DEFINITELY FACET REPLACEMENT

THE BIG THREE

TFAS® CONSTRUCT
TFAS
FLEXION – EXTENSION RADIOGRAPHS

INTRAOPERATIVE TRANS-LAMINAR TFAS

FACET ARTHROPLASTY WITH TOTAL DISC REPLACEMENT
INDICATIONS

- Lumbar spinal stenosis/NEUROGENIC CLAUDICATION
- Moderate to severe (lateral recess)
- Spondylolisthesis (grade I)
- Lumbar Facet Degeneration/Hypertrophy
- Spinal Instability
- Iatrogenic Instability
- Total facetectomy

CLINICAL BENEFITS OF TOTAL FACET ARTHROPLASTY

- Complete versus partial removal of facets
- Allows for safer, more comprehensive decompression
- Eliminates the possibility of further degeneration and recurrence
- Removes a potential source of low back pain
- No fusion
- Patients get full range of back motion
- Normal spine biomechanics are restored preventing future adjacent segment issues
- No bone graft harvest procedure and associated pain
- Biomechanics
  - Stabilize the spinal segment
  - Preserve segmental biomechanics
  - Avoid fusion and therefore minimize stress on adjacent levels

TFAS® Kinematic Testing

Kinematics

The TFAS® effectively restores the Quality of Motion

TFAS®-restored QUALITY OF MOTION in clinical trials demonstrate TFAS (a non-fusion, non-fuseable implant) re-establishing the characteristic biomechanical signature of the intact spine in both flexion as well as extension.

SPINE BIOMECHANICS

INTACT

Δ System Energy

Applied Moment (Nm)

Flexion/Extension Angle (deg)

TFAS® U.S. IDE
SUBJECT DEMOGRAPHICS

- Number of Subjects with collected data: 189
  - 154 TFAS® Fusion Control
  - Mean BMI: 29.7
  - Female: 101
  - Male: 88
  - Age Range: 50-85
  - Mean Age: 64.52

U.S. IDE
ZCQ SYMPTOM ASSESSMENT TFAS

A 0.5 point decrease is considered to be a clinically significant improvement.
A 3 point decrease is considered to be a clinically significant improvement.
**U.S. IDE RANDOMIZED PATIENT SATISFACTION TFAS**

![Bar chart showing patient satisfaction results over time.](chart)

**RESULTS 36 MONTHS TFAS**

**VAS**
- Clinically 81% of these patients improved their back pain when compared to their last postoperative visit.
- Clinically 95.8% of these patients with TFAS had clinically significant improvement in their Leg Pain from preoperatively when compared to their last postoperative visit.

**DATA TRENDS: ZURICH CLAUDICATION QUESTIONNAIRE (ZCQ) ACADIA**

[Graphs showing data trends for ZCQ Symptomatic Severity, ZCQ Physical Function, and ZCQ Satisfaction.](graphs)
Patient Profile

- 61-year-old male – small business owner
- Severe lower extremity and low back pain
- Symptoms persisted for 7+ years
- Failed conservative care includes
  - Physical therapy for many years
  - ESIs for many years (45 days - best response)
  - Survived by altering his positions
Diagnosis
Lumbar Spinal Stenosis

Patient Work-up
• Neurologic exam suggested bilateral L4/5 root involvement
• Neurogenic intermittent claudication symptoms
• Imaging – Plain films, CT & MRI
  o MRI confirmation of severe stenosis, and lateral recess narrowing at L4/5
  o Grade 1 spondylolisthesis
  o L4/5 disc height ≥ adjacent disc heights

History
• Female; age 69; BMI 24 kg/m²
• Back and right leg pain; symptomatic for two years
• Lateral, lateral recess and central canal stenosis at L4-5
• Grade 1 spondylolisthesis at L4-5
• Treated conservatively with medications and epidural injections
• Previous fusion in thoracic spine

Operative Data
• Surgery on 7/23/09: ACADIA® at L4-5
• Decompression with laminectomy and facetectomy at L4-5
• Op time 2 hrs 55 mins; EBL 75cc

  • 69 months post-op
Case Study: 12 Months X-rays

Flexion  Extension

Case Study: 24 Month X-rays

Lateral  AP

Case Study: 24 Month X-rays

Flexion  Extension
TOPS CURRENT IDE STUDY

Biomechanics of TOPS™ System

Posterior Arthroplasty

- Provides near-normal motion in axial rotation—even after a wide decompression

Source: HJ Wilke, Spine, Nov. 15, 2006

TOPS™ QUALITY OF MOTION

- Provides near-normal motion in flexion, extension, lateral bending, axial rotation and sagittal translation—even after a wide decompression

Source: HJ Wilke, Spine, Nov. 15, 2006
Normal motion for the Adjacent Levels

- Normal motion protects the adjacent levels

![Graph showing normal motion for adjacent levels](image)

Source: BMI Cunningham, MD, Orthopaedic Spinal Research Laboratory, Towson, MD

Worldwide Single-level TOPS Outcomes

![Graph showing worldwide single-level TOPS outcomes](image)

Source: BW Cunningham, MSc, Orthopaedic Spinal Research Laboratory, Towson, MD

Worldwide Single-level TOPS Outcomes

Nine patient outcomes at 6 to 7 years

![Graph showing patient outcomes at 6 to 7 years](image)
POSTERIOR ARTHROPLASTY ADVANTAGES

- Treat Late-Stage Pathology
- Replace the Function of all Structures Removed during Decompression
- Re-create Normal Motion
- Straightforward to Implant
- No Screw Loosening
- Withstands Shear Loads
- Simple Revision Strategy
- Excellent Clinical Outcomes
FUSIONS DRAG YOU DOWN AND YOU STOP MOVING

THE FIRST TFAS PATIENT (SURGERY DATE 2005) SEEN IN AUGUST 2008

THANK-YOU