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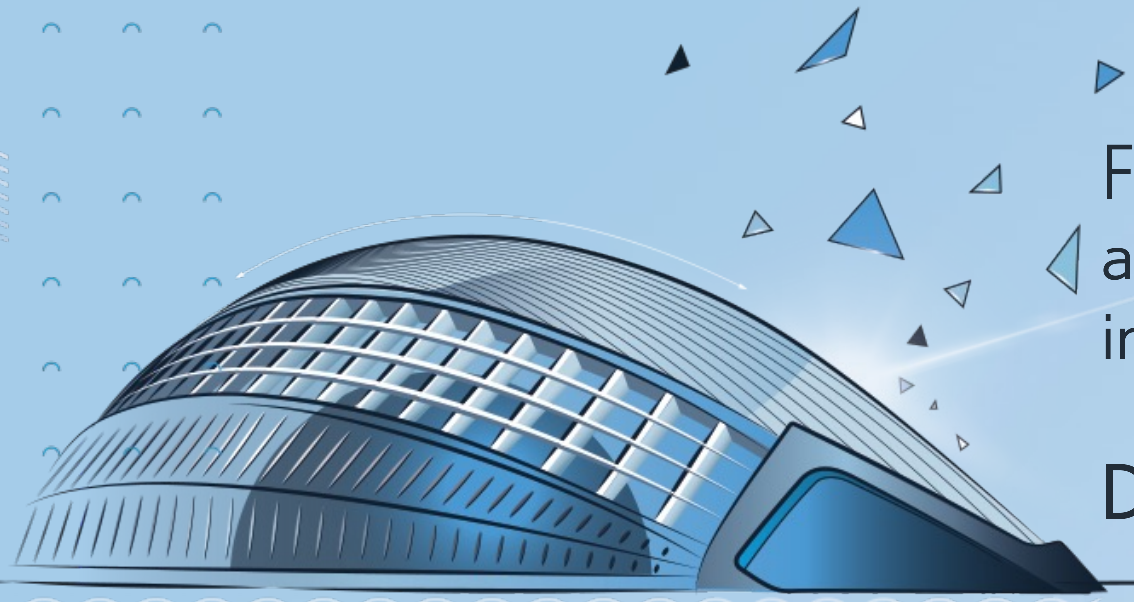


From fusion to functional fusion: The quest for an anatomical & biomechanical balance with spinal instrumentation

Dr. Pierce D. Nunley

Medical Director – Spine Institute Louisiana
Associate Professor – LSUHSC Dept. of Orthopaedic Surgery

SENSE 2nd International Spine Expert Symposium

June 23 – 25, 2022 / Valencia – Spain

SPINE INSTITUTE OF LOUISIANA

Questions to Consider

Have you ever wondered how much excessive force some instruments apply into constructs and ultimately the anatomy? How might that impact results?

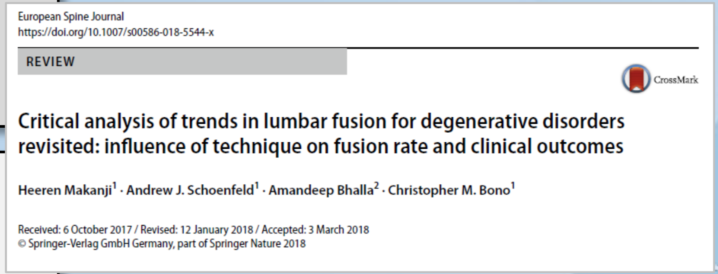
Have you ever thought about why some set screws are loose compared to others when performing a revision? What is causing this?

Have you ever considered what causes implants to make a squeaking noise during assembly? Why might this matter?

Background - Outcomes in Spine Surgery

Fusion is achieved in 85% to 95% of the cases and the outcomes of comparable procedures remained constant since the 80´s[1].

Clinical success was achieved in only 53% of the cohort, as measured by function (ODI)[1].

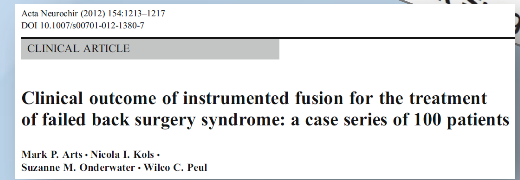


The authors conclude:

"The outcomes of comparable procedures were about the same"

Failed Back Surgery Syndrome (FBSS) is reported in the literature 10% and 40%[2-6].

The rates are similar to several decades ago[3].
The incidence increases with more complex surgeries[2].



Failed Back Surgery Syndrome

Journal of Pain Research
Dovepress
open access to scientific and medical research
Open Access Full Text Article
REVIEW

Failed back surgery syndrome: current perspectives

This article was published in the following Dove Press journal:
Journal of Pain Research
7 November 2016

New Instability Secondary to Altered Biomechanics Following Surgery

settling of the facet joints into a new position may compress the exiting nerve root between the superior pedicle above and the disc and pedicle below, an event known as "vertical stenosis" [88]. Discectomy may also create changes in the biomechanics of the spine, resulting in increased load distribution on adjacent segments accelerating preexisting disc degeneration [89]. This finding has been termed "transition syndrome" and has been reported to occur in up to 36% of patients following lumbar spinal fusion [89].

Postoperative factors leading to FBSS:

- Altered biomechanics
- Progression of degenerative changes

Increased tension of ***muscles*** controlling spine movements.

Increased load burden in ***adjacent structures***, leading to an acceleration of degenerative changes.

Degenerative changes of the spine include ***facet*** arthropathy

Changes in the ***discs*** can lead to central or foraminal stenosis.

Chan CW, Peng P. Failed Back Surgery Syndrome. Pain Medicine 2011; 12: 577–606.

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Background - Outcomes in Spine Surgery

At 15-year follow-up 37.5 **%** of the patients required a new surgical treatment because of **ASD**[7].

3 of 4 patients reported that they were dissatisfied with their outcome[7].

Eur Spine J (2016) 25:1550–1557
DOI 10.1007/s00586-016-4469-5

ORIGINAL ARTICLE

Adjacent segment degeneration and revision surgery after circumferential lumbar fusion: outcomes throughout 15 years of follow-up

José I. Maruenda[1] · Carlos Barrios[2] · Felipe Garibo[1] · Borja Maruenda[3]

Screw loosening rate: **15.2%.**
82% of loosened screws were pulled out during rod connection[12].

At 1-year ODI (disability) and VAS (pain) significantly higher in patients with screw loosening[12].

ORIGINAL ARTICLE — SPINE SURGERY AND RELATED RESEARCH

Risk Factors for Clinically Relevant Loosening of Percutaneous Pedicle Screws

Tetsuro Ohba[1)], Shigeto Ebata[1)], Hiroki Oba[1)2)], Kensuke Koyama[1)] and Hirotaka Haro[1)]

1) Department of Orthopaedic Surgery, University of Yamanashi, Chuou-city, Japan
2) Department of Orthopaedic Surgery, Shinshu University, School of Medicine, Matsumoto-city, Japan

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Risk of **revision** increased from 2006 to 2014[8].

Rates increasing up to >40% in long-term FU studies[9−11].

Spine Deformity
www.spine-deformity.org
Check for updates
Spine Deformity xx (2019) 619–626

Revision Risk After Primary Adult Spinal Deformity Surgery: A Nationwide Study With Two-Year Follow-up

Frederik T. Pitter, MD[a,*], Martin Lindberg-Larsen, MD, PhD[b], Alma B. Pedersen, MD, PhD, DMSc[c], Benny Dahl, MD, PhD, DMSc[d], Martin Gehrchen, MD, PhD[a]

ELSEVIER
The Spine Journal ■■ (2017) ■■–■■
THE SPINE JOURNAL

Clinical Study

Long-term outcomes of transforaminal lumbar interbody fusion in patients with spinal stenosis and degenerative scoliosis

Swamy Kurra, MBBS[a], William F. Lavelle, MD[a,*], Michael P. Silverstein, MD[b], Jason W. Savage, MD[c], R. Douglas Orr, MD[b]

Background - Outcomes in Spine Surgery

Main reasons for revision surgery

Spine Deformity
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www.spine-deformity.org
Spine Deformity xx (2019) 619–626

Revision Risk After Primary Adult Spinal Deformity Surgery: A Nationwide Study With Two-Year Follow-up

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[b]Department of Orthopedic Surgery and Traumatology, Odense University Hospital, J.B. Winsløvsvej 4-5000, Odense C, Denmark
[c]Department of Clinical Epidemiology, Aarhus University Hospital, Olof Palmes Allé 43-45-8200, Aarhus N, Denmark
[d]Department of Orthopedic Surgery, Texas Children's Hospital & Baylor College of Medicine, Houston, TX 77030, USA
Received 28 May 2018; revised 6 September 2018; accepted 21 October 2018

67% may be linked to mechanical stress

Revision risks after two years for 553 patients surgically treated for adult spinal deformity

20% were revised within the two-year FU

The most common reason for revision was Implant failure **38.2%**

Reasons for revision in the 110 patients.

Reasons	n (%) (95% CI)
Implant failure	42 (38.2)
Infection	13 (11.8)
Curve progression	12 (10.9)
Pseudarthrosis	12 (10.9)
Neurologic deficit	12 (10.9)
Other	9 (8.2)
PJK	8 (7.3)
Unknown	2 (1.8)

16 due to loosening of screws, rest due to implant breakage

Summary – Outcomes in Spine Surgery

What science says…

- Fusion: in 85% to 95% of the instrumented cases[1]
- The outcomes: comparable procedures remained constant since the 80´s[1]
- Solid Fusion is not a predictor of good long-term clinical outcome[1]
- Failed Back Surgery Syndrome (FBSS) has been created to “explain” poor outcomes [7−11]
- Revision rates reported in the degenerative & deformity spine surgery literature are significant[2−6]
- Implant failure is the most common seen reason for re-surgery[13]

Is there a common factor?

Multifactorial issue

Controllable Risk Factors During Surgery

Intra-surgical reasons leading to unsatisfactory results, can be explained directly or indirectly by a ***Mechanical / Biomechanical*** reason

Commonly Controlled Risk Factors

- Protecting the facet joint of the adjacent segment during pedicle screw placement
- Sagittal alignment

OPPORTUNITY TO IMPROVE RESULTS

Uncommonly Controlled Risk Factor

- Mechanical forces being applied during instrumentation
- Coronal & Axial alignment

Recent PSS developments aim to minimize the applied forces and thus possibly reduce the biomechanical complication rate after instrumented posterior lumbar fusion surgery.

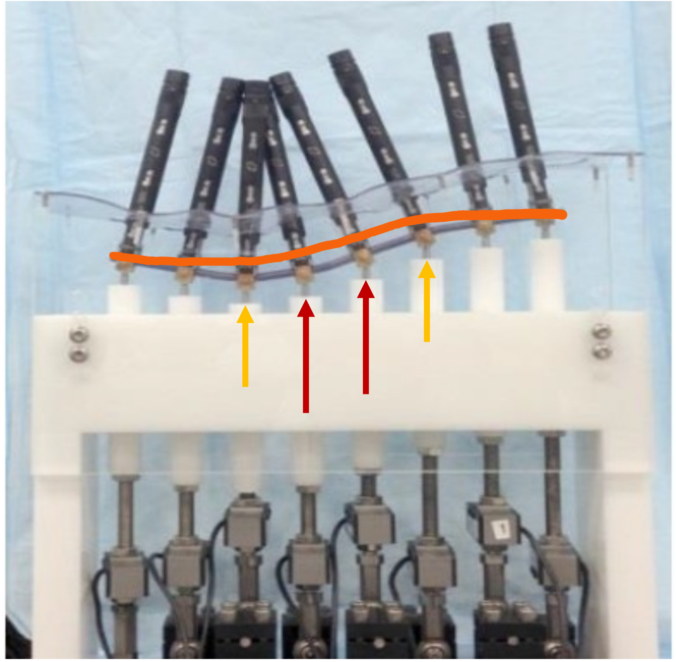
Mechanical Factors – Rod Contouring Impact

NuVasive®, Inc.
May, 2014

Long Construct Pedicle Screw Reduction and Residual Forces are Decreased Using a Computer-Assisted Spinal Rod Bending System

Antoine G. Tohmeh, MD; Robert E. Isaacs, MD; Zachary A. Dooley, MS; Alexander W. L. Turner, PhD

Tohmeh AG, Isaacs RE, Dooley ZA, Turner AWL. Long Construct Pedicle Screw Reduction and Residual Forces are Decreased Using a Computer-Assisted Spinal Rod Bending System. NuVasive®, Inc. May 14



60% lower residual force for the computer-assisted rod vs. the manually bent rod

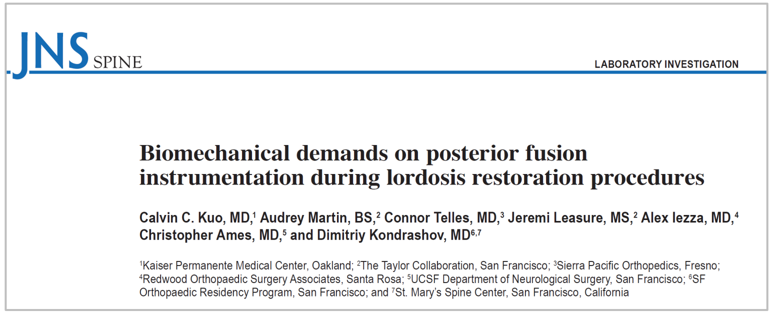
20% of screws with a load peak > 500N for the manual rod bending (vs. 0% with computer assisted Rod bending)

39% of screws with a load peek > 300 N with manual rod bending (vs. 5% with computer assisted Rod bending)

According to the research of Wagnac E, et al.[1]:

- >300 N – Cancellous bone failure
- At 628 N – Cortical bone failure

Mechanical Factors – Correction Methods Impact


JNS SPINE LABORATORY INVESTIGATION

Biomechanical demands on posterior fusion instrumentation during lordosis restoration procedures

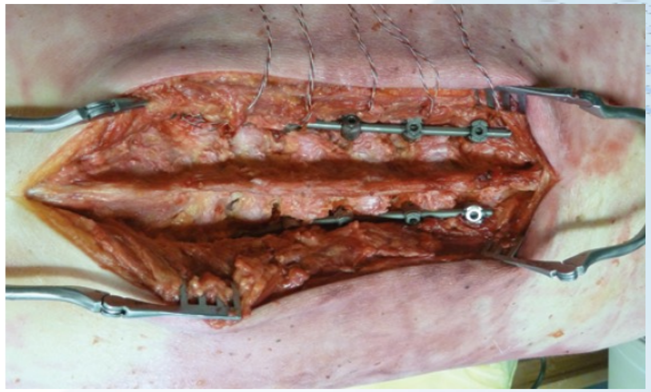
Calvin C. Kuo, MD,[1] Audrey Martin, BS,[2] Connor Telles, MD,[3] Jeremi Leasure, MS,[2] Alex Iezza, MD,[4] Christopher Ames, MD,[5] and Dimitriy Kondrashov, MD[6,7]

[1]Kaiser Permanente Medical Center, Oakland; [2]The Taylor Collaboration, San Francisco; [3]Sierra Pacific Orthopedics, Fresno; [4]Redwood Orthopaedic Surgery Associates, Santa Rosa; [5]UCSF Department of Neurological Surgery, San Francisco; [6]SF Orthopaedic Residency Program, San Francisco; and [7]St. Mary's Spine Center, San Francisco, California

Kuo CC, et al. Biomechanical demands on posterior fusion instrumentation during lordosis restoration procedures. J Neurosurg Spine 2016 Sep;25(3):345-51.

In situ bending
Once locked the rod is contoured into lordosis using in situ sagittal benders.

In situ bending imparted the largest Intra-OP loads



Compression/distraction is the second worse in stress overload

In any type of correction, the technique generating less stress:
Cantilever bending technique

Cantilever bending
Pre-bent rod sequentially reduced into the screws, climbing 1 screw at a time (L4 to L1)

Unintentional Stress – System Design

Heavy Instruments with High COG

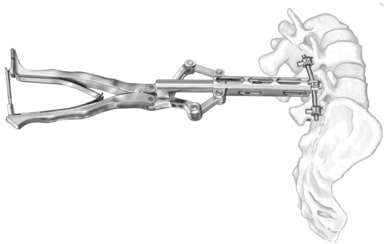
Weight: ~1.7 lbs. to 2.7 lbs. reduces tactile feel and insertion feedback.

High COG: ~70% weighted at the top and 35% longer reduces control and can apply ~<u>40x more mechanical stress</u>

Instruments Block Poly & Rely on Seating Forces

Blocked Poly: Preventing orthogonal implant alignment which create mismatches

Seating Force: Pulls spine to rod which increases mechanical stresses onto spine



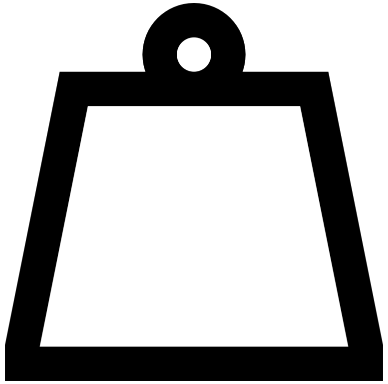
Flat Set Screws that Apply Friction

Flat Design: Limits ability to adjust to orthogonal alignment during last ½ turn

Friction: Increases chances for improper locking and cold welding

Forced Fixation Defined

Unknowingly applying forces and mechanical stresses when assembling and locking a pedicle screw construct which may result in implant loosening and hardware failure.



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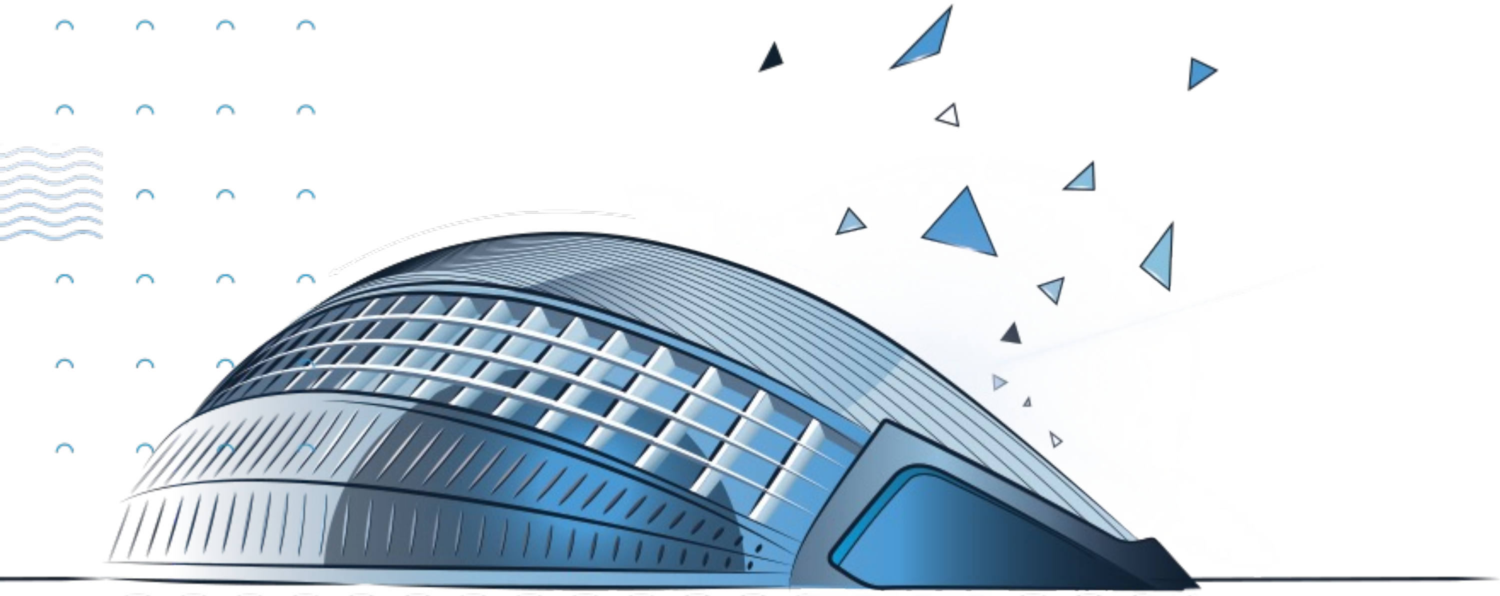

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Clinical Impact of Stress Overload

Failure of Monoaxial Pedicle Screws at the Distal End of Scoliosis Constructs: A Case Series

Pramod B. Voleti, MD[a], Francis H. Shen, MD[b], Vincent Arlet, MD[c,*]

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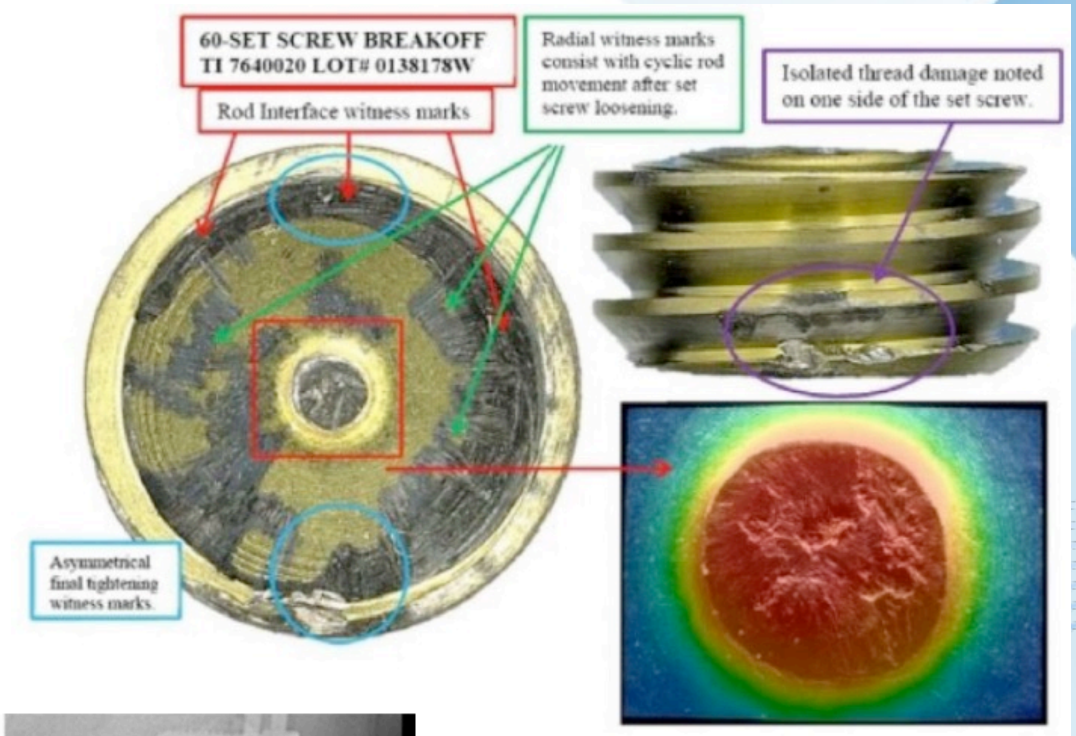
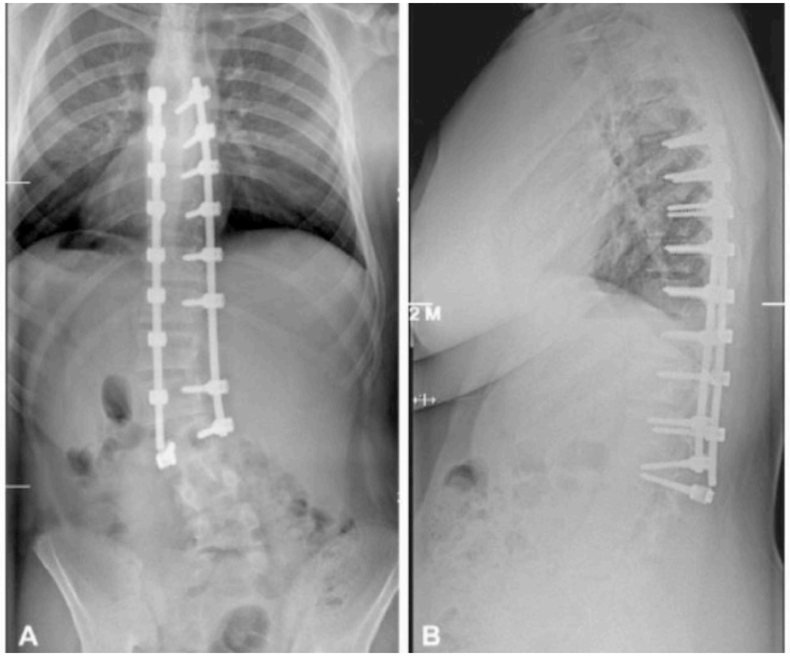
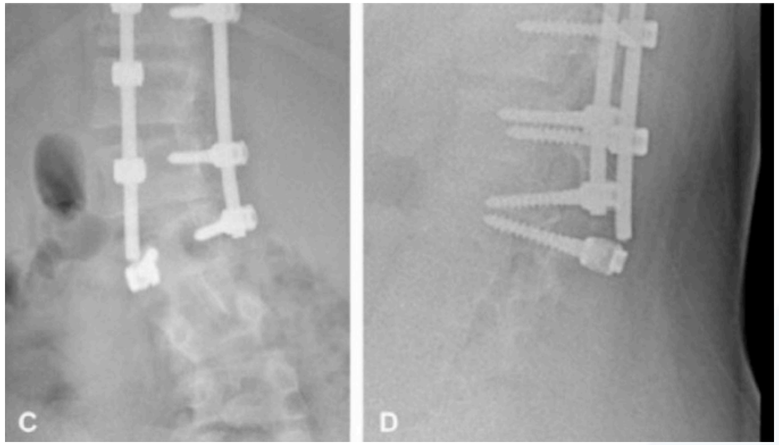
[b]Department of Orthopaedic Surgery, University of Virginia, 415 Ray C Hunt Drive, Third Floor, Charlottesville, VA 22908, USA
[c]Department of Orthopaedic Surgery, Department of Neurosurgery, University of Pennsylvania, Washington Square West Building, 235 South 8th Street, Philadelphia, PA 19106, USA

Received 6 May 2013; revised 27 November 2013; accepted 28 November 2013

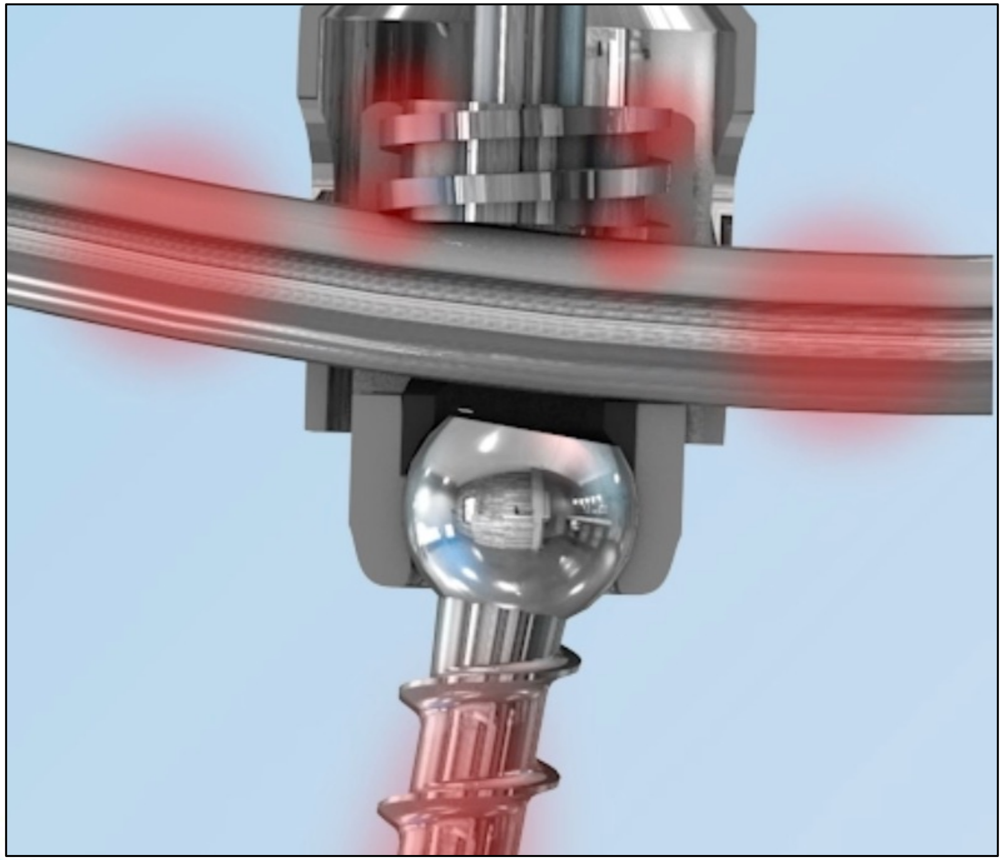






Misaligned rod-screw interfaces >
Stress Overload >
Cold Welding >
Implant Failure

Unintentional Stress – Implant Effects



90° alignment **mandatory:** for correction and fixation

Misalignment, increased friction

Anything limiting the alignment creates stress overload (Crossbow effect – **elastic** potential energy)

Friction and stress overload creates cold welding

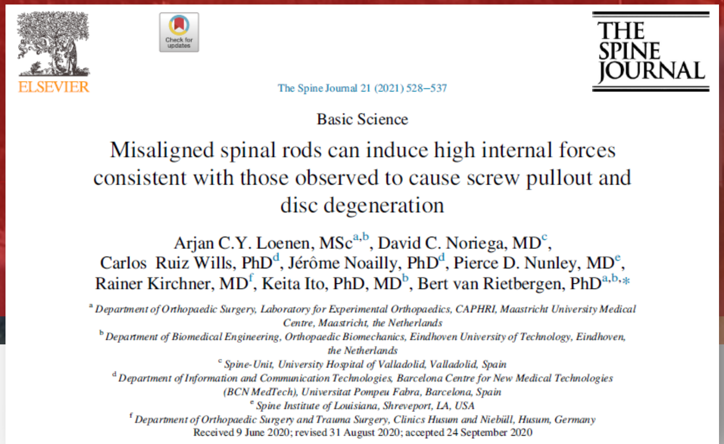
Cold welding blocks any further reduction or alignment capabilities

EINDHOVEN UNIVERSITY OF TECHNOLOGY

Finite Element Analysis of Spinal Misalignments after Posterior Instrumentation

Dr. ir. Bert van Rietbergen
Ir. Arjan Loenen

The Spine Journal 21 (2021) 528–537



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The Spine Journal 21 (2021) 528–537

THE SPINE JOURNAL

Basic Science

Misaligned spinal rods can induce high internal forces consistent with those observed to cause screw pullout and disc degeneration

Arjan C.Y. Loenen, MSc[a,b], David C. Noriega, MD[c], Carlos Ruiz Wills, PhD[d], Jérôme Noailly, PhD[d], Pierce D. Nunley, MD[e], Rainer Kirchner, MD[f], Keita Ito, PhD, MD[b], Bert van Rietbergen, PhD[a,b,*]

[a] Department of Orthopaedic Surgery, Laboratory for Experimental Orthopaedics, CAPHRI, Maastricht University Medical Centre, Maastricht, the Netherlands
[b] Department of Biomedical Engineering, Orthopaedic Biomechanics, Eindhoven University of Technology, Eindhoven, the Netherlands
[c] Spine-Unit, University Hospital of Valladolid, Valladolid, Spain
[d] Department of Information and Communication Technologies, Barcelona Centre for New Medical Technologies (BCN MedTech), Universitat Pompeu Fabra, Barcelona, Spain
[e] Spine Institute of Louisiana, Shreveport, LA, USA
[f] Department of Orthopaedic Surgery and Trauma Surgery, Clinics Husum and Niebüll, Husum, Germany

Received 9 June 2020; revised 31 August 2020; accepted 24 September 2020

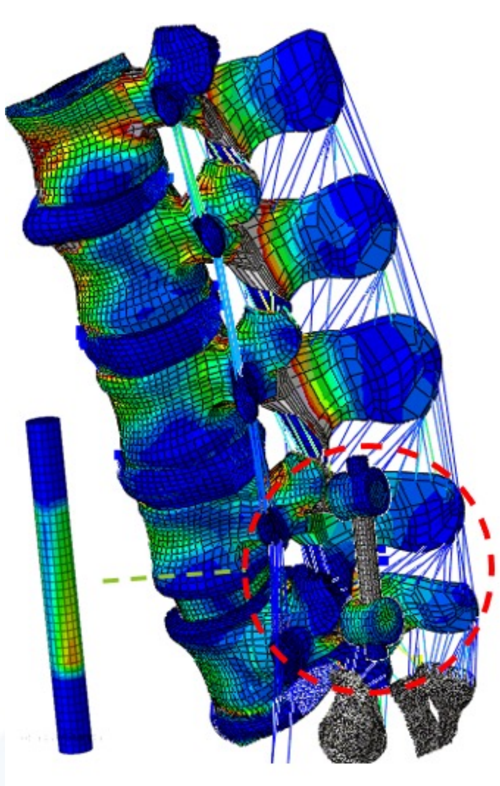
Background & Purpose

- Manual contouring of rods is often required intraoperatively for proper alignment of the rods within the pedicle screw heads.

- Residual malalignments are frequently reduced by using dedicated reduction devices. The forces exerted by these devices, however, are uncontrolled and may lead to excessive reactive forces.

- As a consequence, the pedicle screw-bone interface may become compromised and surrounding tissue may experience unfavorable biomechanical loads.

- The biomechanical loads on surrounding tissue and induced deformations from the reduction have not been well described previously. Additionally, it is unexplored whether the correction of the malalignment alters the biomechanical behavior of the lumbar spine during physiological movements postoperatively.



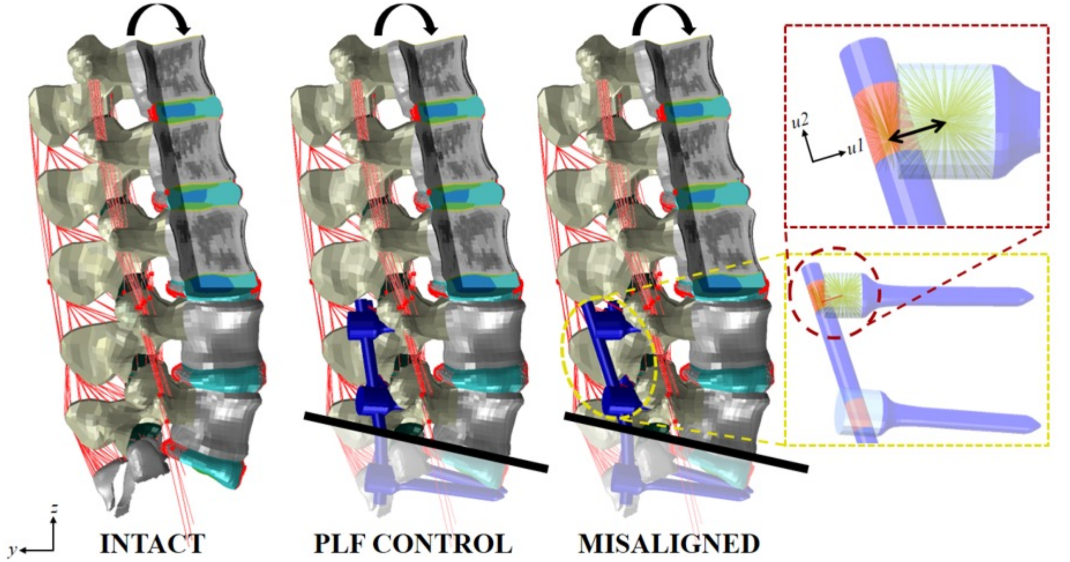
PURPOSE
To predict whether the reduction of misaligned posterior instrumentation might result in clinical complications directly after reduction, and during a subsequent physiological flexion movement.

Methods

A patient-specific, total lumbar spine finite element model was available from previous research [1,2]. The model consists of:

- *poro-elastic intervertebral discs with Pfirrmann grade dependent material parameters*
- *linear elastic bone tissue with stiffness values related to the local bone density*
- *the seven major ligaments per spinal motion segment described with a hypo-elastic stress-strain relationship.*

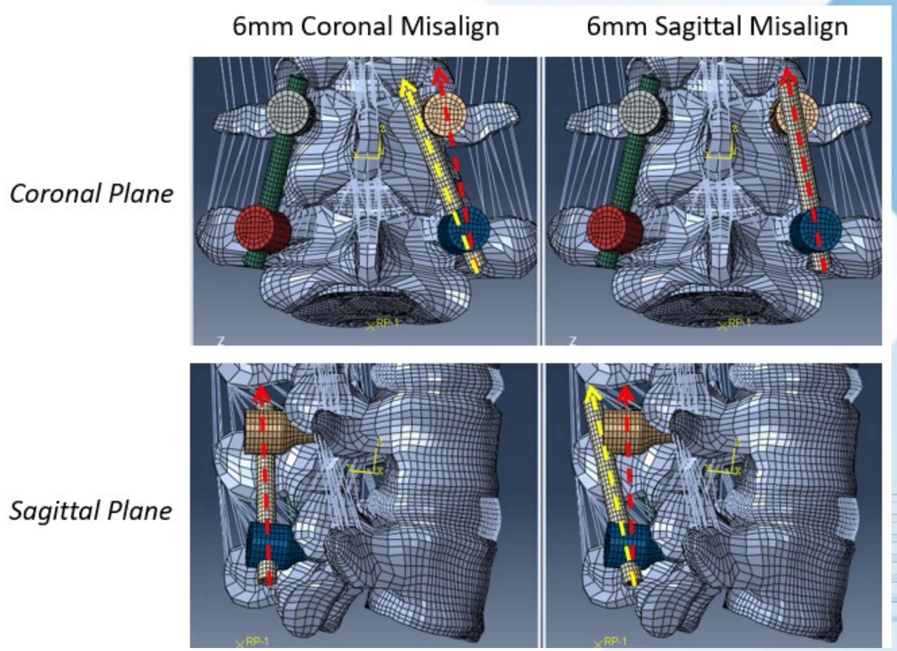
Titanium instrumentation was implemented in this model to simulate a posterolateral fusion.

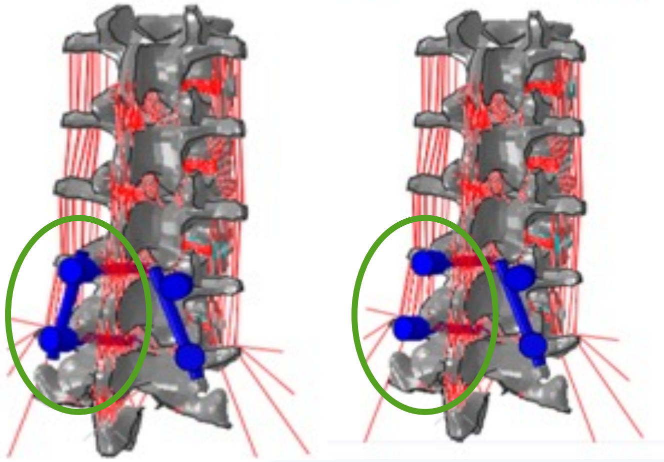


References:
1. Malandrino et al, Front Bioeng Biotechnol, 3:5, 2015. 2. Rijsbergen et al, PLoS one, 13(8):e0200899, 2018

Methods

- A misalignment of 6mm was introduced between the rod and the screw head at L4 in the coronal and sagittal plane respectively.
- These misalignments were computationally reduced after which a physiological flexion movement of 15° was prescribed.
- Two clinical situations regarding the presence of a contralateral rod were analyzed, Situation I and II.
- Non-instrumented and well-aligned instrumented models were added as control groups.



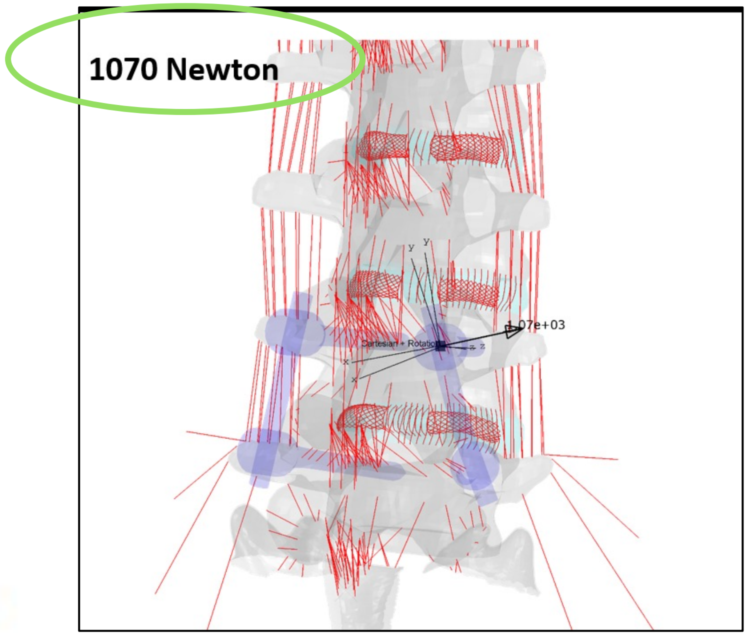


Situation I and II are visualized for the coronally misaligned rod.

Results

- Forces of up to 1.0 kN were required to correct the induced misalignment of 6mm.

	Pulling force [kN]
Coronal misalignment	
Situation I	*0,9*
Situation II	*0,7*
Sagittal misalignment	
Situation I	*1,0*
Situation II	*0,7*



>300N may lead to cancellous bone failure
>628N may lead to cortical bone failure[1]

1. Wagnac E, et al. Biomechanical analysis of pedicle screw placement: a feasibility study. Research into Spinal Deformities 7. IOS Press, 2010. doi:10.3233/978-1-60750-573-0-167

These results indicate, that there might be a considerable risk for screw pullout intraoperatively, during the correction, or postoperatively because of misalignment.

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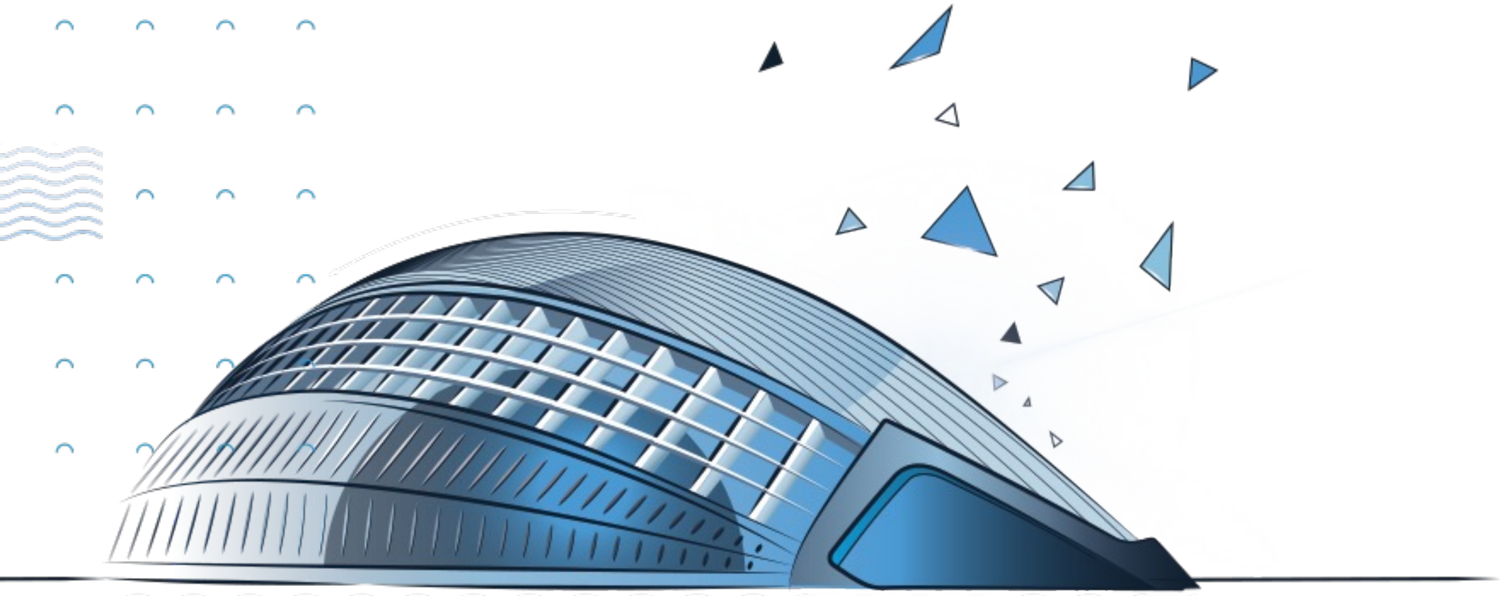

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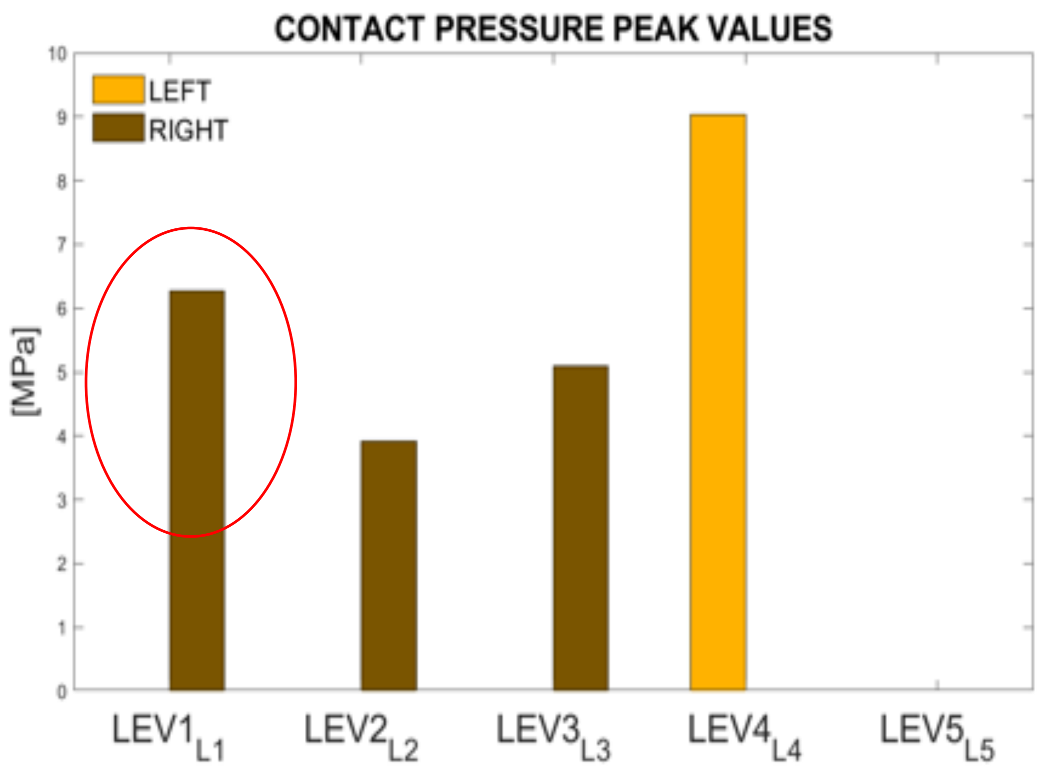
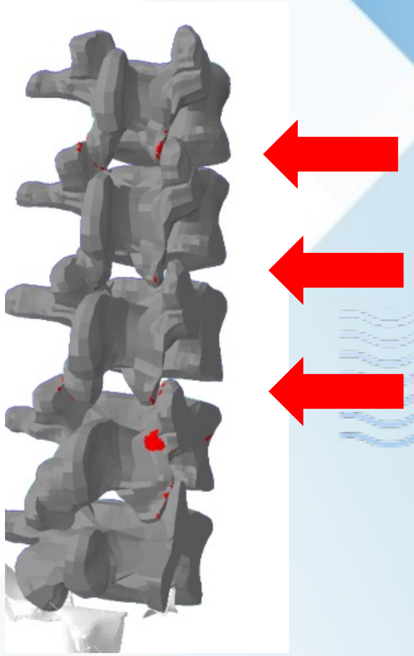
Results

- Asymmetrical increased facet contact pressures of up to >6 MPa were encountered cranial to L4-5 after the correction of the misalignment.

- The facet contact pressures in the misaligned model are substantial and asymmetrical suggesting **unnatural joint loading in the misaligned models**.



Bone tissue at risk



"Although there is no particular damage threshold for facet pressure, overloading is generally suggested to accelerate degeneration of the joint[1]". [1] Jaumard NV, et al. J Biomech Eng 2011

Results

- The **discs and vertebrae** demonstrated significant increased abnormal forces as a result of the correction procedure.

Vertebral Bone Tissue (mm^3)

	L1	L2	L3	L4	L5
COR I	-	-	-	44,6	-
COR II	-	-	-	21,7	-
SAG I	-	-	-	0,6	12,1
SAG II	-	-	-	-	3,3

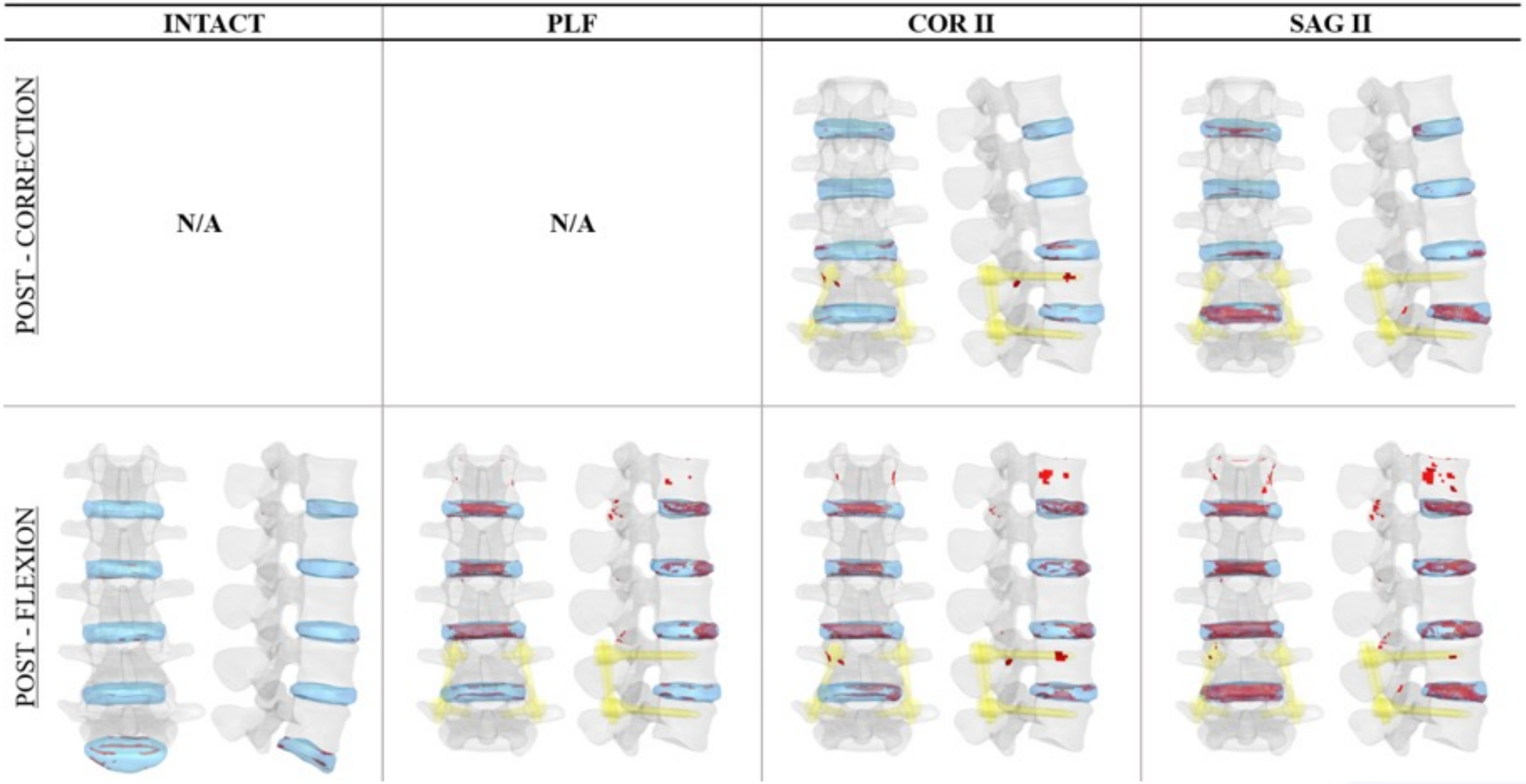
Potential **multiple Intra-trabecular fractures** in the surrounding bone tissue which may potentially create pain.

Intervertabral Disc Tissue, IVD (cm^3)

	L1L2	L2L3	L3L4	L4L5	L5S1
COR I	-	-	-	-	n/a
COR II	-	-	0,2	0,1	n/a
SAG I	0,1	-	0,1	3,5	n/a
SAG II	0,2	-	0,3	3,9	n/a

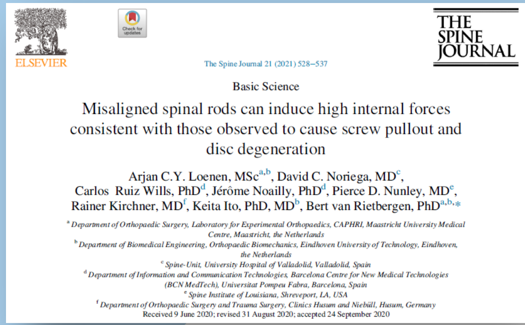
Potential **annular tear** in the adjacent disc L3-L4 during the correction.

Results



Graphical representation indicating the ***tissue volumes being at risk*** after correction and flexion
- grey: vertebrae,
- blue: IVDs,
- red: tissue at risk)

FEA – Impact Summary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Basic Science

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Received 9 June 2020; revised 31 August 2020; accepted 24 September 2020

Finite Element Analysis of Spinal Misalignments after L4-5 Posterior Instrumentation

Reduced Pull Out Strength
Pull out forces of 1070N with 6mm sagittal rod reduction. >300N cancellous failure / >600N cortical failure

Axial Deformity Creation
6mm coronal rod reduction induced substantial rotations from 3-5 deg. in the axial plane

Increased Facet Pressure
6mm coronal rod reduction resulted in excessive facet contact pressures of up to 40x in 3 levels above

Trabecular Fracturing
6mm coronal rod reduction created 44mm^3 of volume around implant

Annular Tearing
6mm coronal reduction created annular tears of 0.2 cm^2 in the adjacent level above

Force Control Design

Light Instruments with Balanced COG

Weight: ~0.3lbs. increases tactile feel and insertion feedback.

Balanced COG: eliminates addition of unintentional mechanical stresses

Instruments Allow Poly & Use Real-Time Data

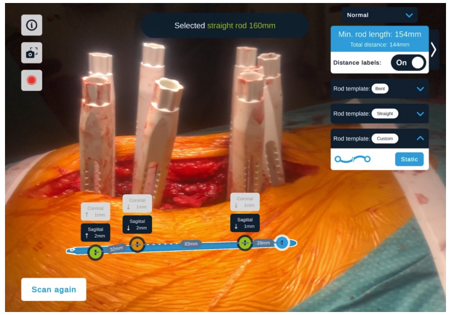
Free Poly: implants freely adjust to an orthogonal alignment

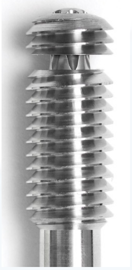
Real-Time Data: smart implants & instruments integrate with ADVISE provide precise implant position and rod contour

Convex Set Screw & Zero Friction Driver

Convex Design: provides ability to adjust to orthogonal alignment and 40% increase in grip

Torque Limiter: precise rod control for correction & fixation





Force Control Design - Biomechanical Study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Original article

Evaluation of the reduction, tightening and gripping performance of an innovative set screw technology for instrumented posterior lumbar fusion: A biomechanical study

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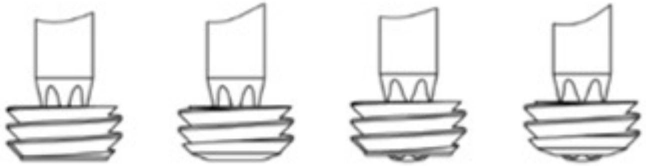
STUDY OBJECTIVE

To compare the mechanical performance of different set screw technologies. The hypotheses are that modifications to the screw and screwdriver unit can:

- improve the quality of set screw tightening
- increase the axial gripping capacity of the construct.



F-S C-S F-STM C-STM

The four set screw technologies under investigation:

F-S: standard flat set screw (control)

C-S: surface is rounded, 10.5 mm convex radius

F-STM: Shaft tip method with flat set screw

C-STM: Shaft tip method with convex set screw

In the ***shaft tip method*** (STM) the stainless-steel set screwdriver passes through the set screw and protrudes by about 0.3 mm with its rounded tip.

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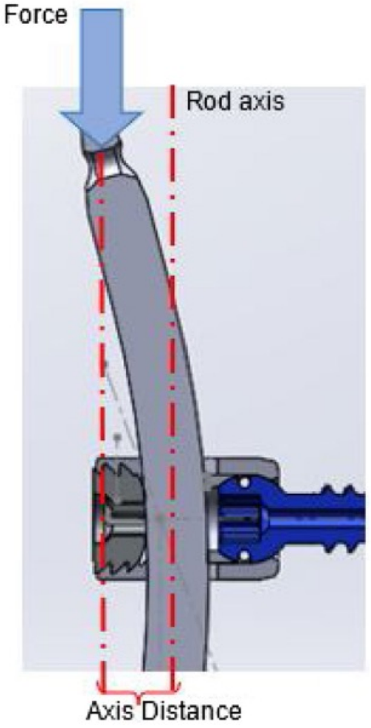

Fig. 6. Principle structure of axial capacity test.

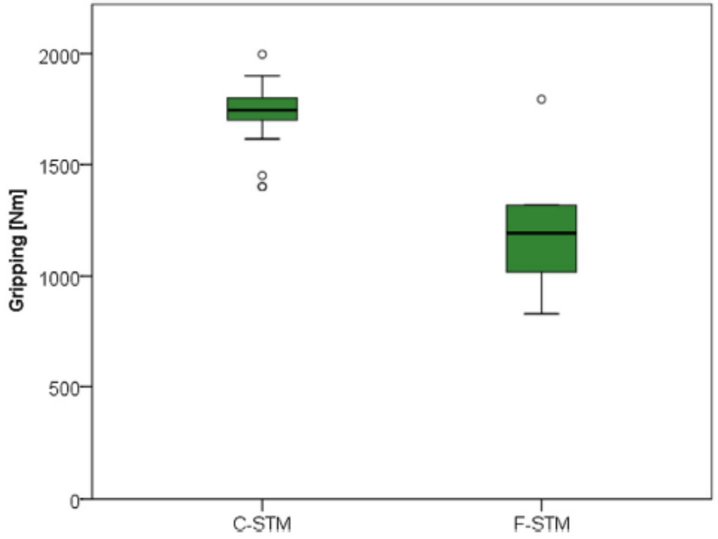

Fig. 8. Axial gripping force by STM groups. The axial gripping value is the highest force applied on the rod for a 1.5 mm displacement.

RESULT

The mean axial gripping force being about ***40% higher for the convex version*** in comparison to the flat version

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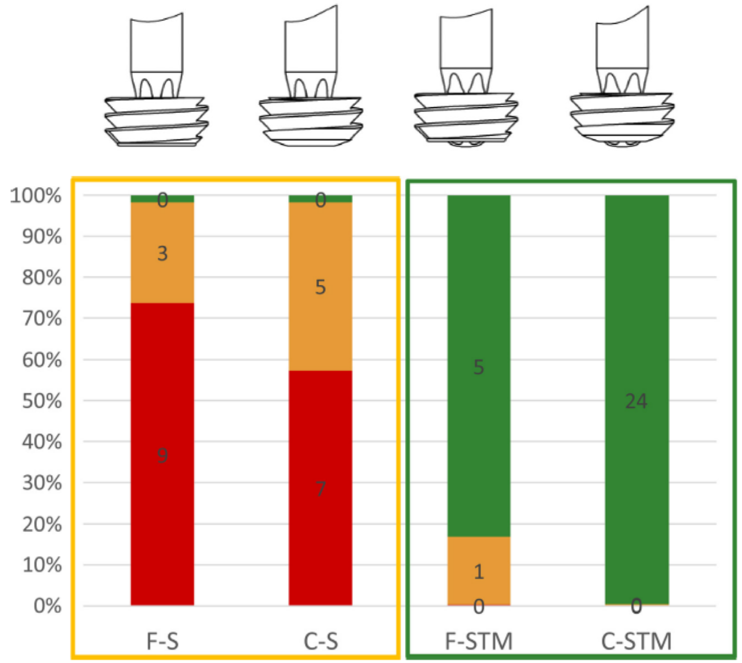


Fig. 7. Classification results of set screw tightening.

Good: the rod is successfully reduced to 0°, and the set screw is fixed

Reduction: the rod is successfully reduced to 0°, but the set screw is not correctly fixed

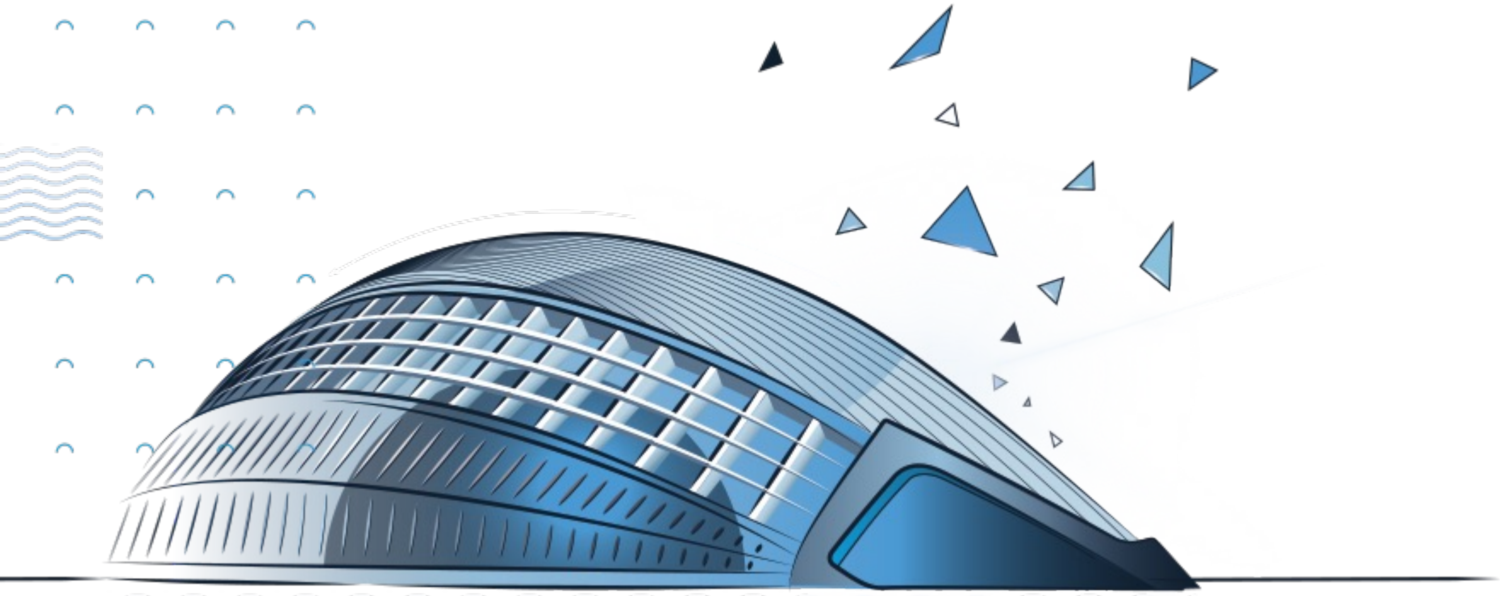
Failed: the rod is not completely reduced to 0° meaning that the alignment between the set screw/ screwdriver and the rod ≠ 90°

Fig. 5. Set screwdriver assembly with pedicle screw and rod.

“C-STM-technology supports controlled fixation in terms of ***applying appropriate forces for correction or fixation*** during PSS assembly with friction-reduced final alignment and tightening to avoid unnecessary mechanical stress acting on the spine”.

Force Control Simulation

sense Spine Expert Network™ for Science & Education



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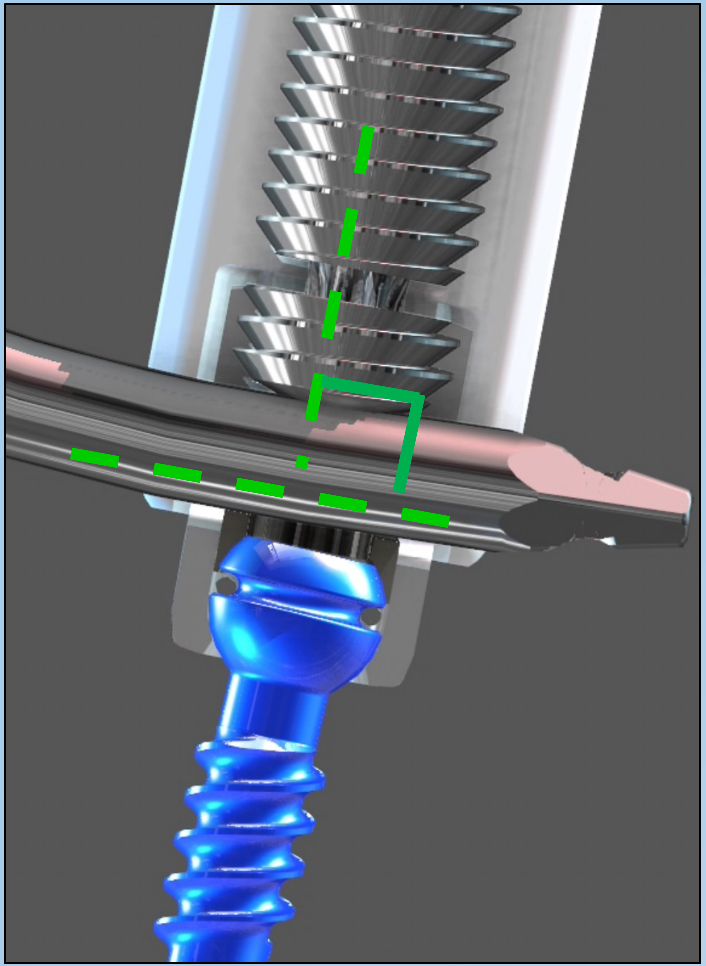
Force Control Summary



Increased reproducibility to control mechanical forces for maximum correction using minimal unintended stress

90° implant interfaces are reproducibly achieved

Lightweight instruments allow for adjustment to mechanical forces

Implant adjustability is maintained throughout final tightening to limit probability for implant mismatching

Friction & mechanical stress are limited during final tightening to help avoid set-screw cold welding and unfavorable results

Thank You!