Instrumentation failure following posterior subtraction osteotomy: the role of rod material, diameter and multi-rod constructs

Andrea Luca*[1], Claudia Ottardi*[2], Maurizio Sasso[2], Liliana Prosdocimo[2], Luigi La Barbera[2,3], Marco Brayda-Bruno[1], Fabio Galbusera[3] and Tomaso Villa[2,3]

[1] Department of Spine Surgery III, IRCCS Istituto Ortopedico Galeazzi, Milan, Italy

[2] Laboratory of Biological Structure Mechanics, Department of Chemistry, Materials and Chemical Engineering "G. Natta", Politecnico di Milano, Milan, Italy

[3] IRCCS Istituto Ortopedico Galeazzi, Milan, Italy

*Andrea Luca and Claudia Ottardi equally contributed

Corresponding author:

Claudia Ottardi, PhD

Laboratory of Biological Structure Mechanics, Department of Chemistry, Materials and Chemical Engineering "G. Natta", Politecnico di Milano

Piazza Leonardo da Vinci, 32

20133 Milano, Italy

Phone: 0039 02 2399 4317

Fax: 0039 02 2399 4286

E-mail: claudia.ottardi@polimi.it

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Abstract

Purpose: Pedicle subtraction osteotomy (PSO) has a complication rate noticeably higher than other corrective surgical techniques used for the treatment of spinal sagittal imbalance. In particular, rod breakage and pseudoarthrosis remain burning issues of this technique. Goal of this study was to investigate the biomechanical performance of several hardware constructs.

Methods: The study was performed using two validated finite element models of the lumbosacral spine (L1-S1) incorporating a PSO on L3 and L4 respectively. Both models were instrumented two levels above and below the osteotomy site. Different combinations of materials (TiAl4V and Cr-Co) and device configurations (bilateral single vs. double rod, rod diameters of 5 and 6 mm) were investigated. The loading was represented considering a force of 500 N (imposed along the spinal curvature and connecting the vertebral bodies) and pure moments of 7.5 Nm in flexion-extension, lateral bending and axial rotation. The results were evaluated in terms of range of motion (ROM), load and stresses acting on the instrumentation.

Results: A comparable ROM was found for all the models. The simulations showed a different behavior of the devices: increasing the stiffness an 8-19% increase of the load was calculated on the rod. However, the stress on the instrumentation resulted higher on Cr-Co devices and on smaller rods. The highest stress reduction (up to 50%) was ensured using double rod constructs.

Conclusions: The bilateral double parallel rods configuration resulted the best in order to reduce the stresses on the spinal fixators at the osteotomy site. However, the high loads acting on the rods with respect to the physiologic condition could slow down the bone healing at the osteotomy site.

Introduction

Fixed imbalance of the spine can severely affect patient's quality of life and may require extensive reconstructive procedures. In the last years osteotomy procedures and especially pedicle subtraction osteotomy (PSO) have been refined and improved to better address adult deformities with severe imbalance of the spine.

Pedicle subtraction osteotomy is widely considered as a powerful technique allowing a correction up to 30-35° through all 3 columns without lengthening the anterior column [1][2]. Although many studies reported satisfactory clinical and radiological results after PSO even at long follow up [3] overall complication rates still remain considerably high ranging from 37% to 59% [4].

PSO has been clearly associated with a high rate of implant failure/pseudoarthrosis: Smith et al [5] found that rod fracture occurred in 22% of PSO patient with a minimum of 1 year follow-up. Rod fracture (RF) can negatively affect clinical outcome by producing pain and loss of deformity correction and it often requires revision surgery.

Multiple risk factors have been shown to influence the incidence of RF and can be divided into three main categories [6-9]:

- Patient-related factors such as age, body mass index, preoperative sagittal imbalance.
- Technique-related factors such as: extent of fusion, fusion to the sacrum, pelvic fixation, insufficient anterior column support, insufficient distal foundation, insufficient correction with residual sagittal spinal malalignment, type of corrective procedure (e.g. PSO), use of dominos and/or parallel connectors, bending and rod contouring, repeated contouring or sharp-angle contouring of the rod (more than 60°).
- Implant-related intrinsic factors: material type (stainless steel, titanium, cobalt chromium alloys), diameter of the rod.

Various technical strategies have been described in order to reduce the risk of implant failure. Focusing on biomechanical aspects Hyun et al suggested the use of a multiple rod construct (multi-RC), instead of the standard 2 rods construct (2-RC), as a safe and effective method to provide increased stability across PSO site [10]. Palumbo et al. [11] recently described an outrigged rod technique to implement the posterior construct enhancing its strength and stability. Interestingly Smith et al. [6] found a lower rate of RF after PSO for patients in whom Cobalt-Chromium (Cr-Co) rods were used (7%) compared with stainless steel (17%) and titanium alloy (25%).

Despite the complexity of the topic and the great clinical interest, to the author's knowledge only one computational work focuses on PSO [12], in which a simplified model was used to represent a PSO performed on L4 and different defect situations. Bending moment and stresses acting on the instrumentation were calculated. However, only few configurations of devices were investigated and a comprehensive analysis of different parameters is still missing in literature.

The aim of the current study was thus to compare, with a numerical analysis, the biomechanical behavior after a PSO of multiple hardware constructs differing for metal type, rod diameters and number of rods (standard 2 rods construct vs 4 rods construct) to find out which one had the best biomechanical performance.

Materials and Methods

The present study was performed by means of a numerical model of the human lumbosacral spine (L1-S1). After the calibration, the intact model was modified in order to replicate the PSO on L3 and L4. A 30° wedge of the vertebral body and the posterior process at the treated level was removed. Details concerning the intact and osteotomy models are reported in literature [13].

The models were subsequently instrumented using polyaxial screws and rods, designed with the software PTC Creo Parametric 2.0 (Parametric Technology Corporation, Needham, MA). The geometry of the screws was slightly simplified to allow for the creation of a hexahedral mesh. The interaction between pedicle screws and vertebrae was defined with embedded elements. The rods were created following the spinal curvature of each model and were constrained to the screw by means of tie constraints. Both rods and screws were meshed with hexahedral elements and a sensitivity analysis was performed on the instrumentation. The average length of the elements was gradually increased (0.6, 0.8, 1 and 1.5 mm) and the stresses acting on the rods in flexion-extension, lateral bending and axial rotation were calculated. The chosen mesh (0.8 mm seeding) ensured less than 3% maximal stress variation on different portions of the rods, compared with the others seeding. The numerical simulations were performed using the software Abaqus 6.12-3 (Dassault Systèmes Ri, Simulia, Providence, RI, USA).

In order to deeply analyze all the biomechanical factors related to the spinal fixation following PSO, different models were created (Table 1) and compared with the aim of studying:

- Effect of material: Chromium-Cobalt vs. Titanium alloy rods (OL3-Cr-Co vs. OL3-Ti, OL4-Cr-Co vs. OL4-Ti);
- Effect of diameter: 5 mm vs. 6 mm rods (OL3-Ti-5mm vs. OL3-Ti, OL4-Ti-5mm vs. OL4-Ti);
- Effect of number of rods: one vs. two bilateral rods configurations as showed in Fig 1 (OL3-Ti-2rods vs. OL3-Ti, OL4-Ti-2rods vs. OL4-Ti).

A follower load of 500 N (applied along the curvature of the spine to consider the muscle forces acting locally) was associated to pure moments of ± 7.5 Nm in flexion-extension, lateral bending and axial rotation to simulate physiological loads, while the sacrum was constrained in all degrees of freedom.

The global range of motion (ROM) of the lumbar spine was calculated for all the typical movements of flexion-extension, lateral bending and axial rotation. In addition, the results were analyzed in terms of forces acting on the anterior column and along the spinal fixator, as well as the maximum von Mises tensile stress on the rods at the osteotomy level.

Results

The global ROM obtained in flexion-extension, lateral bending and axial rotation resulted similar within all the models (Fig 2), due to the presence of the spinal fixators. The largest variations were found in lateral bending and axial rotation. In details, by changing the material of the rod a reduction up to 3% was calculated in lateral bending whereas a 10% decrease was found in axial rotation. The reduction of the diameter from 6 to 5 mm caused an increment between 4 and 5% for both movements. Moreover, the insertion of a second rod induced a 2-3% reduction of the ROM for both lateral bending and axial rotation.

An evaluation of the load acting on the anterior column (on the fractured surface of L3 or L4) and along the rods at the osteotomy level was performed (Table 2). The forces were calculated after the compression of the spine due to the follower load. Spinal fixators having 5 mm titanium rods induced a load distribution of about 70/30% among the anterior and posterior column. However, increasing the stiffness of the spinal fixation, a higher load on the instrumentation was observed. Thus using 6 mm titanium rods an 8% increase was found, while with a Cr-Co alloy or double rods the load on the posterior part of the model increased up to 45-49%.

In addition, the maximum von Mises tensile stress was calculated for each configuration (Tables 2). A stress reduction up to 50% was calculated on the fixation devices (principal rod) after the introduction of a secondary rod (Table 3). On the contrary using a Cr-Co alloy instead of Ti6Al4V lead to a general stress increase in all the movements (between 26% and 39%). The smaller variations in terms of stresses (5-19% increase) were obtained reducing the diameter of the rods. Fig 3 shows the stress distribution on the right rod (comparable to the left rod) in the different cases, with a particular focus on the section of the device at the osteotomy level. As can be noted, the maximum tensile stress was always located in the posterior part of the rod, at the osteotomy level.

Discussion

The PSO is the most commonly performed procedure in the lumbar spine for fixed sagittal imbalance. The biomechanical changes in an osteotomized spine have been recently described by our study group [13]: PSO consistently induces a significant increase of all ROMs, especially regarding axial rotation (45- 58%) and lateral bending (up to 43%). The instability seems to further increase when the PSO is performed at a lower level (L4 instead of L3). Furthermore, the load distribution in the anterior and posterior column of the intact model (85% and 15%, respectively) [l3] is certainly different from the instrumented condition following instrumented PSO, in which the load on the rods is between 30 and 49% depending on the device configuration. The spinal fixators are therefore highly stressed due to the instability induced with the osteotomy and the consequent change of the load path. The results is a higher risk of hardware failure with respect to instrumented fusions not involving osteotomies, which is already very well described for this procedure [6].

Purpose of the present study was to evaluate, focusing on the intrinsic implant-related factors, different hardware constructs in order to find out which one had the best biomechanical performance, especially in terms of risk of mechanical failure. Based on its intrinsic and mechanical properties (highest elastic modulus, density and highest ultimate tensile strength) Chromium-Cobalt rods often appear more resistant to fatigue loading, with a lower rate of failure than titanium alloy [5, 14, 15]. Another interesting aspect is the less notch sensitivity showed by Cr-Co compared to Ti6Al4V: this detail may play a significant role in the PSO procedure where rods are often bent to angle of 20° to 60° [5, 14]. On the other hand, we found an increase of the load and stress acting on the Cr-Co device with respect to those in Ti6Al4V, due to the increased stiffness of the structure. This stress increase may have a double negative effect: the increase of stresses on the device may itself promote the fatigue fracture of the rods and furthermore the decreased anterior load may render the osteotomy site more susceptible to pseudoarthrosis.

Although the present study revealed differences in the load and stress distribution of Cr-Co and Ti6Al4V devices, some factors related to the fatigue life of materials were not considered. Therefore, those results are not enough to determine which material exhibits the lower fracture risk and further investigations should be conducted before suggesting one of them as a standard in the clinical practice. In our daily practice Cr-Co rods are used in every time a PSO is planned.

Focusing on the effect played by the rod diameter, our findings pointed out that the use of 5 mm rods leads to a decrease of the load on the fixator, due to the lower overall stiffness with respect to a 6 mm device. Nevertheless, a stress increase was found probably due to the predominant effect of the reduction of the resistant section of the rod on the lower stiffness of the fixator. Also in literature a lower incidence of hardware failure was found for rods with higher diameters [6]. Accordingly, if it is possible from a clinical point of view, we suggest the use of rods having a bigger diameter.

Besides, we studied the biomechanical effect of using multi-RC: Hyun et al. [10] reports a significant differences in the occurrence of rod breakage (rod breakage 2-RC: 11 vs. multi-RC: 2, P = 0.002) with a lower rate of revision surgery for pseudoarthrosis with the multi-RC. Our numerical analysis showed a 10% load increase on the instrumentation of multi-RC compared to single rod configurations, due to the higher global stiffness of the posterior fixation. Moreover, this result is associated to a reduction of the stresses on the primary rod, at the osteotomy level. The presence of two rods bonded together with dominos substantially modifies the moment of inertia of the implant inducing a lower stress on the single components. Since the reduction of the stress concentration at the osteotomy site probably preserves the rod reducing the fracture risk, a multi-RC may be suggested. We also studied whether the position of the secondary rod may play a role in the stability of the implant: based on our results, placing the secondary rod as much posterior as possible allows achieving a significant reduction of the stresses acting on the construct. In our surgical practice, the secondary rod is placed medial and posterior in respect to the primary rod.

However, it can be observed that the load acting on multi-RC, due to the higher stiffness, is considerably higher than the load distribution of the intact spine, reducing the mechanical stimuli on the anterior column (fundamental factor for an appropriate fracture healing). Therefore, further studies should be carried out to investigate alternative surgical options. Our group already reported about the role of an adequate anterior column support to reduce the risk for hardware failure in the management of revision surgery after PSO [16], which may provide a global redistribution of the loads and consequently an additional decrease of the mechanical stresses on the posterior instrumentation.

Limitations of this study must be taken into account. The contacts between the different components (embedded elements and tie constraints) were simplified. The rods were modeled without considering the residual stresses caused by the intraoperative bending procedure and biological factors (e.g. consolidation of the fracture) were not included in the analysis. Even if the maximum stresses predicted on the rods are far from the critical values of the materials, the comparison between the various conditions is still reliable. Anyway, FE models are very sensitive and predictive tools that help to study the biomechanics of the spine in different conditions (as PSO for example).

The study was focused only on some intrinsic implant-related factors that may play an important role in the hardware failure/rod breakage process. The undisputed relevance of the sagittal spinopelvic balance restoration and of the biological factors that may prevent a solid fusion at the osteotomy site leading to pseudoarthrosis were considered outside of the scope of this study.

Conclusion

Our data indicates that the configuration with bilateral double parallel rods produces the higher stress reduction on the implants at the treated level. However, since the load insisting on the posterior column is noticeably higher than in the physiological condition, the fracture surface could be not adequately stimulated. Therefore, in order to increase the load on the anterior column and support the bone healing other configuration of devices will be investigated. Further studies should focus on the biomechanical role of interbody supports in addition to the traditional posterior instrumentation.

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Competing interest

This study has no competing interests to disclose.

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Figure 1

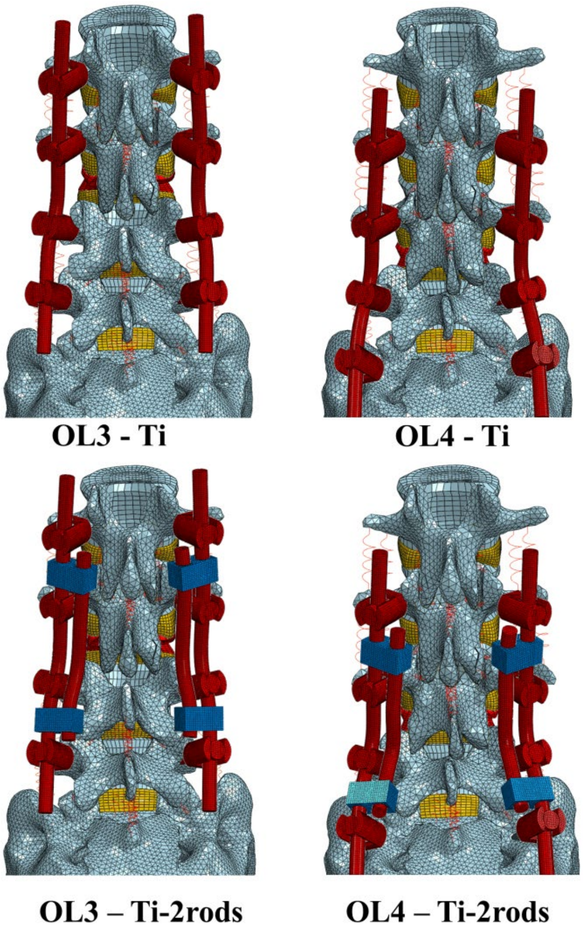

Figure 2

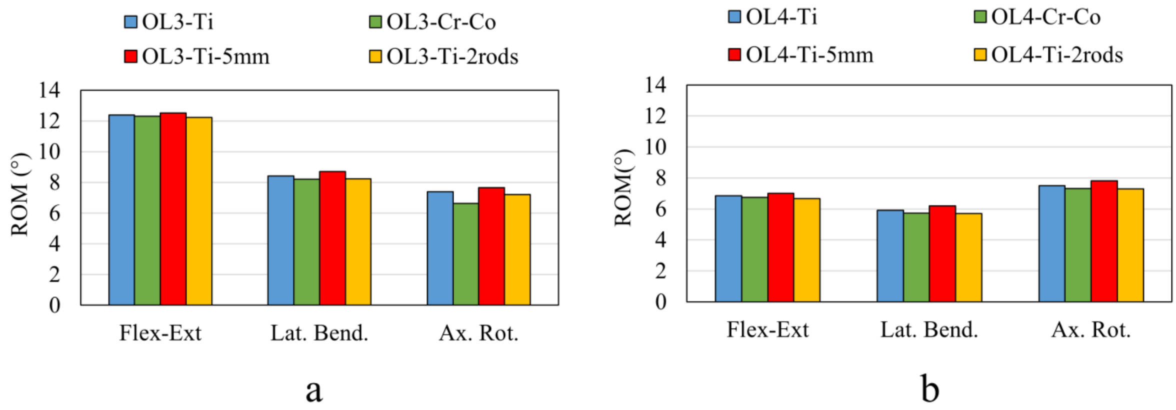

Figure 3