FACET REPLACEMENT

Wayne Cheng, MD
Bones and Spine

HISTORY

MOTION PRESERVATION

Charite' (depuy)

Prodisc (synthes)

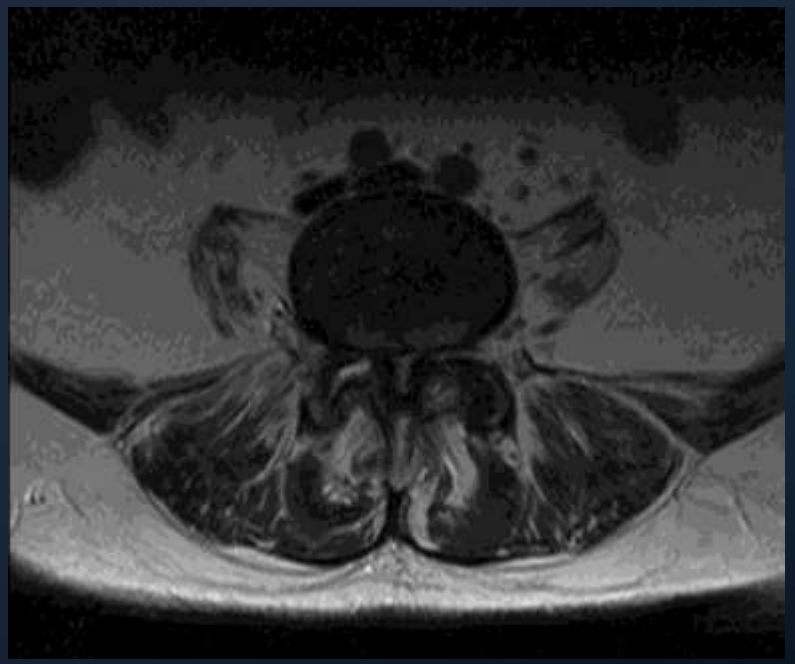
Maverick (Medtronic)

Flexicore (stryker)

MOTION PRESERVATION
Dynesys

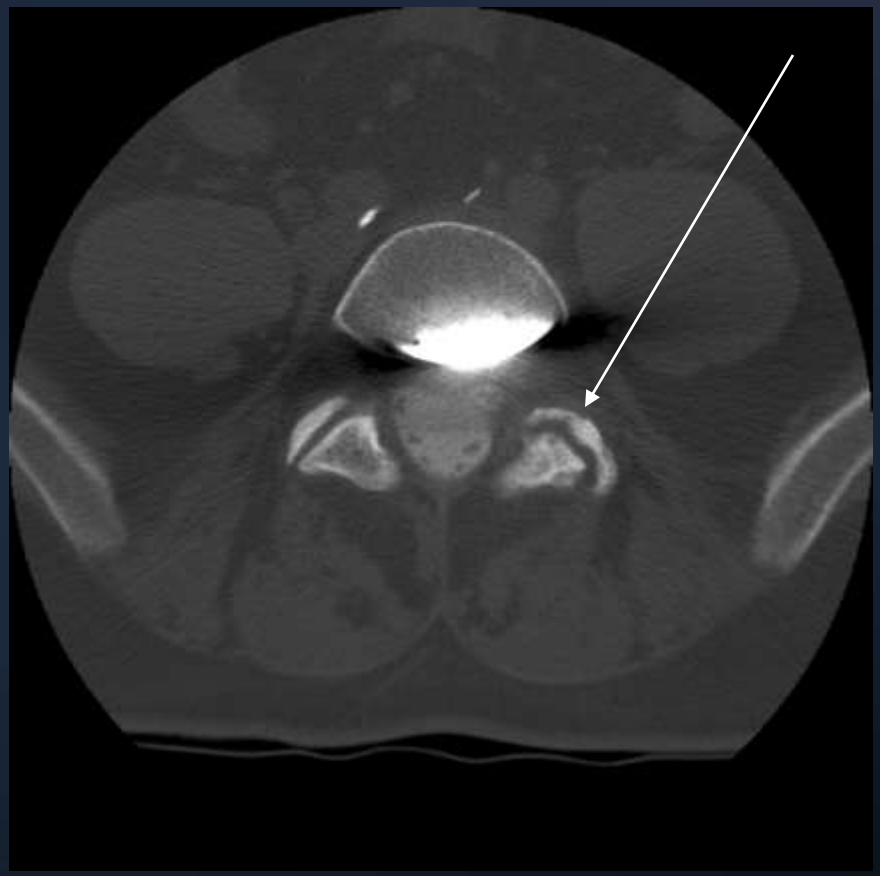
DYNAMIC STABLIZATION
Diam

Instability and Stenosis



Not the answer

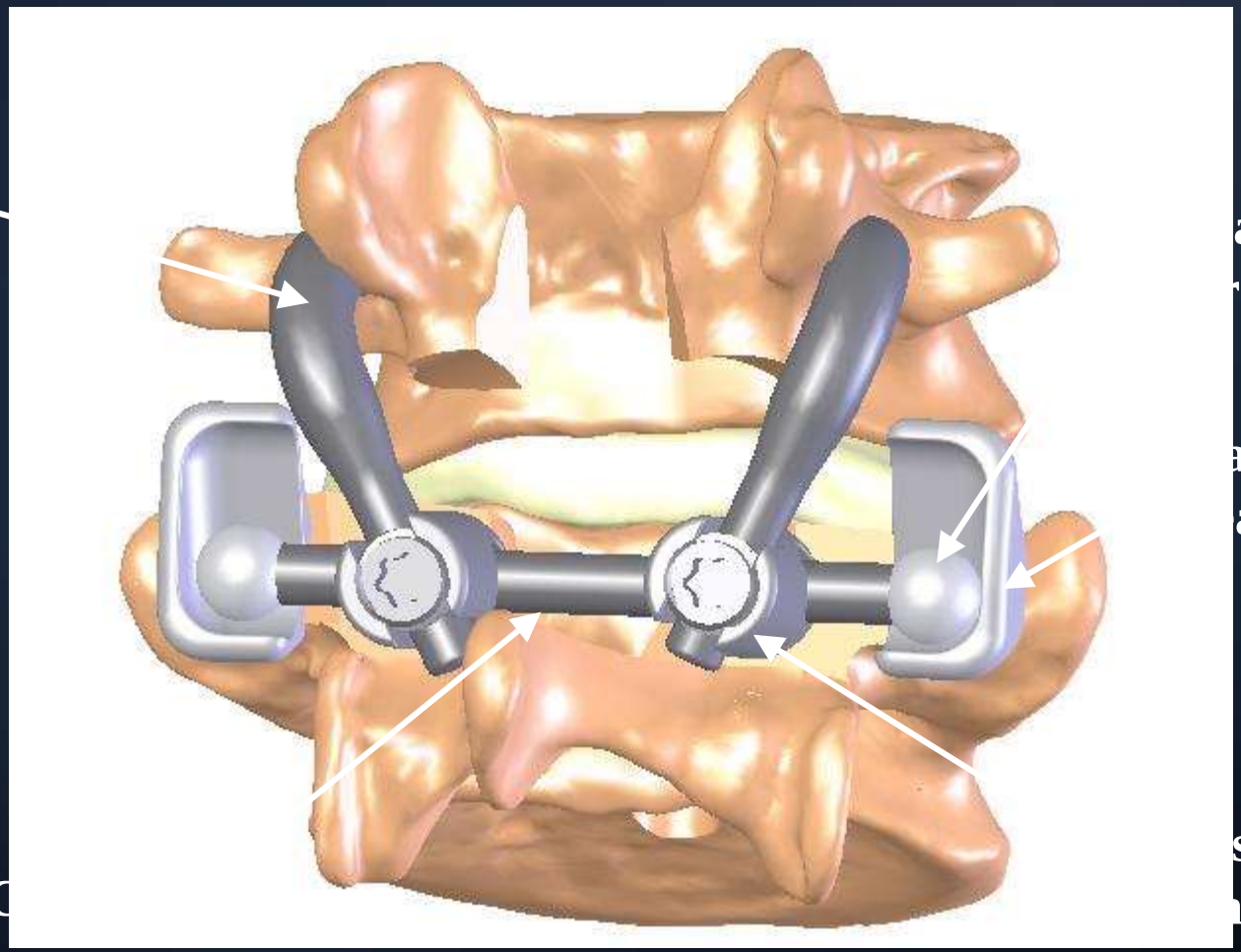
facet arthropathy



Fuse all Listhesis?

- Herkowitz,JBJS,1991
- Prospective/random.
- 50 pts
- 3 year f/u
- Post op olisthesis:
  - 96% non fused group
  - 28% fused group
- Op results:
  - 96% good or excelnt. (fused group)
  - 44% good or excelnt (nonfused group)

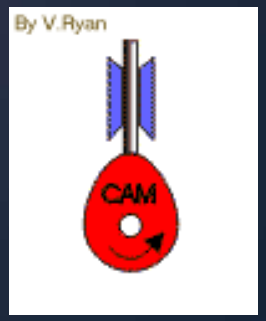
TFAS® Implant Features



Giving Facets Their Due

Spinal facets joints:

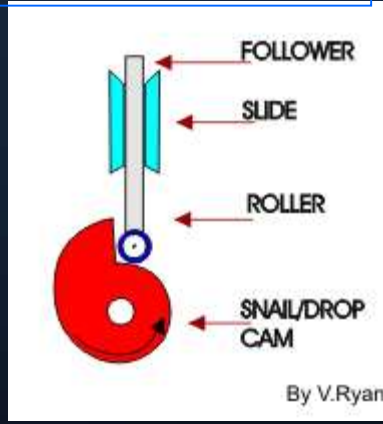
- Physiologically and biomechanically complex synovial joints
- Both allow and limit motion (by their shape, size, location, and orientation) between vertebral bodies
- Load Bearings – Compression and shear
- Protect the lumbar disc from excessive stress and assist lumbar discs in allowing motion and controlling shear forces



Spinal facets' function can be affected:

- Their biomechanical activity and pathology is as important and can be as painful and debilitating as that of the intervertebral disc
- Damage to and pain from the diarthrodial facet joints and their corresponding capsular ligaments can be independent of surgical intervention for other causes like:
  - Trauma, Disease and Degeneration

Cam-like behavior



Degenerated Facets and Stenosis can be surgically treated with a properly designed implant

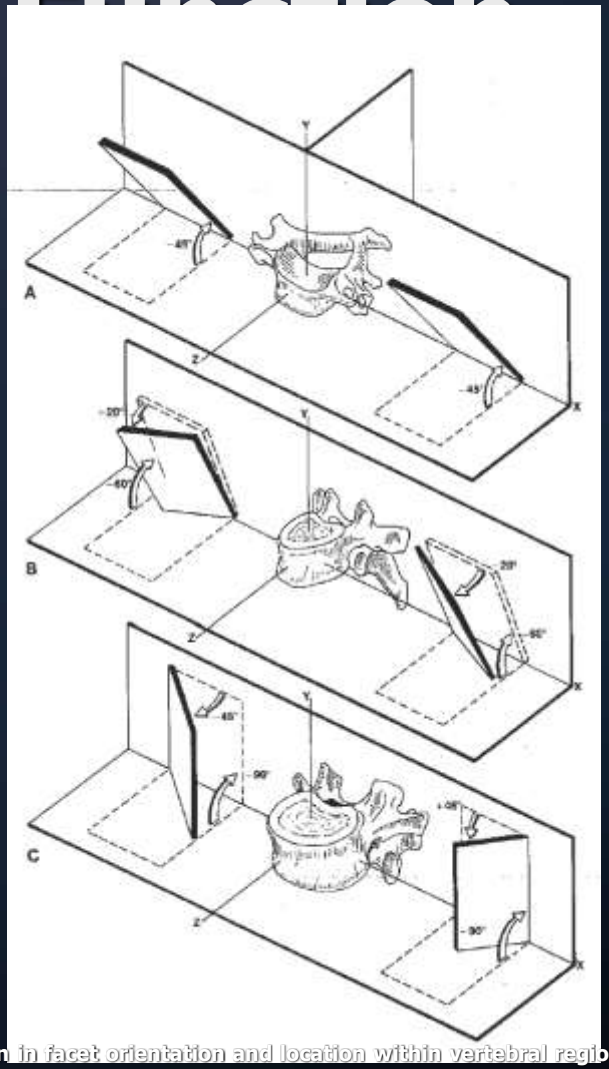
Location Based Facet Function

Cervical spine:

- Lowest effective transmitted loads in the spine
- Most freedom in lateral bending, extension and axial torsion
- Facets are located laterally, almost in the coronal plane and are "tilted" in abduction to allow for these motions

Lumbar spine:

- Axial rotation and lateral flexion are limited, the facets act like "cam-like" stops for hyper-extension and axial torsion
- Main motion is flexion-extension
- Subjected to the highest load magnitudes
- Facets are larger, more centrally located, and oriented in a more sagittal (adducted) manner - almost parallel along that sagittal plane



Variation in facet orientation and location within vertebral regions (White and Panjabi, Clinical Biomechanics of the Spine, 2nd Ed.).

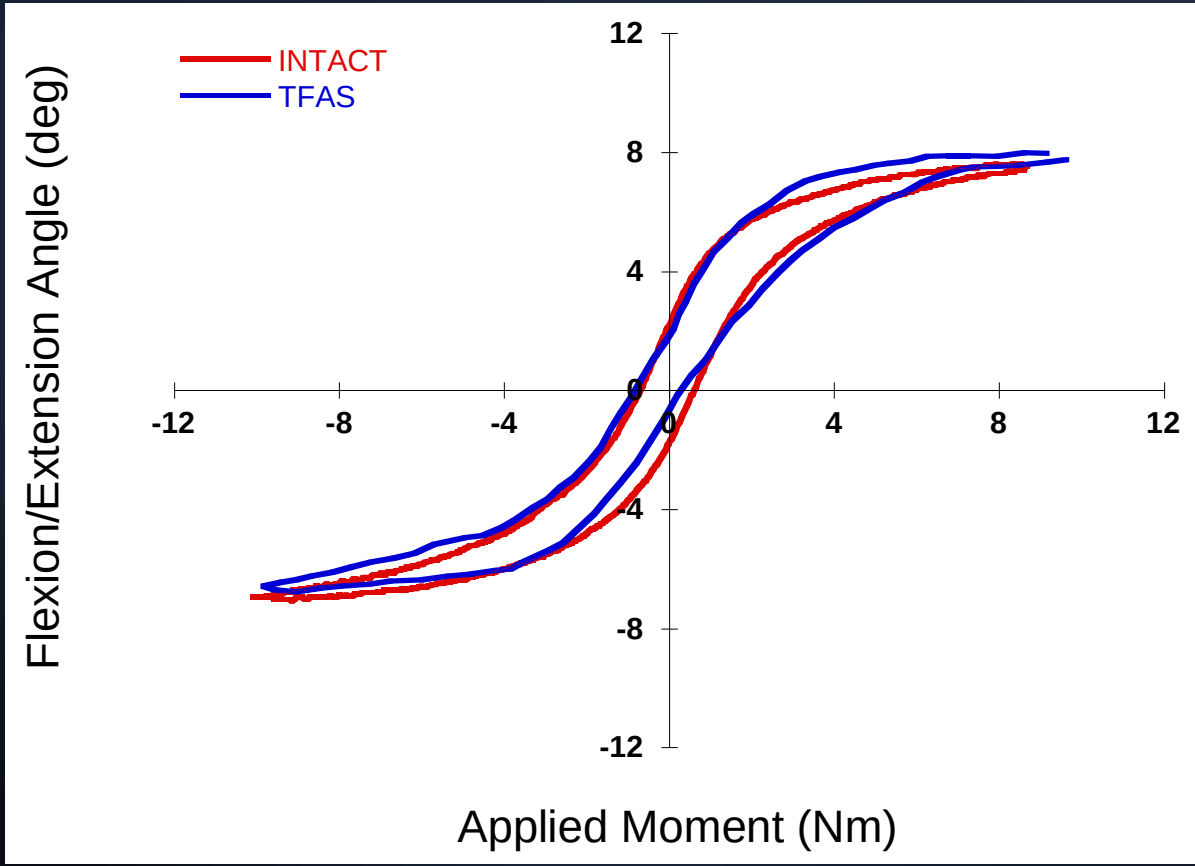
Range of Motion L45

Mahfouz "In vivo 3dkinematic analysis of the lumbar spine L45"

	Normal	Degenerative
Flex + ext	14.46	8.59
translation	1.68	3.23
Lateral bending	9.12	2.22
rotation	4.83	2.58

TFAS® Kinematic Testing

Kinematics



•The TFAS™ effectively restores the Quality of Motion*

✓ TFAS™ restored **QUALITY OF MOTION** to an otherwise unstable FSU (*no facets or posterior ligaments*), that is ***reestablishing the characteristic kinematic signature of the intact spine in both its limits as well as profile.***

* Zhu Q, Larson CR, Sjovold SG, Rosler DM, Keynan O, Wilson DR, Cripton PA, Oxland TR. "Biomechanical evaluation of the Total Facet Arthroplasty System: 3-dimensional Kinematics," Spine. 2007 Jan 1;32(1):55-62.

TFAS® Static and Fatigue Testing

- Tested per ASTM F-1717 (modified)
- Fatigue testing to 10 million cycles

Lateral Load

Anterior/Posterior Load

Cranial/Caudal Load

TFAS® Fixation Testing

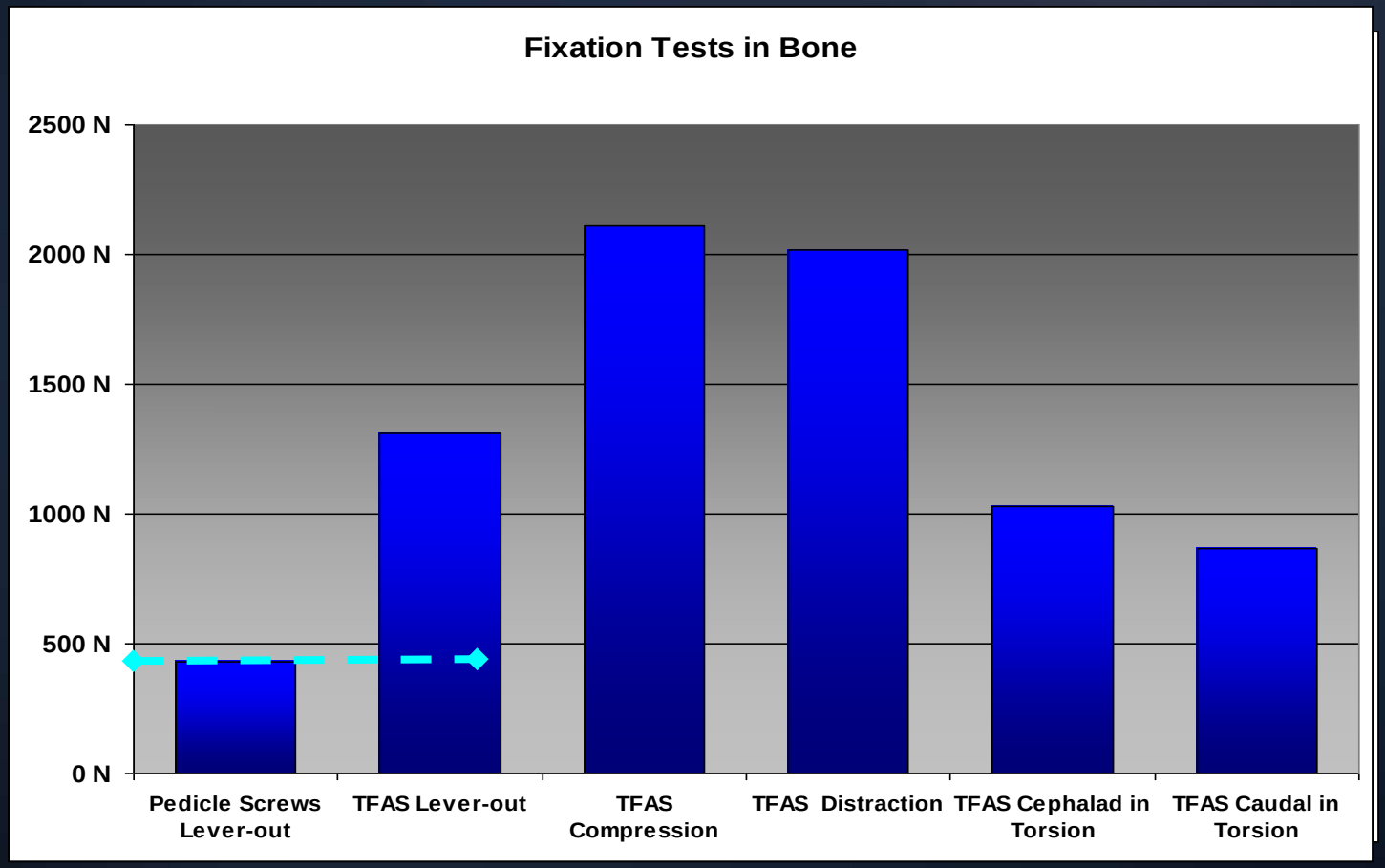
Fixation Strength

- Supports ≥ 2.5 times maximum static in vivo loads
- Supports ≥ 3 times maximum fatigue in vivo loads
- Supports ≥ 2 times ultimate fixation strength of pedicle screw based fixation system in bone

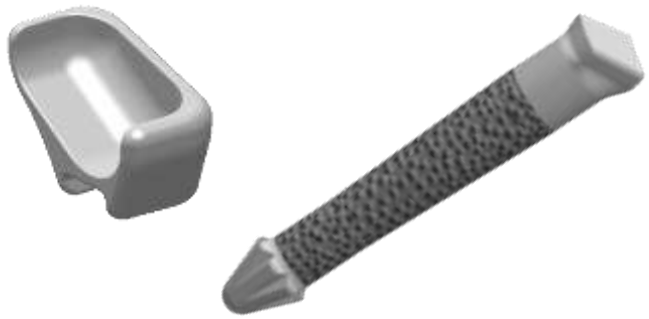
✓No dissociation or failure between PMMA and anchor under maximum static loading

✓Strength and stability at max ADL loads for 10-million cycles

TFAS® Fixation Testing Results



TFAS™ Components



Caudal Bearing and Stem

Crossbar with Cephalad Bearings

Clamp Housing with Set Screw

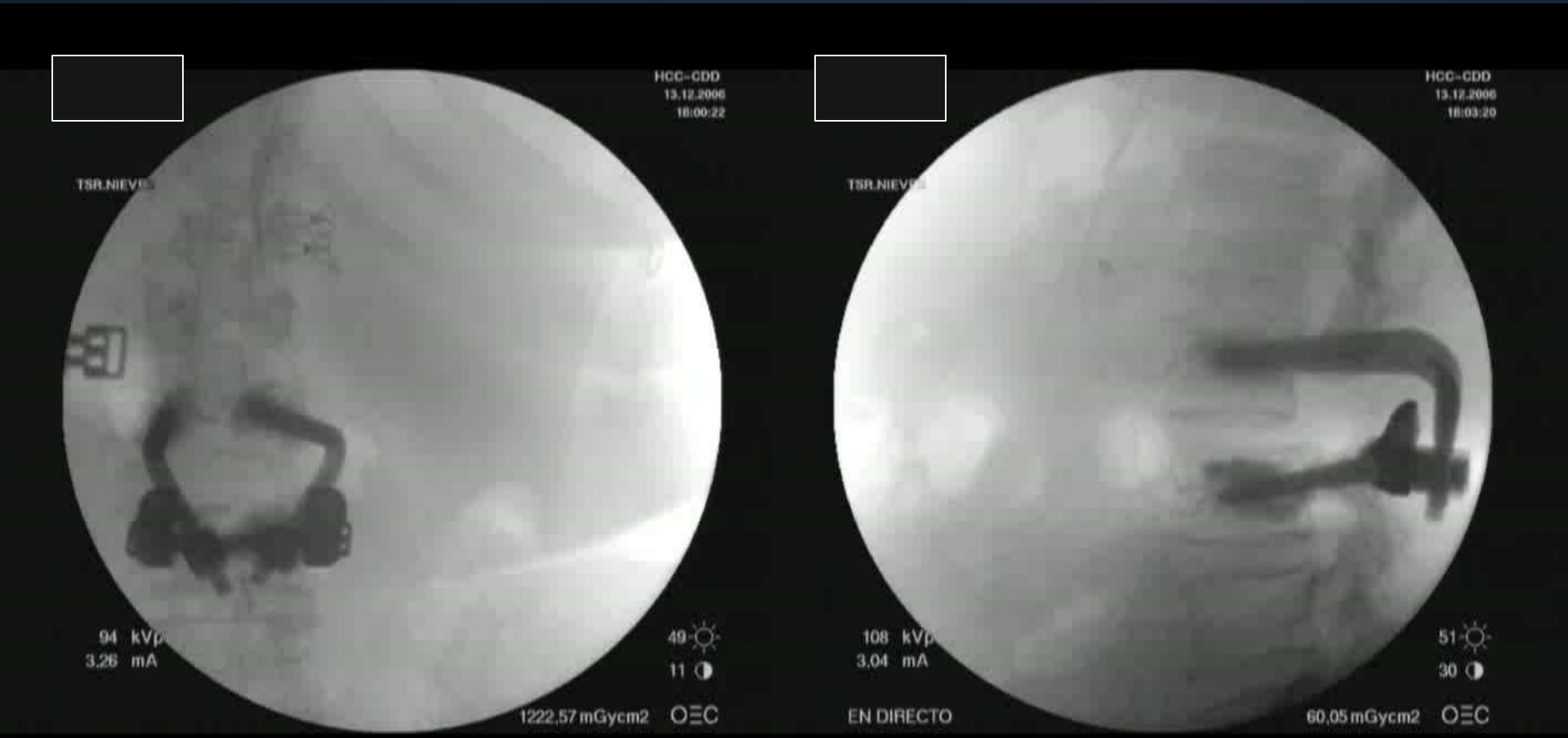
Cephalad Stem

In-vivo Kinematics

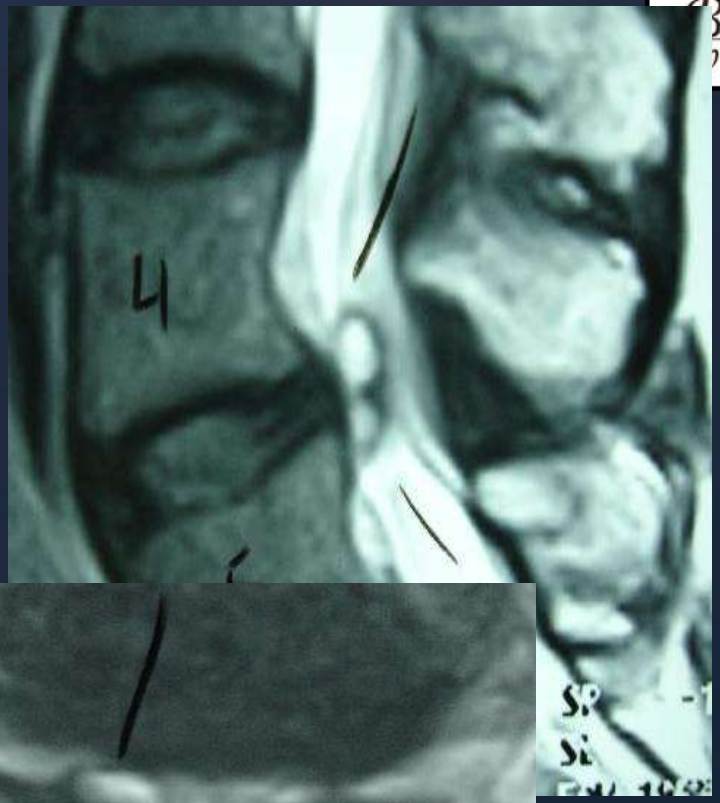
Cine-fluoroscopy

Flexion/Extension - A/P

Flexion/Extension - Lat.



Courtesy of Guillermo Bajares, MD Caracas, Venezuela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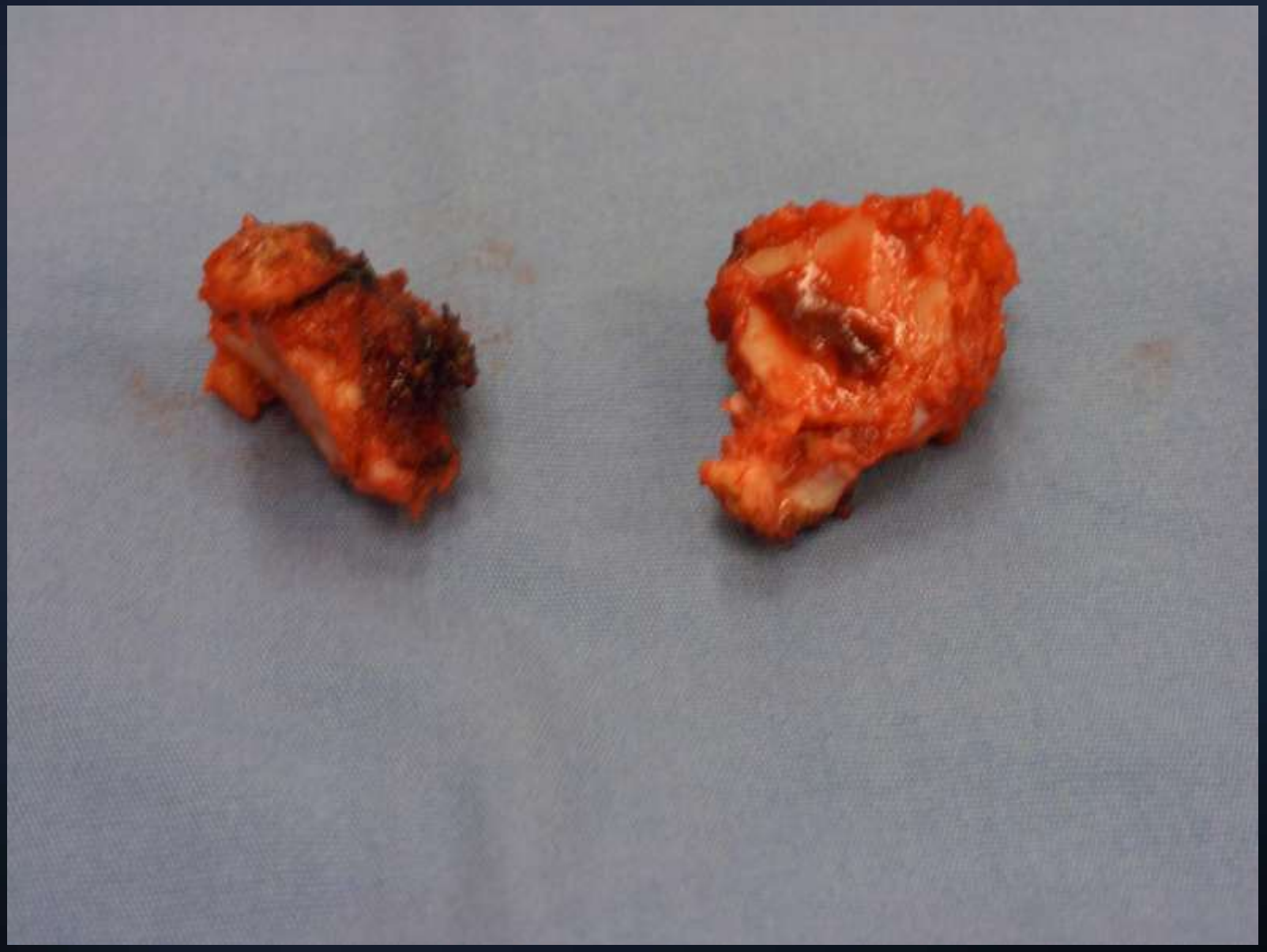

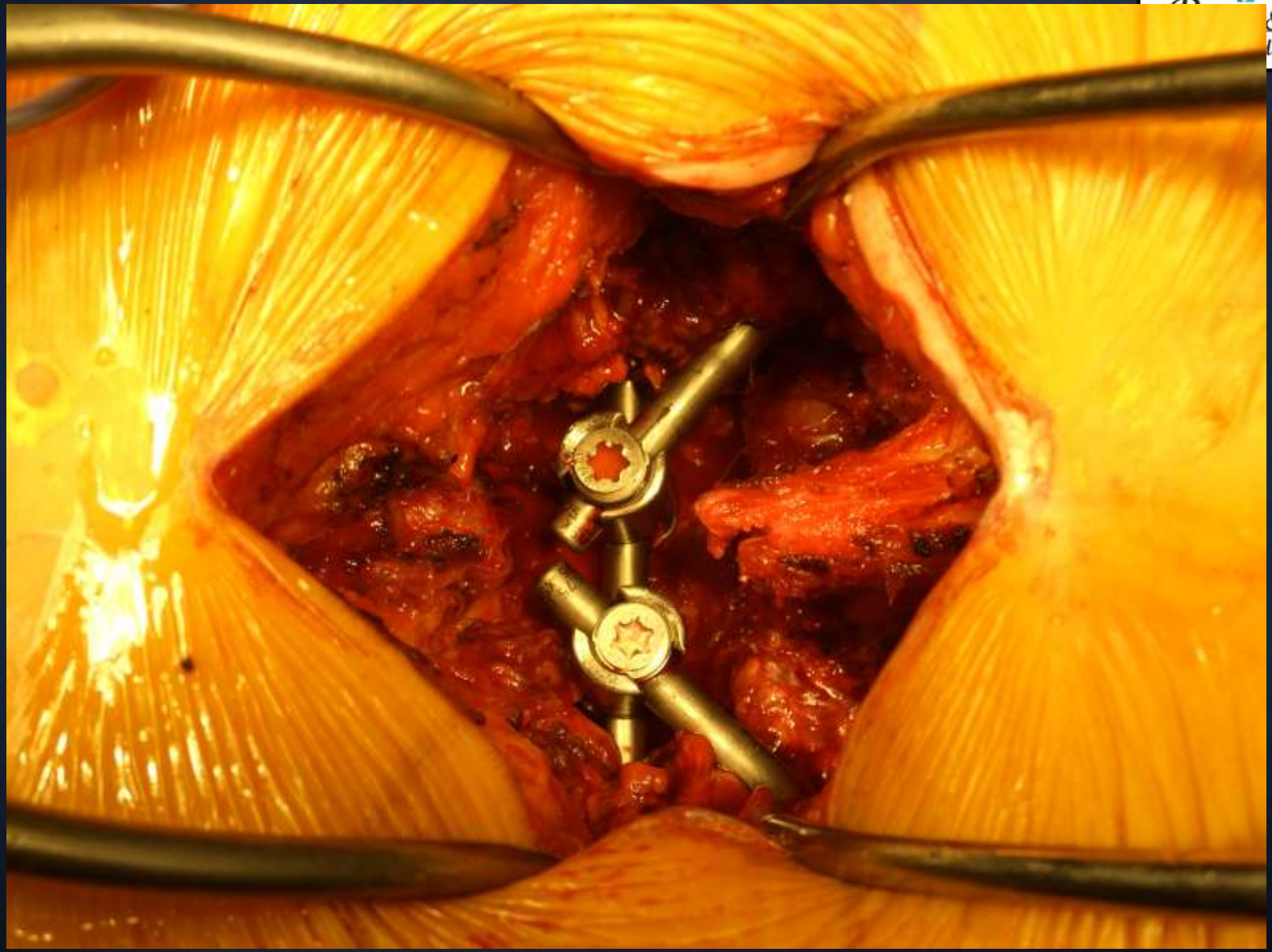

IDE STUDY

Loma Linda University

Clinical Study Design

- Pivotal, multi-center, prospective randomized controlled clinical trial
- Non-inferiority trial comparing the **Total Facet Arthroplasty System** to decompression and instrumented spinal fusion
- Control – posterior pedicle screw fusion system with autologous bone graft
- No BMP may be used. The use of graft extenders is allowed.
- 2:1 randomization
- Minimum 24 month follow-up

Patient Enrollment

- **300 patients** ~ Maximum 450 patients
- **Non-randomized subjects** ~ The first 5 patients at each clinical site will be implanted with TFAS to minimize learning curve effects
- **Preliminary safety analysis** ~ Data on first 20 implantations submitted to FDA when those patients reach 3 months of follow-up

Inclusion Criteria

- Degenerative spinal stenosis, central or lateral, at spinal levels L3-4 or L4-5, with radiographic confirmation of the following:
  - Evidence of thecal sac and/or cauda equina compression;
  - Evidence of nerve root impingement by either osseous or non-osseous elements;
  - Evidence of hypertrophic facets with encroachment into the central canal or lateral recess.
  - No greater than Grade I degenerative spondylolisthesis at the stenotic level;

Inclusion Criteria **(cont.)**

- Intermittent neurogenic claudication
- Skeletally mature male or female between age 50 and 85, inclusive
- No more than three levels of degenerative lumbar spinal stenosis requiring decompression
- ZCQ ≥ 15 on "patient symptom" and ≥ 10 on "patient function" during screening
- Failed to conservative care for a minimum duration of six months

Exclusion Criteria

- Prior or planned lumbar fusion or disc replacement
- Two or more previous surgeries at involved level
- Is obese, as defined by a patient body mass index >40 (wt in lbs X 703/height in inch^2)
- Osteoporosis or osteopenia with DEXA-T score less than -2.5, absolute density of less than 0.9 gm/cc per a previous diagnosis or is at significant risk for these conditions due to predisposing factors per the surgeon's judgment
- Significant scoliosis (Cobb > 25°)

Primary Outcome Measures
Individual Patient Success

- 0.5 point improvement from pre-op in the "Patient Symptoms" section of the ZCQ
- 0.5 point improvement from pre-op in the "Physical Function" section of the ZCQ
- Maintenance or improvement in neurologic status - no new permanent neurological deficits
- No revision, removal, supplemental fixation or re-operation at the involved spinal level.

- Solid fusion – control patients only

Secondary Outcome Measures

- Range of Motion
- VAS for Back and Leg Pain
- SF-36 Quality of Life
- Patient Satisfaction

THANK YOU