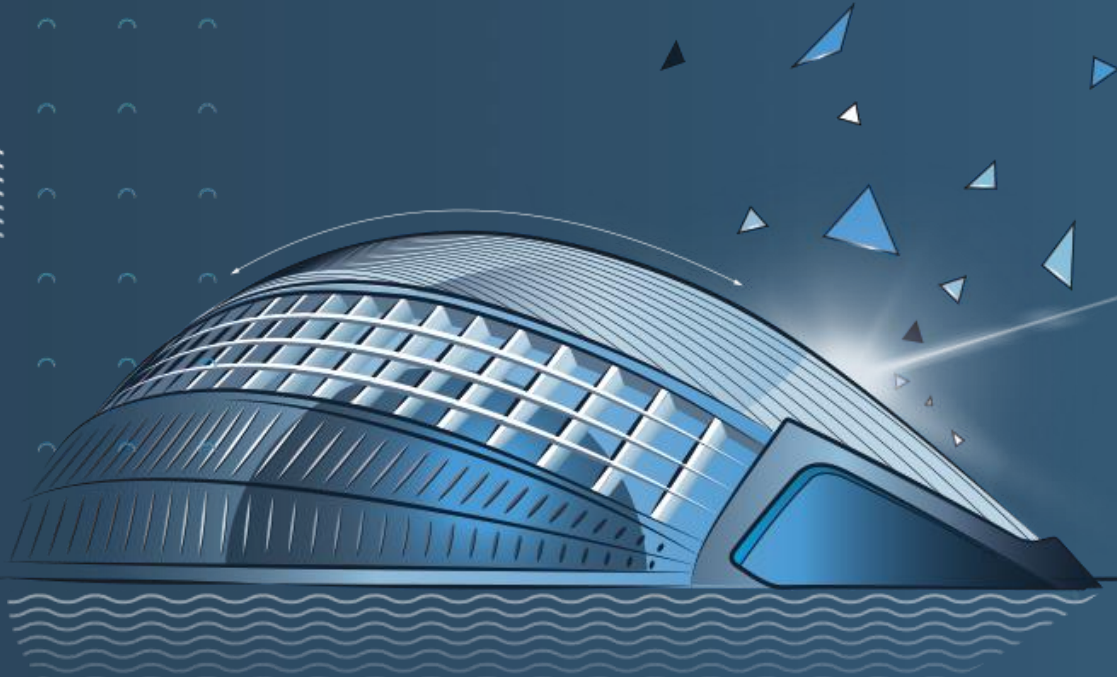


**sense**

Spine Expert Network<sup>TM</sup>  
for Science & Education



The impact of surgical fixation  
technique on pedicle screw  
anchorage

**SENSE**

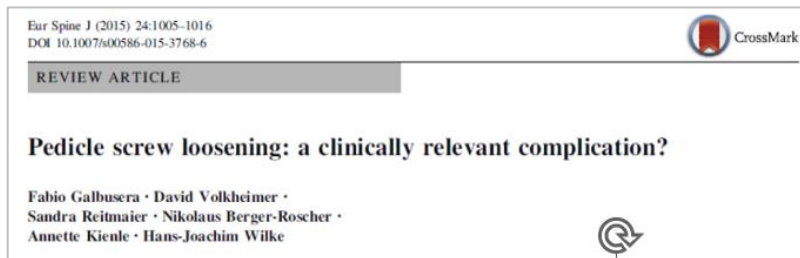
2nd International  
Spine Expert Symposium

Ass. Prof. Dr. Konstantinos  
Kafchitsas

June 23 – 25, 2022 / Valencia – Spain

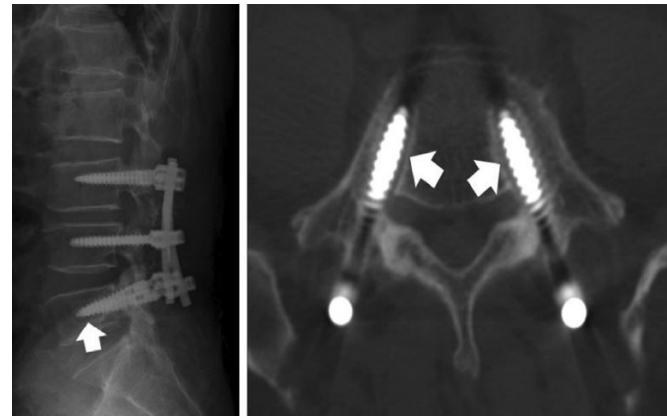
# Pedicle Screw Loosening Rates

*“Pedicle screw loosening is one of the most frequently reported complications of thoracolumbar posterior fixation in the literature”.*



## LITERATURE REVIEW

- 509 retrieved papers
- 43 full papers reviewed
- Standardization lacking regarding the radiological assessment
- When CT was used, markedly higher loosening rates were observed

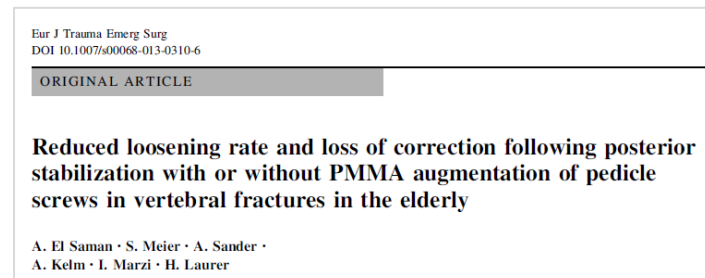


*“Posterior motion-preserving implants seem to have a significant risk of clinically relevant screw loosening, which could be related to the **high stresses acting at the screw–bone interface**”.*

Image from Kang SH, et al. J Korean Neurosurg Soc.

## RESULT

- Up to **15%** in non-osteoporotic patients
- Reports **> 60%** in osteoporotic bone



## RESULT

In un-cemented pedicle screws, in osteoporotic bone, the screw loosening rate was **62.8 %**

# Screw Loosening Definition

Original Article



## Screw Loosening in Posterior Spine Fusion: Prevalence and Risk Factors

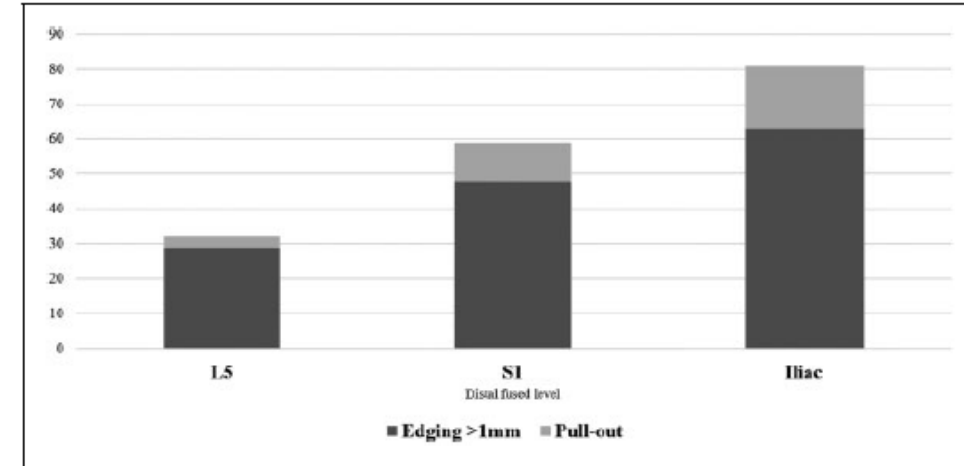
Laura Marie-Hardy, MD, MSc<sup>1</sup>, Hugues Pascal-Moussellard, MD, PhD<sup>1</sup>, Anne Barnaba, MD<sup>1</sup>, Raphael Bonaccorsi, MD<sup>1</sup>, and Caroline Scemama, MD, MSc<sup>1</sup>

Global Spine Journal  
2020, Vol. 10(5) 598-602  
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## RETROSPECTIVE COHORT STUDY

Study aim to define the prevalence of screw loosening in spinal fusion, defined as:

- a pulled-out screw
- OR
- a radiolucent rim >1 mm around the screw



**Figure 2.** Rate of loosening for both definitions (rim >1 mm around at least 1 screw and screw pull-out) according to the distal level of the fusion.

## RESULT

Prevalence

**9.6%** when defined by partial pull-out

**40.4%** when defined by osteolysis >1 mm

"The risk factors that seemed most important were osteoporosis, sagittal imbalance (PI/LL >10°), and the use of CrCo rods".

# Pedicle Screw Loosening Rates

Systematic literature search in **January 2022**, PubMed papers published in 2000 or later.

- 182 publications were screened
- 37 papers reported in-vivo studies with screw loosening rates in > 50 patients
- English or German
- Pooled loosening rates were calculated

## RESULT

- Patient-related loosening rate: **15.1%**  
(863/5,710; CI 14.2%-16.0%, range 0%-63.4%).
- Screw-related loosening rate: **3.8%**  
(585/15,333; CI 3.5%-4.1%, range 0%-20.3%).

# Screw Loosening Impact

■ ORIGINAL ARTICLE ■ SPINE SURGERY AND RELATED RESEARCH

## Risk Factors for Clinically Relevant Loosening of Percutaneous Pedicle Screws

Tetsuro Ohba<sup>1)</sup>, Shigeto Ebata<sup>1)</sup>, Hiroki Oba<sup>1,2)</sup>, Kensuke Koyama<sup>1)</sup> and Hirotaka Haro<sup>1)</sup>

1) Department of Orthopaedic Surgery, University of Yamanashi, Chuo-city, Japan

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

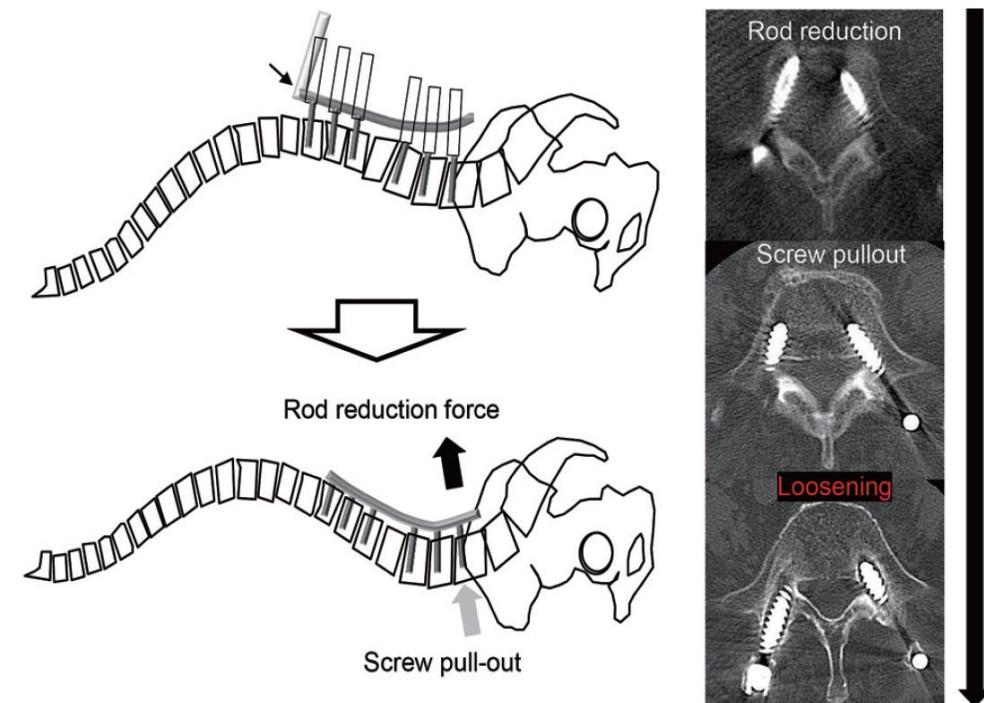
## CLINICAL STUDY

- To clarify the association between the pull-out length and screw loosening 1 year post op.
- To evaluate the influence of pedicle screw loosening on clinical outcomes.

**16.2%** screw pull-out rate

**15.2%** screw loosening rate at 1-year postop

**82%** of loosened screws had been pulled out during rod connection (stress overload).



**Figure 3.** Representative case with screw pull-out during rod reduction, resulting in screw loosening at the LIV. Abbreviations: LIV=lower instrumented vertebra



# Screw Loosening Impact

1-year postop ODI (disability) and VAS (pain) were significantly higher in patients with screw loosening.

**Table 2.** Comparison of Clinical Outcomes with or without Loosening.

	Overall (n=32)	Loosening (-) (n=11)	(+) (n=21)	P
Pain score before surgery				
ODI <sup>#</sup> (%)	53.9±27	59±29	51.3±26.9	0.59
RDQ <sup>#</sup> (points)	17±6.4	14±8.5	17.9±5.9	0.38
VAS <sup>#</sup> (Lumbar)	7.1±3.7	7.3±3.2	6.9±2.6	0.18
Pain score after surgery				
ODI <sup>#</sup> (%)	22.8±19.8	10.8±9.6	29±21.9	<0.05*
RDQ <sup>#</sup> (points)	8.7±6.8	6±4.4	10.1±7.5	0.28
VAS <sup>#</sup> (Lumbar)	3.4±2.6	1.3±0.9	4.7±2.5	<0.05*

ODI=Oswestry Disability Index; RDQ=Roland-Morris Disability Questionnaire; VAS=visual analog scale

In a 2nd study from same research team, comparing different rod reduction methods:

## PRIMARY RESEARCH

Utility of a Computer-assisted Rod Bending System to Avoid Pull-out and Loosening of Percutaneous Pedicle Screws

Tetsuro Ohba, MD, PhD, Shigeto Ebata, MD, PhD, Kotaro Oda, MD, Nobuki Tanaka, MD, and Hirotaka Haro, MD, PhD

**89.3%** of loosened pedicle screws had developed the screw pull-out during the rod connection.

# Neo Implant Failure Rate

## A Single-Center Post Market Clinical Follow-Up on The Use of The Neo Pedicle Screw System<sup>TM</sup>

Dr. Y Abdalla, Nordwest-Krankenhaus, Sanderbusch, Germany

	Preop	Intra-op	VAS at final FU (6mo-2y)	X-rays for fusion assessment (1y-2y)
Patients (N)	150	150	108	112

	Mean (range, SD) / N (%)
Age in years	66 (18-91, 15)
Preoperative VAS pain	8,0 (4-10, 1,1)
Gender	
Male	69 (46%)
Female	81 (54%)
Indication	
Trauma	94 (62,7%)
Degeneration	51 (34,0%)
Neoplasm	2 (1,3%)
Others	3 (2,0%)

### RESULTS

Fusion rate: **93.8%**

Screw loosening rate: **2.3%** (22/941 screws)

Hardware fractures: **0**

**Rate of SSI:** **2.7%** (4/150 patients)

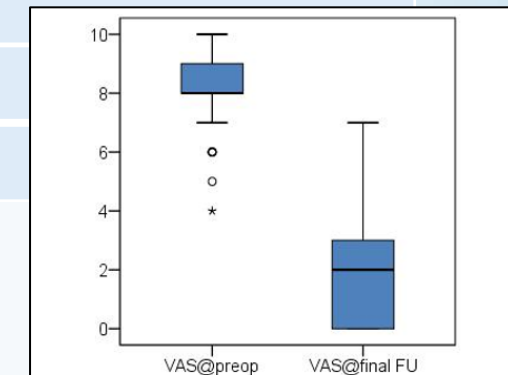
Deep SSI **1.3%**

Superficial SSI **1.3%**

### Improvement in Pain (VAS)

Baseline to Final FU **6.2**

Abdalla Y, Hajdari S. New approaches to proven technology: force control posterior thoracolumbar fusion with an innovative pedicle screw system. (Submitted, in review)



VAS pain improvement: preoperative vs. final FU

# Preliminary Work

## Segmental Assessment and Visualization of Trabecular Bone Mineral Density in Vertebrae



TECHNISCHE  
UNIVERSITÄT  
DARMSTADT

S. Wesarg<sup>1</sup> and A.S. Ghassemi Hosseini<sup>1</sup> and M. Erdt<sup>2</sup> and K. Kafchitsas<sup>3</sup> and M.F. Khan<sup>4</sup>

<sup>1</sup>Interactive Graphics Systems Group (GRIS), Technische Universität Darmstadt, Germany

<sup>2</sup>Dept. Cognitive Computing & Medical Imaging, Fraunhofer IGD, Darmstadt, Germany

<sup>3</sup>Clinic and Polyclinic for Orthopedics and Orthopedic Surgery, Universitätsmedizin Mainz, Germany

<sup>4</sup>Institute for Diagnostic and Interventional Radiology, Goethe University, Frankfurt/M., Germany



UNIVERSITÄTSmedizin.  
MAINZ



BMD Assessment with Dual Energy CT



Eur Radiol

DOI 10.1007/s00330-014-3529-7

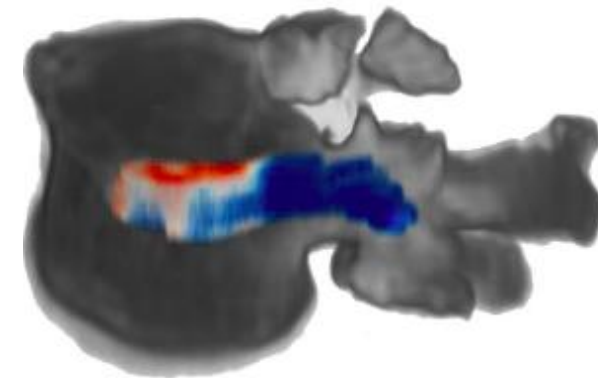
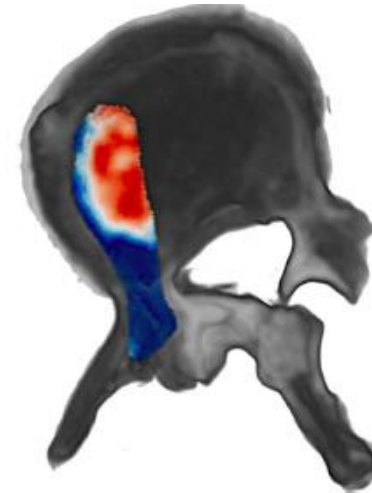
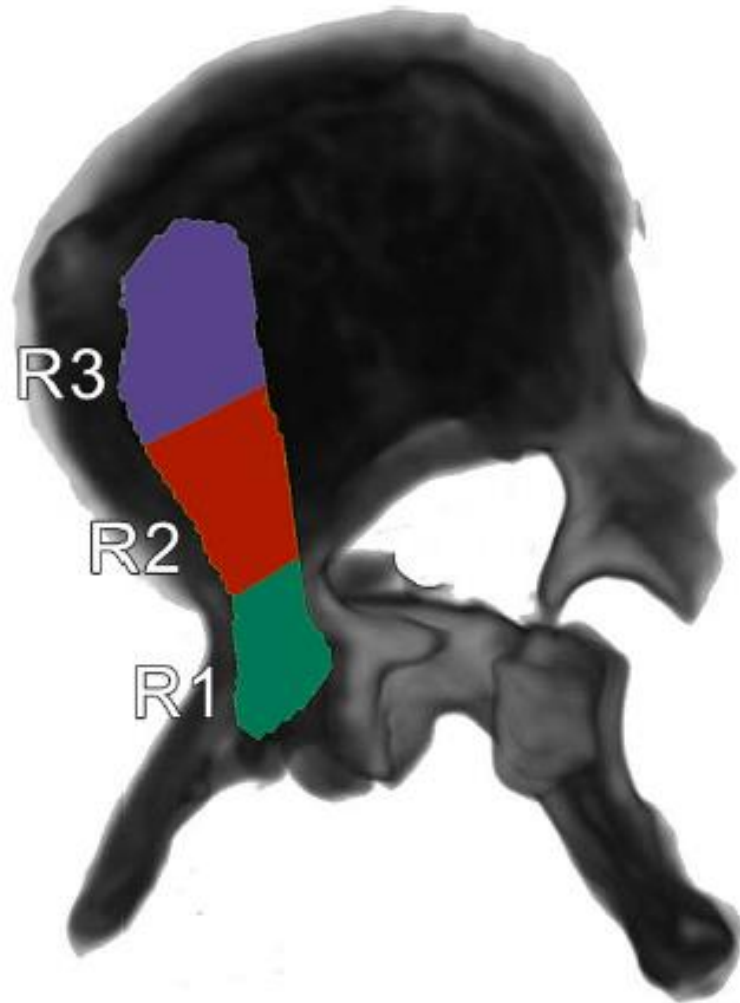
MUSCULOSKELETAL

# **Quantitative dual-energy CT for phantomless evaluation of cancellous bone mineral density of the vertebral pedicle: correlation with pedicle screw pull-out strength**

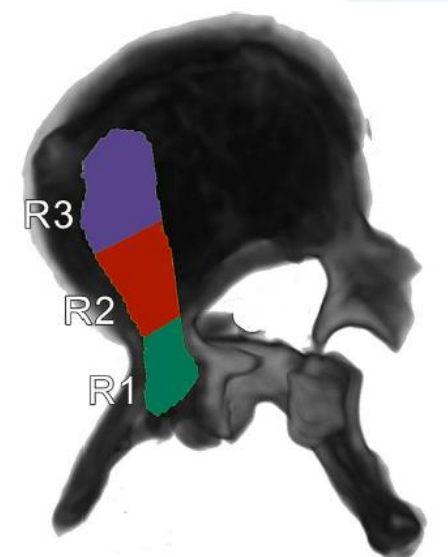
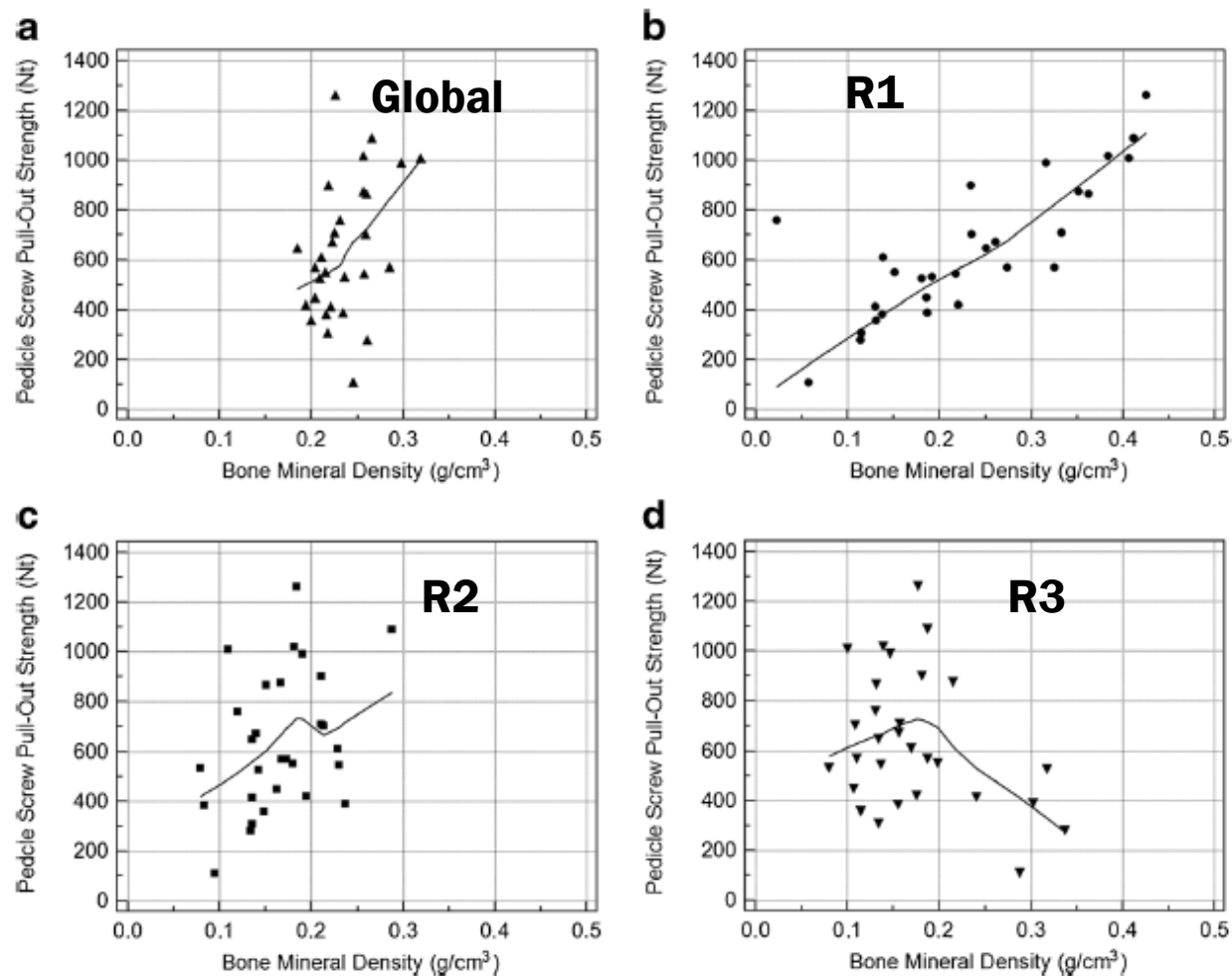
**Julian L. Wichmann • Christian Booz • Stefan Wesarg • Ralf W. Bauer •  
J. Matthias Kerl • Sebastian Fischer • Thomas Lehnert • Thomas J. Vogl •  
M. Fawad Khan • Konstantinos Kafchitsas**

Received: 17 July 2014 / Revised: 6 October 2014 / Accepted: 19 November 2014  
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# Material und Method



## Results

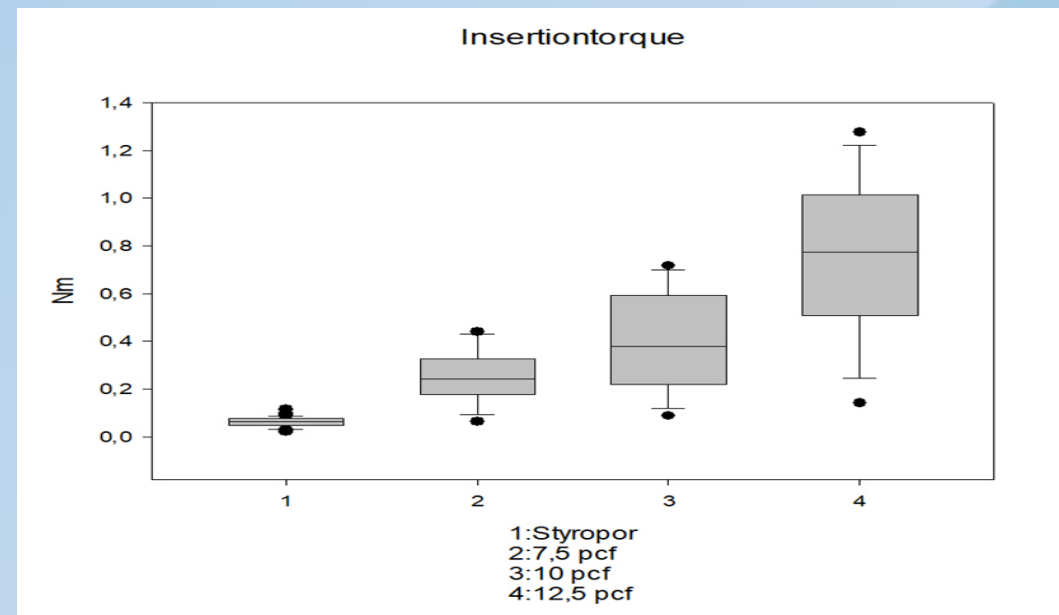


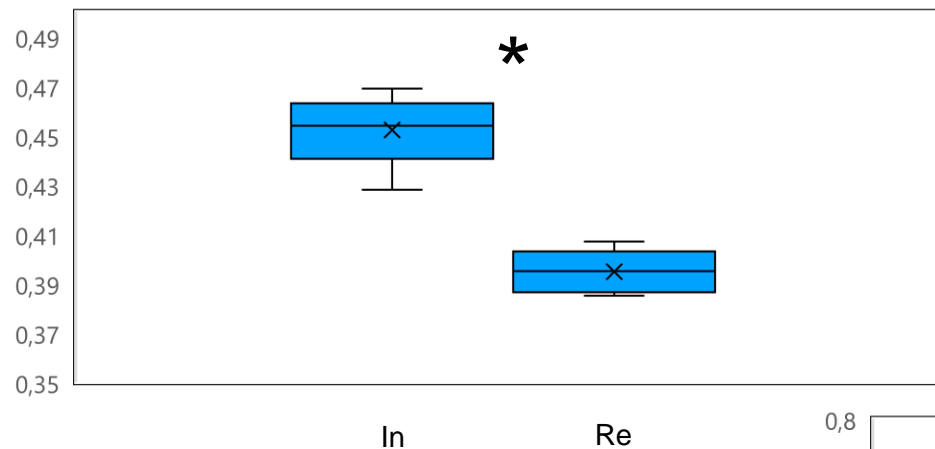
**R1≠R3**  
**R1≠R2**  
**R2=R3**

# Insertion Torque & Extraction Torque

Kafchitsas K, Drees P, Spanidis E, Rauschmann M.  
Correlation of the pedicle screw insertion torque with pedicle bone quality. Revision of the surgical technique intraoperatively: to cement or not to cement. Eur Spine J (2020) 29:2914/P49.

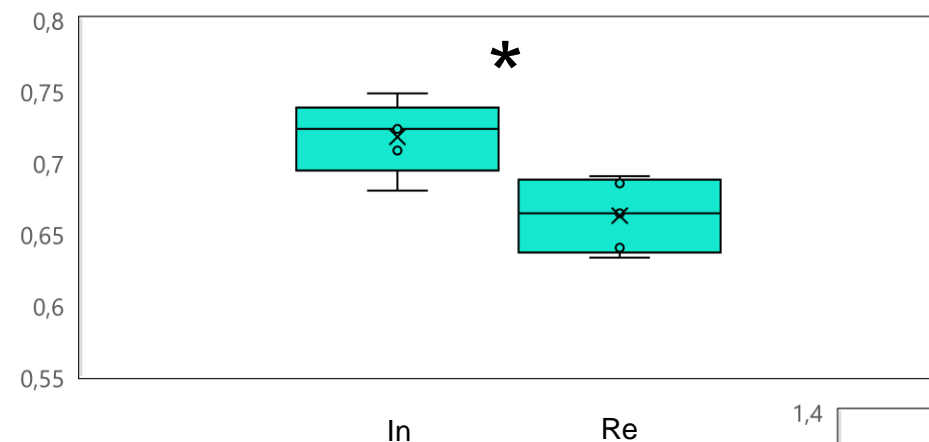
- In an earlier study we investigated the anchorage behavior of pedicle screws in different host material densities by means of insertion torque (IT) and extraction torque (ET).





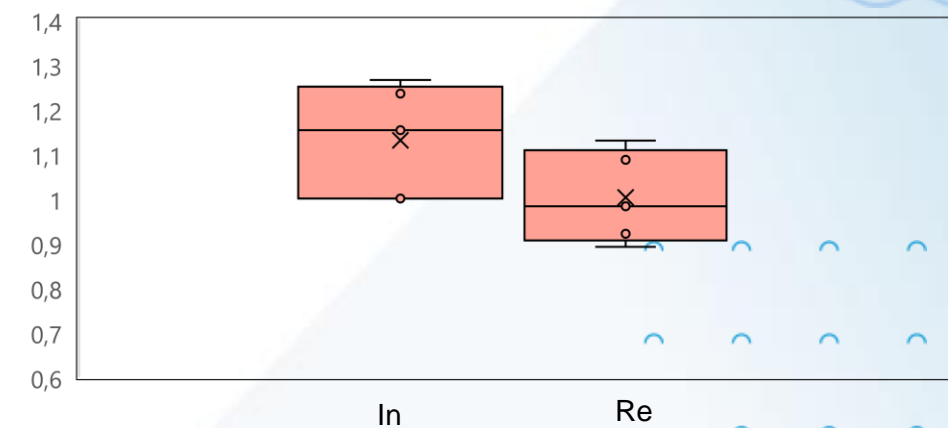
## Primärimplantation (PP Modus)

Eindreihen (Insertion)  
Ausdreihen (Removal)



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.

The magnitude of the ***difference between IT and ET represents the amount of loss in biomechanical behavior or so-called loss of bone purchase.***





# Insertion Torque

Several in vitro studies confirmed correlations between IT and pull-out force

Okuyama K, Sato K, Abe E, et al. Spine (Phila Pa 1976). 1993 Nov;18(15):2240-5.

Lu WW, Zhu Q, Holmes AD, et al. J Orthop Res. 2000 Sep;18(5):808-14

Kang DG, Lehman RA Jr, Wagner et al. Spine (Phila Pa 1976). 2014 Sep 15;39(20):1640-7.

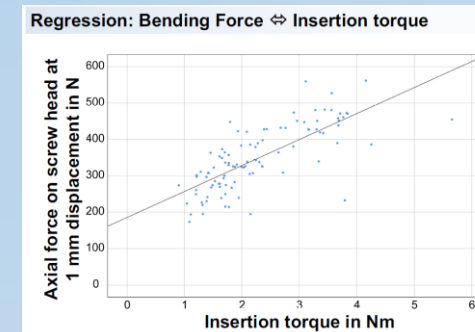
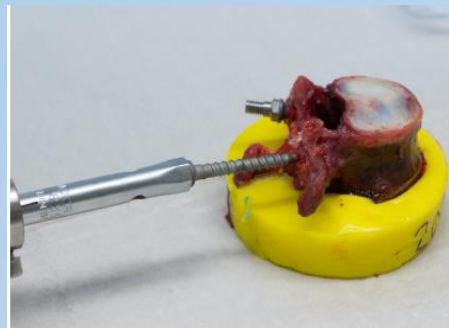
Wichmann JL, Booz C, Kafchitsas K, et al. Eur Radiol. 2015 Jun;25(6):1714-20

Jansen JU, Zengerle L, Hackenbroch C, Tao Y, Wilke HJ. **Prediction of screw loosening: Is it possible via measuring the insertion torque?** An in vitro study. Oral presentation at: EUROSPINE 2021, Vienna, Austria.

➤ Insertion torque as a predictor of loosening risk long discussed  
(Okuyama 2000; Sanden 2010; Helgeson 2013; Matsukawa 2019; Weidling 2020)

## Aim of the study:

Does the insertion torque predict screw loosening?



➤ Regression:  
bending force ~  
insertion torque  
( $R^2$  Linear = 0.558;  $p = 0.0002$ )

## Summary

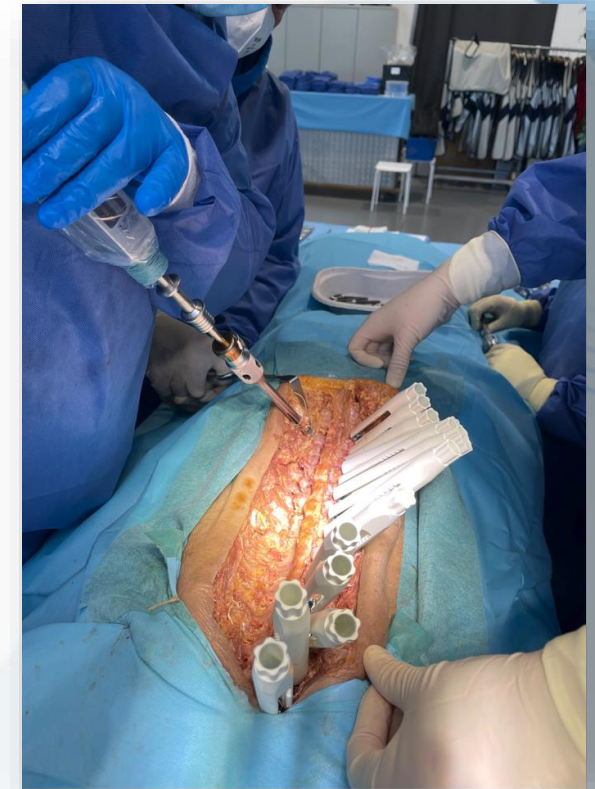
- Insertion torque as an alternative prediction method ✓
- Perhaps thus more patient safety (Radiation ↓, screw augmentation ↓) ✓

# Biomechanical Study

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

## STUDY OBJECTIVE

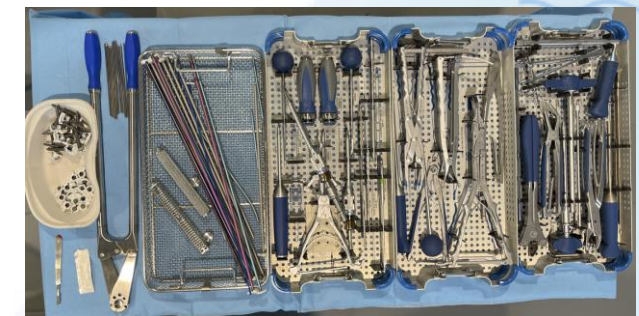
- Reduction and tightening of the rods are mechanically critical processes that may lead to overloading of the implant construct and surrounding tissues.
- The aim of the study is to investigate the impact of the reduction and tightening procedure to the pedicle screw-bone anchorage.



# Biomechanical Study

## MATERIAL & METHODS

- Neo Pedicle Screw System™ vs. CD Horizon™ Solera™ representing different fixation philosophies:
  - **Controlled force fixation (CF)**
  - **Standard fixation (SF)**
 in a human cadaveric study model, two human cadaver specimens (T5-S1).
- Measuring the amount of **Insertion Torque (IT) vs. Extraction Torque (ET)** needed for the insertion and extraction of the same pedicle screw in the vertebral body.
- The presumption: **A big difference ( $\Delta$ : IT-ET) will indicate stress overload** applied to the construct during the instrumentation assembly jeopardizing the screw bone anchorage.



# CONTROLLED FIXATION PRINCIPLE #3

Mechanical Force Awareness & Control Required



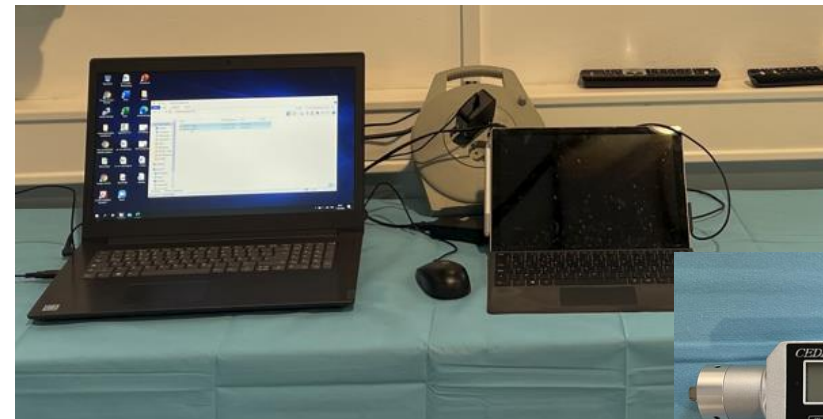




# Biomechanical Study

## MATERIAL & METHODS

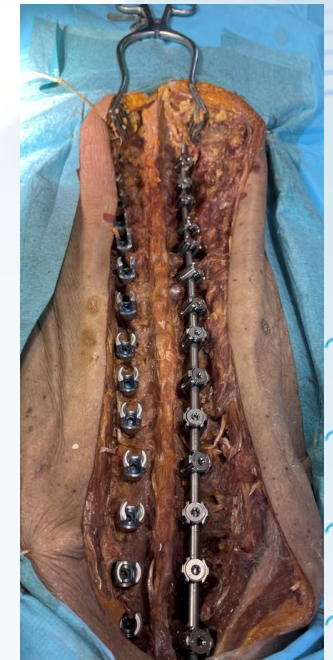
- Per side and cadaver, 14 polyaxial pedicle screws were inserted under radiographic control according to the respective surgical technique into the torsos mounted on a table.
- The **Insertion Torque (IT)** was digitally recorded by a method using a modified torque screwdriver covering 0.01Nm to 4.0Nm (accuracy of  $\pm 0.5\%$  F.S.)



# Biomechanical Study

## MATERIAL & METHODS

- Prior to placement the rod (Ø 5.5mm TI) was cut to the length of the construct and bent as required *in accordance with the manufacturer's surgical technique*.
- After final tightening of all screws on one side, the specimen was left in place for 40-110 minutes before the rod was removed and the screws were extracted.
- Again, the **Extraction Torque (ET)** of each pedicle screw was measured and documented.

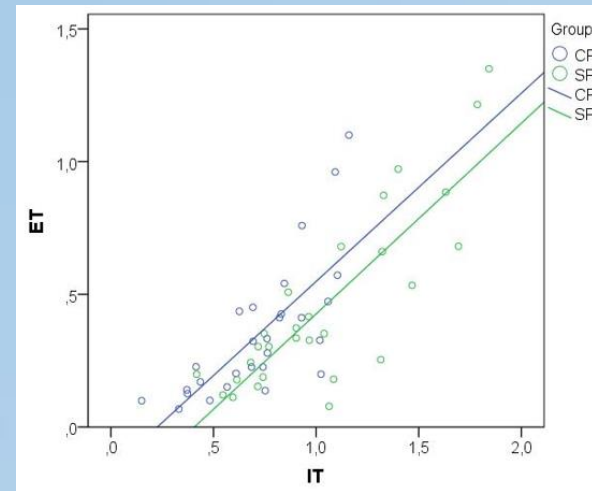




# Biomechanical Study

## RESULTS

- IT and ET correlate statistically significant with each other for both **CF** ( $r=0.792$ ;  $p<0.001$ ) and **SF** ( $r=0.783$ ;  $p<0.001$ ).
- Higher torque losses were seen in the SF group compared for the CF group.
- Torque losses (delta from IT to ET) are statistically significant ( $p<0.001$ ) between the two fixation philosophy groups.



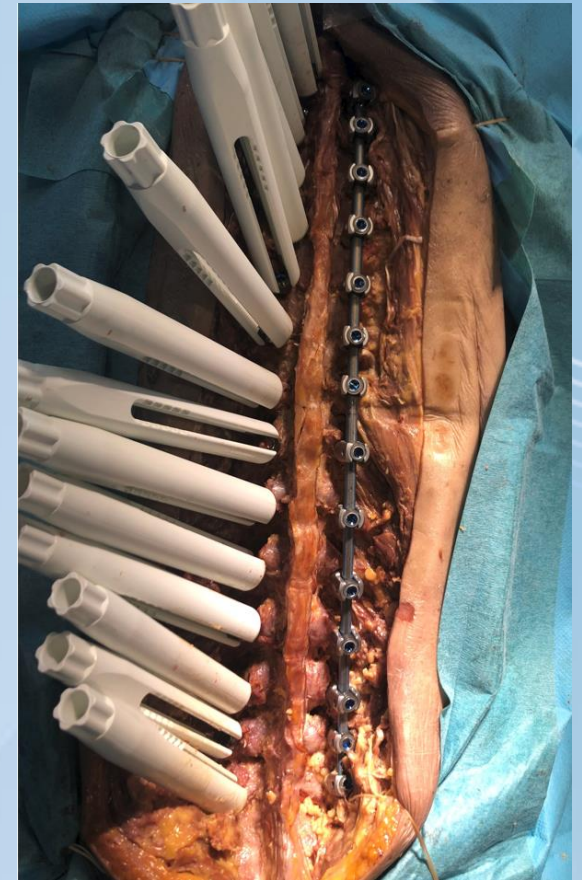
**High (Delta: IT-ET) value =  
Indicate stress overload**

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	

# Biomechanical Study

## CONCLUSIONS

- The reduction and tightening of the rod-screw interface has a relevant influence on the bone purchase of pedicle screws.
- Losses of biomechanical behavior are higher if instrument assembly is performed with a standard fixation surgical technique.
- Force Control fixation technique alters the biomechanical behavior to a lesser extent, and results in lower forces during reduction and tightening of the pedicle screw construct.
- Utilizing surgical techniques that avoid unnecessary load application during screw-rod assembly could potentially decrease screw loosening, construct failure and reoperation rates, and improve clinical outcomes.



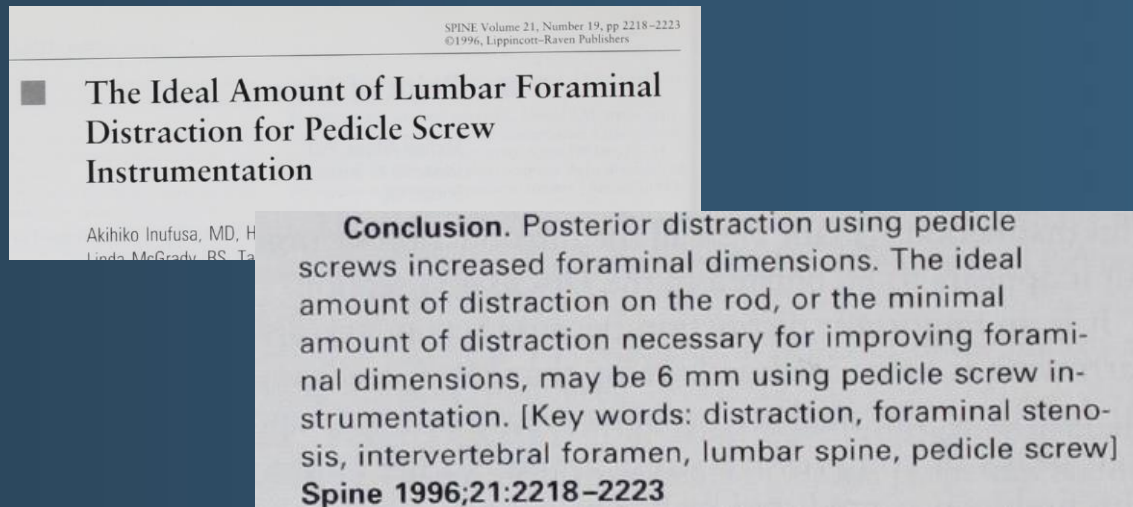
# Effects of Distraction over Pedicle Screw Heads





# Effects of Distraction over Pedicle Screws

- Few publications can be found discussing distraction using the pedicle screws.
- Inufusa A, et al. showed in his paper from 1996 that increased foraminal dimensions could be achieved by distraction over the pedicle screws.



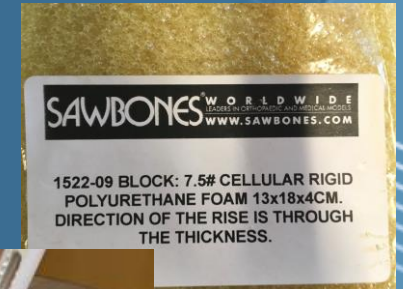
However, can external loads, such as those frequently generated by minor distractions via the pedicle screws, lead to a deterioration of the biomechanical behavior?

- To our knowledge, there are no suitable in vivo data on this.
- Biomechanical effects of distraction when using growth rod instrumentation for the treatment of scoliosis have been investigated.
- Concluding that there is a relationship between screw loosening and distraction forces.

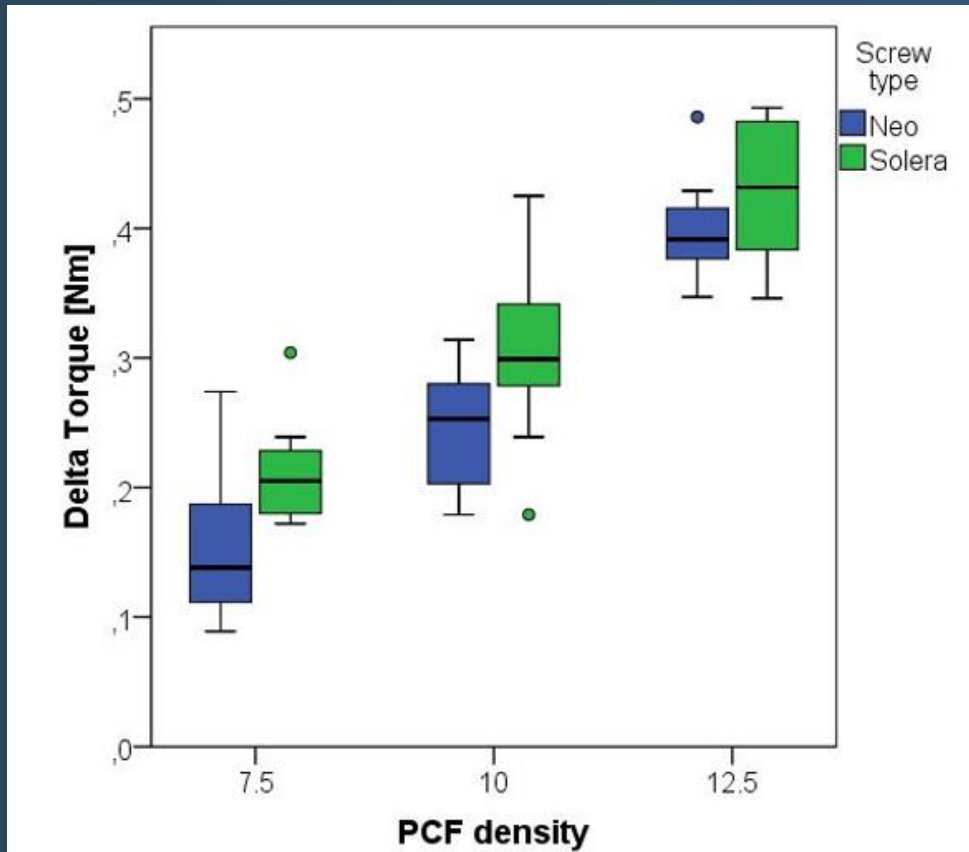
# Effects of Distraction over Pedicle Screws

## MATERIAL & METHODS

- Sawbones® blocks of different densities were used for measuring the insertion torque (IT) & extraction torque (ET) of the pedicle screws.
- The screws were inserted and distracted using forces up to 100N.
- ( $\Delta$ : IT-ET) was calculated for pedicle screws
  - Distraction was performed
  - No distraction



# Effects of Distraction over Pedicle Screws



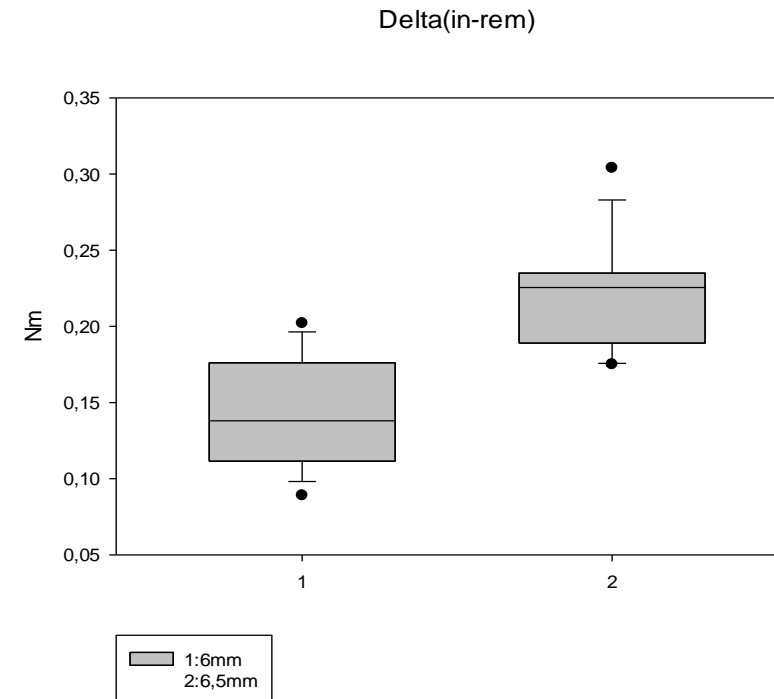
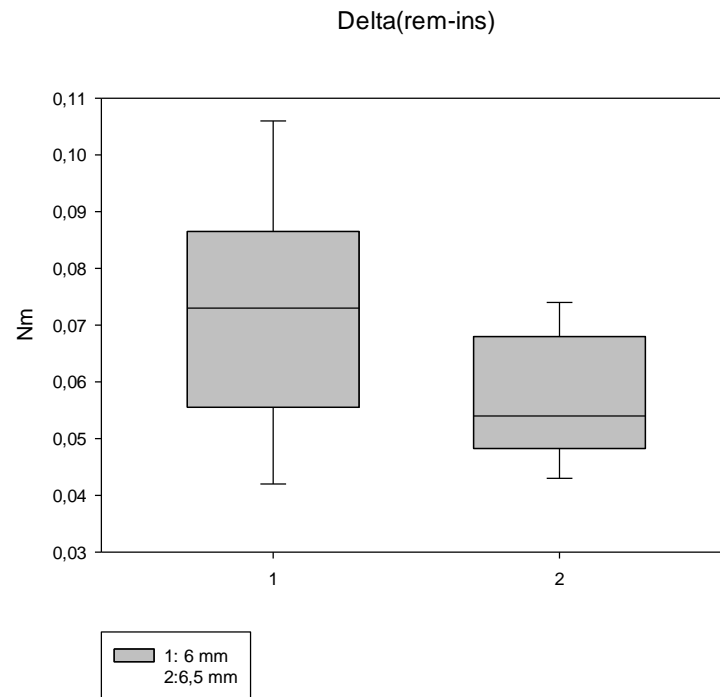
*Torque losses between IT and ET with distraction. Delta torque (IT vs. ET) for Neo pedicle screws and Solera pedicle screws in rigid polyurethane foam blocks of certain densities when distraction forces of 100N are applied to the pedicle screws.*

## RESULTS

Up to almost 10 times higher values for ( $\Delta$ : IT-ET) was seen when distraction forces were applied over the pedicle screws.

# Definition: $\Delta$ (Insertion-Removal)

## After Distraktion







Thank you

