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Biomechanical comparison of different rod-to-rod connectors to a conventional titanium- and cobalt chromium posterior spinal fixation system

Uwe Vieweg [a], Johannes Keck [a], Sven Krüger [b], Mohammad Arabmotlagh [c], Michael Rauschmann [c], Christoph Schilling [b,*]

[a] Krankenhaus Rummelsberg, Department of Surgical and Conservative Spine Therapy, Rummelsberg, Germany
[b] Aesculap AG, Research & Development, Tuttlingen, Germany
[c] Sana Klinikum Offenbach, Department of Spine Surgery, Offenbach, Germany

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ABSTRACT

Introduction: Several types of rod-to-rod connectors are available for the extension of spinal fixation systems. However, scientific literature regarding the mechanical performance of different rod-to-rod connector systems is lacking.

Research question: The goal of this study was to evaluate the mechanical characteristics of axial and lateral rod connectors in comparison to a conventional pedicle screw rod (titanium and cobalt chromium) construct.

Material and method: Six types of instrumentations were investigated in a standardized test model to quantify the mechanical differences: 1: titanium rod; 2: titanium rod with axial connector; 3: titanium rod with lateral connector; 4: cobalt chromium rod; 5: cobalt chromium rod with axial connector; 6: cobalt chromium rod with lateral connector. All groups were tested in static compression, static torsion and dynamic compression and statistically compared regarding failure load and stiffness.

Results: In static compression loading, the use of connectors increased the construct stiffness, but unaffected the yield load. The use of a cobalt chromium rod significantly increased by approximately 40% the yield load and stiffness in comparison to the titanium rod configurations. Under dynamic compression, a similar or higher fatigue strength for all tested groups in comparison to the titanium rod configuration was evaluated, with the exception of titanium rod with axial connector.

Conclusion: Biomechanically, using rod connectors is a secure way for the extension of a construct and is mechanically equal to a conventional screw rod construct. However, in clinical use, attention should be paid regarding placement of the connectors at high loaded areas.

1. Introduction

The introduction in the early 1980's of internal fixators in its present form had a considerable effect on the operative treatment options in spine surgery (Dick and Rickert, 2015), such as temporarily or permanent stabilizing vertebral fractures, correction of deformities or spondylolistheses and other kinds of instabilities or degenerative changes. However, frequently accompanied late complications for this treatment include adjacent segment degeneration, proximal junctional kyphosis or scoliosis, reported with an incidence between 5 and 25% depending on the used fusion technique (Park et al., 2004). The exact cause and reason for the appearance of adjacent segment degeneration is still not well understood and is controversially discussed. It seems to be a result of mechanical compensation of loading and deformation in the transition area of stabilized and native spine. This could be indicated by increased intradiscal pressure, higher facet loading and hypermobility (Park et al., 2004; Weinhoffer et al., 1995).

In most cases, revision surgery is indicated and a cranial or caudal extension of the dorsal instrumentation is inevitable. Moreover, a complete revision of the internal pedicle screw rod construct is often performed. Consequently, for the placement of additional pedicle screws, the complete length of the instrumentation has to be accessed in order to

* Corresponding author. Am Aesculap-Platz, 78532, Tuttlingen, Germany.
E-mail address: christoph.schilling@aesculap.de (C. Schilling).

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exchange the existing rod into a longer one. A larger approach increases the risk for the postoperative course of the patient due to high degree of soft tissue trauma, longer operation time, high blood loss and higher risk of infection, often accompanied with the need of increased pain medication (Uribe et al., 2014; Phan and Mobbs, 2016).

An alternative procedure to avoid a complete revision of the construct and to substantially reduce soft tissue trauma is to link the new rods to the already existing internal fixator by means of axial or lateral connectors (Fig. 1). These are available in different lengths and designs as well as for the combination of different rod diameters. Depending on the present in situ condition, a corresponding connector type could be individually chosen by the surgeon. Clinically, studies have shown, that the extent of the surgery by employing rod connectors without prior instrumentation revision could be reduced. It was considered to be a safe alternative treatment and could reduce surgical time, blood loss, risk of complications and medical costs. Furthermore it was reported, that better early post operative outcomes could be achieved with the rod-connectors due to less surgical trauma (Pisuitthanakan et al., 2022; Tan et al., 2021).

However, scientific literature regarding the mechanical performance of different rod-to-rod connector systems in comparison to a standard pedicle screw rod instrumentation, either with titanium or cobalt chromium rod, is lacking so far.

Our hypothesis is that the usage of connectors alter the mechanical situation of a construct in terms of stiffness, failure load or fatigue strength in comparison to a normal spinal arthrodesis. Thus, it is important to get a better understanding whether the individually chosen extended connector constructs are mechanically sufficient for the treated situation. Therefore, the goal of this study was to evaluate the mechanical characteristics of axial and lateral rod connectors in comparison to a conventional pedicle screw rod construct, as well with the use of titanium (Ti6Al4V) and cobalt chromium (CoCr) rods in a rigorous side by side manner using a standardized testing model.

2. Material and Method

To quantify the mechanical differences under standardized testing condition, six types of instrumentations of the Ennovate® pedicle screw system (Aesculap AG, Germany) were investigated according to ASTM F1717-21 (F04 Committee, 2021) (Fig. 2): group 1: Ø 5.5 mm titanium rod (TiR), group 2: titanium rod with axial rod connector (TiRax), group 3: titanium rod with lateral rod connector (TiRlat), group 4: Ø 5.5 mm cobalt chromium (CCR), group 5: cobalt chromium rod with axial rod connector (CCRax) and group 6: cobalt chromium rod with lateral connector (CCRlat). All groups were tested in static compression bending (n = 5), static torsion (n = 5) and dynamic compression bending (5 million cycles, n = 6) (Fig. 2). All the performed tests were destructive, therefore for each test new specimens were used. In total 96 vertebrectomy specimens with 384 pedicle screws were utilised for the complete testing.

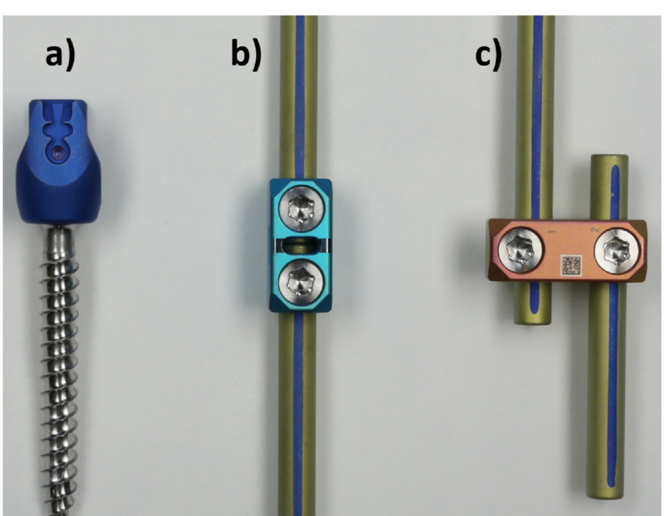

Fig. 1. Lumbar spinal fixation system Aesculap® Ennovate® (Aesculap AG, Germany) used in the present study: a) polyaxial pedicle screw b) axial rod connector c) lateral rod connector.

The constructs were assembled with four pedicle screws, four set screws and two rods using the intended instruments and tightening torque according to the surgical technique. Cannulated bone screws Ø4.5 × 45 mm were used as they represent the worst case configuration. For the axial connector constructs, the short axial rod connector size utilizing a single set screw to clamp the spinal rod within the connector was selected as the worst case. For the lateral connector constructs, the largest lateral offset (11 mm) and one-side-open rod connection clamping was selected as the worst case. All tested implants were produced under series conditions. To ensure the active length of 76 mm as defined in ASTM F1717-21, a rod length of 100 mm was chosen for the defined test setup (group 1 and group 4). For the axial rod connector constructs, two 50 mm pieces of rod, bridged by an axial rod-to-rod connector, were used on each side of the bilateral test construct (group 2 and group 5). To assemble a vertebrectomy model based on ASTM F1717-21 with domino rod-to-rod connectors, the position of the screws in the test blocks was modified. The upper two polyaxial screws were positioned 5.5 mm closer to the midline of the construct specified in ASTM F1717-21. The lower two polyaxial screws were positioned 5.5 mm farther from the midline of the construct specified in ASTM F1717-21. This test setup matched the 11 mm offset of the chosen worst case lateral connector and did not alter the lever arm for load application (group 3 and group 6).

The quasi static tests were performed using a bi-axial quasi static testing machine Zwick Z010 (Zwick-Roell, Ulm, Germany). For the static compression bending tests, the axial force was applied displacement controlled at a rate of 5 mm/min; whereas for the static torsion tests, a loading rate of 60 deg/min was used according to ASTM F1717-21. The load/torque and the displacement/angular displacement data are recorded during testing.

To evaluate the fatigue performance of the different implant configurations, a sinusoidal load profile at 5 Hz was applied with a ratio R (F_{min}/F_{max}) = 10 for up to 5 million cycles or failure, whichever occurred first. The test environment was saline solution (0.9% NaCl). For each test group the maximum run-out load was established, which means at least two constructs must reach the endurance limit of 5 million cycles without failure at the same load level. The differences between the run-out load and a load that results in a failed construct had to be less than 10% of the run-out load. All load data (max/min peak load of a sine) and displacement data (max/min peak of displacement of a sine) produced during testing were digitally sampled every 2000 cycles. The parts were optically analyzed regarding failure.

The groups were compared regarding the mechanical parameters (yield load and stiffness for the static compression and torsion loading modes) using an ANOVA followed by a post hoc test (Scheffe Test). Prior to the analysis the normal distribution (p-p plots) and the homogeneity of variance (Levene Test) was verified. All analyses were performed with a significance level of p = 0.05 (Statistica 13, Dell Inc.).

3. Results

3.1. Static compression bending

In the static compression loading mode, TiRax showed a significant increase in bending stiffness (8.0 ± 1.3%; p = 0.02) compared to TiR, whereas TiRlat decreased not significantly by 3.0 ± 2.3% (p = 0.71). For the bending yield load, no difference could be determined between the tested titanium groups (p < 0.81). The use of a cobalt chromium rod significantly increased bending yield load and bending stiffness in comparison to the titanium rod configurations (p < 0.001). Within the cobalt

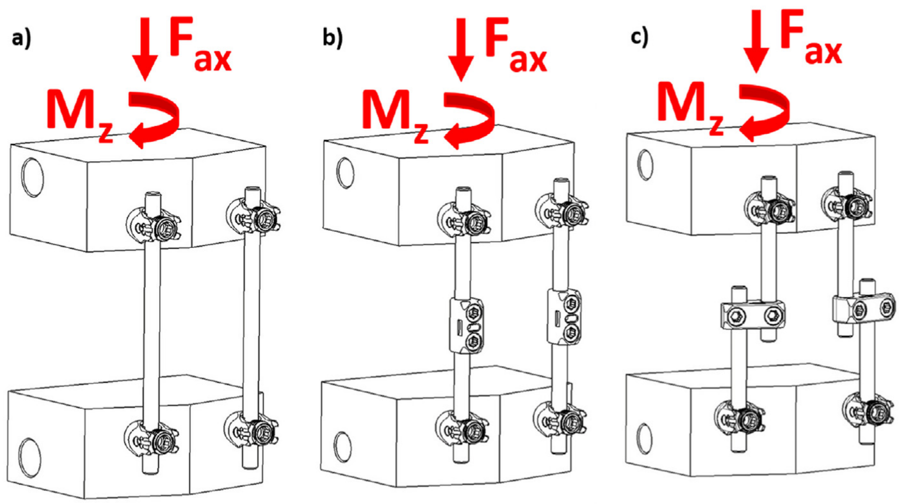

Fig. 2. Vertebrectomy constructs according to ASTM F1717-21 for the six different instrumentation types: a) standard configuration of pedicle screw rod construct (TiR, CCR), b) axial rod connector configuration (TiRax, CCRax) and c) lateral connector (TiRlat, CCRlat).

chromium rod configurations, CCRax increased the bending stiffness ($p = 0.001$) but CCRlat ($p = 0.45$) was at the same level compared to CCR. No differences were found for bending yield load within the cobalt chromium constructs ($p > 0.46$) (Fig. 3a and b, Table 1).

3.2. Static torsion

The torsional stiffness was significantly higher for TiRlat ($+38.0 \pm 6.6\%$; $p = 0.001$) but not for TiRax ($+11.0 \pm 5.1\%$; $p = 0.11$) in comparison to TiR. Also for the yield torque a significant increase could solely be determined for TiRlat ($+41.9 \pm 8.1\%$; $p = 0.001$), but remained the same for TiRax ($-1.5 \pm 9.7\%$; $p = 0.99$) compared to TiR. The constructs CCR, CCRax and CCRlat significantly increased bending yield torque and torsional stiffness in comparison to the titanium rod configurations TiR and TiRax ($p < 0.001$) but TiRlat was not different to CCR, CCRax and CCRlat ($p > 0.71$). Within the cobalt chromium rod constructs, no difference in torsional stiffness could be evaluated ($p > 0.34$). Regarding the yield torque, CCRlat showed a significant increase compared to CCR and CCRax ($p < 0.05$), whereas the yield torque of CCR and CCRax were not different ($p = 0.98$) (Fig. 4a and b, Table 1).

3.3. Dynamic compression bending

Under dynamic compression testing, a similar fatigue strength for TiR and TiRlat was evaluated, while the fatigue strength of TiRax decreased by 16% (Fig. 5, Table 1). All titanium rod constructs showed the same failure mode, namely rod breakage in the area of the set screw clamping mechanism in the screw body (Fig. 6). The use of the cobalt chromium rod increased the fatigue strength for CCR by 16% and for CCRax by 8% compared to TiR, whereas the CCRlat construct remained at the same level. Interestingly, the failure mode for the cobalt chromium rod constructs changed to breakage of the pedicle screw in the region of the screw entrance point at the polyethylene load blocks (CCR, CCRax) (Fig. 7) and loosening within the connector clamping (CCRlat).

4. Discussion

This study directly compares different rod-to-rod connectors and different rod materials in a standardized test model. The results show that the usage of a rod-to-rod connector as well as the choice of the rod material has an impact on the stiffness of the screw-rod construct. The CCR increases significantly the stiffness of the tested constructs in static compression and static torsion loading compared to TiR. The axial connector leads to an increase of the bending stiffness for both rods (TiRax, CCRax), but had no effect regarding the torsional stiffness. No change on the bending stiffness was seen for the lateral connector, whereas a significant increase was observed in torsional stiffness in combination with the titanium rod.

The rod connectors had no significant influence on the evaluated yield loads, with exception of the lateral connector in static torsion loading (TiRlat, CCRlat). The yield load for the CCR was significantly higher in both static loadings compared to the TiR. The primary failure mode for all static constructs was slippage of the polyaxial clamping of the screws. Thus, the evaluated significant increase of the bending yield loads when using a CCR instead of a TiR shows a change in the loading situation of the pedicle screws when changing the stiffness of the construct. We hypothesize that the bending of the titanium rod and subsequently the whole test construct during the loading changes the loading situation within the pedicle screws, leading to a decreased yield load of the tested TiR constructs. A similar effect can be observed on the torsion testing, where a higher torsional stiffness indicates a higher torsional yield load even though the primary failure mode is still slippage of the polyaxial clamping.

The dynamic compression bending testing shows no failures of the rod connectors. For the TiR group, the failure mode was breakage of the rod for all tested constructs. The TiRax decreased the run-out-load compared to the TiR, which corresponds to the higher bending stiffness evaluated in the static compression test. This means the local stiffening of the rod with the axial connector leads to a higher stress of the residual rod, resulting in a decreased run-out-load. No rod failures were observed for the CCR group. The typical failure mode was breakage of the Ø 4.5 mm bone screws (CCR, CCRax) or rod loosening within the connector clamping (CCRlat), which occurred at equal (CCRlat) or higher loads (CCR, CCRax) compared to TiR constructs.

To our best knowledge, this is the first study for a direct mechanical comparison of the different herein investigated construct configurations. We consciously decided to use the vetebrectomy model according to ASTM F1717-21. This offers a rigorous side by side comparison of the mechanical performance across device designs in a worst-case scenario, which is desirable for engineering and regulatory purposes (Graham et al., 2014). Furthermore, other possible connector configurations (e.g. long axial connectors with four set screws to clamp the rod or closed-closed lateral connectors with a smaller lateral offset) would have shown better mechanical performance, since the results here reported represent the worst case. We are aware that the vertebrectomy model is not the most common clinical scenario and has its limitations regarding physiological load transfer without anterior load support (La Barbera et al., 2016, 2017; Villa et al., 2014). In clinical practice the rod

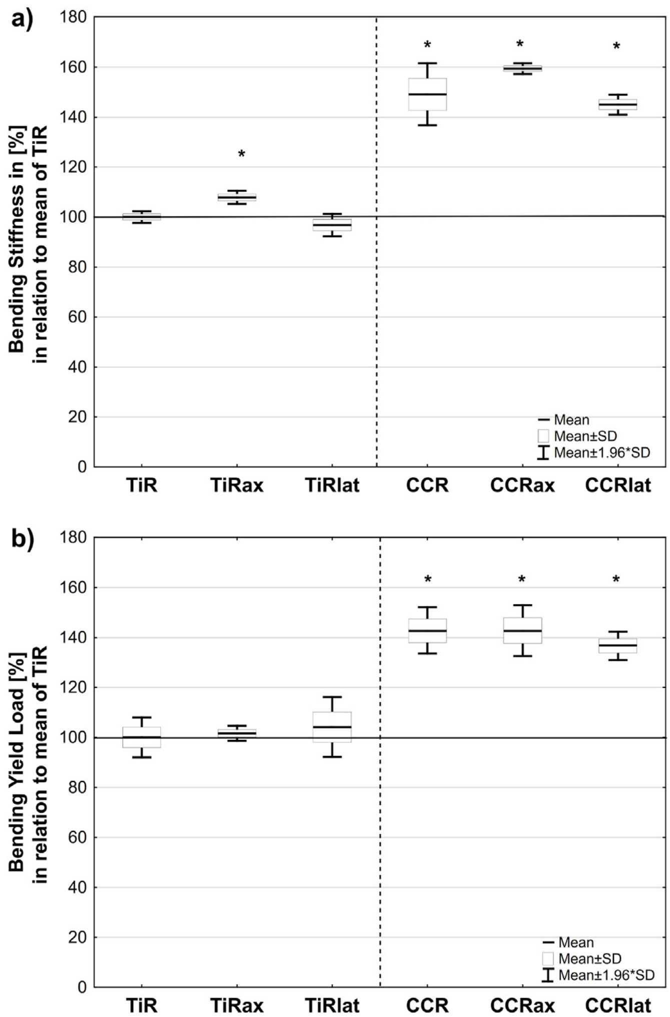

Fig. 3. Results of all tested configurations normalized to the results of TiR for static compression bending loading according to ASTM F1717-21: a) bending stiffness b) bending yield load. *Statistically significant difference compared with TiR.

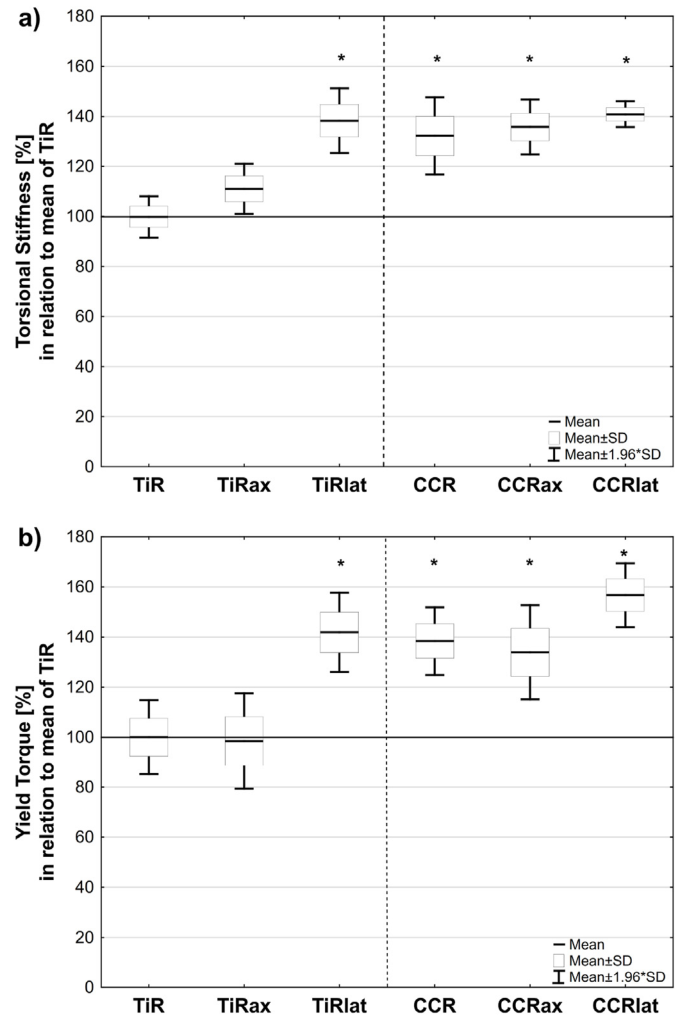

Fig. 4. Results of all tested configurations normalized to the results of TiR for static torsional loading according to ASTM F1717-21: a) torsional stiffness b) yield torque. *Statistically significant difference compared with TiR.

connectors are often placed closer to the screws. However, to guarantee a rigorous side by side comparison of all included instrumentation variants, a standardized test method acc. to ASTM F1717 is a mandatory prerequisite. With this model the stress concentration is highest in the middle of the rod. Therefore the connector types were placed symmetrically in the middle between the screws (screw distance is defined by ASTM F1717 to 76 mm). We can only speculate about the influence of connector placement closer to the screw. It could have as well a positive as a negative influence on the fatigue performance. But it is important, that the relative comparison for all tested instrumentations is given by the standardized test conditions.

Our focus was to evaluate and compare the isolated mechanical performance of the different instrumentations in a single treated segment. Here we can also only speculate about the fatigue performance when adjacent instrumented segments are involved. Besides, there is no standardized test method available for a multi-segmental evaluation, which could be used for a fair mechanical comparison of different

Table 1
Result summary for all test configurations and loading modes as absolute values (Mean ± SD) with corresponding results from Peck et al. showing the 5th, 50th and 95th percentile (Peck et al., 2021).

		TiR	TiRax	TiRlat	CCR	CCRax	CCRlat	Peck et al. (Peck et al., 2021) 5th percentile	Peck et al. (Peck et al., 2021) 50th percentile	Peck et al. (Peck et al., 2021) 95th percentile
Bending Stiffness	[N/mm]	26.1 ±(0.3)	28.1 ±(0.4)	25.3 ±(0.6)	38.9 ±(1.7)	41.6 ±(0.3)	37.9 ±(0.5)	18.9	31.5	48.4
Bending Yield Load	[N]	239.4 ±(9.8)	243.3 ±(3.6)	249.2 ±(14.6)	341.7 ±(11.4)	341.6 ±(12.5)	327.1 ±(7.0)	203	293	472
Torsional Stiffness	[Nm/deg]	1.9 ±(0.1)	2.1 ±(0.1)	2.6 ±(0.1)	2.5 ±(0.2)	2.6 ±(0.1)	2.2 ±(0.1)	1.2	2.4	4.6
Torsional Yield Load	[Nm]	11.1 ±(0.8)	10.9 ±(1.1)	15.7 ±(0.9)	15.3 ±(0.8)	14.8 ±(1.1)	17.3 ±(0.7)	5.3	9.7	20
Run Out Load	[N]	250	210	250	290	270	250	120	194	254

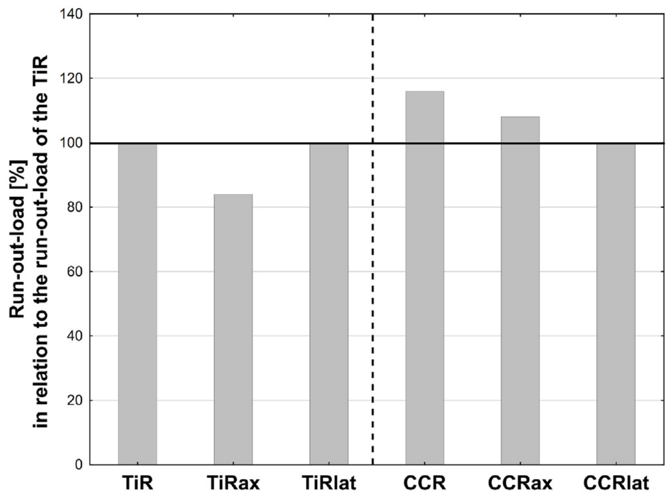

Fig. 5. Run-out-load levels for the different test groups in relation to the run out load level of TiR (run out load level of TiR is equal to 100%).

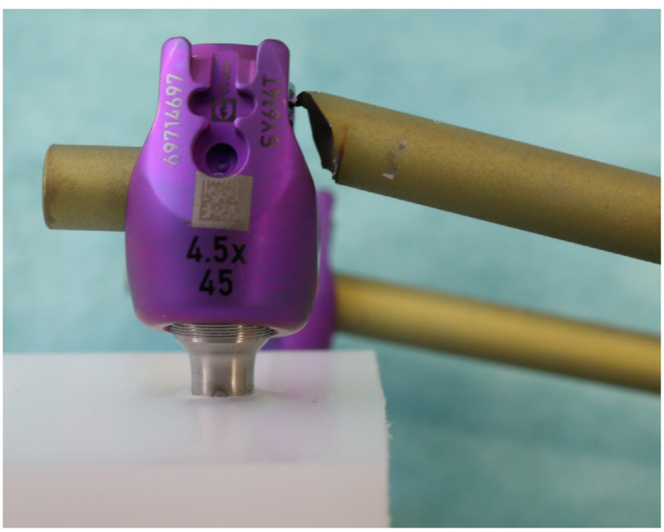

Fig. 6. Typical failure mode of a titanium rod construct: rod breakage.

instrumentations.

Welke et al. (2018) performed an in vitro study investigating the primary stability of a continuous rod compared to an axial and a lateral connector. They found no significant differences between the intersegmental range of motions of the different instrumentations. The increase of stiffness on the treated segment when using an axial connector shown in the vertebrectomy model is significant but on a low level, which might not be detectable in an in vitro study due to the sensitivity of the measurement itself. However, an effect on the fatigue strength could be shown thus long term effect in clinical application is still possible.

In a FEA study by Luca et al. (2017) on different rod constructs, the authors also found comparable range of motion results for all rod configurations in case of pedicle subtraction osteotomy. Meanwhile, the different stiffness of the constructs altered the stress situation within the rod, which may have an influence on bone healing or the endurance properties of the construct.

In a clinical application of a pedicle screw instrumentation, the free length of the rods clamped in a rod connector is smaller compared to the vertebrectomy setup investigated in this study. Though the loading situation in-situ is also more complex, it can be assumed that the effect of stiffening shown for the axial rod connector in compression bending loading is applicable to the clinical situation and, due to the reduced free length of the rods, might be even more prominent. This effect has to be taken into account when using axial rod connectors in sensitive clinical situations. Especially in the region of the apex, the use of axial connectors should be strictly avoided and an alternative construct using a four rod technique should be considered. In a study by Barton et al., it was shown that there is an increased risk of rod fractures when using connectors and fusion constructs that cross both the thoracolumbar and lumbosacral junction (Barton et al., 2015).

Fig. 7. Typical failure mode of a cobalt chromium rod construct: screw breakage.

An increased stiffness of the pedicle screw construct may lead to accelerated adjacent segment disease (Park et al., 2004). On the other hand, a higher segmental stiffness could offer more support in cases of instability. However, attention should be paid regarding the negative effect on the fatigue strength. Is yet unknown if this assumptions can be transferred to the clinical application.

Several studies (Kim et al., 2005; Kramer et al., 2001; Grass et al., 2006) show that open implantation of an internal fixator leads to a pronounced damage of the multifidus muscle due to the extensive preparation. Furthermore, indirect damage is caused by injury to the rami posteriores nervi spinalis. Consecutively, there is a denervation of the muscle segment and thus a loss of function (Röder, 1994). Any regenerative processes take place only very slowly (Grass et al., 2006). A later revision with complete opening of the scar and preparation of the rod will lead to a further, renewed destruction of the muscle segments in regeneration. The use of connectors reduces this re-destruction in large parts, since the old rod must be exposed only to a small extent.

From a clinical point of view, our results presented here show that the use of rod-to-rod connector systems is very well suited to extend existing dorsal instrumentations since the mechanical performance is not compromised. The extension of an internal fixator with such connectors offers several advantages over a complete rod replacement. Especially with longer instrumentations, it is not necessary to expose the rod over its entire length. As a result of that smaller approach, significantly lower blood loss, a shorter surgery time, a lower risk of infection, as well as a shorter hospitalization time and a lower postoperative need for pain medication can be expected as shown in several studies (Pisuitthanakan et al., 2022; Tan et al., 2021). But this should further be proven in clinical comparative studies.

5. Conclusion

In the present in vitro study, the mechanical performance of pedicle screw constructs using different rod and connector options was evaluated. The results show that the rod- and connector type has an influence on the construct stiffness, whereas the static failure load in compression bending and torsion stay at the same level or increases in comparison to a continuous titanium rod configuration. For the fatigue strength, we could show that the run-out load slightly decreases only for the axial connector, which could be related to a higher construct stiffness for this type of construct. Overall, it could be stated that the usage of rod connectors with titanium as well as cobalt chromium rods is, from a biomechanical point of view, a secure way for the extension of a construct. However, attention should be paid during clinical use regarding the placement of the connectors at high loaded areas, where loading in the free rod could be increased, causing a possible reduction of fatigue strength.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Christoph Schilling reports a relationship with Aesculap AG that includes: employment. Sven Krueger reports a relationship with Aesculap AG that includes: employment. Michael Rauschmann reports a relationship with Aesculap AG that includes: consulting or advisory. Uwe Vieweg reports a relationship with Aesculap AG that includes: non-financial support. Johannes Keck reports a relationship with Aesculap AG that includes: non-financial support. Mohammad Arabmotlagh reports a relationship with Aesculap AG that includes: non-financial support.

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