AO Technical Commission

AOTC Osteoporotic Spine Surgery Task Force (OSSTF)
Task Force Members

Maarten Spruit
Nijmegen
Chairperson

Rick Bransford
Seattle

Christian Mazel
Paris

Izzy Lieberman
Dallas

Osmar Moraes
Sao Paulo

Jean Ouellet
Montreal

Kota Watanabe
Tokyo

Qian Bangping
Nanjing
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.
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

Risk factor assessment
- Prior fracture at or after age 50 years (hip, spine, pelvis, femur, humerus)
- Known osteopenia/osteoporosis
- Taking oral steroid >7.5 mg
- Radiographic osteopenia and/or old, asymptomatic compression fracture (as defined by orthopedic surgeon)
- Fracture risk assessment tool (FRAX) for major osteoporotic fracture (MOF) ± bone mineral density (BMD) ≥ 20%

Yes

Refer for further investigations* with fracture liaison service / as per local guidelines

Low - moderate risk

High risk

Very high risk

No

Schedule surgery

Treat with antiresorptive** or anabolic** and consider surgical delay

Treat with anabolic** if possible and strongly consider surgical delay

* See Table 1
** See Table 2

Flowchart provided by Neil Binkley, University of Wisconsin, USA
# Risk classification and treatment

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

### 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)

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

NB: Most guidelines may recommend more advanced tests depending on the local context or type of clinic.
References (Table 1)


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


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

<table>
<thead>
<tr>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical pilot hole size 71.5% of pedicle diameter</td>
</tr>
<tr>
<td>Small diameter hole + tap versus non-tapping: no clear yes or no</td>
</tr>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

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 $\rightarrow 491.72 \pm 187.2$ N

Cortex inferosuperior screw pull-out $\rightarrow 822.16 \pm 295.73$ N

Cortex superoinferior screw pull-out $\rightarrow 644.14 \pm 201.97$ N

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

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.

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

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.

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 $>10^\circ$ 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Young's modulus, MPa</th>
<th>Poisson's ratio</th>
<th>Cross-section, mm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical bone</td>
<td>12,000</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Cancellous bone</td>
<td>100</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>End plate</td>
<td>3,000</td>
<td>0.25</td>
<td></td>
</tr>
<tr>
<td>Anterior longitudinal</td>
<td>15</td>
<td></td>
<td>40</td>
</tr>
<tr>
<td>Posterior longitudinal</td>
<td>10</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>Ligamentum flavum</td>
<td>8</td>
<td></td>
<td>30</td>
</tr>
<tr>
<td>Interspinous</td>
<td>10</td>
<td></td>
<td>40</td>
</tr>
<tr>
<td>Ligamentum flavum</td>
<td>15</td>
<td></td>
<td>40</td>
</tr>
<tr>
<td>Intertransverse</td>
<td>10</td>
<td></td>
<td>1.8</td>
</tr>
<tr>
<td>Capsular</td>
<td>7.5</td>
<td></td>
<td>30</td>
</tr>
<tr>
<td>Nucleus pulposus</td>
<td>1.0</td>
<td>0.499</td>
<td></td>
</tr>
<tr>
<td>Annulus fiber</td>
<td>4.2</td>
<td>0.45</td>
<td></td>
</tr>
<tr>
<td>Fusion mass (Ti)</td>
<td>110,000</td>
<td>0.28</td>
<td></td>
</tr>
</tbody>
</table>
Young’s modulus can be used to predict the elongation or compression of an object as long as the stress is less than the yield strength of the material.
Poisson’s Ratio = \frac{Lateral Strain}{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

<table>
<thead>
<tr>
<th>Fusion model</th>
<th>Max. screw stress, MPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2-L5 fusion</td>
<td>106.50</td>
</tr>
<tr>
<td>T4-L5 fusion</td>
<td>48.14</td>
</tr>
<tr>
<td>T10-L5 fusion</td>
<td>45.50</td>
</tr>
<tr>
<td>T11-L5 fusion</td>
<td>44.68</td>
</tr>
<tr>
<td>T12-L5 fusion</td>
<td>42.66</td>
</tr>
<tr>
<td>L1-L5 fusion</td>
<td>49.97</td>
</tr>
<tr>
<td>L2-L5 fusion</td>
<td>48.71</td>
</tr>
<tr>
<td>L3-L5 fusion</td>
<td>47.59</td>
</tr>
</tbody>
</table>
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