AO Technical Commission

AOTC Osteoporotic Spine Surgery Task Force (OSSTF)

Final Report

Task Force Members

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Meetings overview

Online – Feb 5, 2021

Online – March 25, 2021

Online – June 5, 2021

Hybrid – Nov 13, 2021

Online – March 19, 2022

Mission in osteoporotic spine surgery (OSS)

To achieve optimal implant-bone fixation strength and construct stability to prevent early implant failure and late fusion//junctional failure with residual deformity

11 References of general reviews of OSS

OSSTF: Defined targets

01

Medical osteoporosis management

02

Surgical planning and technique

03

Junctional failure prevention

OSSTF-Target 1

Medical osteoporosis management

Jean Ouellet
Izzy Lieberman
Maarten Spruit

Invited endocrinology and bone health specialists

Neil Binkley

University of Wisconsin

Angela Cheung

University of Toronto

Kassim Javaid

University of Oxford

Suzanne Morin

McGill University

Online meetings

- May 13, 2021
- May 26, 2021
- Sept 17, 2021

Overarching objective

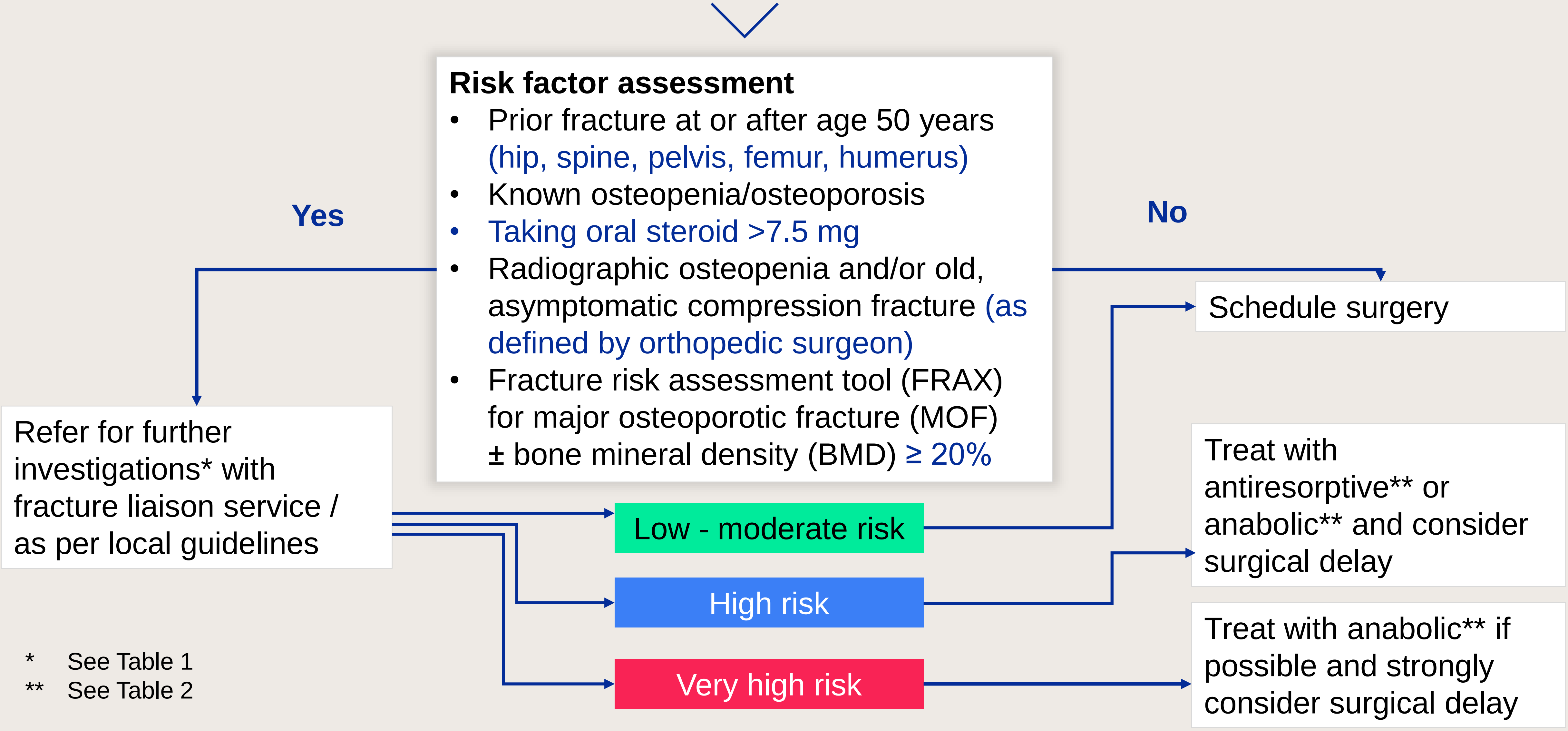
Optimize medical management of patients' bone health in the context of instrumented spine surgery in adults aged 50 or older.

The guidelines need to be widely applicable to promote adoption.

Defined specific objectives

1a.	Which patients require evaluation for bone health in a preoperative setting?
1b.	Which investigations need to be done to evaluate bone health?
2.	Algorithm to categorize patients as low-moderate, high, or very high risk.
3.	Which medical management is appropriate if major spine surgery is planned within the next 3 or 12 months?
4.	Which medical management is appropriate after emergency spine surgery?

Patient aged ≥ 50 years considered for elective spine surgery



* See Table 1

** See Table 2

Flowchart provided by Neil Binkley, University of Wisconsin, USA

Risk classification and treatment

Risk classification	Treatment approach
Normal bone/low risk	Optimize calcium/vitamin D if needed and proceed with surgery
Osteopenia/intermediate risk	Optimize calcium/vitamin D if needed and proceed with surgery
Osteoporosis/high risk	Optimize calcium/vitamin D; antiresorptive or anabolic therapy and consider delay in surgery
Severe osteoporosis/very high risk	Optimize calcium/vitamin D; anabolic therapy if possible and suggest delay of surgery if possible. If anabolic therapy not feasible, use antiresorptive therapy

Definitions

- Normal: FRAX w/out BMD < 10% or no fracture after age 50 years then no dual energy x-ray absorptiometry (DXA) & no bone health optimization (BHO) referral. For others after BHO evaluation; normal BMD, MOF < 20%, no prior fracture, normal trabecular bone score (TBS) and Hounsfield unit (HU) when available
- Osteopenia/intermediate risk: Lowest T-score -2.4 or better, no prior fracture, MOF risk < 10%
- Osteoporosis/high risk: Lowest T-score -2.5 to -3.4, recent fracture (within 2 years), MOF risk 20–30%
- Severe osteoporosis/very high risk: Lowest T-score ≤ -3.5 OR MOF risk > 30% OR recent fracture OR multiple prior fractures

Table 1

Recommended investigations for patients being assessed for osteoporosis (provided by Suzanne Morin, MD)

Biochemical tests	Imaging
Calcium	BMD measurement (hip and spine) by DXA
Creatinine	Lateral radiograph of the thoracic and lumbar spine or DXA-based vertebral fracture assessment
Alkaline phosphatase	
Thyroid-stimulating hormone	
25-hydroxyvitamin D	
Serum protein electrophoresis in patients with vertebral fractures	

NB: Most guidelines may recommend more advanced tests depending on the local context or type of clinic.

References (Table 1)

1. Osteoporosis Canada: **Papaioannou A et al**. 2010 clinical guidelines for the diagnosis and management of osteoporosis in Canada. *CMAJ.* 2010 Nov 23;182(17):1864−73
2. National Osteoporosis Foundation: **Cosman F et al.** Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int.* 2014 Oct;25(10):2359−2381.
3. Scientific Advisory Board of the European Society for Clinical and Economic Aspects of Osteoporosis (ESCEO) and the Committees of Scientific Advisors and National Societies of the International Osteoporosis Foundation (IOF): **Kanis JA et al.** European guidance for the diagnosis and management of osteoporosis in postmenopausal women. *Osteoporosis Int.* 2019 Jan;30(1):3−44
4. National Osteoporosis Guideline Group 2017 https://www.sheffield.ac.uk/NOGG/NOGG%20Guideline%202017.pdf. Accessed 2017.

Table 2

Anti-osteoporotic medication: summary of time to onset and scale of benefit at the spine (provided by Kassim Javaid, MD)

Agent	Time to benefit as measured by nadir/ peak bone turnover marker change	Benefit at spine as measured by spinal bone density at 1 year	Comments
Alendronate(1)	3-6 months(2)	4.5%	Weekly antiresorptive oral agent. Requires no swallowing issues and good adherence
Risedronate(3)	3-6 months(2)	4%	Weekly antiresorptive oral agent. Requires no swallowing issues and good adherence
Zoledronate(4)	< 1 month(5)	3.9%	Annual antiresorptive infusion. Requires good renal function.
Denosumab(6)	< 1 month	7.4%	6 monthly antiresorptive subcutaneous injection. Concerns about off-effect
Teriparatide(7)	< 1 month	6.5%	Daily anabolic subcutaneous injection for up to 2 years then switch.
Denosumab and Teriparatide(7)	< 1 month	8.4%	
Romosozumab(8)	< 1 month	14%	Monthly anabolic subcutaneous injection for 1 year then switch. Contraindicated if previous/ recent myocardial infarction or stroke.

References (Table 2)

1. **Black DM, Cummings SR, Karpf DB, et al.** Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures. *Lancet.* 1996 Dec 7;348(9041):1535−1541.
2. **Hosking D, Adami S, Felsenberg D, et al.** Comparison of change in bone resorption and bone mineral density with once-weekly alendronate and daily risedronate: a randomised, placebo-controlled study. *Curr Med Res Opin*. 2003;19(5):383−394.
3. **Harris ST, Watts NB, Genant HK, et al.** Effects of risedronate treatment on vertebral and nonvertebral fractures in women with postmenopausal osteoporosis: a randomized controlled trial. Vertebral Efficacy With Risedronate Therapy (VERT) Study Group. *JAMA*. 1999 Oct 13;282(14):1344−1352.
4. **Black DM, Delmas PD, Eastell R, et al.** Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. *N Engl J Med*. 2007 May 3;356(18):1809−1822.
5. **Reid IR, Brown JP, Burckhardt P, et al.** Intravenous zoledronic acid in postmenopausal women with low bone mineral density. *N Engl J Med.* 2002 Feb 28;346(9):653−661.
6. **Cummings SR, San Martin J, McClung MR, et al.** Denosumab for prevention of fractures in postmenopausal women with osteoporosis. *N Engl J Med*. 2009 Aug 20;361(8):756−765.
7. **Leder BZ, Tsai JN, Uihlein AV, et al.** Denosumab and teriparatide transitions in postmenopausal osteoporosis (the DATA-Switch study): extension of a randomised controlled trial. *Lancet*. 2015 Sept 19;386(9999):1147−1155.
8. **Saag KG, Petersen J, Brandi ML, et al.** Romosozumab or alendronate for fracture prevention in women with osteoporosis. *N Engl J Med.* 2017 Oct 12;377(15):1417−1427.

OSSTF-Target 2

Surgical planning and technique

Rick Bransford
Maarten Spruit
Kota Watanabe
Qian Bangping

Objectives

1.	Screw hole preparation and fill
2.	Screw purchase
3.	Anchor points-screw trajectory
4.	Augmentation
5.	SI-ilium fixation
6.	Fusion bed preparation

Goals after collecting relevant literature and organizing it in group access dropbox files

- Can we draw (preliminary) conclusions from literature?
- Any next steps based on these conclusions?
- Recommendations?

1. Screw hole preparation and additional techniques

The probe or 3.2 mm drill pilot hole preparation no clear difference in human anatomical specimen of osteoporotic Th vertebra model (fatigue test). Comparable for lumbar pedicles
Critical pilot hole size 71.5% of pedicle diameter
Small diameter hole + tap versus non-tapping: no clear yes or no
Fill entire trajectory pilot hole (allograft [1//2 mm], hydroxyapatite (HA) granules or sticks): all studies use torque measurement for initial screw grip and fatigue (toggle) as well as pull-out for failure test. Mix of synthetic and human anatomical models

8 references

Screw hole preparation and additional techniques: conclusions

- Smaller pilot hole – makes sense
- Under tapping – makes sense
- Cross-link – triangulation
- Sublaminar wires
- Laminar hooks
- Pedicle hooks
- Other advancements in pedicle fixation

Summary – lots of options, variable data, no clear consensus or conclusions

Next steps and recommendations: pilot hole preparation

1. Probe or drill not so relevant (surgeon preference and training)
2. Undersizing hole and (not) tapping are more relevant: needs evaluation in design testing
3. Pilot hole grafting in any manner can be considered in index surgery
4. Torque measurement makes sense in clinical practice

   Torque measurement tool design
5. Mechanical testing must include toggle fatigue and pull-out as standard

2. Screw purchase: conclusions

Cement augmentation is most important factor contributing to pull-out strength

Larger diameter screws increase pull-out by 35% per mm

Expandable screws (anterior to pedicle lock) increase critical pull-out load

Expandable screw design not clear (where, how many %, mechanism, material, reversible option)

Less rigid connection of screw to tulip/rod may prevent screw purchase loss

8 references

Expandable screw designs: examples

Next steps and recommendations: screw purchase

Expandable screws designs need more work

Screw – polyaxial head connection needs more work

Improved load sharing: mechanical versus cement augmentation

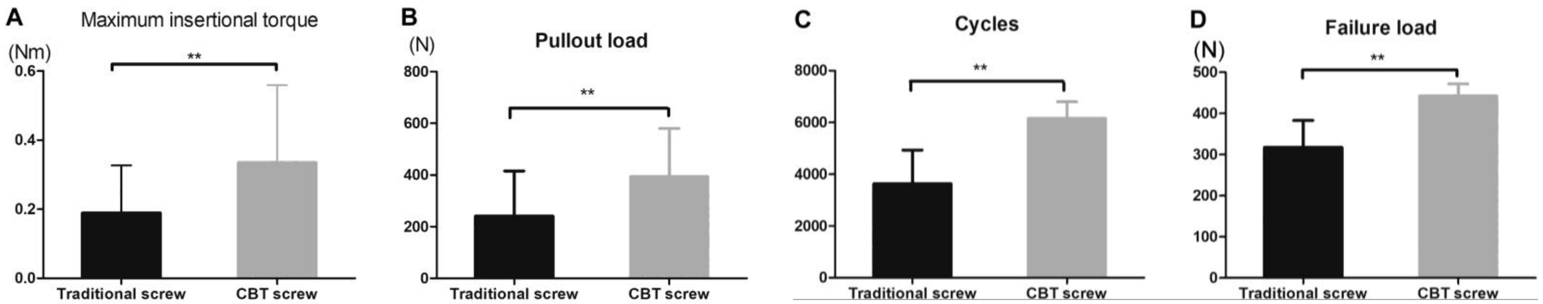
3. Anchor points—screw trajectory

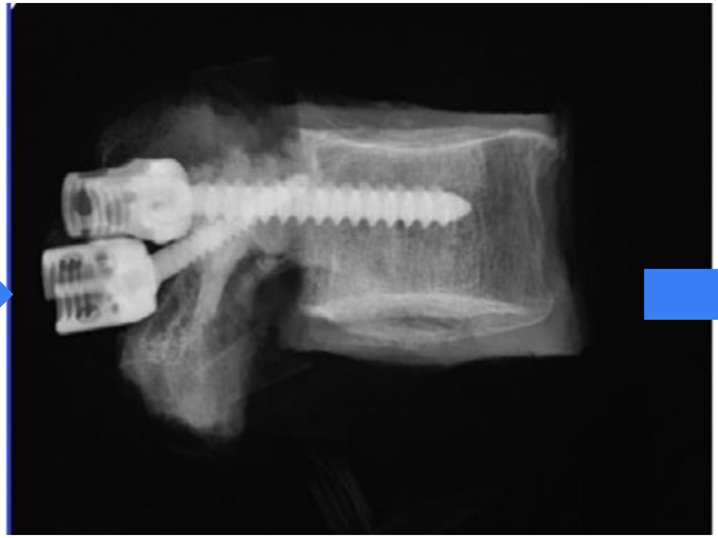
- Bicortical caudal direction
- Bicortical ± cement augmentation
- Traditional trajectory (TT) and cortical bone trajectory (CBT) combined (crossed trajectory)
- CBTs increase purchase and load of failure in osteoporotic spine versus TT
- Midline Cortical (MC) Trajectory: superior load of cyclic load failure over CBT
- Revision of TT-CBT or CBT-TT screws is a challenge
- 14 references

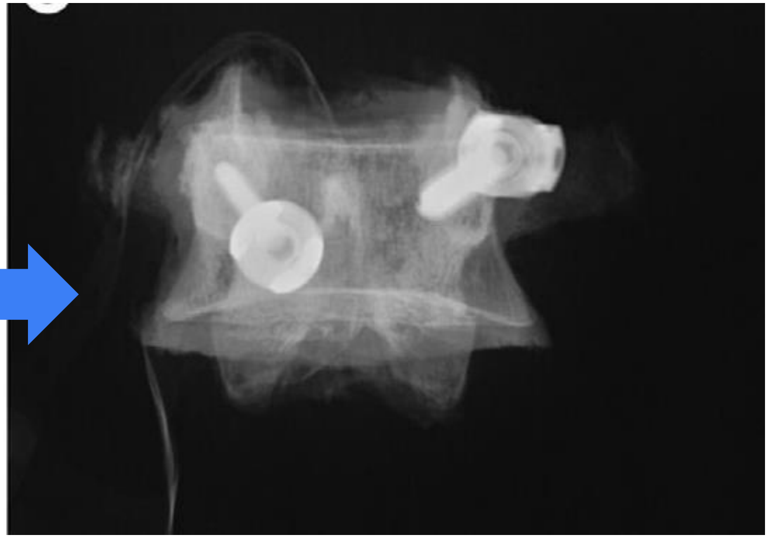
Screw trajectory 1

Traditional trajectory screw

Cortex screw (Yu)

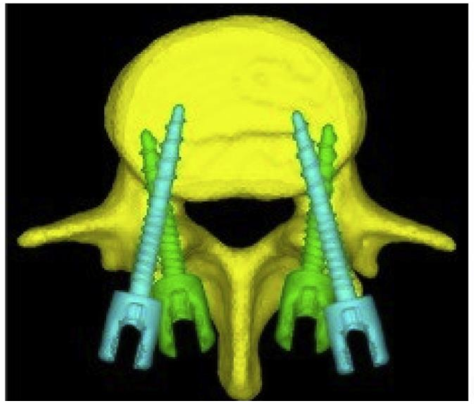


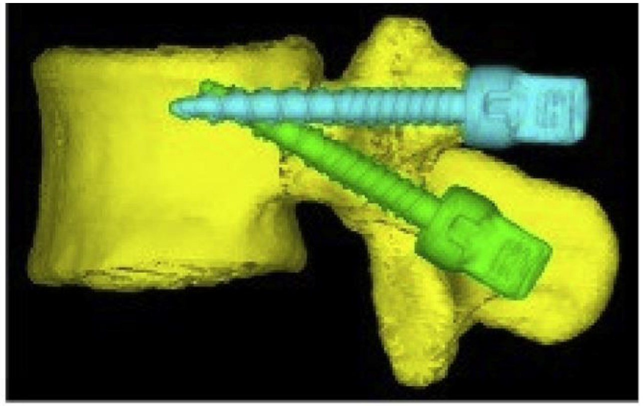




Screw trajectory 2

Double screw
(Jiang)



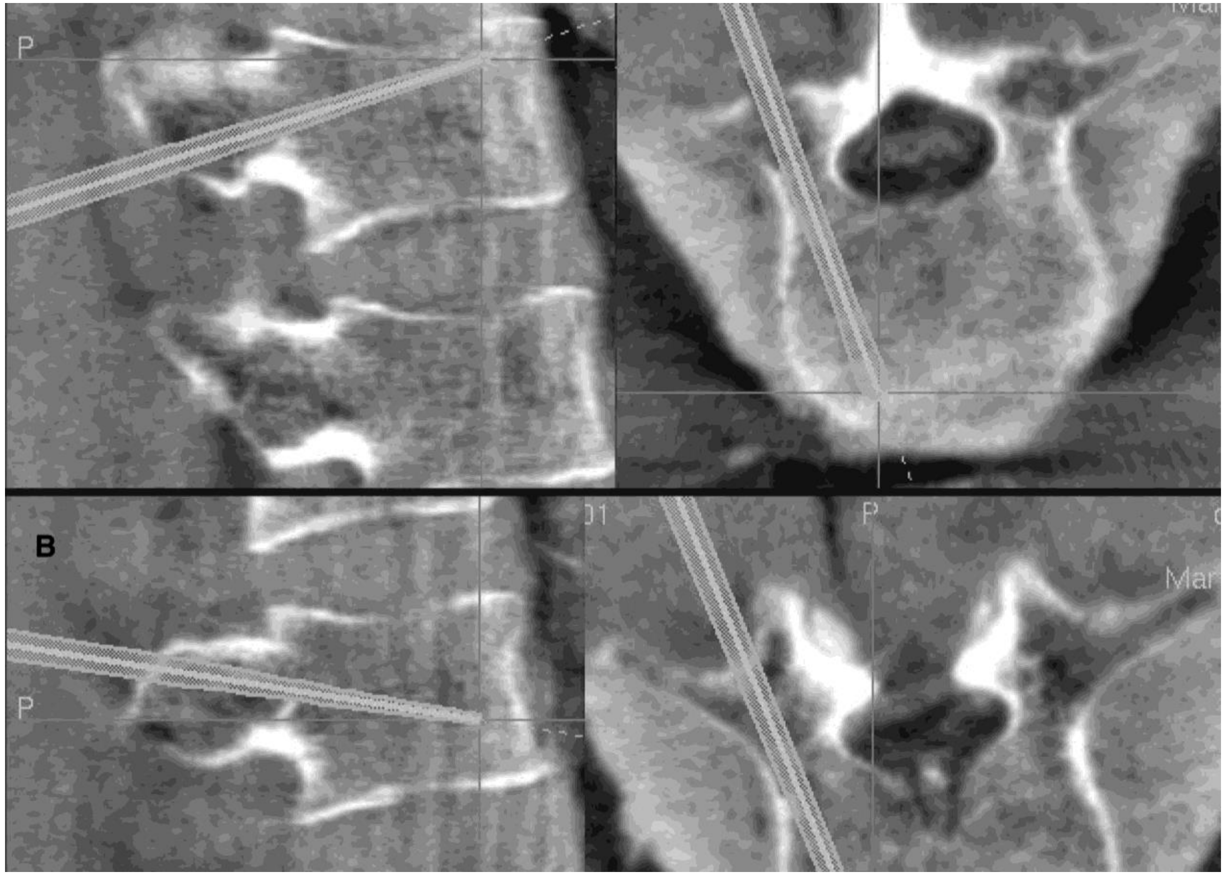


Cross trajectory
(Matsukawa)

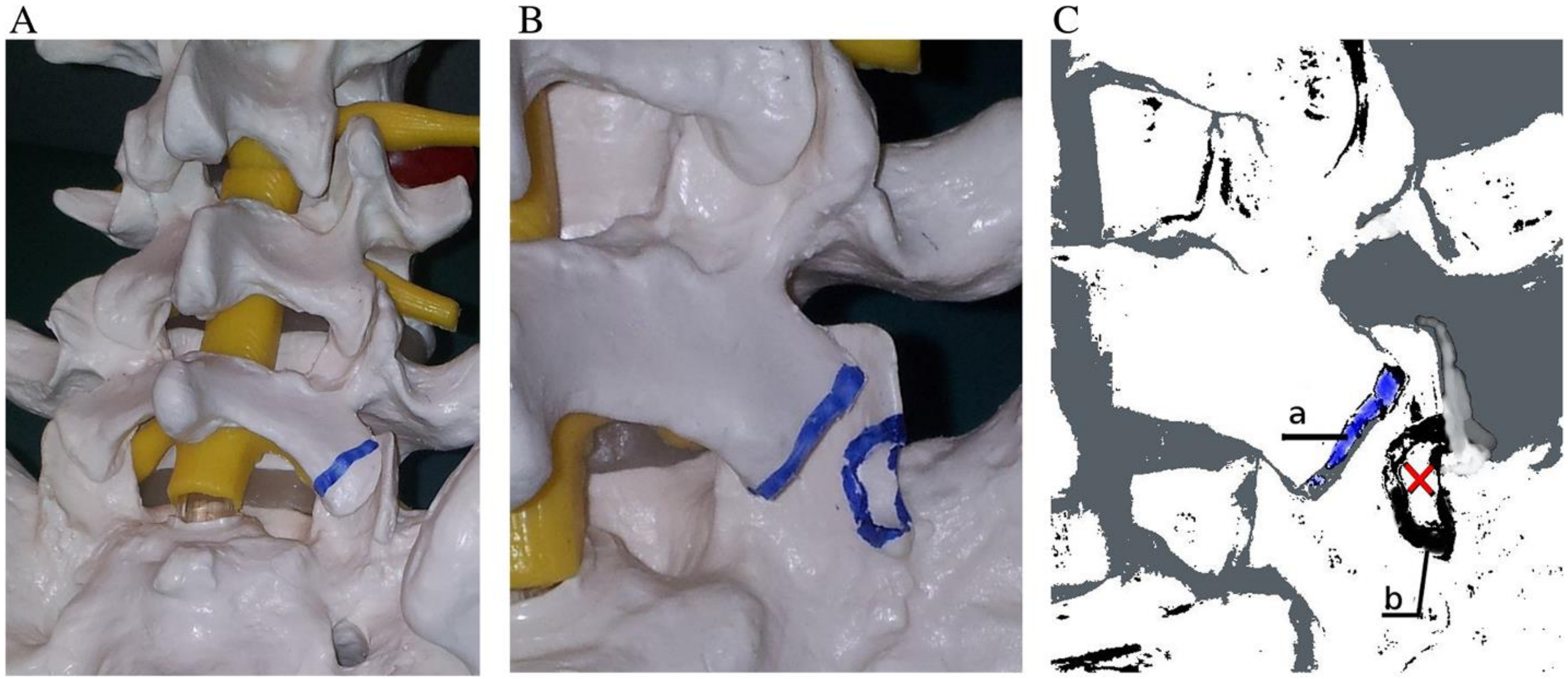
Screw trajectory 3

Cortical superior fixation to pedicle (Matsukawa)

Caudal screw trajectory (Battula)



Screw trajectory 4



S1: upward and medial (**a**) versus below and lateral (**b**)

Summary

Lots of options, variable data, limited data in live patients, no clear consensus, or conclusions. Probably more clinical studies necessary.

Screw trajectory
Pull-out data

Conventional pedicle screw pull-out → 491.72 ± 187.2 N

Cortex inferosuperior screw pull-out → 822.16 ± 295.73 N

Cortex superoinferior screw pull-out → 644.14 ± 201.97 N

Cortical inferosuperior and cortical superoinferior trajectories attained **67%** and **30%** higher pull-out

- **Singkat DA et al.** *Int J Spine Surg.* 2020 Jul 27.

Next steps and recommendations: anchor points and trajectory

Interesting trajectory concepts need more clinical work even though there is a lot of ‘mechanical’ literature already

Can we produce alternative screw trajectory options not mentioned in literature?

4. Augmentation

What do we mean by “augmentation”

1. Expandable screws (discussed in part 1)
2. “Cement”—what cement?
3. Calcium phosphate
4. Calcium apatite
5. Hydroxyapatite

Differing understandings

Fenestrated screws?
Cement then screw?
Volume of cement?
Type of cement?
Level above only?
Vertebroplasty?
Kyphoplasty?

Augmentation

- The worse the osteoporosis, the better the improvement with augmentation.
- The cement-augmented fenestrated pedicle screw was superior biomechanically to the alternative "solid-fill" technique.
- Cement extravasation in as high as 79%.
- The use of cement-augmented fenestrated pedicles decreased screw pull-out and improved fusion rates; however, the clinical outcomes were similar to those with traditional pedicle screw placement.

Yamaan SS et al. *World Neurosurg.* 2020 Nov;143:351−361.

Augmentation

- Screw augmentation increased the pull-out strength by 47%, cycles to failure by 31%, and failure loads by 21% compared with the screw in the original pedicle (P <.05).
- Higher rates or loosening at cranial and caudal ends

Chongyu J et al. *Spine J.* 2019 Aug;19(8):1443−1452.

Augmentation

01

Various augmentation choices

02

Very little comparative data

03

Complications occur, revision strategies limited

04

How do we predict which patients will benefit and need it?

5. SI-Ilium

Additional ilium screws have the highest potential to protect the S1-anchorage. Additional L5/S1-translaminar-screws can increase stability of the lumbosacral junction without bridging the iliosacral joint, whereas lamina hooks showed no significant biomechanical benefit.

Volkheimer D et al. *Clin Biomech.* 2017 Mar;43:34−39.

SI-Ilium fixation: iliac versus S2-iliac

Summary—This is something that we seem to have fairly well figured out.
No real difference in various “techniques”.
Proved to be beneficial with minimal downside.

6. Fusion bed preparation

Could find no literature discussing differences in fusion bed preparation in patients with osteoporosis versus those without osteoporosis.

Pseudarthrosis rates are higher, but no guidance exists how to improve bony fusion.

Summary—No consensus. Huge variability. Big opportunity.

Opportunities target 2: surgical planning and technique

- Develop torque measurement tool and study clinical application
- Design screws for better purchase—expandable vs augmentation (bone, dowels, cement)
- Additional fixation options—hooks, "blades", bands, wiring?
- Study pedicle screw bone trajectories versus osteoporotic bone tolerance
- Soft "tulips"/rod transitions (tapered rod)
- Best graft options in OS fusion? Location and graft type

OSSTF-Target 3

Junctional failure prevention

Christian Mazel
Osmar JS de Moraes

Adjacent level failure

01

Proximal junctional kyphosis (PJK)

Is characterized by increased kyphosis at the upper instrumented vertebra segment

(Glatter Spine 2005)

02

Proximal junctional failure (PJF)

Is the next step that usually requires surgery

Proximal junctional kyphosis

- Radiographic finding with >10º increase of vertebral body kyphosis
- Short-term complication of adult spinal deformity (ASD) surgery
- Not always symptomatic and does not always require additional surgery

Proximal junctional failure

- Clinical presentation with pain, deterioration of balance, and neurological impairment
- Short- to mid-term complication after ASD surgery
- More surgery frequently necessary

Risk factors

- Fixation length
- Sagittal alignment
- Poor bone health
- High BMI
- Age

Fixation length

Proximal junctional kyphosis and proximal junctional failure are common problems after long-segment (>5 levels) thoracolumbar instrumented fusions in the treatment of ASD.

Sagittal alignment

Multifactorial issue, but

Flatback with decrease of **pelvic incidence minus lumbar lordosis (PI-LL) and pelvic tilt (PT)**

→ significantly higher risk of PJK

Flatback with increase of **thoracic kyphosis (TK)**

→ significantly higher risk of PJK

Preventing PJK and PJF

Evaluation of stresses in the upper adjacent levels by preoperative finite element analysis of the future instrumentation

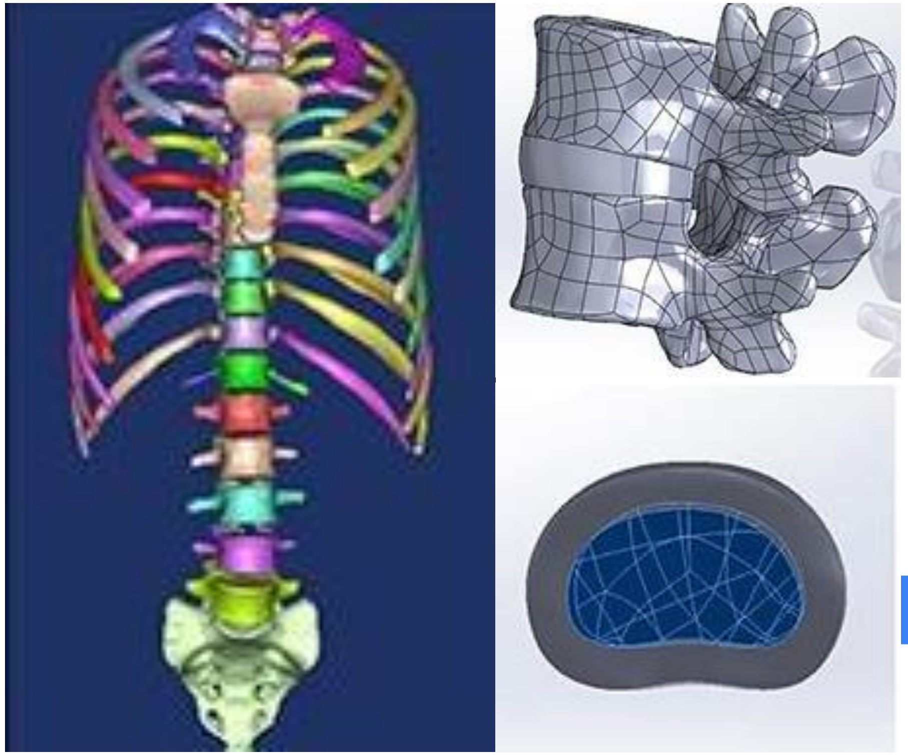
Initial set-up and experience by

Osmar JS de Moraes (Sao Paulo)

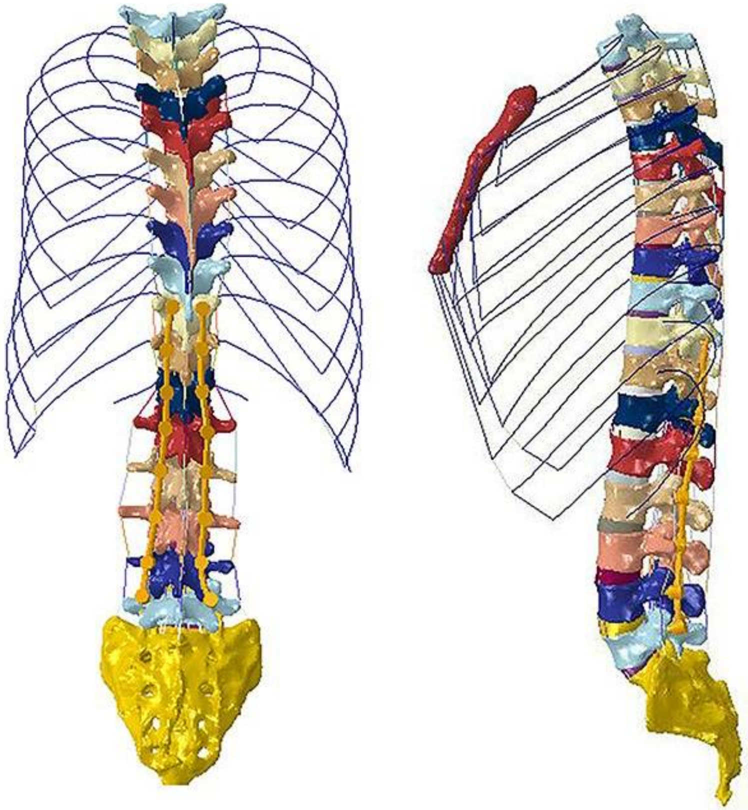
Construction of geometric models

- Computed tomography images imported into Mimics software (Materialise, Belgium)
- Vertebral bodies segmented according to the different gray-scale values of the vertebral bone and surrounding tissue
- 3D reconstruction using 2D imaging data of the segmented vertebral bodies to produce T1-S1 3D geometric models

Reconstructed Model of T1-S1



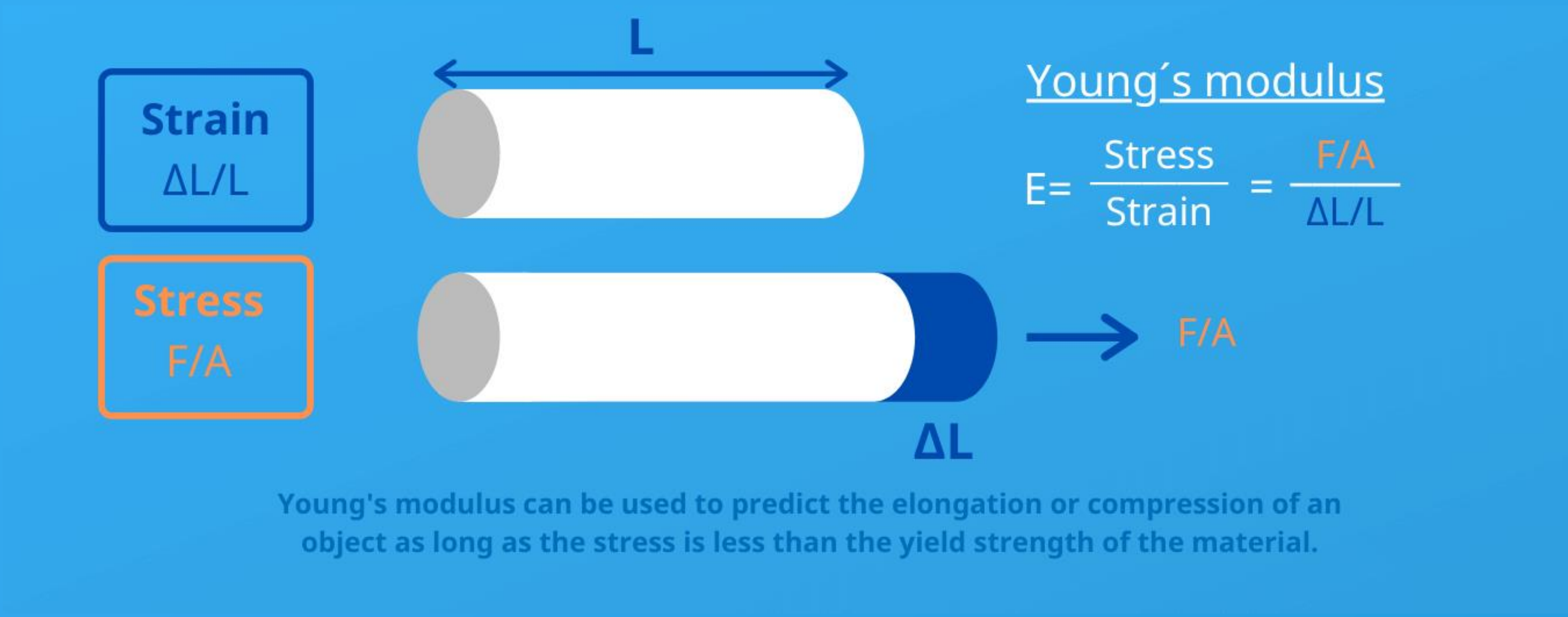
+ Ribcage, ligaments, and discs

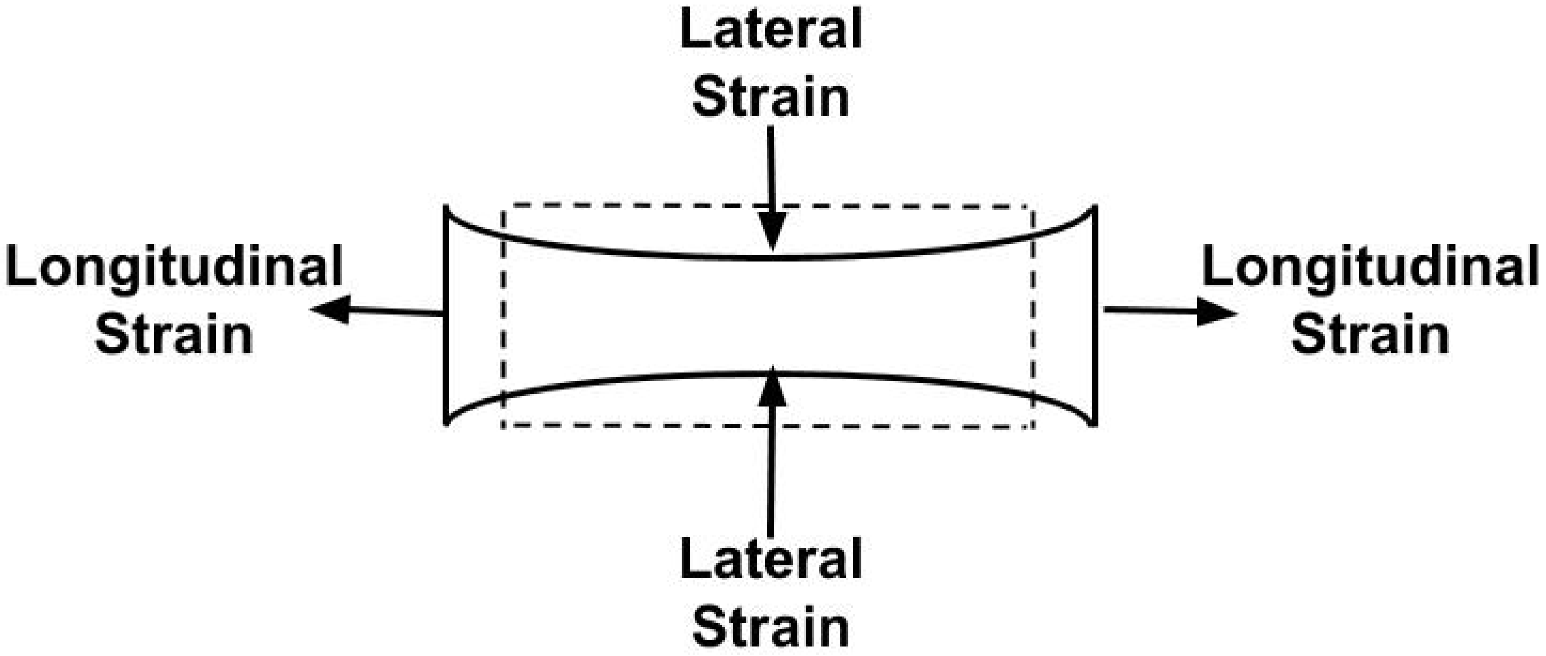


Material properties used in the model

Component	Young's modulus, MPa	Poisson's ratio	Cross-section, mm^2
Cortical bone	12,000	0.3	
Cancellous bone	100	0.2	
End plate	3,000	0.25	
Anterior longitudinal	15		40
Posterior longitudinal	10		20
Ligamentum flavum	8		30
Interspinous	10		40
Ligamentum flavum	15		40
Intertransverse	10		1.8
Capsular	7.5		30
Nucleus pulposus	1.0	0.499	
Annulus fiber	4.2	0.45	
Fusion mass (Ti)	110,000	0.28	

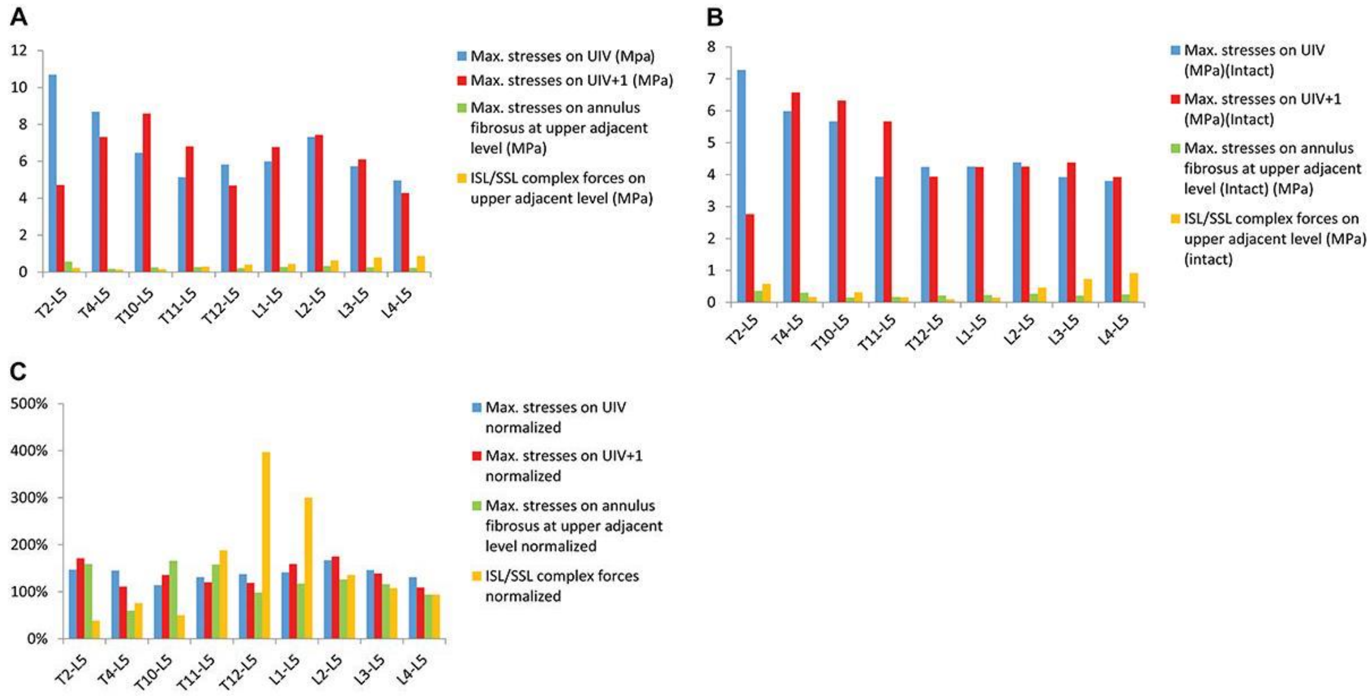
Young’s modulus



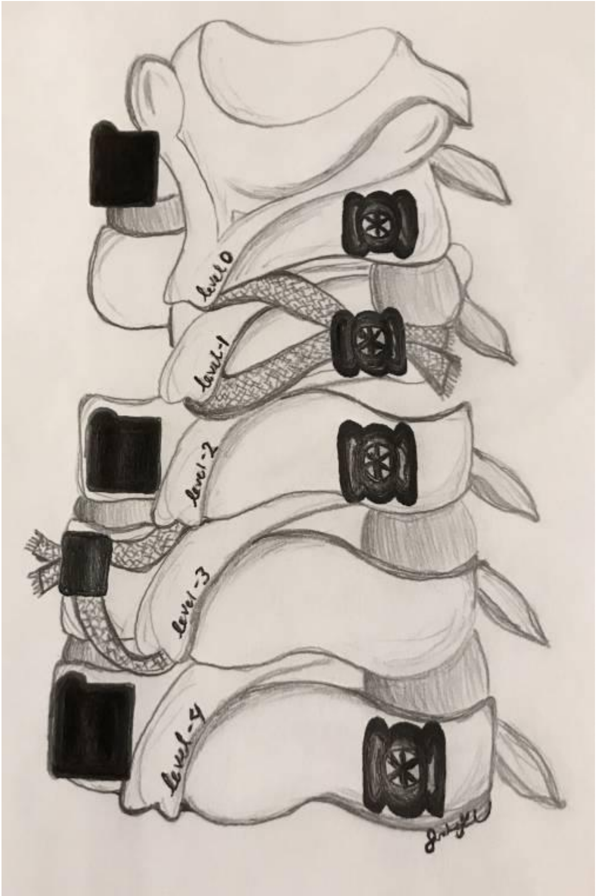


$$\text{Poisson's Ratio} = \frac{\text{Lateral Strain}}{\text{Longitudinal Strain}}$$

Stresses at upper end of different constructs



Example of top ending of construct



Selection of nine fusion models and comparison of the maximum von Mises stresses on the pedicle screw

Fusion model	Max. screw stress, MPa
T2-L5 fusion	106.50
T4-L5 fusion	48.14
T10-L5 fusion	45.50
T11-L5 fusion	44.68
T12-L5 fusion	42.66
L1-L5 fusion	49.97
L2-L5 fusion	48.71
L3-L5 fusion	47.59

Opportunities using construction of geometric models

New materials for reinforcement

Expandable screws

Local measure of pressure/axial load using cheap chips

Mechanical models suitable for clinical practice

Next steps

Proposal by Osmar de Moraes

Feasible technique, not expensive and reproducible in ASD surgery group

- Build a tool to prevent PJF?
  Customized? Algorithm planning?
  Better construction/screws/anterior support size?

Surgical strategy

No specific surgical strategy has definitively shown to lower the risk of PJF as the result of a multifactorial etiology.

Different technical options:

- Rod stiffness
- Prophylactic polymethylmethacrylate (PMMA) augmentation
- Bands, tethers, and ligaments
- Soft-landing solutions

Rod stiffness

The use of CoCr rods is effective in ensuring stability of the posterior spinal construct and accomplishment of spinal fusion. Furthermore, **results indicate that junctional kyphosis may occur more frequently in CoCr systems than in Ti systems.**

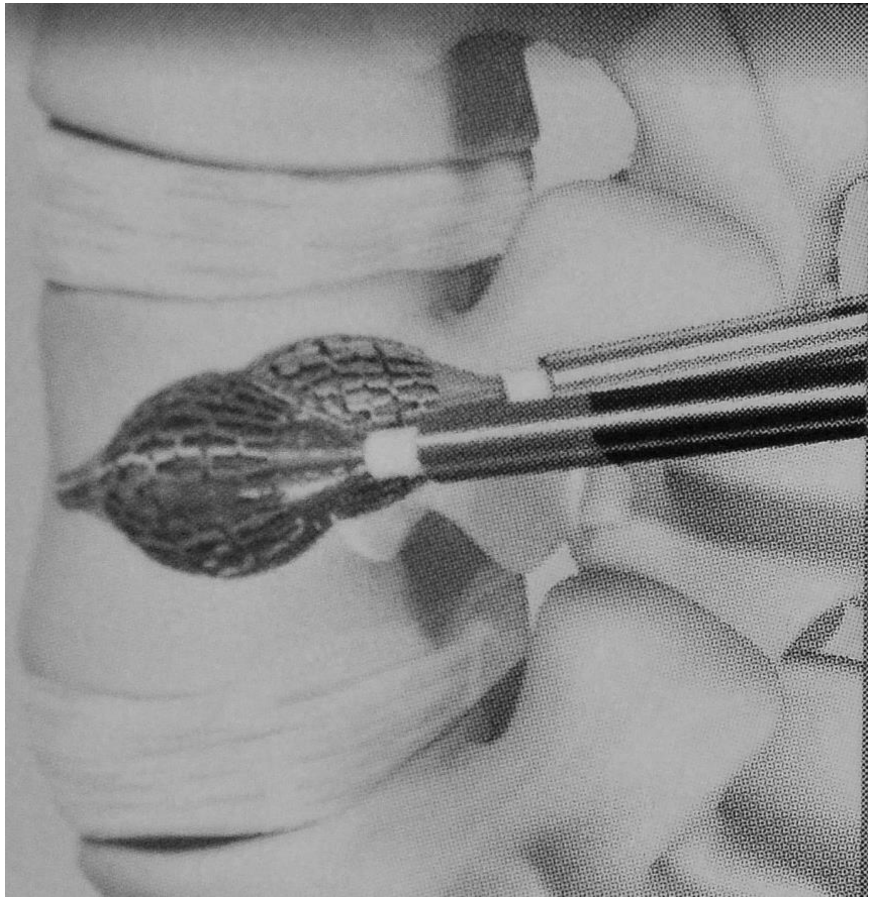
Increasing the rod stiffness by using CoCr rods can prevent **rod breakage** but adversely **affect the occurrence and the time of PJK.**

Prophylactic PMMA cement augmentation

- Aim is to decrease the incidence of PJK and PJF in patients treated with prophylactic PMMA cement augmentation at the uppermost instrumented vertebrae (UIV) and rostral adjacent vertebrae (UIV+1)
- Is one of the most popular solutions today
- Needs cannulated and perforated screws
- Drawback—PMMA leaks

Upper level PMMA supplementation

- Stent
- Vertebroplasty
- Kyphoplasty



Bands tethers ligaments

Sublaminar band placement has been suggested as a possible technique to prevent PJK and PJF but carries the theoretical possibility of a paradoxical increase in these complications as a result of the required muscle dissection and posterior ligamentous disruption.

Soft-landing solutions

Aim

Avoid excessive stress at the instrumentation level upper part of the construct and at the non-instrumented upper levels

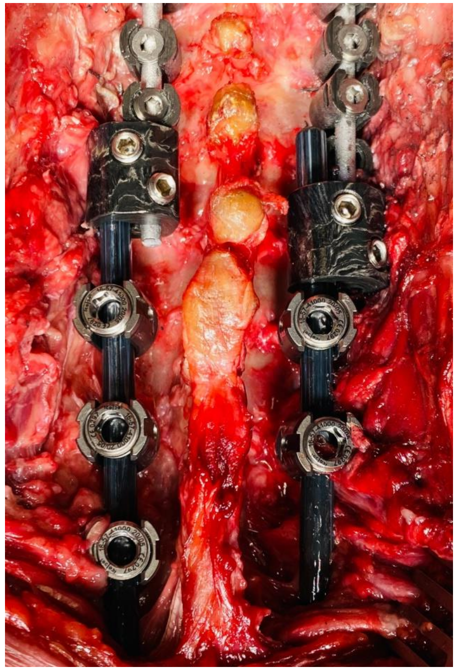
Solutions

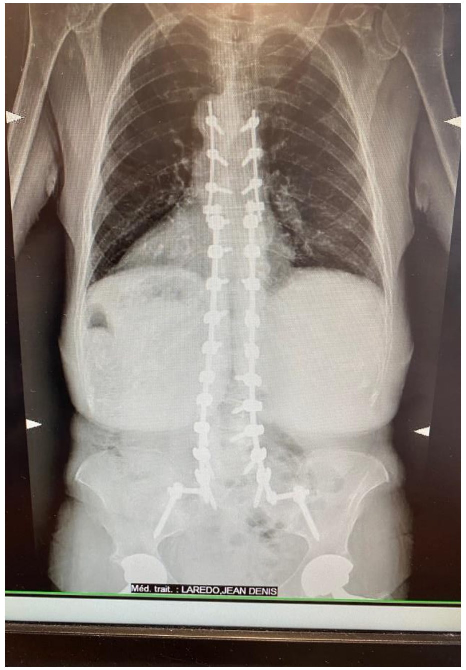
- Less rigid rods
- Change of rod diameter at upper part of instrumentation
- Flexible device at upper part of instrumentation

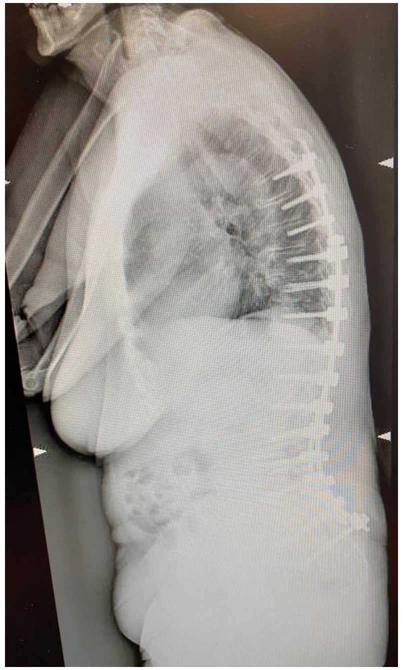
Two different diameter rods at the upper level

Option 1:

3.5 mm diameter proximal Ti rod instrumentation and 5.5 mm thoraco lumbar rod instrumentation connected with dominos end-to-end or lateral/lateral



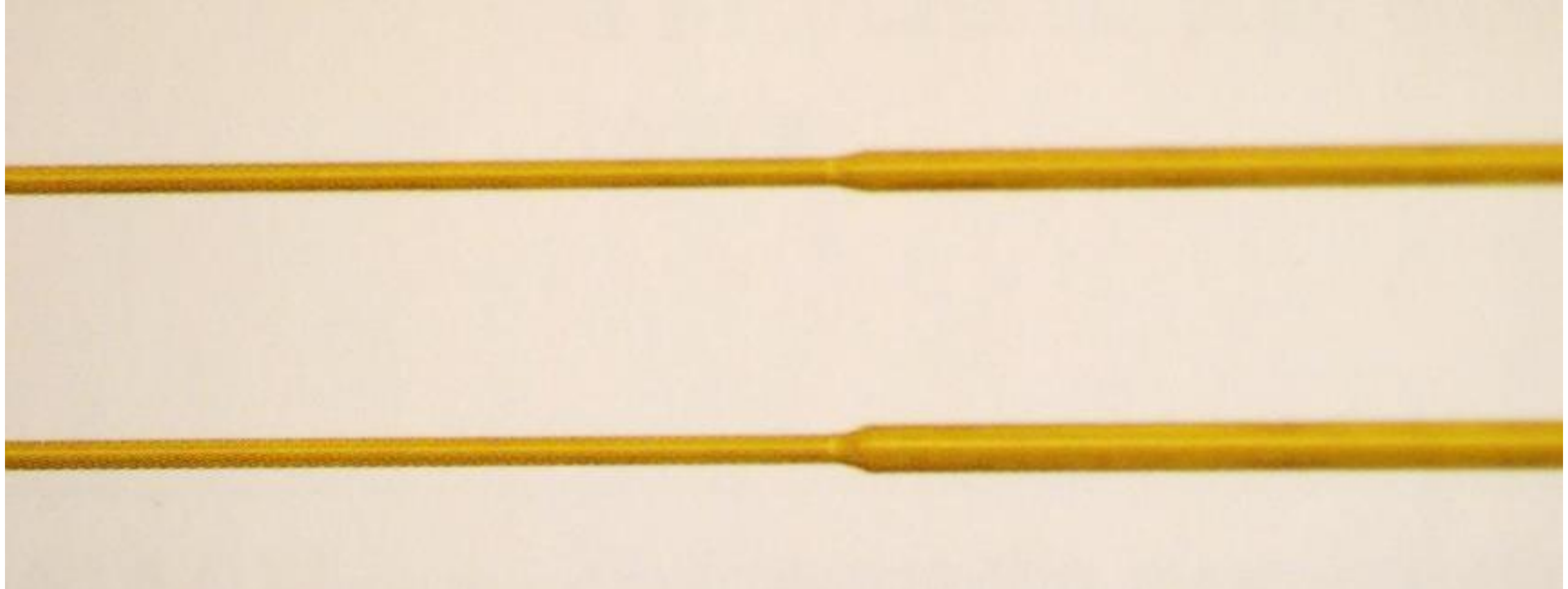




Two different diameter rods at the upper level

Option 2:

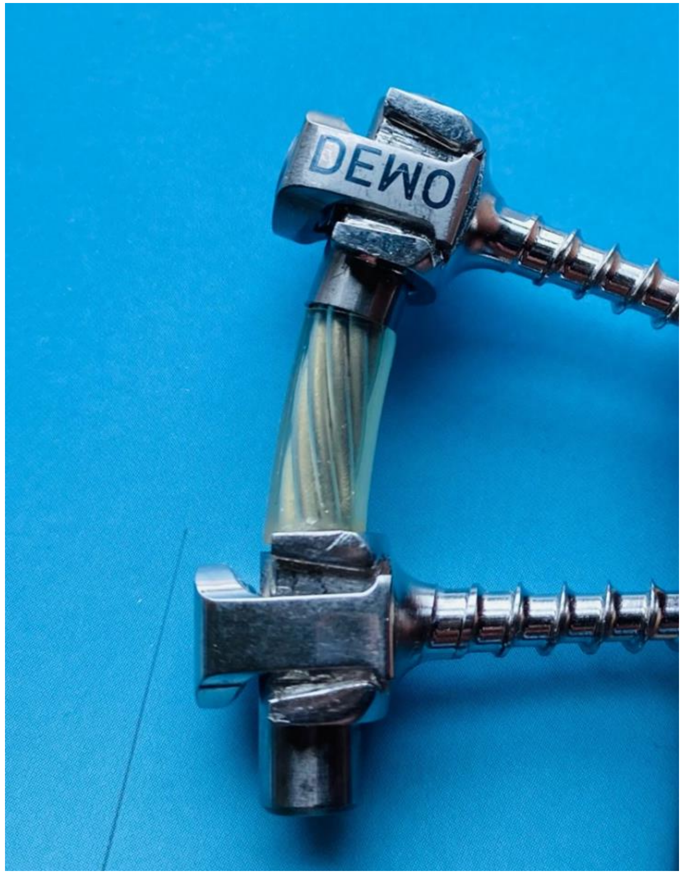
Rod with two different diameters 3.5–5.5 mm



Upper levels flexible devices

Option 1:

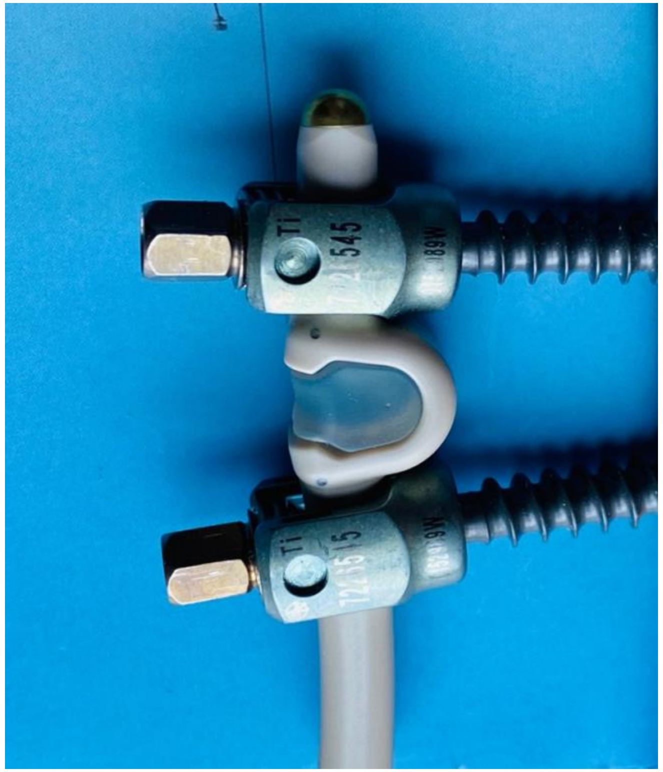
Cable

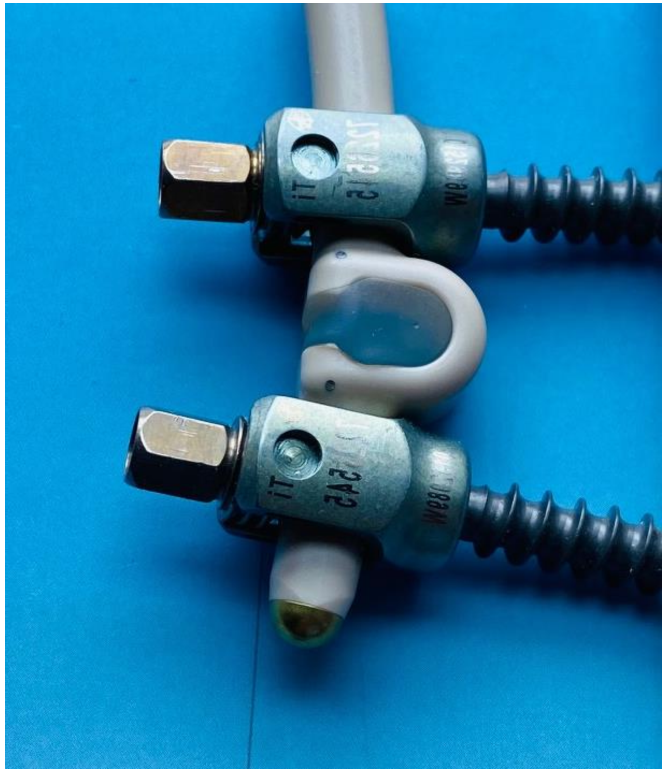


Upper levels flexible devices

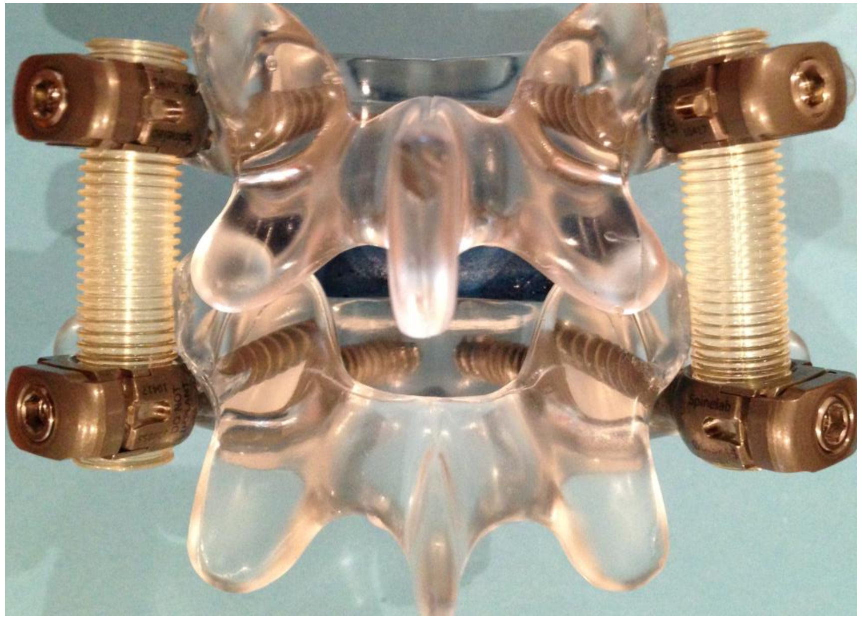
Option 2:

Bumper





Other flexible devices



Achievements: Osteoporotic Spine Surgery Task Force

Recommendations for:

- Which surgical patients aged 50 years or older need bone quality assessment with what investigations
- Surgical Risk Category Algorithm
- Medical management of osteoporosis in surgical patients

Surgical planning and technique: Literature standards, recommendations, and opportunities for further research and development

Junctional kyphosis and failure prevention: standards from literature, preoperative implant stress evaluation at upper end of long constructs, and opportunities for development for soft-landing devices

References not in slides are collected in Mendeley database

AO Technical Commission

Thanks AO ITC for the support

Contact: M Spruit, MD, AO TC Spine Chairperson

AO