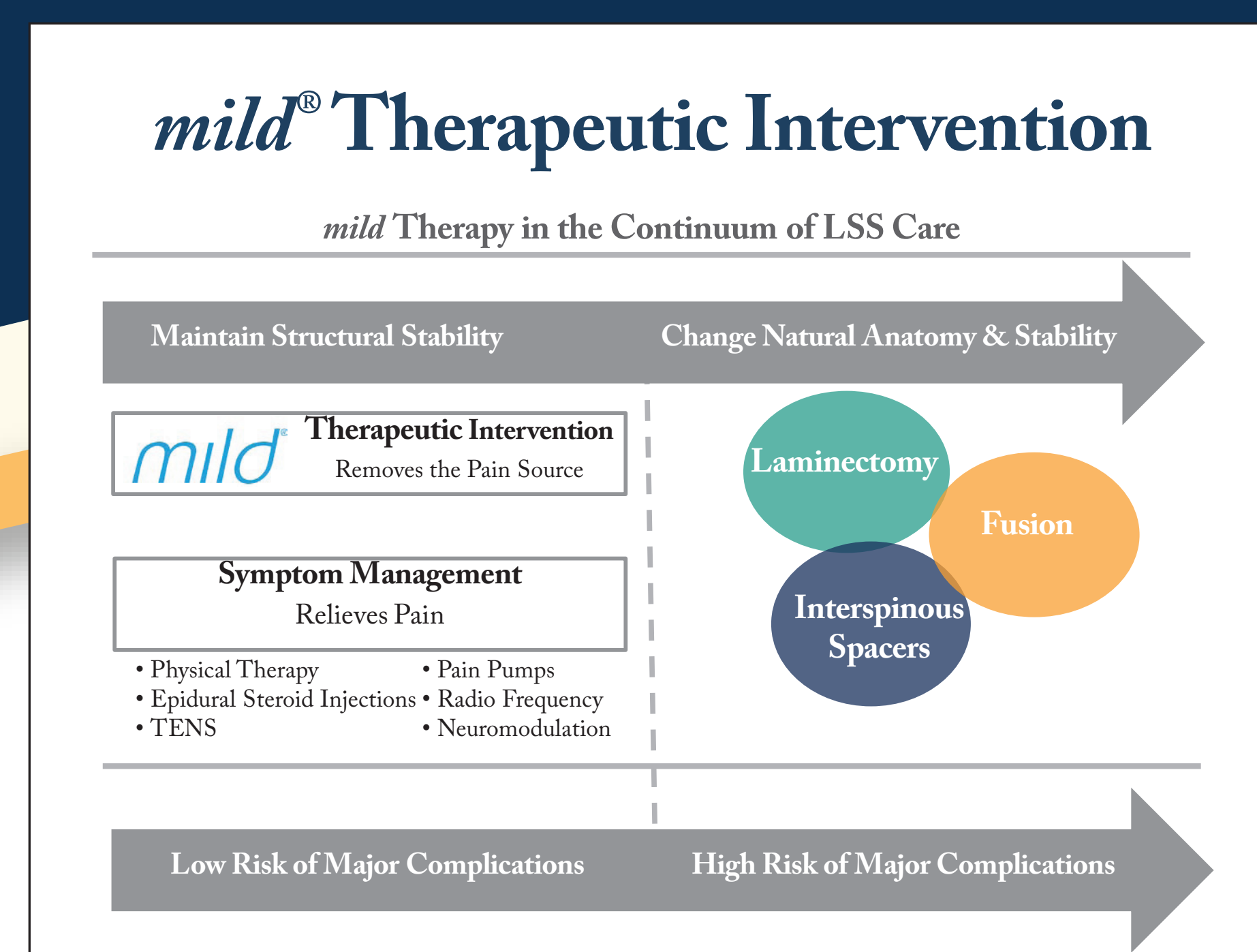


mild[®]: Report of Single-Center Clinical Study Outcomes and Discussion of Patient Selection

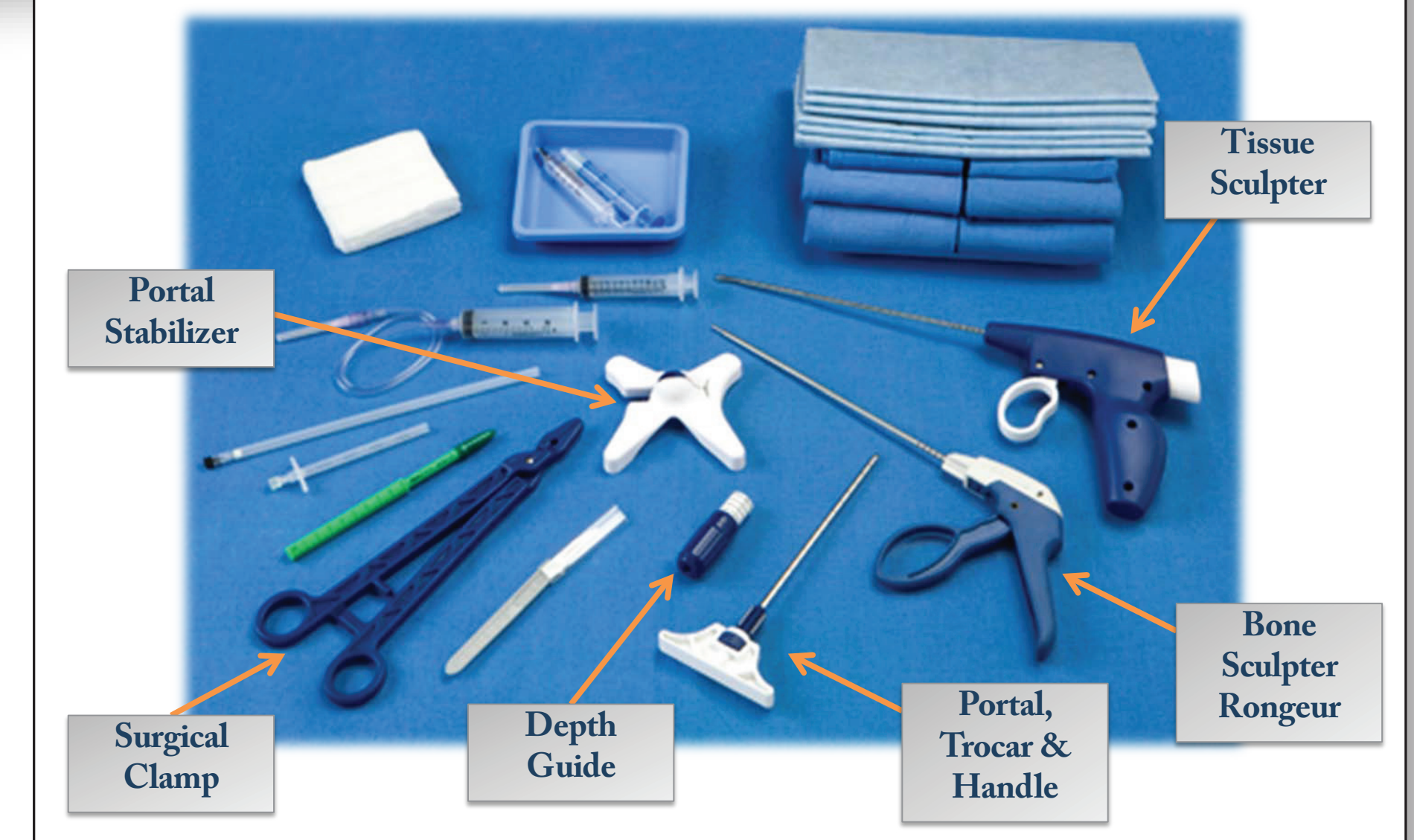
Author:
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mild[®] Procedure Candidates

- Primary Criteria
 - Neurogenic claudication with radiologic evidence of lumbar spinal stenosis
 - Co-morbidities such as osteophytes, facet hypertrophy and disc protrusion are typical.
 - Ligamentum flavum hypertrophy a factor
 - Dural sac cross sectional area reduced, requiring intervention to restore space.
 - Unilateral or bilateral symptomatology.
 - One or more levels of stenosis.

mild[®] Device Kit



Background

Lumbar spinal stenosis (LSS) is a common source of low back pain. *mild*[®] is a commercially-available treatment for pain relief from symptomatic LSS. This procedure uses a dorsal approach with epidurogram and fluoroscopic image guidance to resect bone and tissue. *mild* treatment creates space in the lumbar spine with minimal structural disruption.

Objectives

To present early *mild* patient outcomes in a single-center study and associated patient selection in the treatment of symptomatic LSS.

Methods

Thirty patients have been treated in this Single-Center Study using the *mild* procedure for lumbar decompression. Appropriate patient selection is emphasized and comprehensive safety and Week 6 pain and mobility outcomes are reported. Outcomes are assessed using validated outcomes instruments including Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire, and SF-12v2[®] Health Survey. This interim report includes VAS and ODI outcomes.

Results

Six week results showed significant reduction of pain (overall mean improvement 2.3 points) as measured by VAS. Improvement in physical function and mobility as measured by ODI was significant (overall mean improvement 16.4 points) and clinically relevant. These patient outcomes demonstrated safe, favorable responses to *mild* therapeutic LSS treatment.

Conclusions

The *mild* procedure is a safe method for improving mobility and reducing pain associated with lumbar spinal stenosis, based on six-week follow-up results to date. The profile for *mild* candidates includes those patients having symptomatic neurogenic claudication resulting from multiple co-morbidities, one of which is hypertrophic ligamentum flavum. Study patients will continue to be enrolled and followed for up to two years post-treatment.

mild[®] Procedure Description

- Posterior approach
- Fluoroscopic imaging
- Small *mild*[®] Portal access (6 G, 5.1 mm)
- General anesthesia not required
- No removal of major spinal support structures
- No implants left behind
- Bilateral one-level operative time < 1 hour

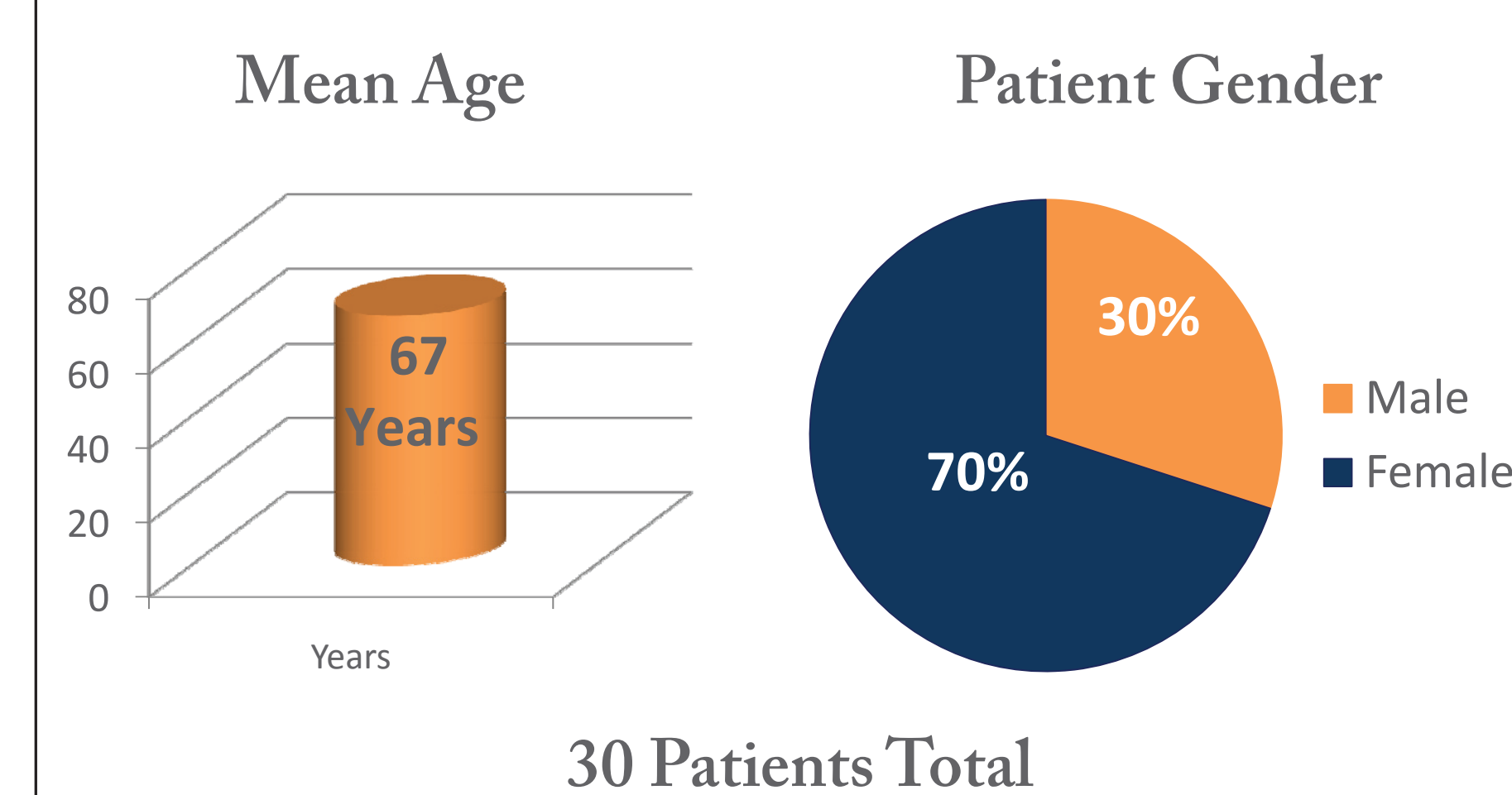
Study Methodology

- Single center analysis = Center for Pain Relief
 - 30 prospective, consecutive study patients
- Patients all tx with *mild* for symptomatic LSS
- Planned follow-up 2 years
- Device/procedure-related Serious Adverse Events
 - Comprehensive to Week 6, N=30 this report
- Patient reported outcomes (VAS & ODI)
 - Week 6, n=10 this report

Key Study Success Goals

- *mild*[®] procedure completed as planned (typically < 1 hour and patient comfort with light sedation)
- No *mild*[®] device/procedure Significant Adverse Events (SAEs)
- Mobility improves 15 points on ODI (An FDA panel has suggested a minimum 15-point change from baseline in ODI score is clinically significant)
- VAS pain score improves minimum of 2 points on 10- point scale

Demographics- Patient



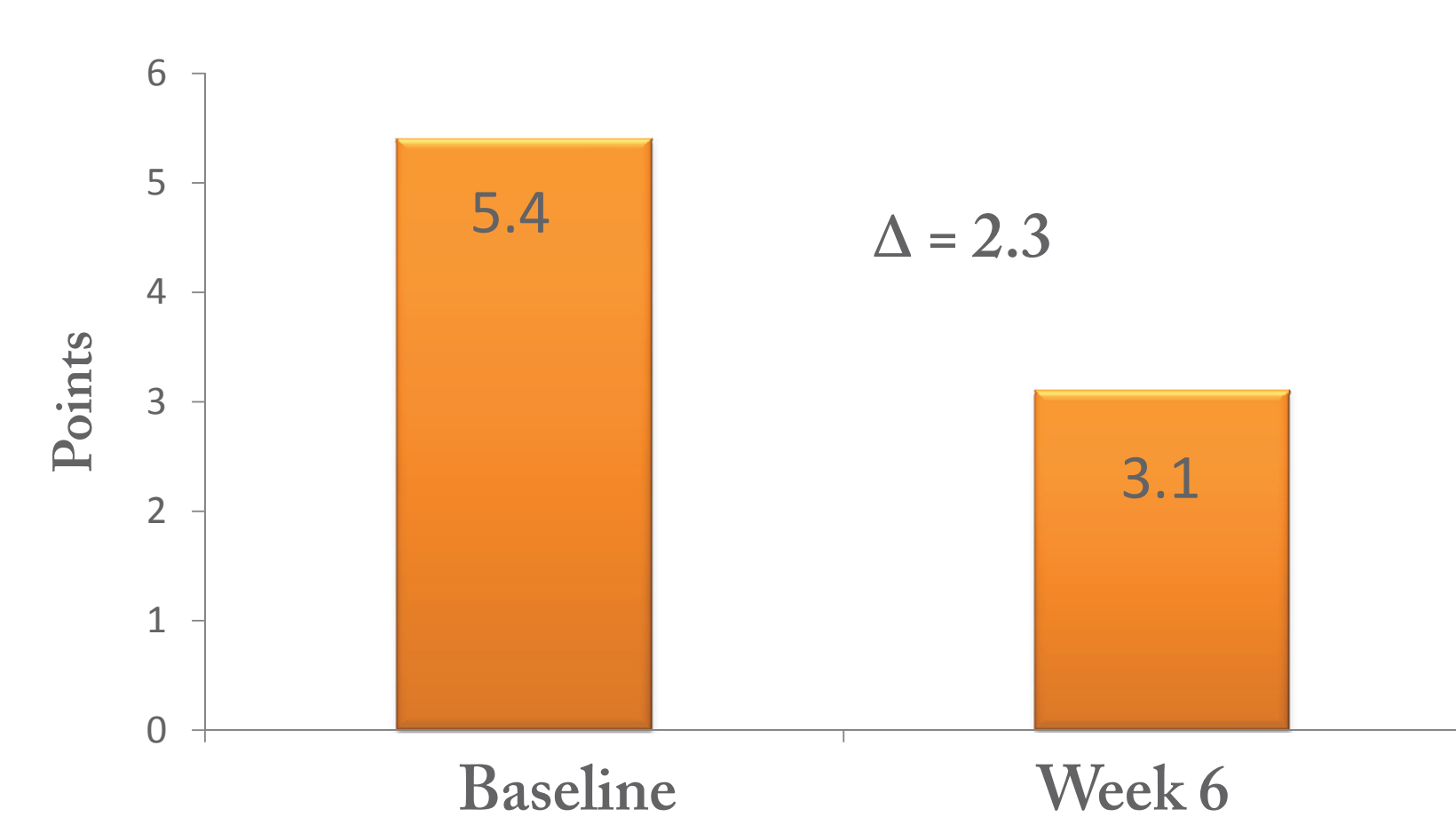
Demographics- Study & Procedure

Single Center	
Location	All cases performed at one U.S. site
Follow-up Range	Up to 6 weeks (Safety) Week 6 (Efficacy)
Length of Stay	All patients discharged the same day
Procedure Time (Mean)	< 1 hour duration

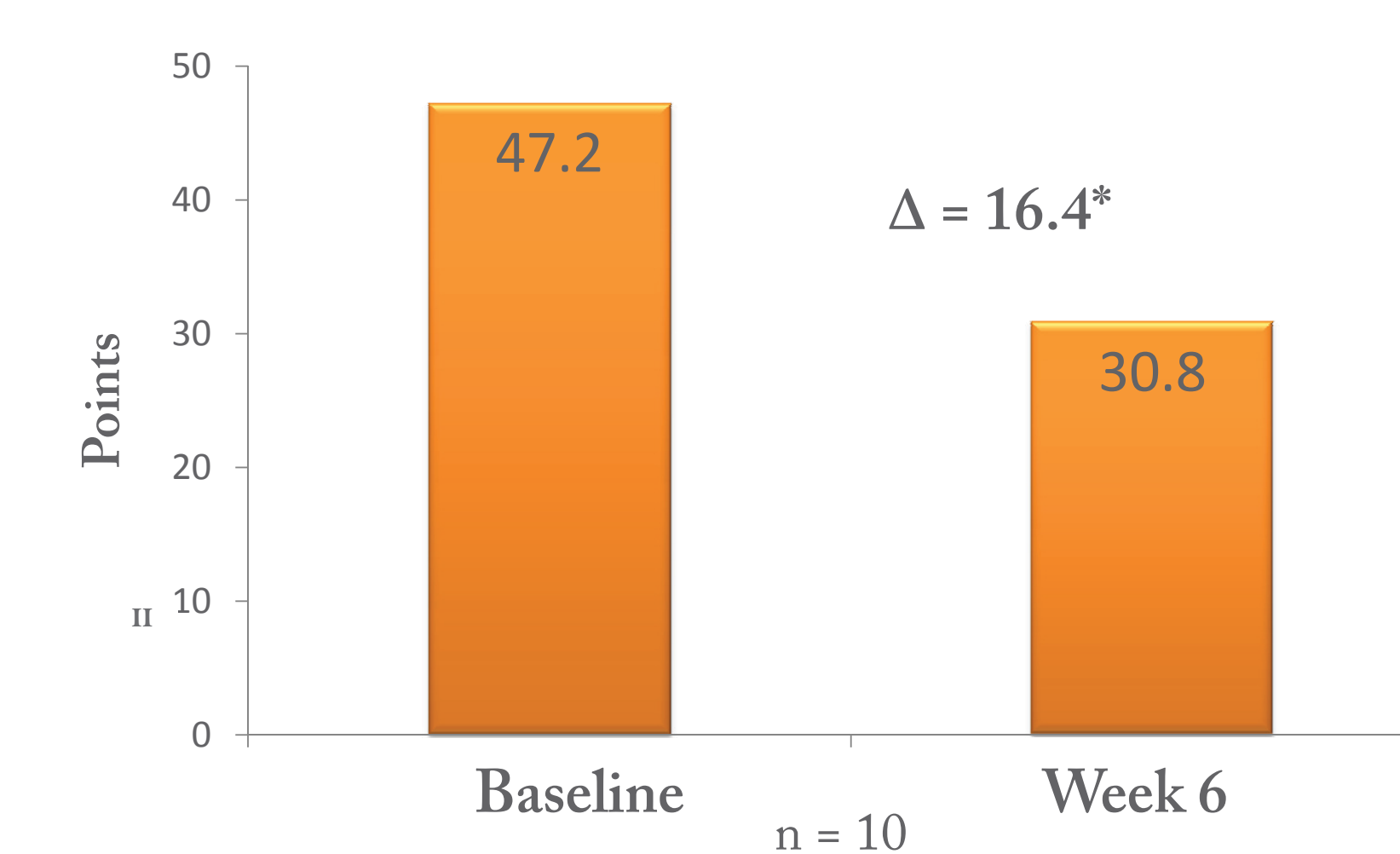
mild[®] Single Center Safety Comparisons

	Meta Analysis <i>mild</i> [®] Patients	Single Center <i>mild</i> [®] Patients	Deer/ Kapural Publication on <i>mild</i> [®] Patients	SPORT [®] LSS Surgical Patients
Number of Patients	263	30	90	394
Dural Tears	0%	0%	0%	9.2%
Blood Transfusions	0%	0%	0%	14.3%
Overall Adverse Events	0%	0%	0%	Intraoperative Complications: 9.9% Postoperative Complications: 12.3%

Mean VAS



Mean ODI



Conclusions

- *mild*[®] provides a safe solution for the treatment of LSS
- Significant improvement in pain and mobility
- *mild*[®] offers an early therapeutic LSS treatment option prior to more invasive surgical treatment

*Clinical significance demonstrated by 15-point ODI improvement (FDA Panel Guidance)