

Preliminary experience with the use of  
*pedicle screws and flexible bar*  
for the treatment of lumbar spinal  
diseases.

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OSPEDALE DI RELIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE

**MIG-Roma**

# Starting point

- The elimination of motion produced by rigid spinal fixation may have consequences:
  1. overloading juxtaposed spinal motion segments (*functional consequences*);
  2. leading to degenerative changes at adjacent levels (*organic consequences*).

# Background

- Adjacent segments degenerative disease to instrumented levels has sparked increasing interest over the last years.
- In order to prevent degenerative disc changes at segments adjacent to fused levels several techniques have been developed, including **pedicle screw fixation with flexible bars** (*semi-rigid dynamic rods*).

# Our “flexible” fixation series

- 36 cases (*10/2009 - 12/2013*)
  - 16 segmental instability with LowBackPain
  - 11 severe lumbar stenosis
  - 2 stenosis with instability
  - 4 A1-A2 lumbar fractures (pts with degenerative disease)
  - 2 mild listhesis with instability

# Osteoporosis

- The incidence of screw loosening increases significantly in patients with severe osteoporosis.
- Biomechanical tests have shown that a pedicle screw that expands within the vertebrae body can substantially improve fixation in the presence of osteoporotic bone.

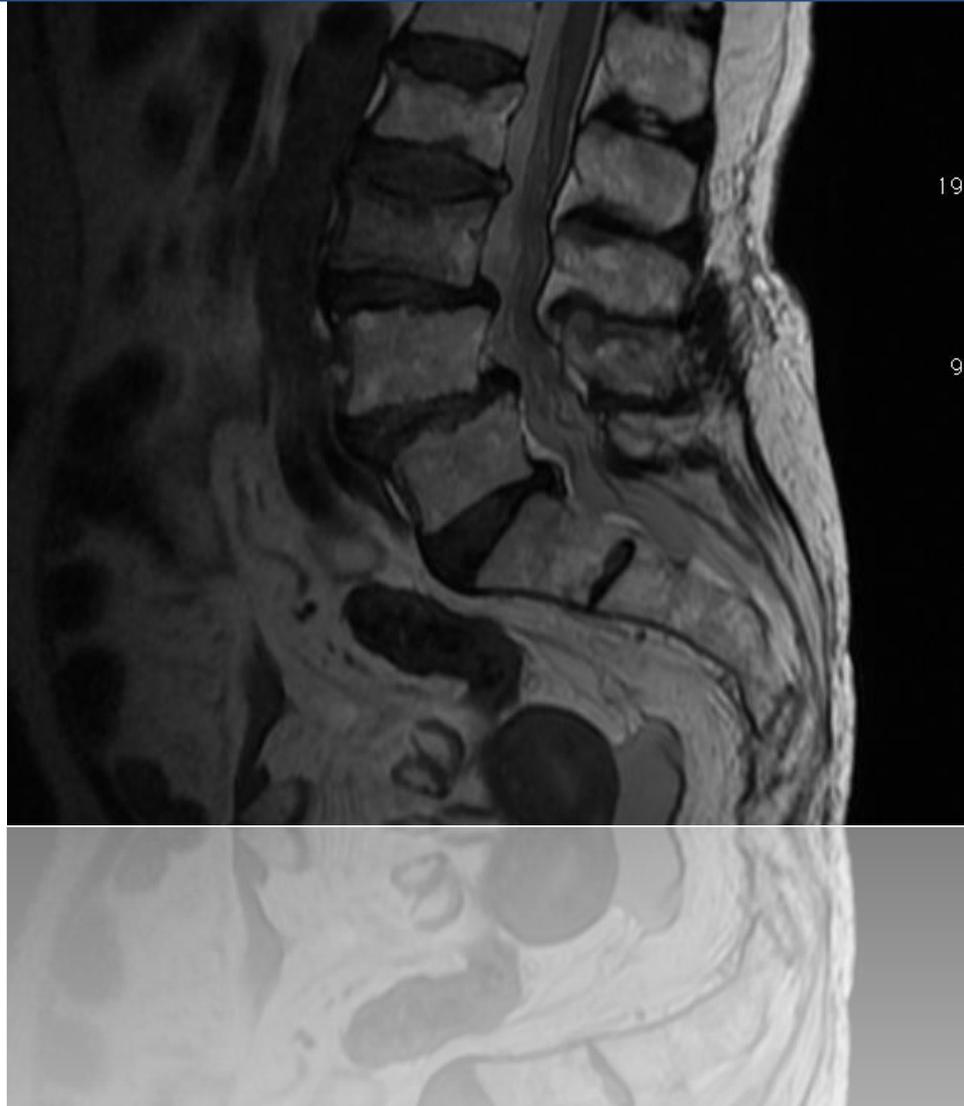
# Osteoporotic series *(5/2012 – 12/2013)*

## Material & Methods

- **15 patients** with lumbar diseases
  - 13 Stenosis +/- Degenerative Lysthesis
  - 2 Traumatic Fractures
- pre-operative DEXA bone mineral density scan (BMD) mean T-score of -2,5
- Adjacent Segment Disease in all cases

# Osteoporotic series

## Typical case



# Technique

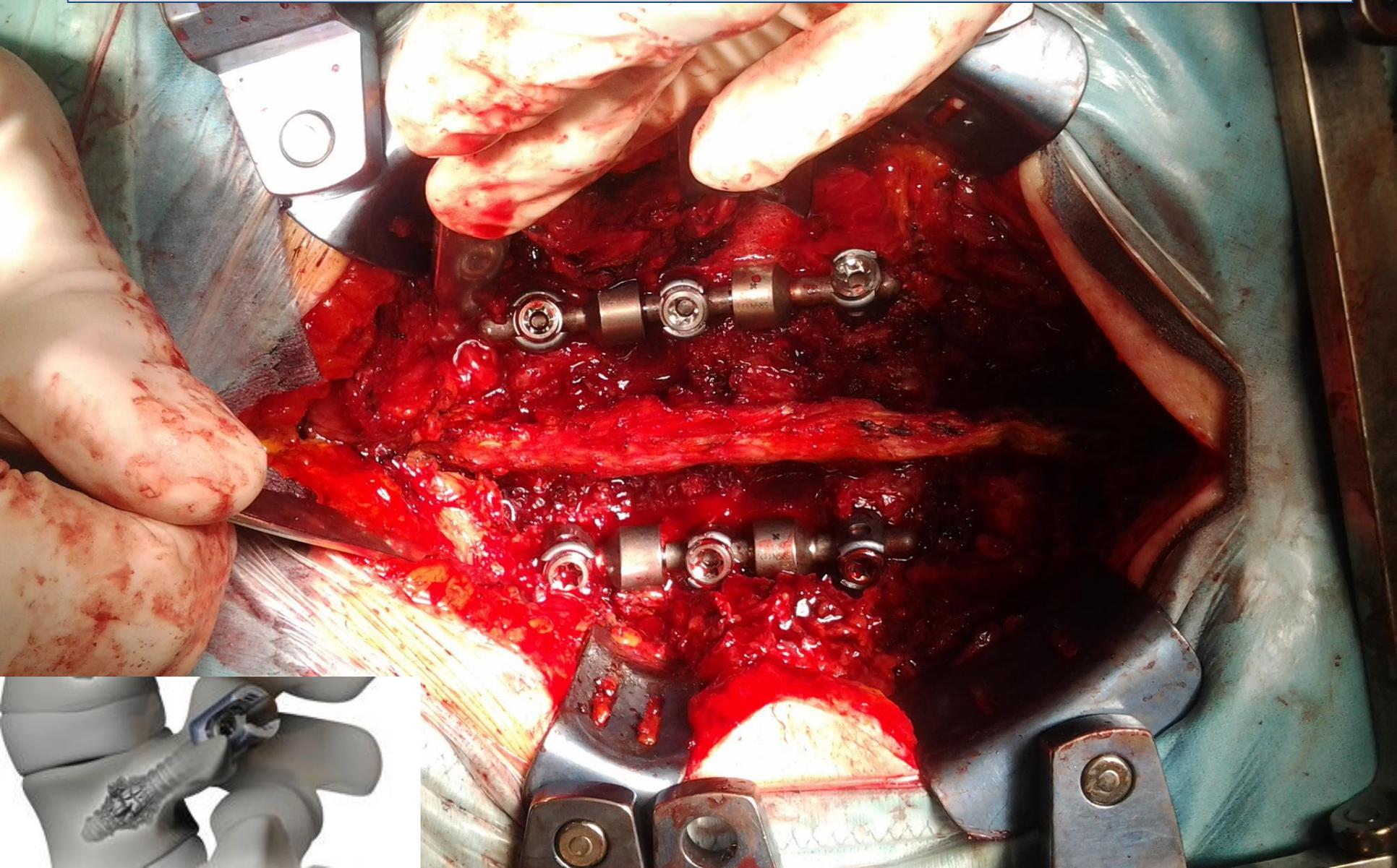
- decompression: laminectomy and/or foraminotomy  
(except for the fractures)
- two or three-level stabilization with

expandable pedicular screws (*Osseoscrew*)

&

semi-rigid dynamic rods (*Isobar Evolution*)

# Technique: Osseoscrew + 2-level Isobar Evolution (Scient'x Aphatec)



# Complications

- Two cases of incidental CSF leakage (unrelated to the devices), both in patients with severe stenosis and lysis, healed after prolonged subfascial drainage

# Results

in 17 cases with  
7-12 months clinical-radiographic followup

- VAS & ODI markedly improved in all cases.
- Two cases had recurrent low back pain
- No instances of screw loosening, or breakage, or pull-out of the screws
- Good screw-bone interface
- Until now, prevention of degenerative disease above the fixed segments



# Final Considerations

- The **raise of intradiscal pressure** at the adjacent levels consecutive to a rigid instrumented segment can be **reduced** when the rigid construct is augmented with a flexible stabilization device, using **semi-rigid dynamic rods**.

# Final Considerations

- Augmentation with titanium expandable screws may represent an advisable solution in pts with documented severe osteoporosis.

# Proposal

- **Multicenter study group** on the efficacy of Osseoscrew + Isobar Evolution implant in osteoporotic patients with:
  1. Degenerative stenosis +/- listhesis
  2. LBP for degenerative/iatrogenic instability
  3. Mild symptomatic spondylolisthesis
  4. A2 lumbar fracture (open or mini-invasive)
  5. Other?

# Conclusion

- The flexible lumbar constructs might have a **possible protecting role** preventing the occurrence of degenerative disc changes at the adjacent segment also in osteoporotic patients.