 mm titanium) was cut to the length of the construct and bent as required in accordance with the manufacturer's surgical technique (CF: Neo system-specific rod bender; SF: manual bending) (Figure 1).

Fig. 1. The system-specific Neo rod bending instrument used for bending of the rods in CF investigational group

After final tightening of all screws on one side, the specimen was left in place for 40 minutes to 110 minutes before the rod was removed and the screws were extracted (Figure 2). Again, the ET of each pedicle screw was measured and documented. The same procedure was then carried out on the opposite side with the comparative fixation philosophy, starting with the adaptation of the rod.

Fig. 2. Human cadaver specimens with instrumentation between T5-S1: Top: Neo pedicle screws with screw extender guides; bottom: Solera pedicle screws with rod in situ after reduction and tightening

Since the method of Kafchitsas et al. was originally tested for a pedicle screw system based on the SF principle with one screw diameter, the validation was extended for CF Neo screws [18]. This was done by inserting pedicle screws with different diameters (Ø6 mm and Ø7 mm; 45 mm) into rigid polyurethane foam blocks of defined densities (7.5 PCF (0.12 g/cc), 10 PCF (0.16 g/cc) and 12.5 PCF (0.19 g/cc), Sawbones®, Washington, USA) and unscrewing them while IT and ET were measured as described above (measures per group: n=5). To investigate the effects of distraction directly across pedicle screw heads, further measurements were made by applying forces of 100N over CF Neo screws (Ø6 mm; n=12) and SF Solera screws (Ø6.5 mm; n=12) for 30 seconds prior to extraction using a modified distraction device with digital force measurement and compared to earlier measures without any distraction (Figure 3)

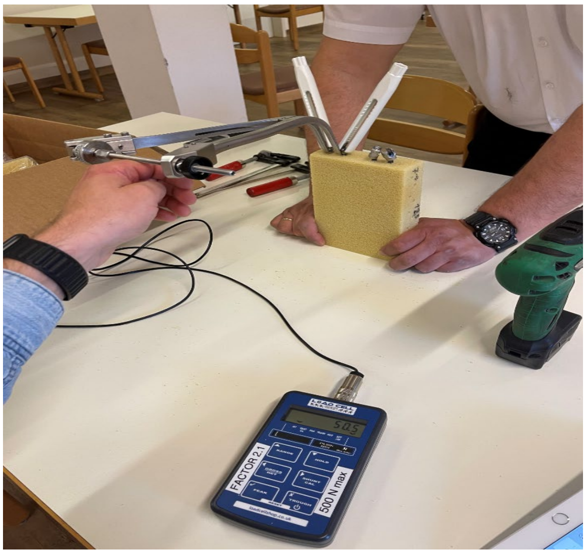

Fig. 3. Distraction across pedicle screws. Device which applies forces of 100N via Neo pedicle screws in polyurethane rigid foam blocks of defined density.

STATISTICS

Statistical analyses were performed using Sigma Plot, version 14 (Systat Software, Inc., San Jose, USA). Depending on the distribution and dependence, a t-test, paired t-test, Wilcoxon rank sum test, was performed for comparisons of means, while correlation analyses were done according to Spearman. Statistical significance is assumed at a p-value<0.05.

RESULTS

The results of the extended validation of the method of Kafchitsas et al. for Neo demonstrate statistically significant lower ETs than ITs ($p \leq 0.004$) at higher torques for 7 mm diameter screws than for those with 6 mm, as well as for higher foam densities, as shown in (Figure 4a and 4b) [18]. The mean torque losses between insertion and extraction range from 23.1% to 31.4%.

When applying distraction forces directly across the pedicle screw heads, statistically significant ($p \leq 0.041$) higher losses between IT and ET (delta) are detectable compared to the recent and previous validation studies conducted under same conditions without distraction. This is true for both pedicle screw types (Neo: factor 1.3 - 2.0; Solera: 3.0 - 6.8) and diameters as well as for all foam densities (Figure 5).

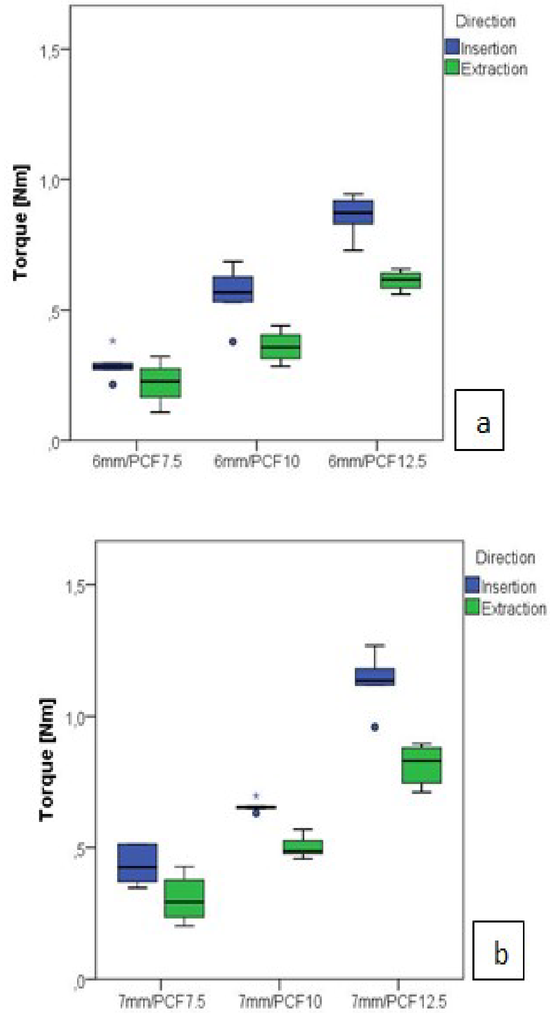

Fig. 4a and 4b. IT and ET by foam density and screw diameter. IT and ET for 6 mm (a) and 7 mm (b) diameter Neo pedicle screws in rigid polyurethane foam blocks of defined densities: 7.5 PCF (0.12 g/cc), 10 PCF (0.16 g/cc) and 12.5 PCF (0.19 g/cc); paired t-test: statistical significance for all pairs

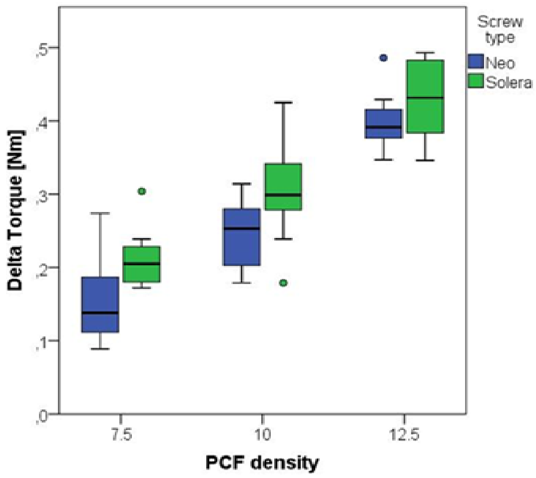

Fig. 5. Torque losses between IT and ET with distraction. Delta torque (IT *vs.* ET) for 6 mm Neo pedicle screws and 6.5 mm Solera pedicle screws in rigid polyurethane foam blocks of certain densities: (7.5 PCF (0.12 g/cc), 10 PCF (0.16 g/cc), and 12.5 PCF (0.19 g/cc)) when distraction forces of 100 N are applied to the pedicle screws

Torque losses between IT and ET (delta) are statistically significant different ($p<0.001$) between the two fixation philosophy groups with higher losses in the amount of 55.8% in the SF group compared to 52.6% for CF. Considering the baseline (IT), statistically significant differences are detectable with higher values in the SF group, but not with regard to ET. Table 1 provides the results of the cadaver measurements by fixation philosophy group (Table 1).

Table 1. Cadaver measurements by fixation philosophy group.

Pedicle screw IT and ET after reduction and tightening of the screw-rod assembly for CF and SF. IT, insertion torque; ET, extraction torque; Delta, IT – ET; CF, controlled fixation; SF, standard fixation; P, between group p-value (CF *vs.* SF using Independent Sample Mann-Whitney U Test)

Measure	Group	N (valid)	Median Torque [Nm]	25% - 75% Torque Interval [Nm]	P
IT	CF	28	0.747	0.503 - 0.931	0.004
	SF	28	0.966	0.724 - 1.327	
ET	CF	28	0.301	0.156 - 0.447	0.272
	SF	28	0.344	0.191 - 0.675	
Delta	CF	28	0.393	0.233 - 0.507	<0.001
	SF	28	0.539	0.437 - 0.681	

As shown, IT and ET correlate statistically significant with each other for CF ($r=0.792$; $p<0.001$) and SF ($r=0.783$; $p<0.001$) (Figure 6).

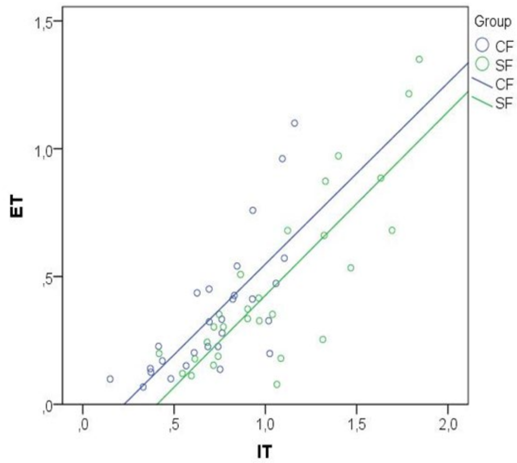

Fig. 6. Correlation of IT and ET. IT *vs.* ET for two different fixation philosophies: controlled fixation and standard fixation

DISCUSSION

The process of reduction and tightening of the rod-screw interface during posterior instrument assembly has a relevant influence on the pedicle screw-bone anchorage. The present in vitro results show a significant difference in the loss of biomechanical behavior after construct assembly between CF and SF with lower purchase losses if the fixation is performed in a less forced way, and greater biomechanical deterioration when the SF technique is used. A baseline comparison shows that statistically significant higher ITs are applied in SF, whereas no differences between the two techniques can be demonstrated for ET.

The ITs and ETs determined in this study agree with the in vivo measures of Sandén et al., who reported average ITs of 0.76 Nm and ETs of 0.29 Nm one year postoperatively, corresponding to an average loss of 61.8%. Pearson et al. recorded in their in vivo study higher IT and ET measures, but a highly consistent mean loss of 58.1%, which may need to be seen in the context of the results of Bühler et al., who reported significantly greater ITs (1.29 Nm) in vivo than in vitro (0.67 Nm) [19-21]. The current results show strong relations between IT and ET for both study groups, CF ($r=0.792$) and SF ($r=0.783$). Similar correlations, although somewhat weaker, were shown in vivo by Sandén et al. [19]

(r=0.591, 95%CI 0.305-0.779), whereas Pearson et al. [20] found a weak correlation between IT and torque loss in percent (R^2=6%) with low predictive value.

The debate on whether and to what extent IT influences the pull-out and loosening behavior of pedicle screws is controversial. Several in vitro studies confirmed correlations between IT and pull-out force as well as between significantly reduced reinsertion IT and pull-out force, between IT and the axial force on screw heads at 1 mm displacement, as well as between IT and the number of cycles leading to screw pullout, whereas other researchers could not confirm IT to be a reliable predictor for pedicle screw and pull-out strength, neither in vivo nor in cadaveric human or calf models [19, 20,22-28].

However, external loads, such as those frequently generated by minor distractions via the pedicle screws, can lead to a deterioration of the biomechanical behavior. In this case, as measured intraoperatively by the author, avoidable forces of 100 N and much more act on the screws. This has a significant impact on screw anchorage, as evidenced in the current bone model by up to 6.8-fold higher losses between IT and ET. To our knowledge, there are no suitable in vivo data on this, however, other authors have used finite element models to investigate the biomechanical effects of distraction when using growth rod instrumentation for the treatment of scoliosis [29, 30]. They concluded that there is a relationship between screw loosening and distraction forces [30].

The present results of the cadaver study show greater losses of bone purchase if the fixation is performed in a standard manner, indicating greater biomechanical overloads. Lower losses, however, such as in the CF group, refer to a more controlled reduction and tightening process by applying only minimal forces to the construct, possibly resulting in less stress on the screw-bone interface and consequently reduced stress release to the construct as well as the surrounding tissues [15]. These interrelationships are supported by the results of the finite element study by Loenen et al., who postulated to apply only "minimal external and unintended forces" during pedicle screw rod tightening, to avoid undesirable biomechanical behavior and consequently reduce postoperative complications [17]. The authors found excessive stresses in the amount of lumbar pedicle screw pullout forces that are required for the correction of small rod-screw misalignments. These forces cause relevant segmental rotations affecting the entire lumbar spine, resulting in an overload of bony and/or intravertebral tissue, depending on the direction of the applied forces. Paik et al. also found a remarkably reduced pullout strength of 48% when using rod persuasion devices, suggesting that a forced reduction maneuver significantly weakens the screw-bone interface [16,17]. The authors concluded from their in vitro study that rod bending and screw placement need to be mindfully executed [16]. This is consistent with the clinical results of Obha et al. who compared the use of a computer-assisted rod bending technique with conventional manual bending [14]. Significantly lower screw pullout lengths and rates, less screw loosening, and better clinical outcomes indicate the superiority of a surgical technique achieving a more precise rod bending. The authors note that screw pullout during rod repositioning and tightening poses a serious risk for postoperative screw loosening and that, consequently, precise rod bending is of significant clinical importance, particularly in longer constructs [14, 31]. The current study results suggest that the different losses of bone purchase can be attributed to differences in surgical techniques, as a force control instrumentation, including a system-specific rod-bending instrument, was used in the CF group compared with the SF group, in which rod bending was performed manually resulting in more forces during screw-rod assembly.

Possible biases due to the different screw diameters used and an influence of different bone densities should be considered. As shown from literature and from the results of the present validation study (see Figure 4a and b), it is known, that IT and ET depend significantly on the surrounding bone density and on screw diameter [18, 20,21,32-35]. Bone density was considered by the study design, in which IT and ET were measured and compared in pairs on the left and right side of the same vertebra for both study groups, which is expected to lead to only minor effects. However, variations in bone density, pedicle morphology, and screw positioning cannot be completely controlled. The outer diameters of the screws compared in this study differ by 0.5 mm due to the specific pedicle screw systems under investigation, which, as expected, is associated with higher ITs for larger diameters. Willett et al. demonstrated an increased holding strength of 47% between 5 mm and 6 mm AO Schanz pedicle screws, and the results of Kwok et al. showed a further increase of 65% between 6 mm and 7 mm diameters, whereas for other screw designs the measured ITs were not solely dependent on the screw diameter [27,35]. Accordingly, in the present study, the 29.3% higher ITs in the SF group can probably be attributed to the 0.5 mm larger screw diameter as well as to minor differences in screw design and instrumentation. However, this did not result in superior bone purchase - measured by ET - indicating significant differences in the process of reduction and tightening between the two fixation philosophies studied. These differences are evidenced quantitatively by significantly higher losses of biomechanical behavior (delta of IT and ET) in standard fixation surgical technique compared with controlled fixation.

Limitations of this investigation include the in-vitro study design with relatively small sample sizes due to restricted availability of specimens, and a lack of biological bone and soft tissue responses in the cadaveric spine. Further biomechanical and clinical studies are needed to confirm the positive effects of controlled fixation.

The results of this study indicate that further biomechanical and clinical studies are warranted comparing common intraoperative practices in posterior thoracolumbar fusion with surgical techniques that avoid unnecessary stress during screw-rod assembly.

CONCLUSIONS

The reduction and tightening of the rod-screw interface has a relevant influence on the bone purchase of pedicle screws. Losses of biomechanical behaviour appear to be greater if instrument assembly is performed with a standard fixation surgical technique. Controlled fixation techniques may result in lower forces during reduction and tightening of the pedicle screw construct. It seems reasonable to investigate further in clinical studies whether a more controlled fixation technique that takes greater account of individual anatomic balance can decrease screw loosening, construct failure, and reoperation rates and improve clinical outcomes.

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ABBREVIATIONS

IT=Insertion Torque, ET=Extraction Torque, CF=Controlled Fixation, SF=Standard Fixation, PCF=Polyurethane Foam Blocks

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