DYNAMIC INTERSPINOUS DEVICE: CLINICAL RESULTS AND EXPANDED CLINICAL INDICATIONS

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DISCLOSURE

The authors have no personal financial or institutional interest in the devices described in this presentation

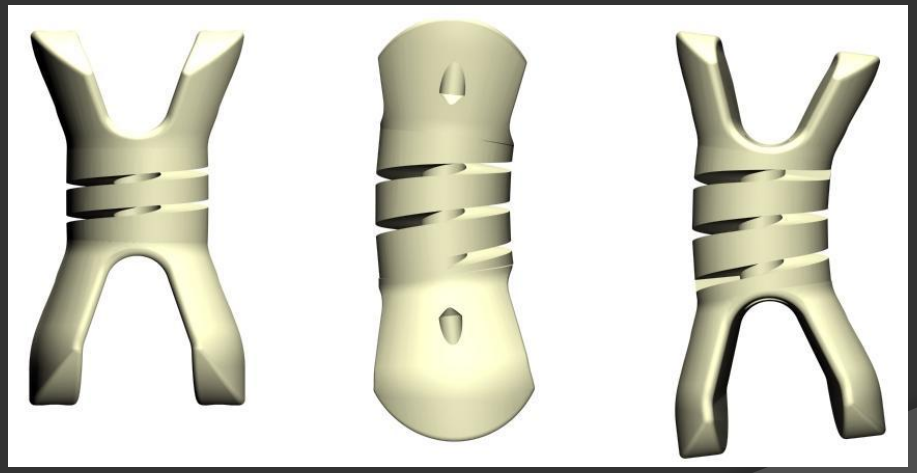
INTRODUCTION

- 1940´s

- Interspinous device
  - percutaneous, MIS, open
  - PEEK, titanium, silicone

INTRODUCTION

- Viking® is a dynamic interspinous device designed to be shock absorver and to provide dynamic stabilization
- PEEK



Compression 2.5 mm | Flexion/Extension 20º | Lateral bending 20º

INTRODUCTION

- Biomechanical effects:
  - unload the facet joints
  - restore foraminal height
  - provide stability (especially in extension)
  - allowing motion

INTRODUCTION - evidence

- Unloads disc pressure

  Zucherman et al. Spine. 2003; 28:26-32

- Randomized study of X-Stop against conservative treatment in stenosis. Superior at 2 years

  Zucherman et al. Spine. 2005; 30: 1351-8

- Results seem maintained at 4 years

  Kondrashov DG et al. J Spinal Disord Tech. 2006; 19: 323-27

INTRODUCTION - indications

- Stenosis with neurogenic claudication
  - Acceptable evidence
- Instability – degenerative spondylolisthesis
  - Biomechanical evidence
- Gross instability – lytic spondylolisthesis
  - No way!

MATERIAL AND METHODS

- Purpose:
  - safety
  - effectiveness
  - validation of new surgical indications

- Retrospective study
- November 2007 to November 2009 (Clínica Neurológica e da Coluna Vertebral)
- 91 interspinous devices (82 patients)
  - 46 interspinous devices (43 patients)

MATERIAL AND METHODS

- Clinical outcomes were recorded with the following scores:

  modified Oswestry low back pain disability questionnaire (m Oswestry) and Visual Analog Scale (VAS), at the following intervals: preoperatively, 6 weeks, 3, 6, 9, 12 ou 24 months

  intra-operative and postoperative complications

  work status

RESULTS

- 46 interspinous devices (Viking®)
- 43 patients, 23 ♀ e 20 ♂
- The average age was 47 (range 13 to 69)
- 40 one level cases, 3 two level cases (46 Viking®)

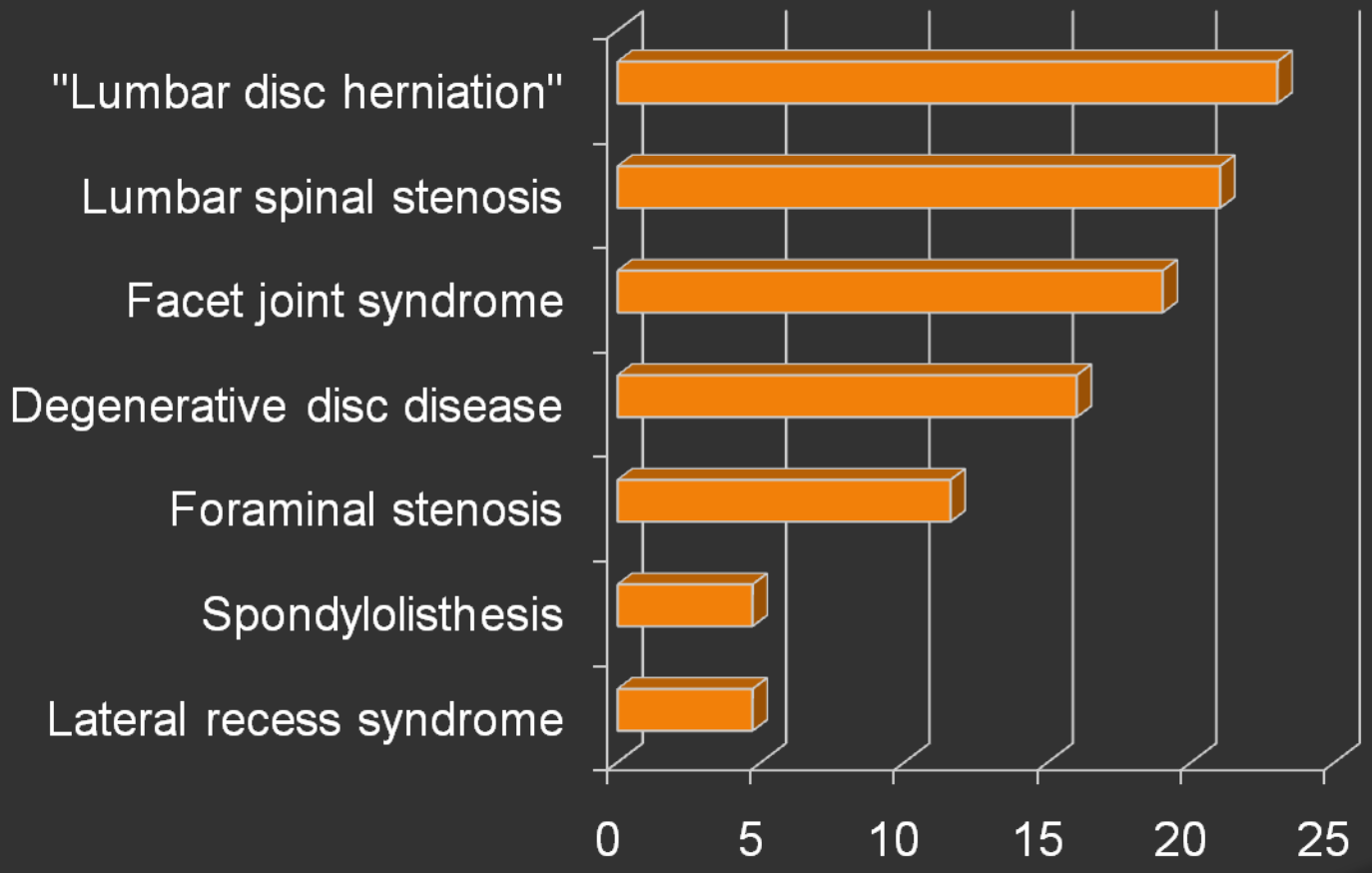
  L3-L4: 5

  L4-L5: 36

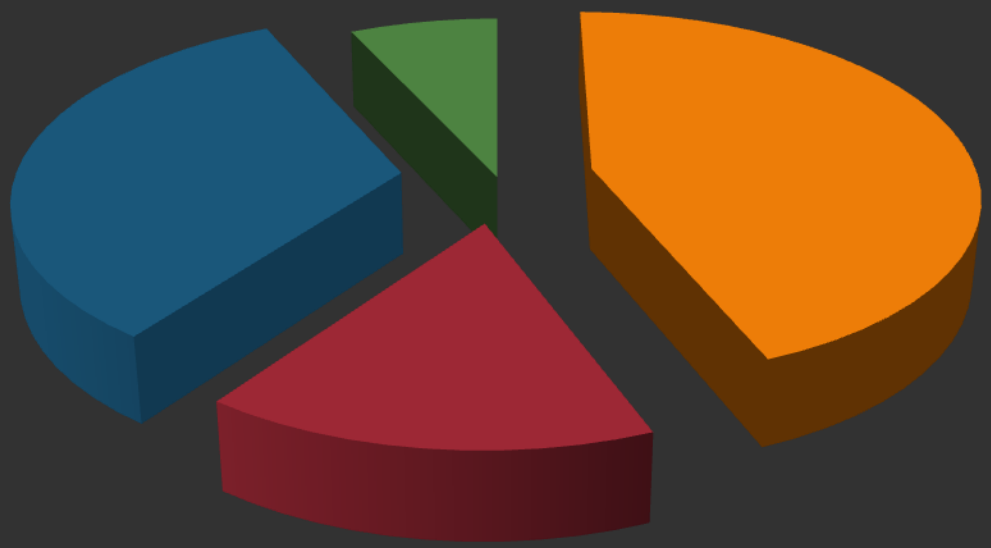
  L5-S1: 5

- No intra-operative or postoperative complications
- The operative time averaged 67 minutes (range 25 to 103 minutes)
- Discharge from hospital averaged 2 days (range 1 to 3 days)
- Average of 11 months follow up (range 6 to 24 months)
- No reoperations

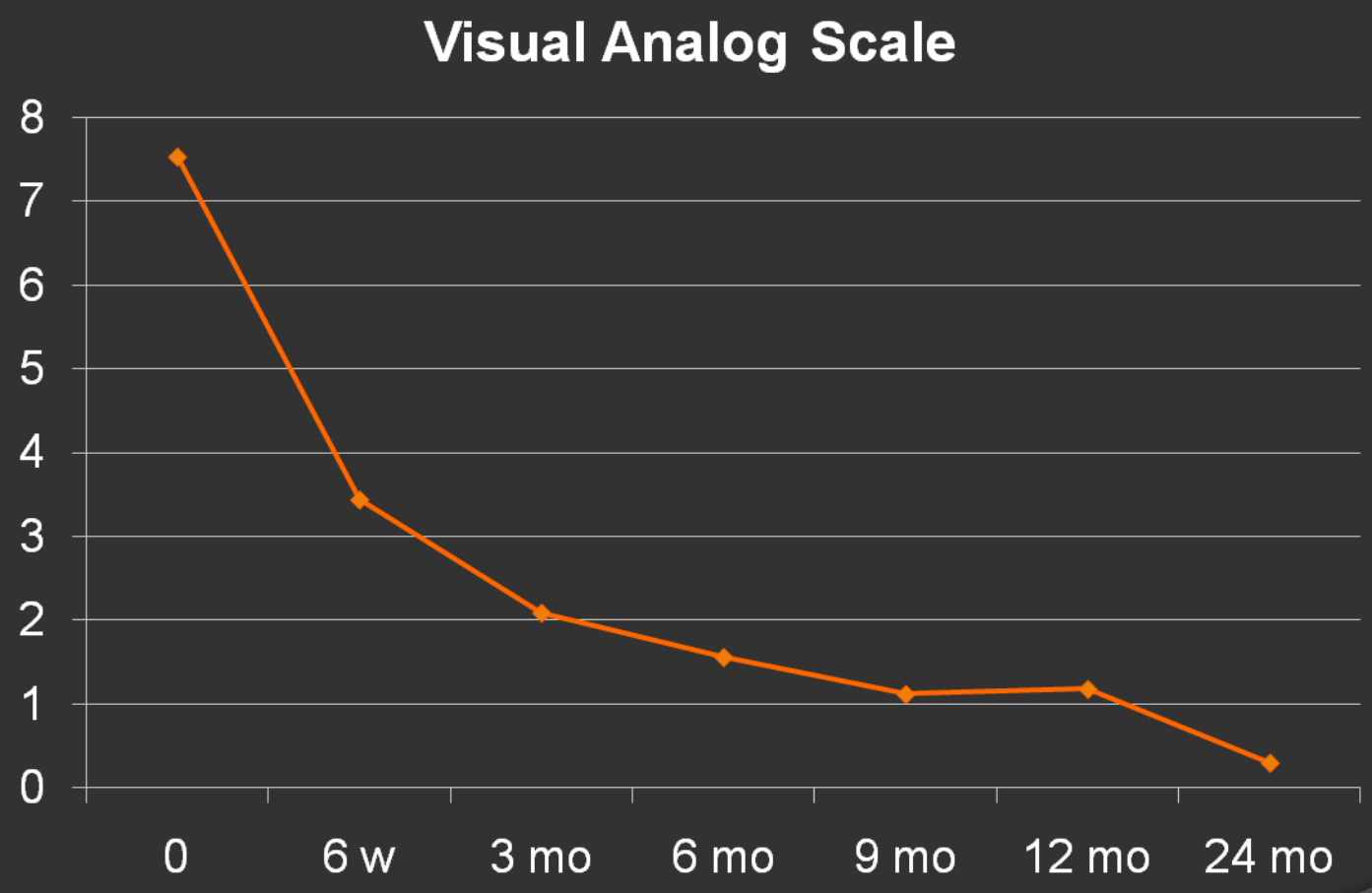
Surgical Indications (%)

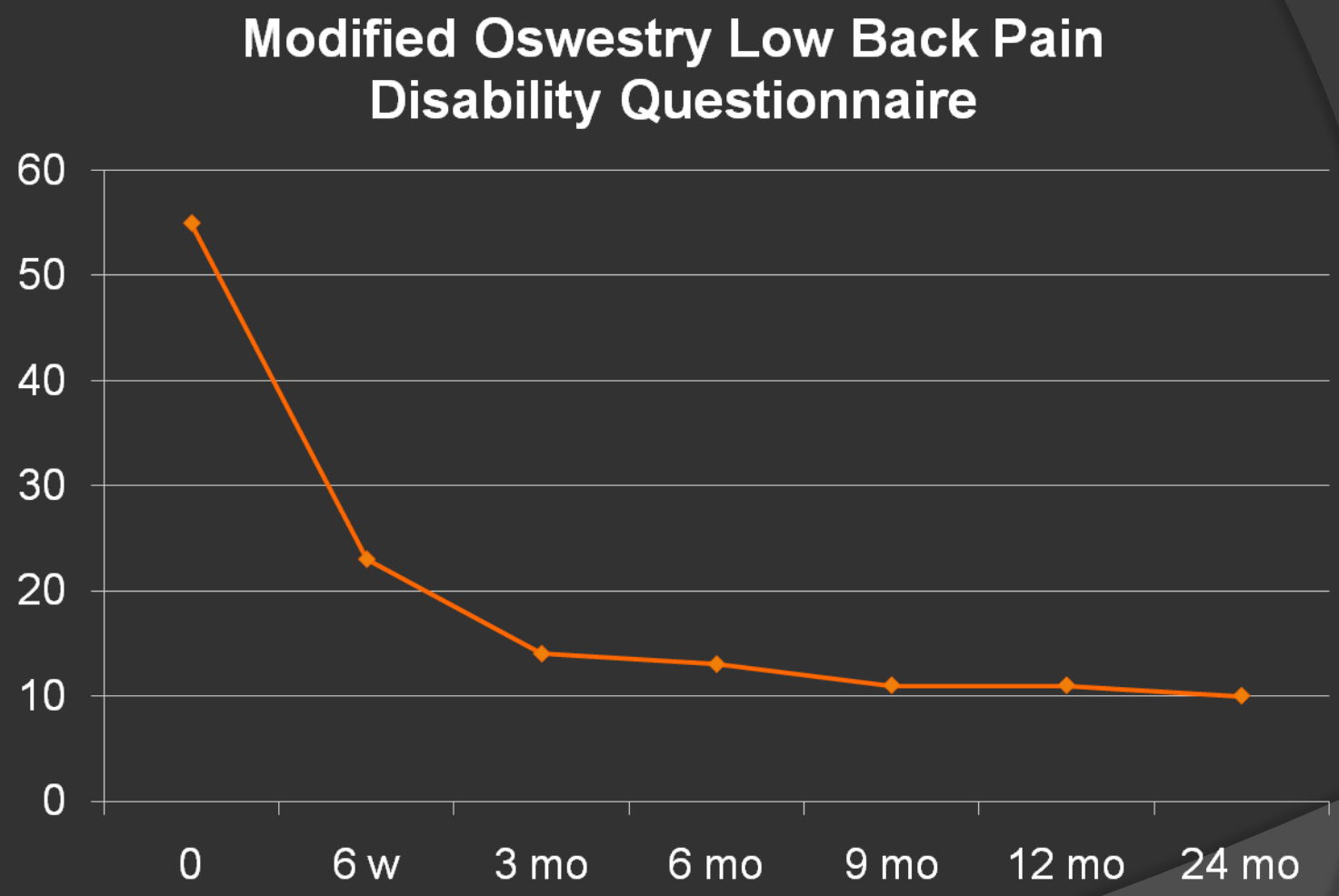


Surgical Approach

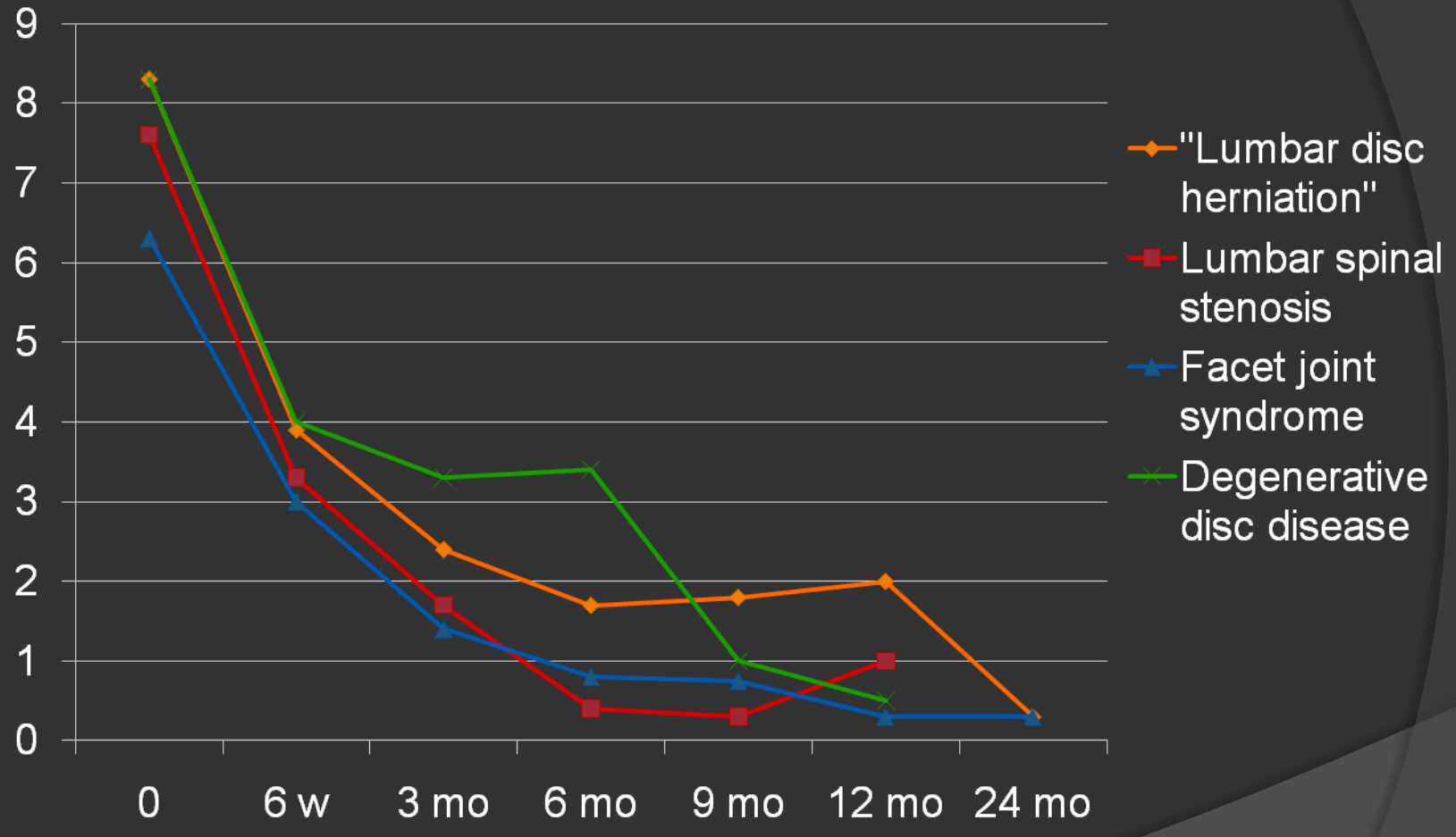


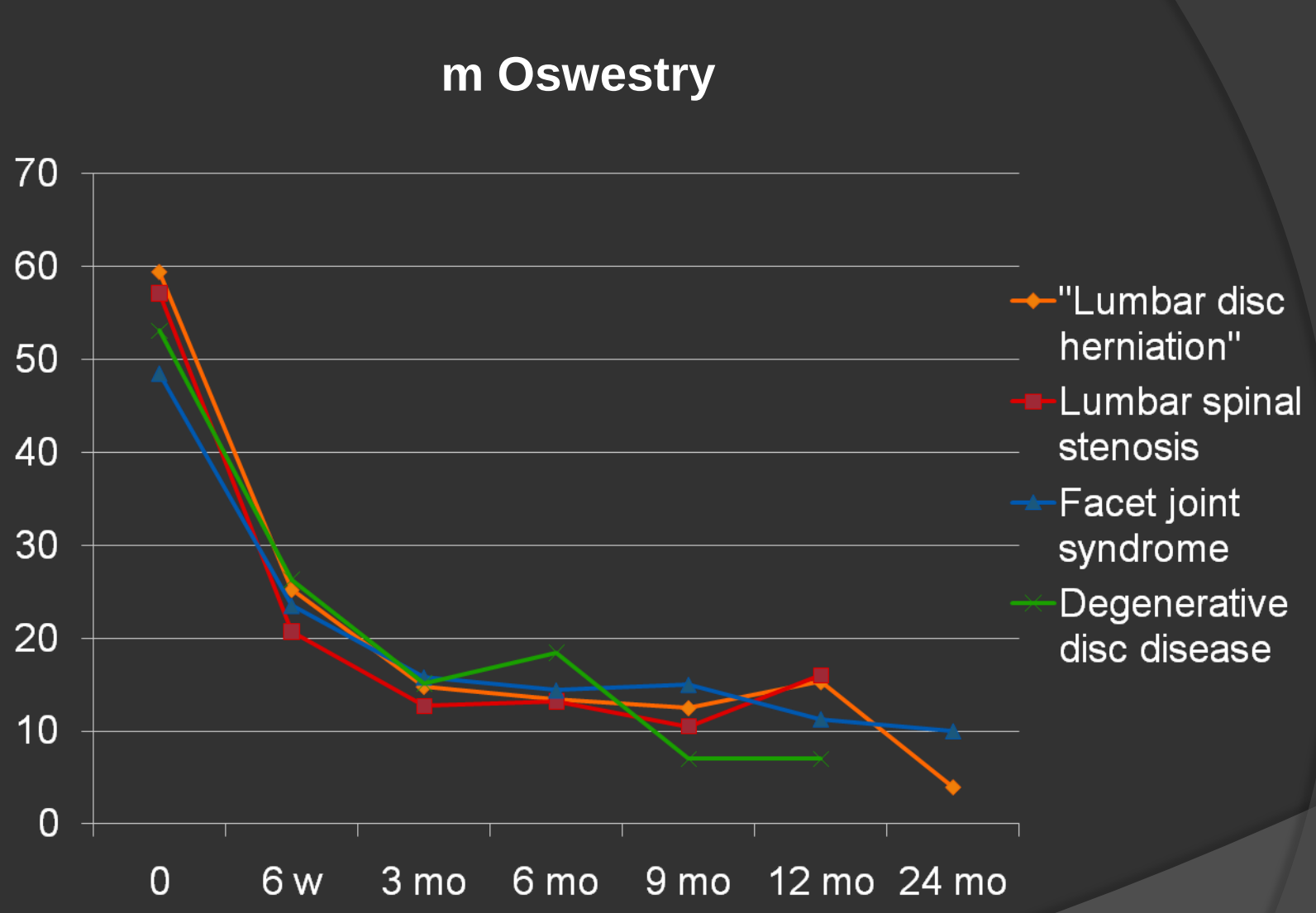
- Interspinous device
- Interspinous device + conservative decompression
- Interspinous device + discectomy
- Interspinous device + fibrosis release


Visual Analog Scale
8
7
6
5
4
3
2
1
0
0
6 w
3 mo
6 mo
9 mo
12 mo
24 mo

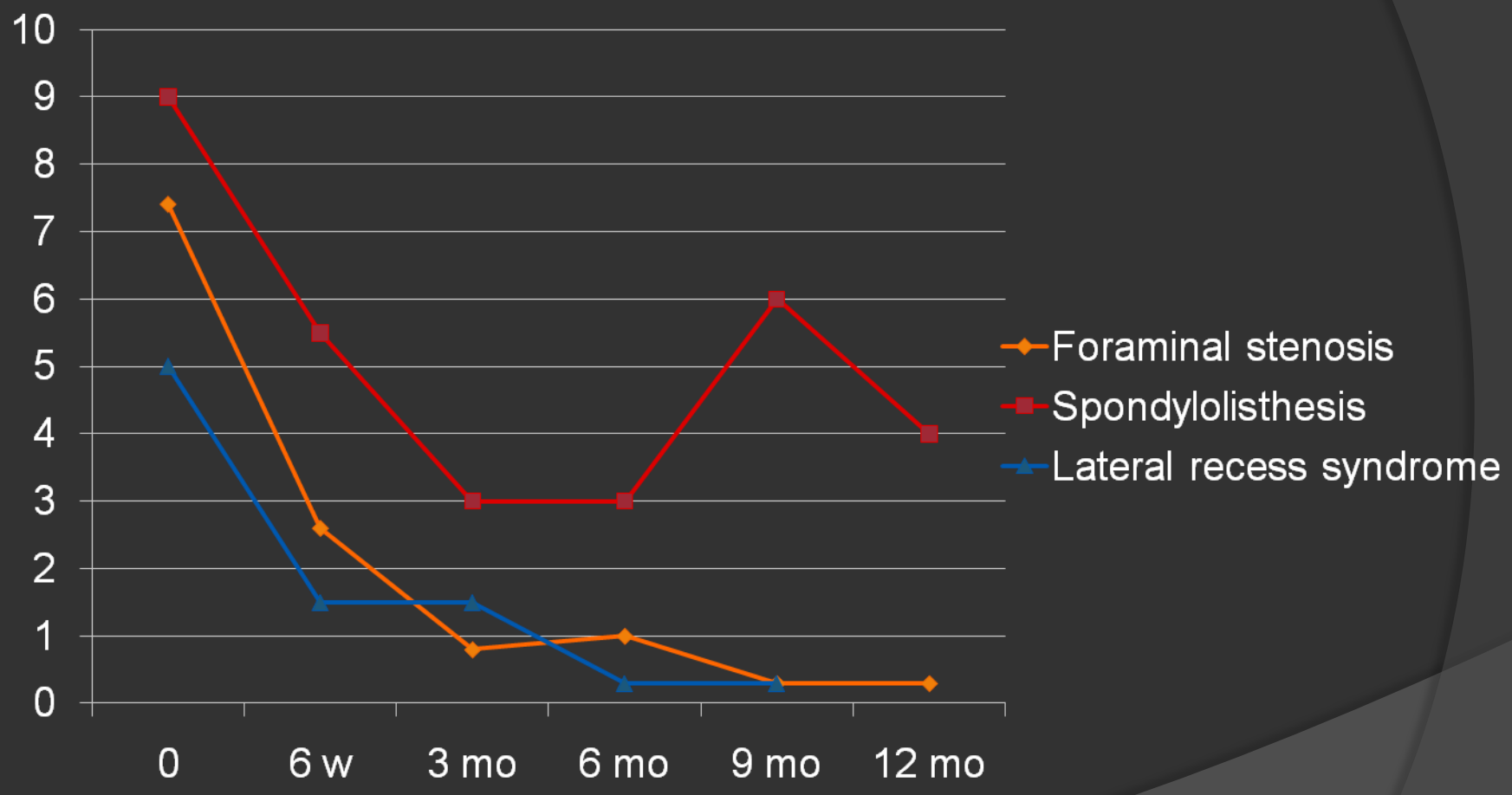

Modified Oswestry Low Back Pain Disability Questionnaire
60
50
40
30
20
10
0
0
6 w
3 mo
6 mo
9 mo
12 mo
24 mo

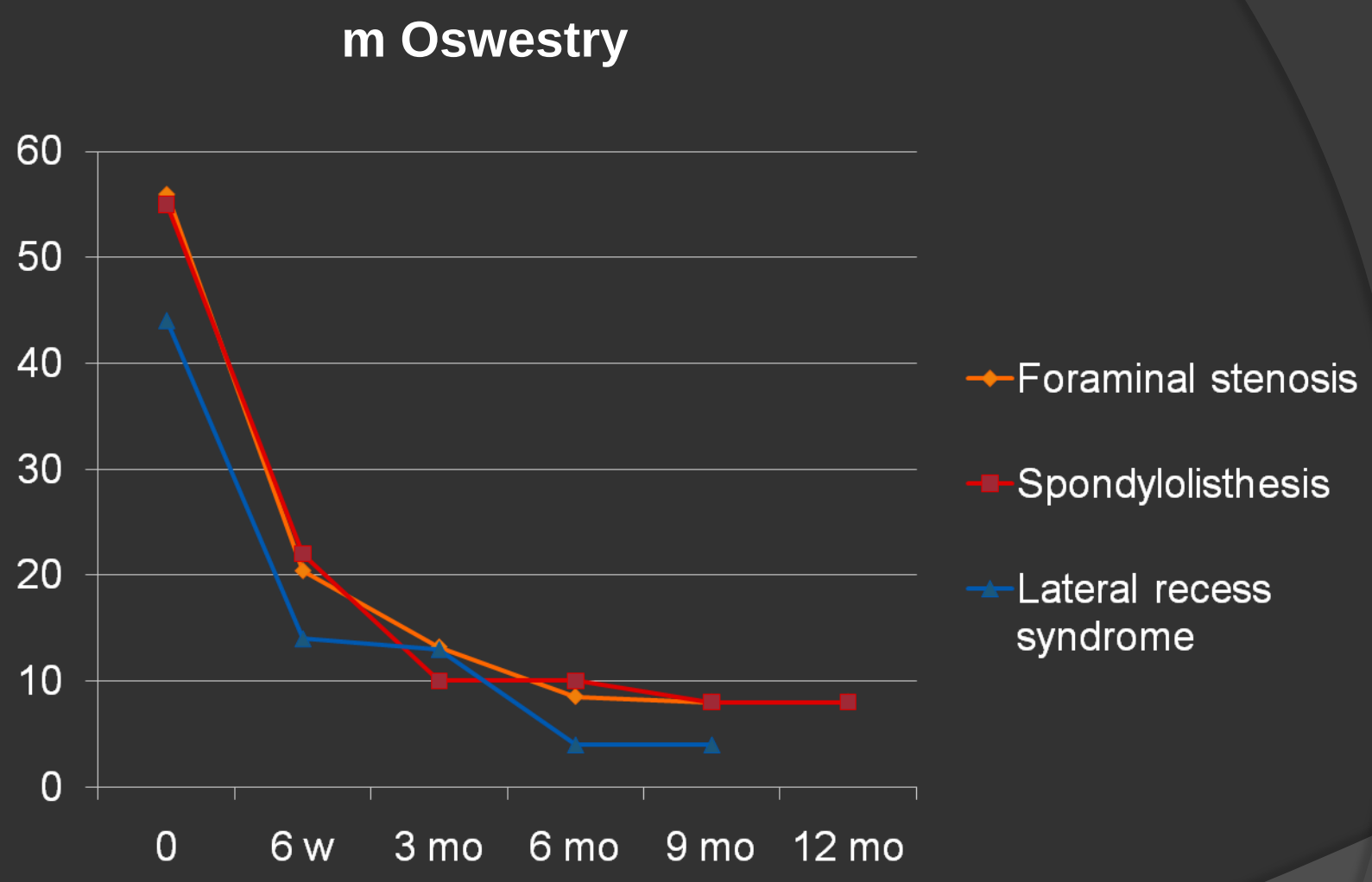
VAS


9
8
7
6
5
4
3
2
1
0
0
6 w
3 mo
6 mo
9 mo
12 mo
24 mo
"Lumbar disc herniation"
Lumbar spinal stenosis
Facet joint syndrome
Degenerative disc disease


m Oswestry
70
60
50
40
30
20
10
0
0
6 w
3 mo
6 mo
9 mo
12 mo
24 mo
"Lumbar disc herniation"
Lumbar spinal stenosis
Facet joint syndrome
Degenerative disc disease

VAS


10
9
8
7
6
5
4
3
2
1
0
0
6 w
3 mo
6 mo
9 mo
12 mo
Foraminal stenosis
Spondylolisthesis
Lateral recess syndrome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60
50
40
30
20
10
0
0
6 w
3 mo
6 mo
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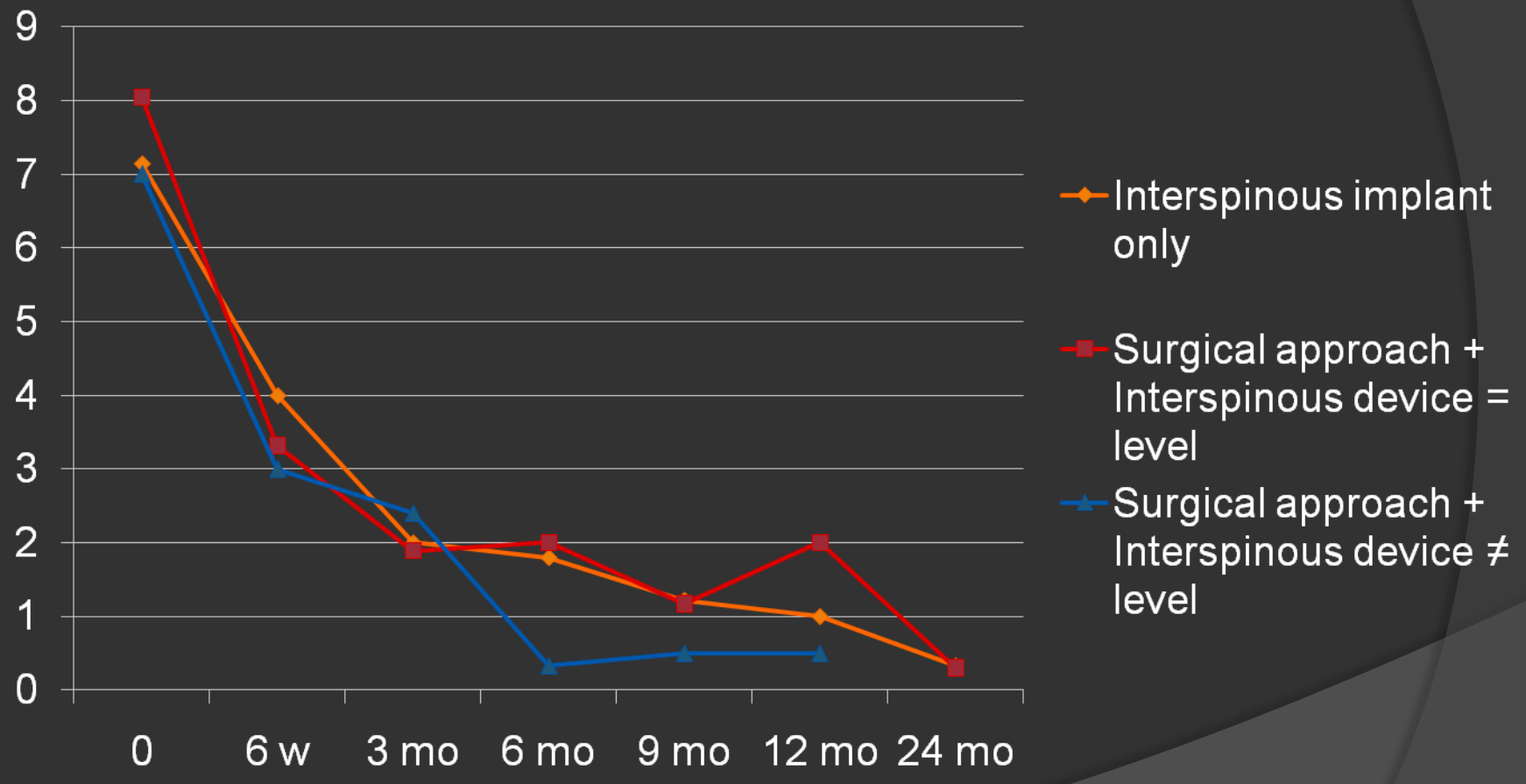
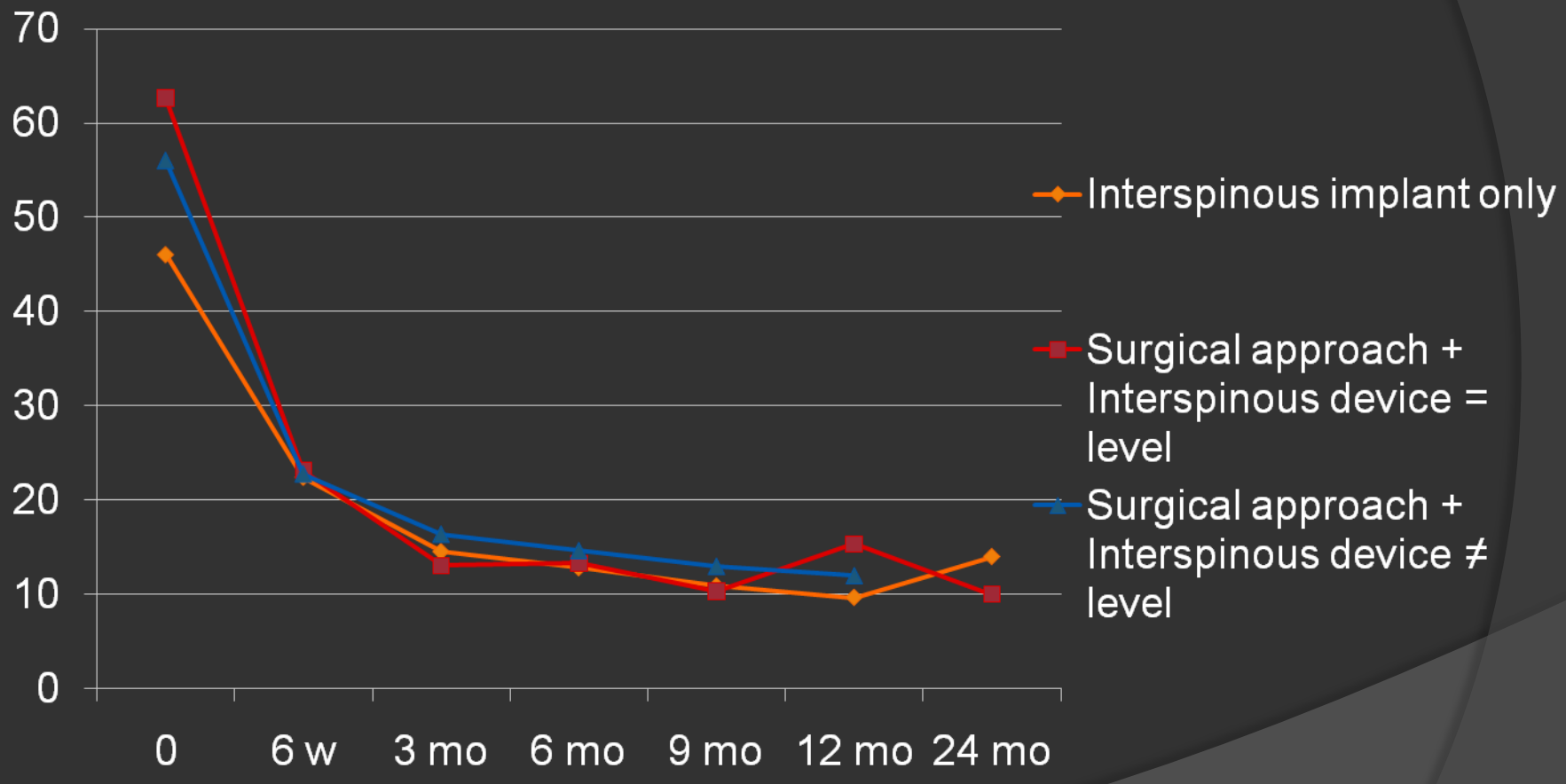
Foraminal stenosis
Spondylolisthesis
Lateral recess syndrome

VAS


9
8
7
6
5
4
3
2
1
0
0
6 w
3 mo
6 mo
9 mo
12 mo
24 mo
Interspinous implant only
Surgical approach + Interspinous device = level
Surgical approach + Interspinous device ≠ level

m Oswestry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30
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0
6 w
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9 mo
12 mo
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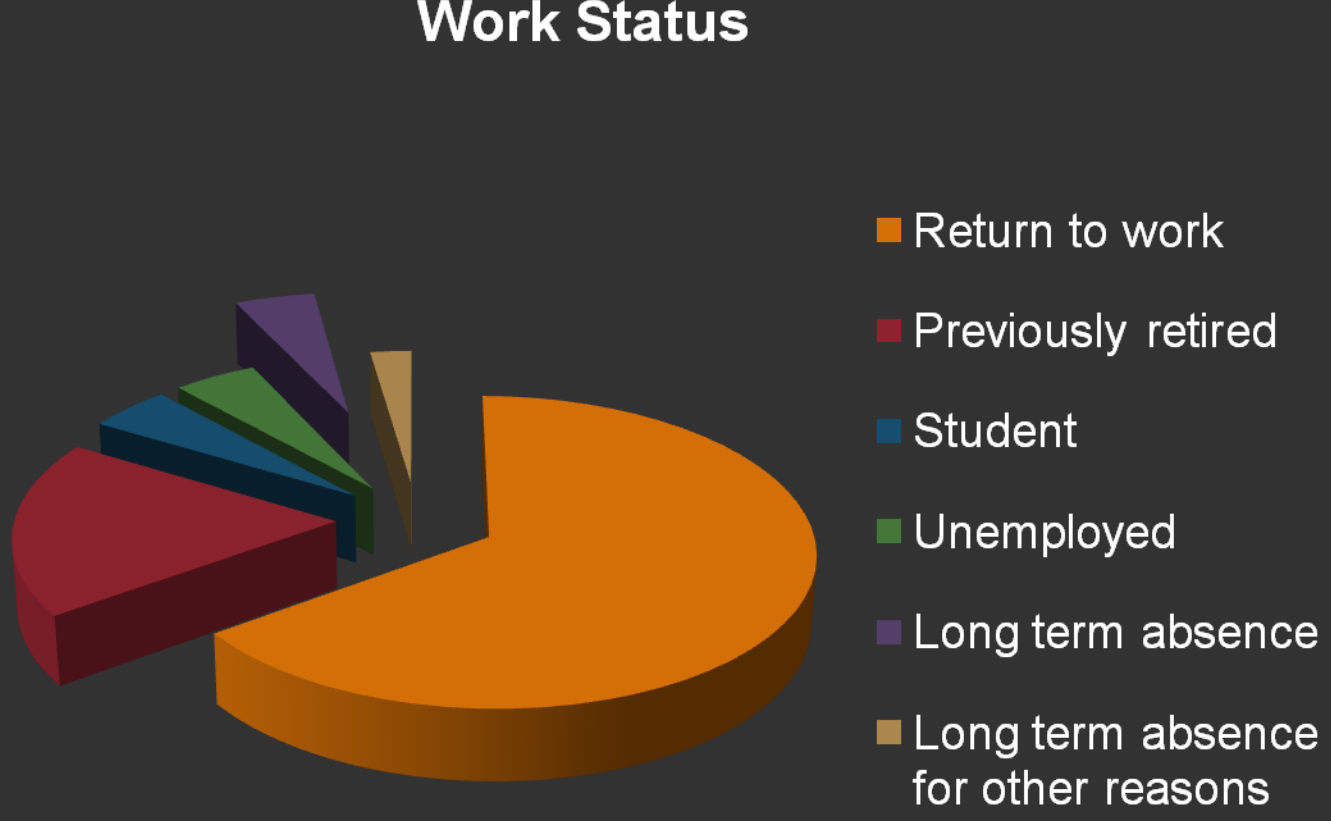
Interspinous implant only
Surgical approach + Interspinous device = level
Surgical approach + Interspinous device ≠ level

Work Status


Return to work
Previously retired
Student
Unemployed
Long term absence
Long term absence for other reasons

CONCLUSIONS

- Interspinous implants are recommended for:
  - central/foraminal spinal stenosis
  - degenerative pathologies of intervertebral disc and facet joints
  - a second discectomy for recurrence of herniated disc
  - discectomy for voluminous herniated disc leading to substantial loss of disc material
  - spondylolisthesis grade I

CONCLUSIONS

- Safe
- Pain relief and function improvement
- Combined surgical approaches
- Lack of complications and reoperations
- Alternative to fusion and disc replacement surgery
- Addicional data and longer term follow up are ongoing


Thank you for your attention