MOTION SPARING TECHNOLOGY

THE DYNESYS EXPERIENCE

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7 April 2007

SPINAL FUSION

- Gold standard for over 30 years
- Millions of patients
- Billions of dollars
- Overall very good results

- Why change now?
- Why look for something different?
- Is newer better?

WHAT ARE WE DOING?

- We are following

  in the footsteps

  of the total joint surgeons.

- 40+ years ago…
- Severe pain, severe DJD of hips and knees

  was treated with joint fusions.

- RESULTS-
- No pain, but…
  awkward gait
  impaired function and lifestyle
- Success? … Partial

THE QUESTION

- Can we get rid of the pain, increase function and improve lifestyle.
- Hence- TKR and THR
- JOINT REPLACEMENT SURGERY
- Huge success
- Impact on society
- Quality of life!

CAN THIS THOUGHT PROCESS AND TECHNOLOGY APPLY TO SPINE

- Lumbar spine segment
- Complex joint
- Tripod
- Many variables
- Centers of motion
- Significant changes with age
- What are our goals

WHAT DO WE WANT TO DO ?

- #1 Decrease pain
- #2 Maintain motion
- #3 Maintain function
- #4 Prevent adjacent level disease

- Neutral zone
- Functional zone

- Normal motion
- Functional motion

MOTION PRESERVATION

- Pedicle based system
- Unload the posterior half of the disc space and the facet joint
- Preserve motion
- Quality of motion vs Quantity of motion
- Restore normal motion? …NO!

- Alternative to fusion ?

- Adjunct to fusion ?

"ANOTHER TOOL IN THE BOX"

- No one device is right for every patient.
- If the patient needs a fusion, do a fusion.
- Different devices for different indications
- An internal brace
- Stabilize/neutralize motion
- Maintain height
  - posterior disc
  - facet joint
  - neural foramin
- Don't burn any bridges

PAIN

- Discogenic
- Facet joint
- Neurologic compression
- Instability
  -bone
  -ligamentous

OFFLOAD THE PAINFUL STRUCTURES

- Discs
- Facet joints
- Strained ligaments
- Enhance stability
  - facet capsules
  - ligamentum flavum
  - tension spinal ligaments
  - normalize motion

INDICATIONS FOR DYNESYS

- Spinal stenosis
- Grade I spondylolysthesis

INDICATIONS ARE CHANGING EVERY DAY

- The more patients I see…
- The more cases I do…
- The more indications I find.

TWEENERS

- DDD
- Back pain
- Leg pain
- Facet joint pain
- Degenerative Scoliosis
- Spondylolysthesis
- Retrolysthesis
- Status post decompression
- Progressive disease … and…

ADJACENT LEVEL DISEASE

- Diagnose it
- Treat it
- Arrest it
- Prevent it

WHAT IS DYNESYS ?

- DYnamic
- NEutralization
- SYStem

HOW DOES DYNESYS WORK?

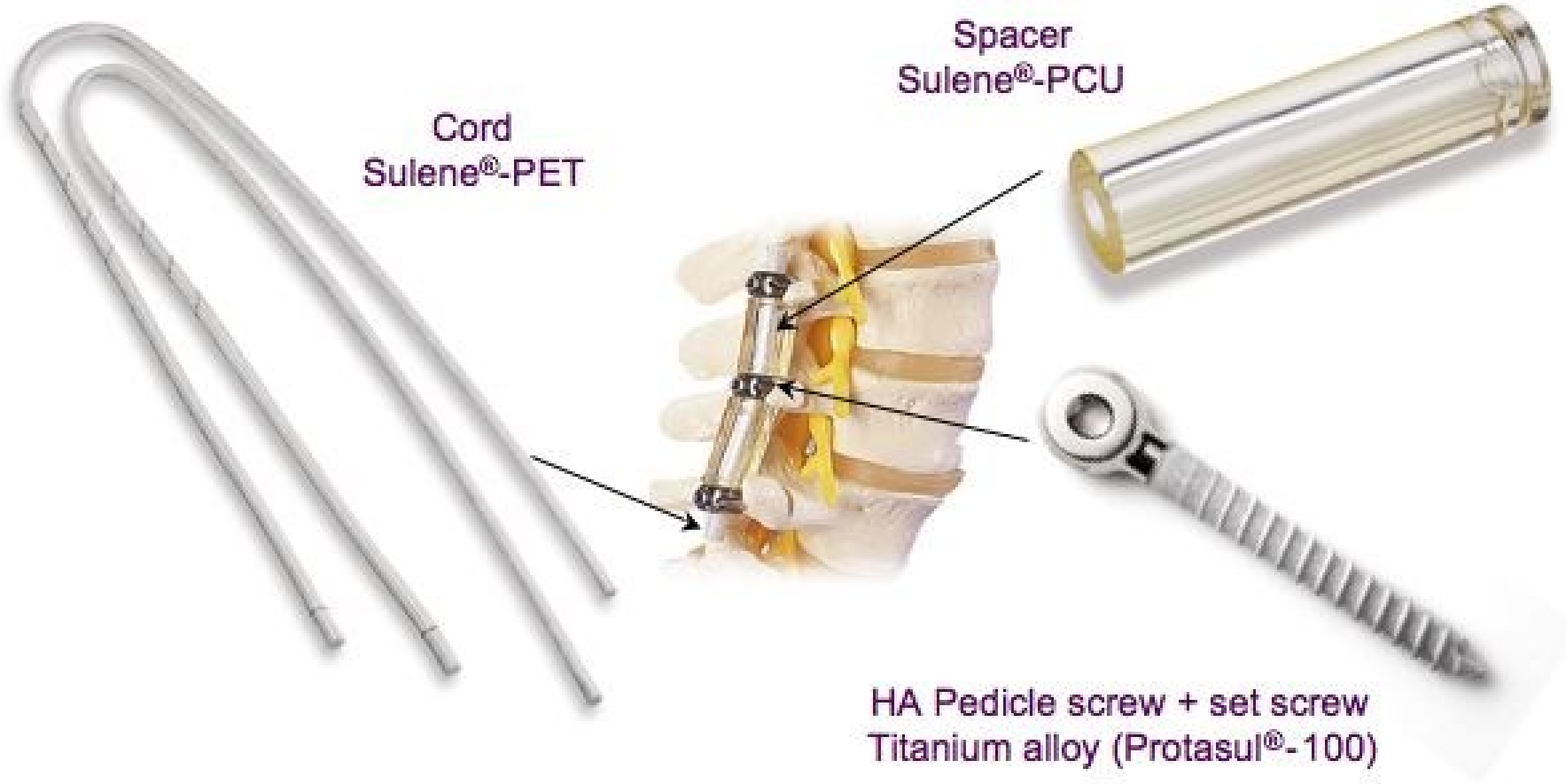
WHAT DOES IT DO?

THE BIOMECHANICS OF DYNESYS

- Unique design
- Engineering unlike any other system

- Screw
- Spacer
- Cord
- Technique

The *Dynesys* System—Functional Overview

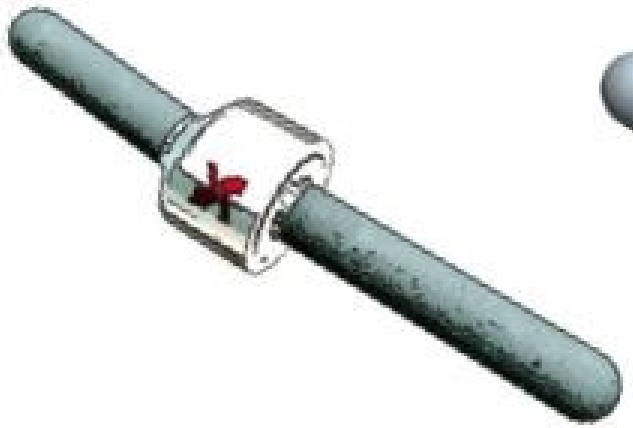


Dynesys System Components
All Designed Expressly for Dynamic Stabilization

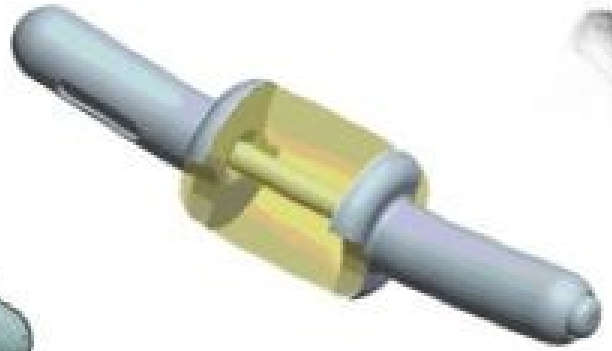
- **Cord**
  - Designed to be pliable
  - Designed to resist tension
  - Specific to patient anatomy
- **Spacer**
  - Designed for flexibility and cushioning
  - Absorbs/releases energy
  - Specific to patient anatomy
- **Screw**
  - Low-profile head
  - Self-tapping design
  - Conical central shaft
    - Designed to compress bone
    - Makes for tight bone/screw interface

The *Dynesys* System—Contrasts/Comparisons

Dynamic Stabilization Technologies



Scient'x
Isobar TTL

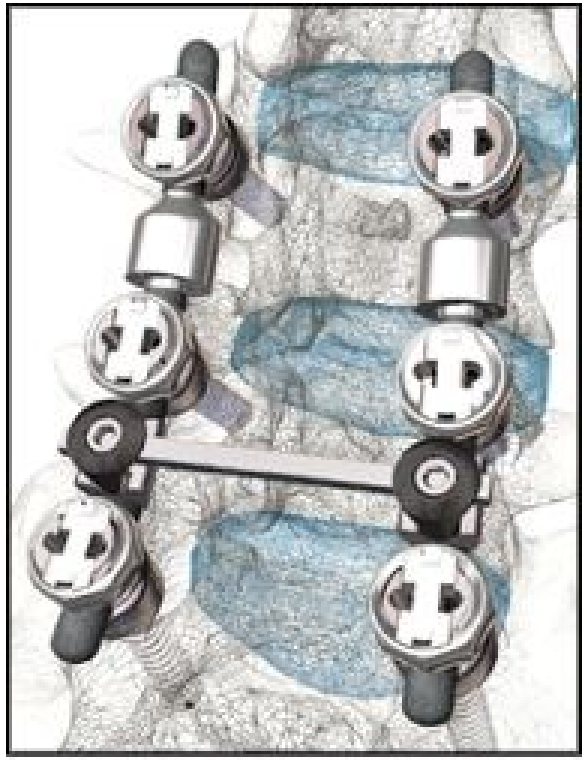


Medtronic
Agile

Zimmer
Dynesys System

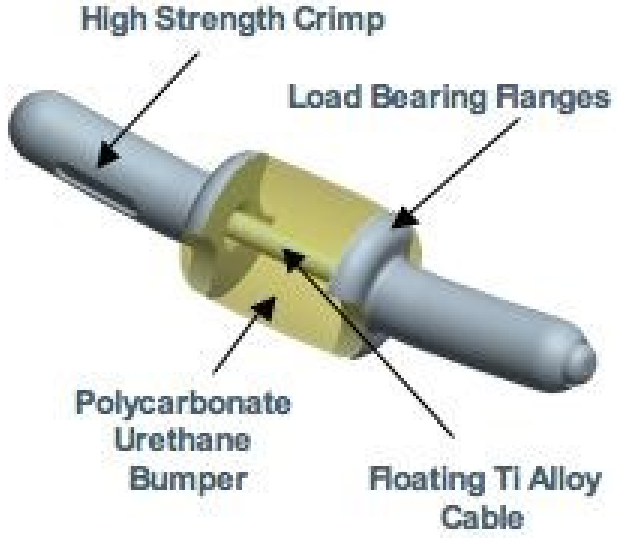
The *Dynesys* System—Contrasts/Comparisons

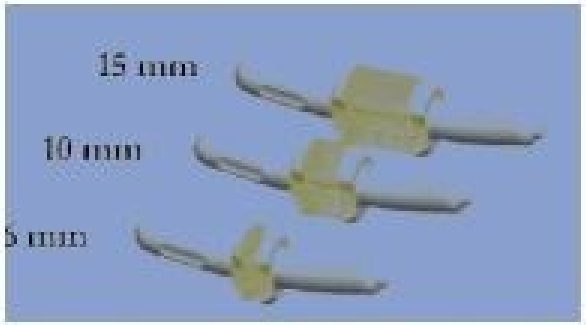
- **SCIENT'X (USA)-Isobar™ TTL**
  - Semi-rigid system with motion-dampening washers
  - All metal components
  - CE Mark obtained in 1998
  - US clearance 2002
- ***Dynesys* System**
  - Non-metal spacer/cord assembly
    - Flexible materials
    - No moving parts
  - CE mark 1999
  - US clearance granted in 2004
    - Over 5,000 cases completed in US



The *Dynesys* System—Contrasts/Comparisons

- **Medtronic-CD Horizon Agile™**
  - Pre-curved, lordotic implant
  - One-level system–available with extended rod
  - HA coated, poly-axial screws
  - Titanium rod with a titanium cable and PCU bumper
  - Pre-determined stiffness with three sizes: 6,10,15mm
  - Anchored with Medtronic CD Horizon & Legacy screw system
  - First implanted in 4th quarter of 2006
  - Biomechanics/sheep study completed
  - European & Australia clinical trial may begin by end of 2006
  - US clearance–October 2006
  - Initial IDE submission in progress

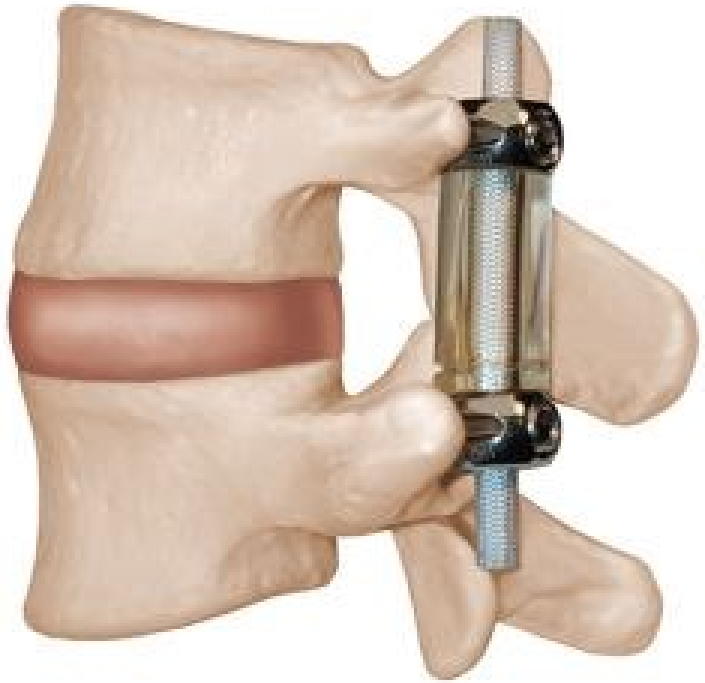




Reference:2006 IMAST P492, Design and Testing of a Novel Posterior Dynamic Stabilization Device, K Foley

The *Dynesys* System—Contrasts/Comparisons

- ***Dynesys* Dynamic Stabilization System**
  - No retrofitted legacy parts
  - Self-conforming implant
  - Low-profil e screw design
  - Multi-level capability
  - Over ten years European experience, and more than 28,700 patients worldwide
    - –Biomechanics/animal studies completed in May 2003
    - –US clearance granted March 2004
    - –US IDE-study with over 400 patients

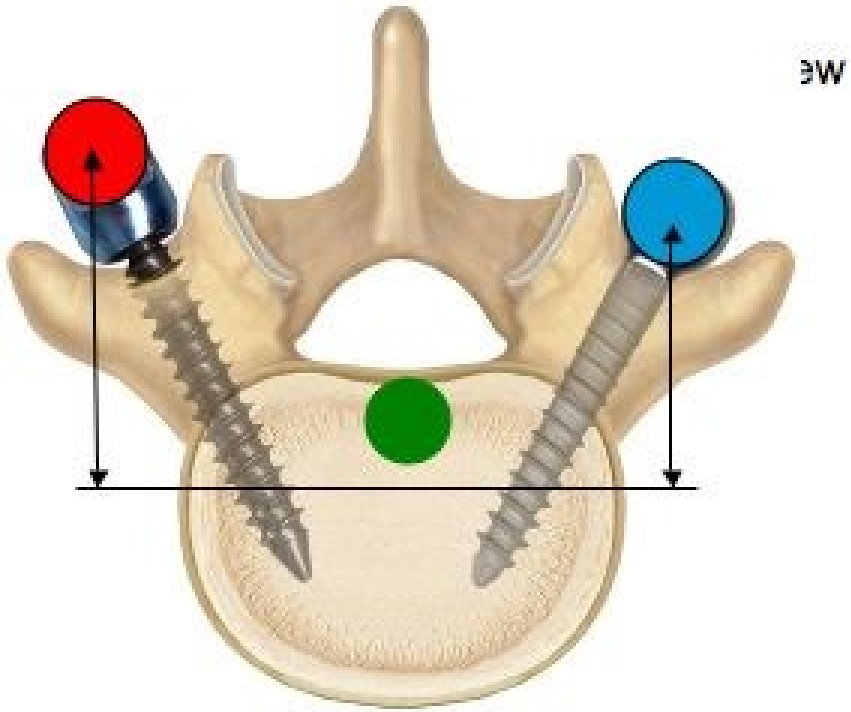


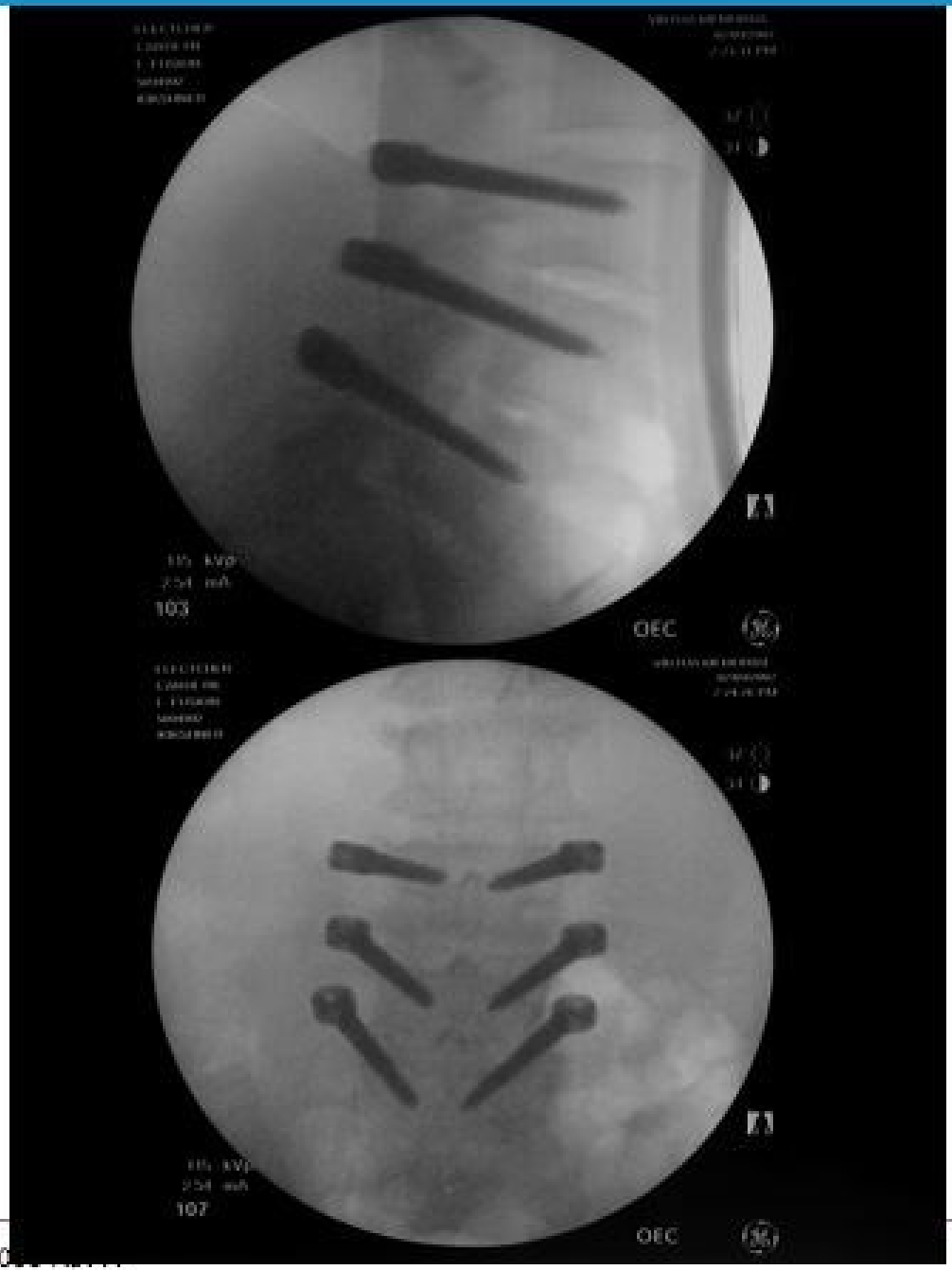
TECHNIQUE

- Lateral
- Longest
- Largest
- Lowest

Dynesys System
Low Profile and Tissue Friendly

- Four **L**s of *Dynesys* Screw-Placement
  - **L**ateral to facets
  - **L**ow trajectory
  - **L**ongest screw
  - **L**argest screw

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OEC
107
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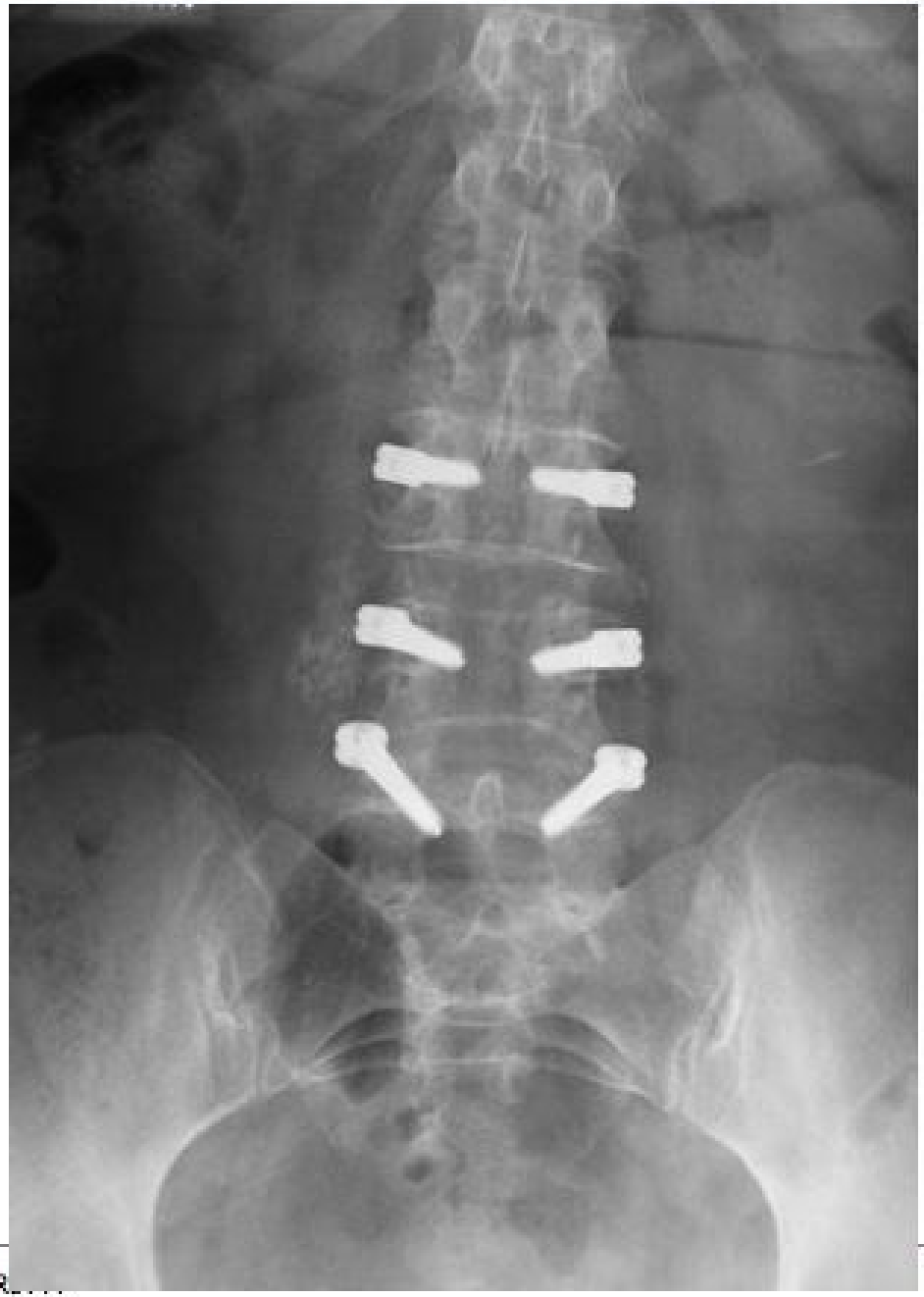

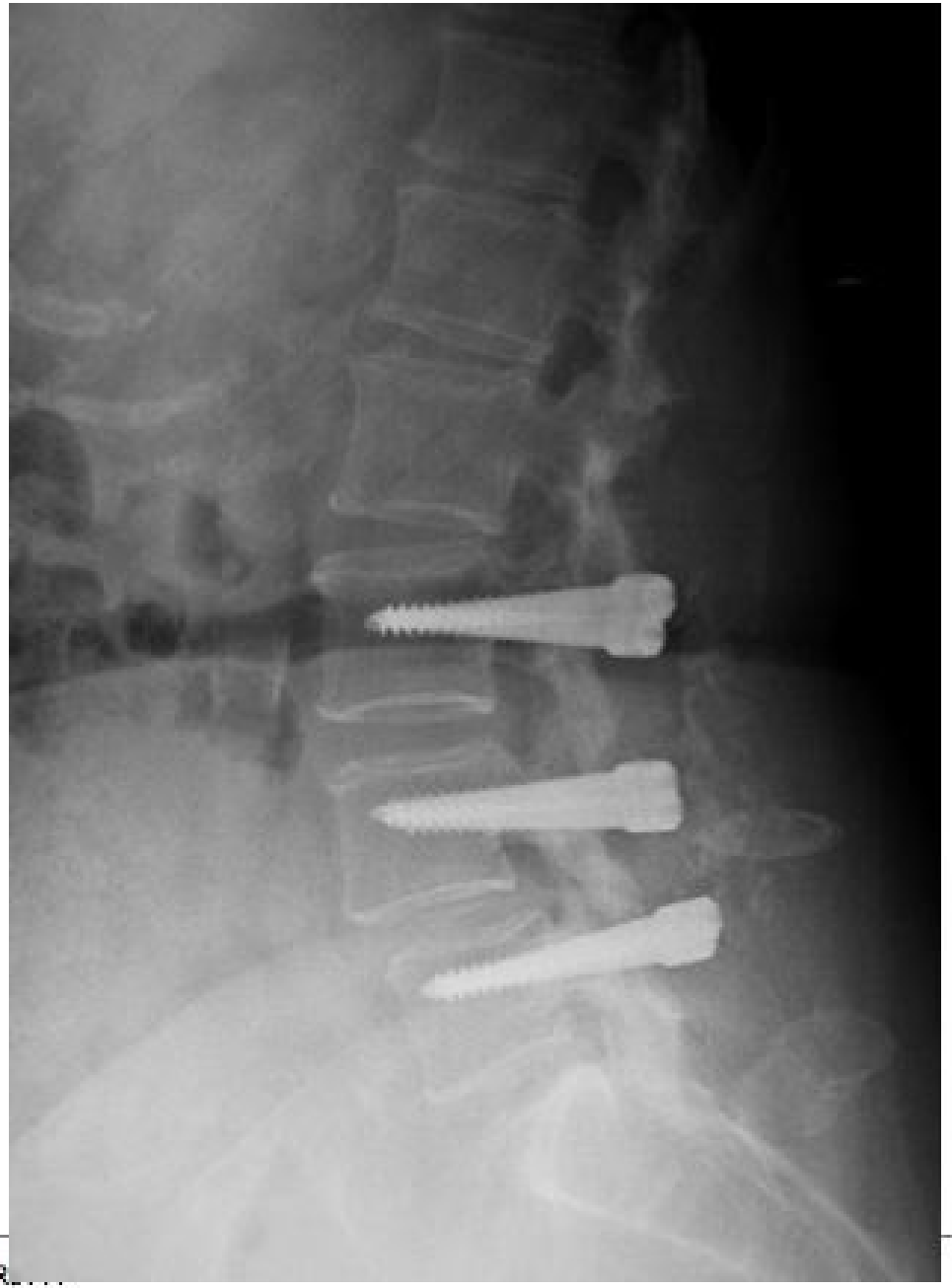

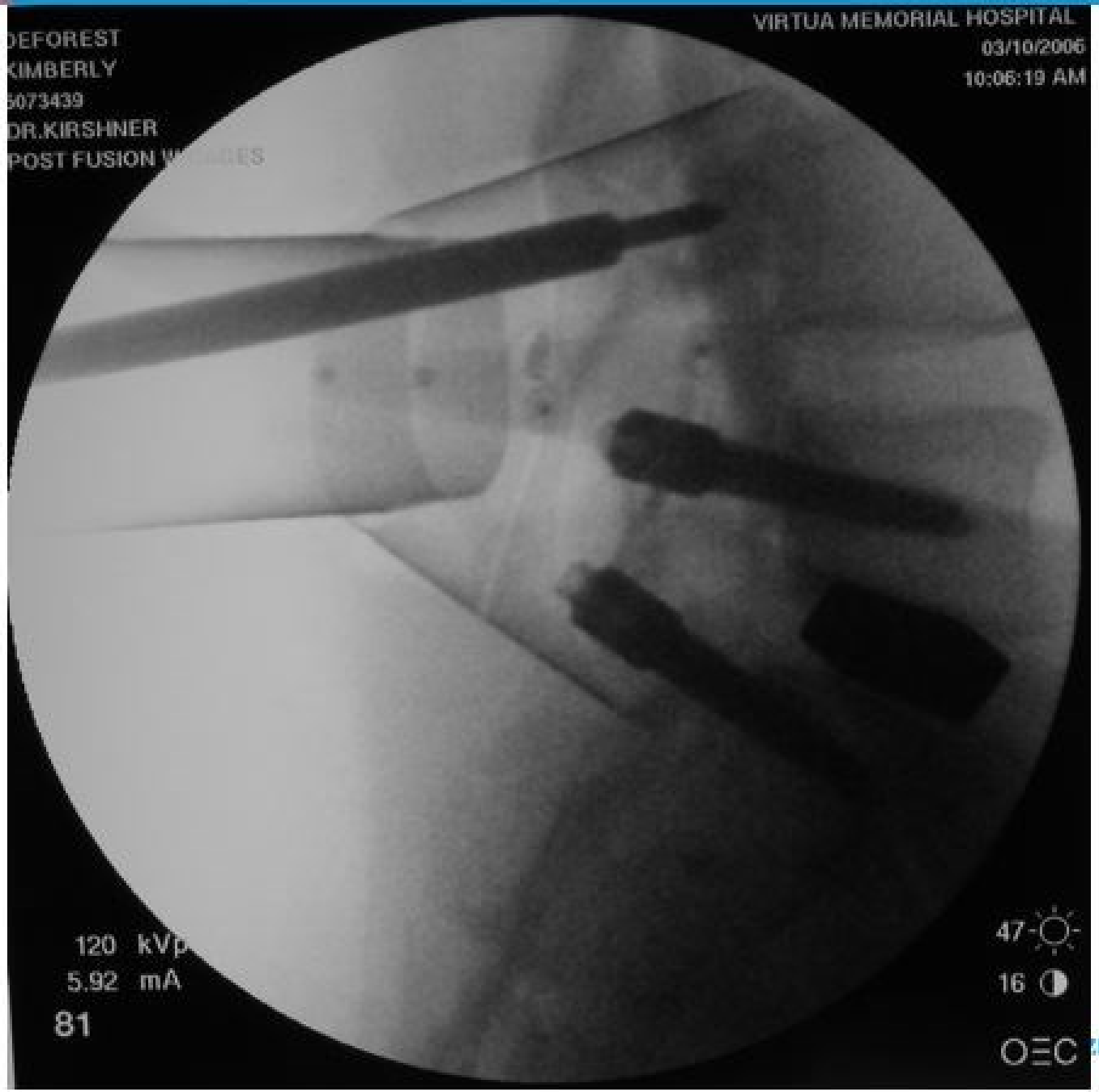
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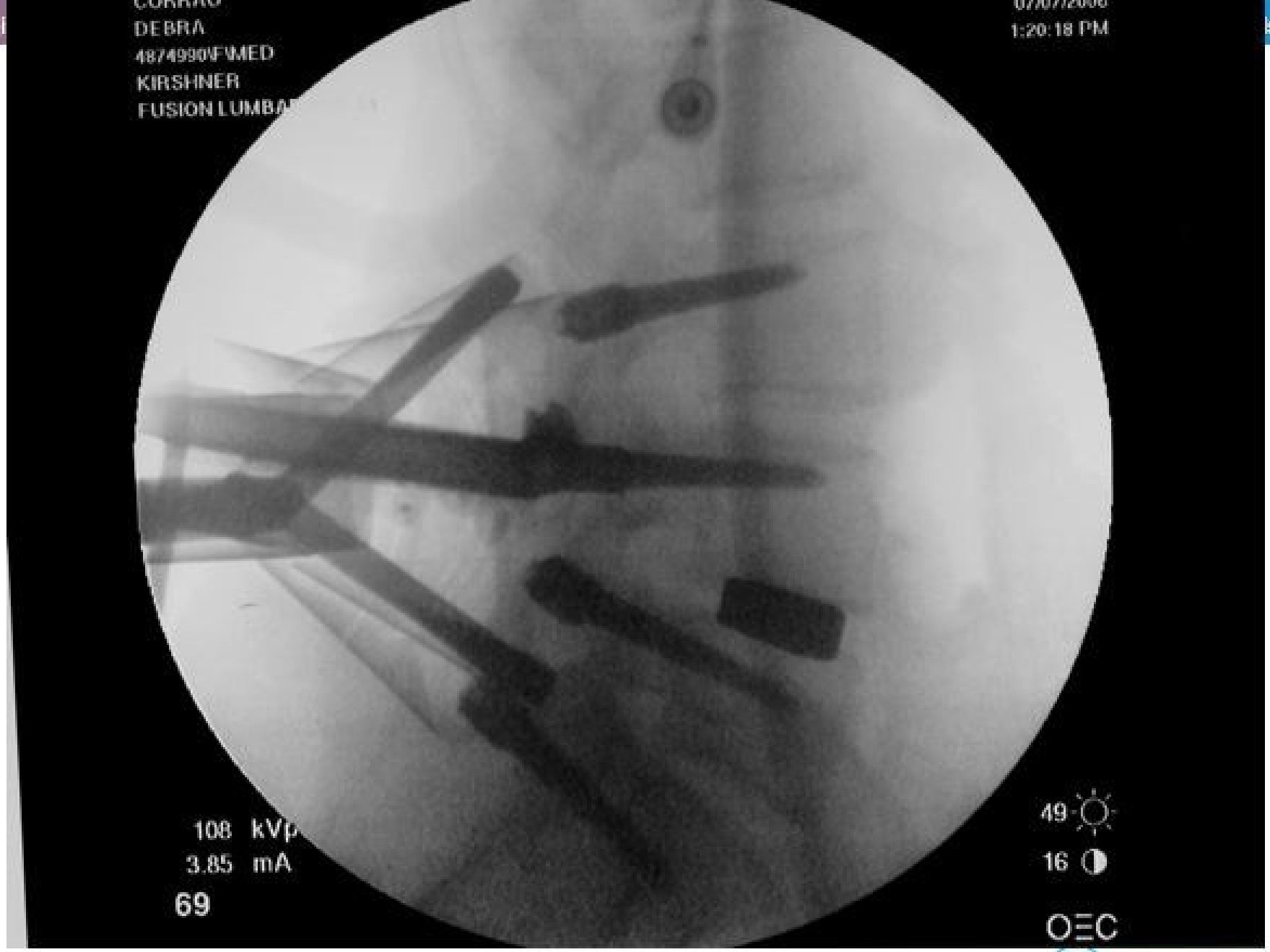
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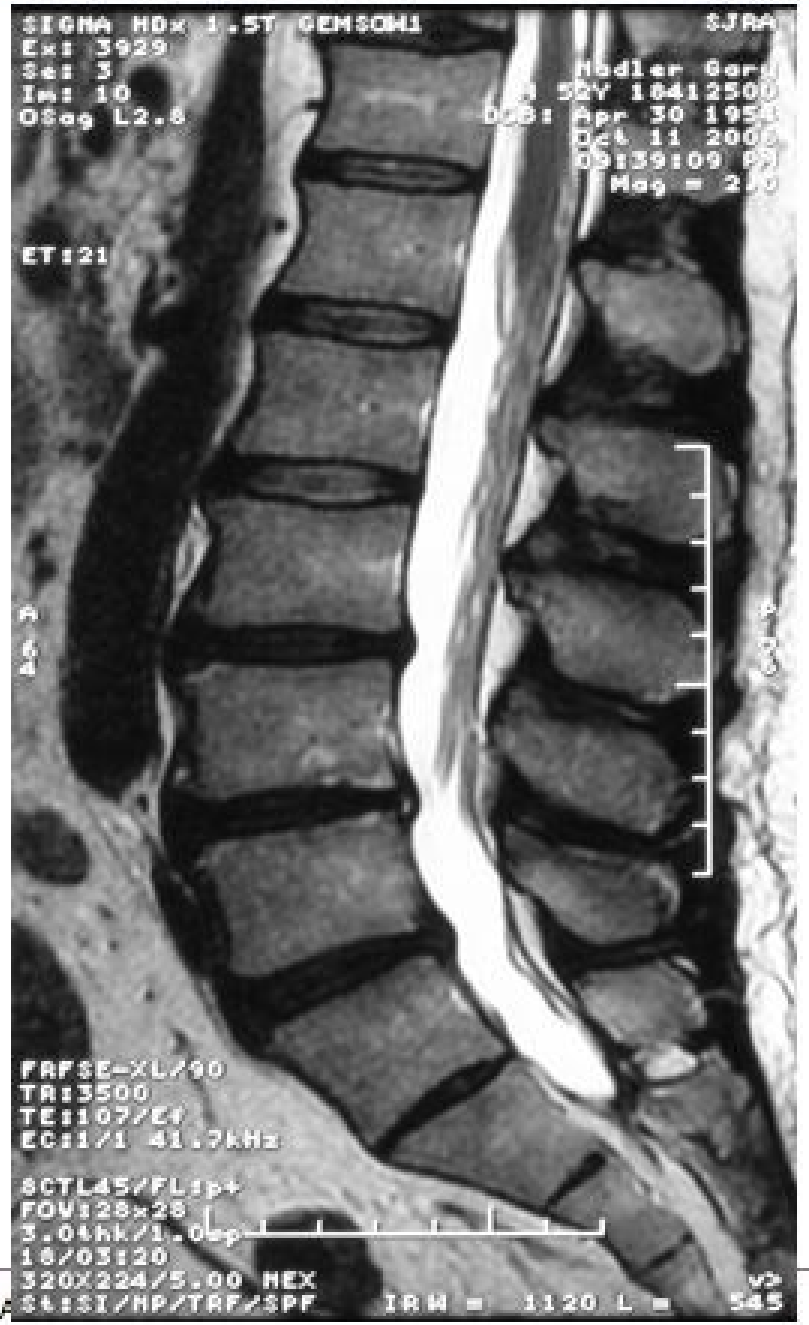
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EC:1/1 41.7kHz
8CTL45/FL:p+
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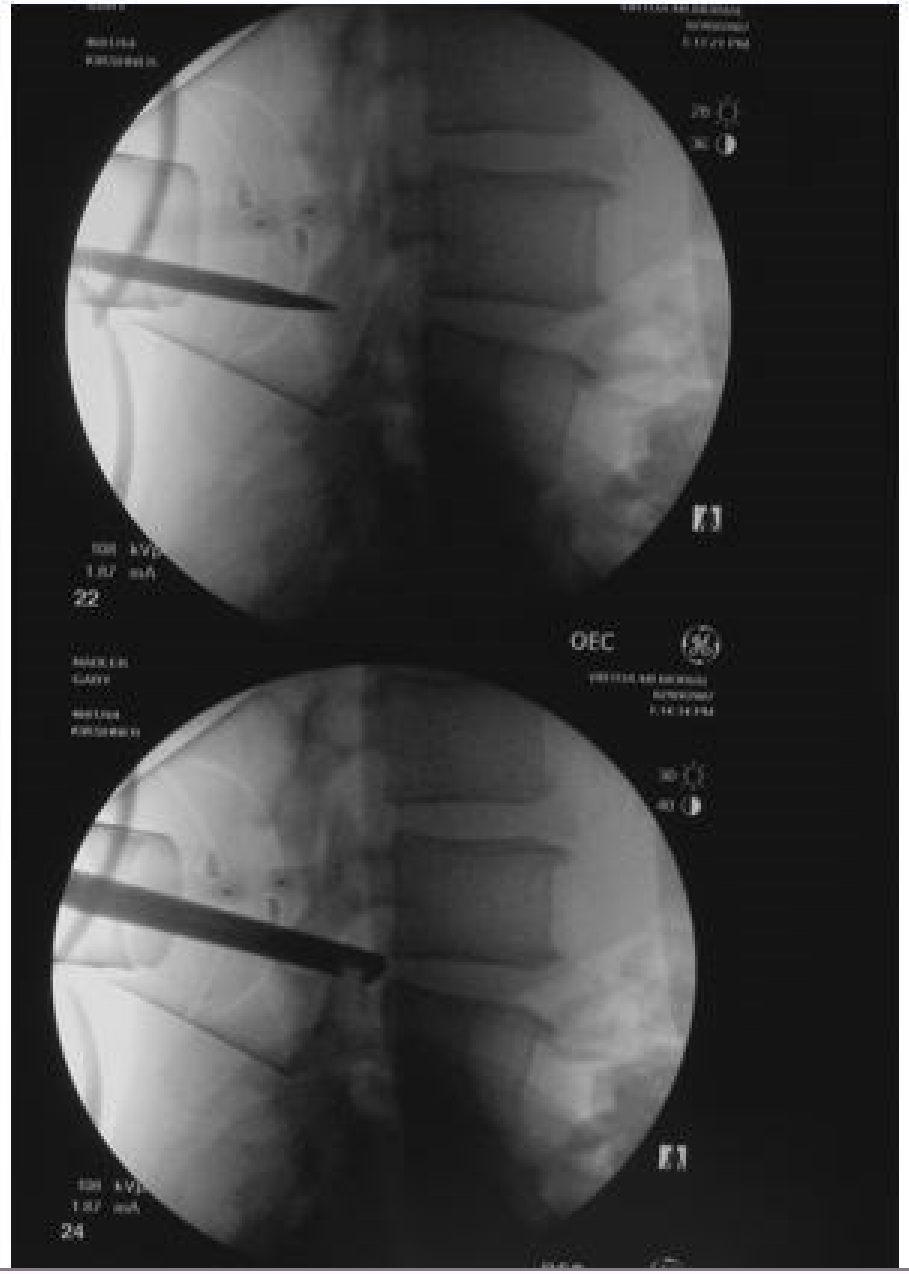
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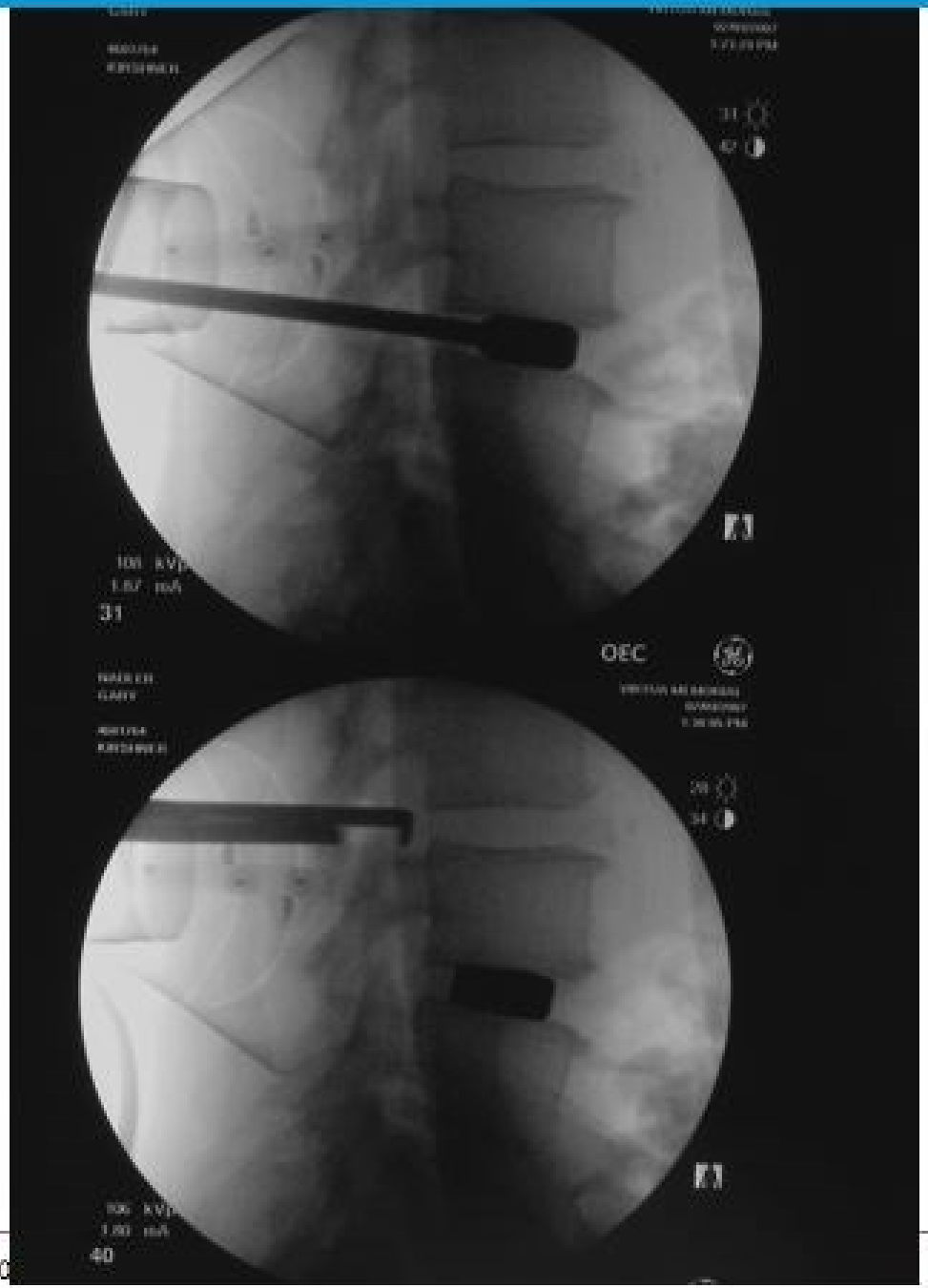
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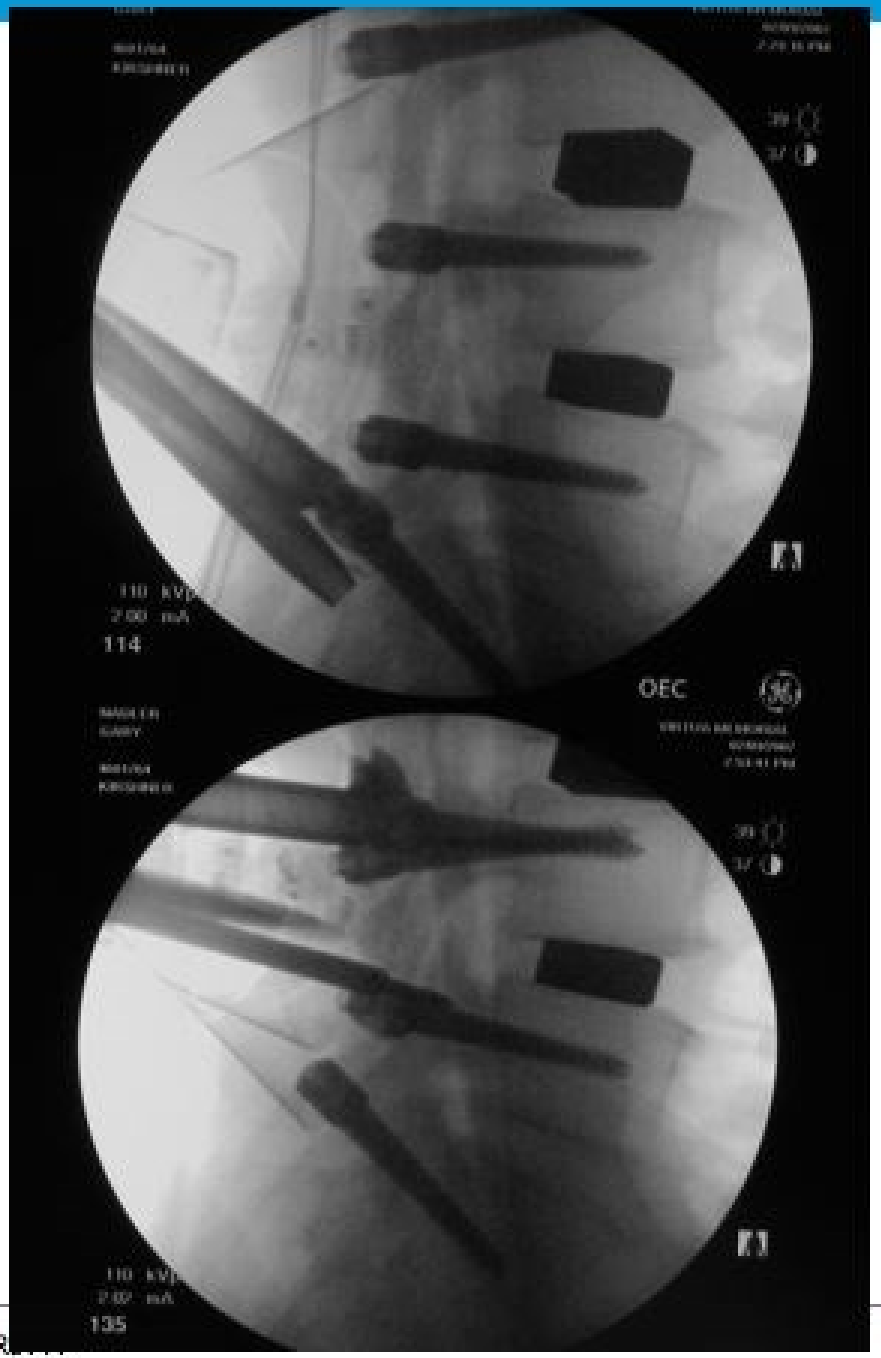
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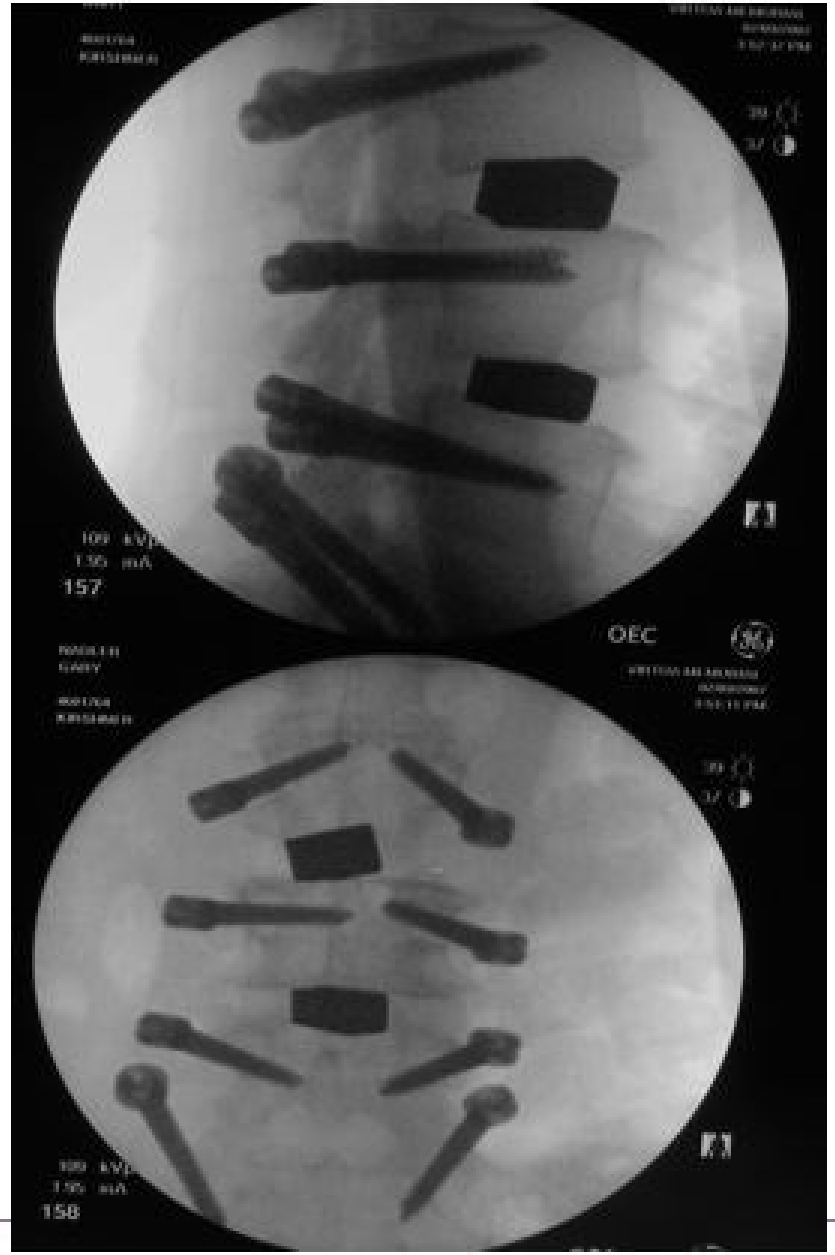
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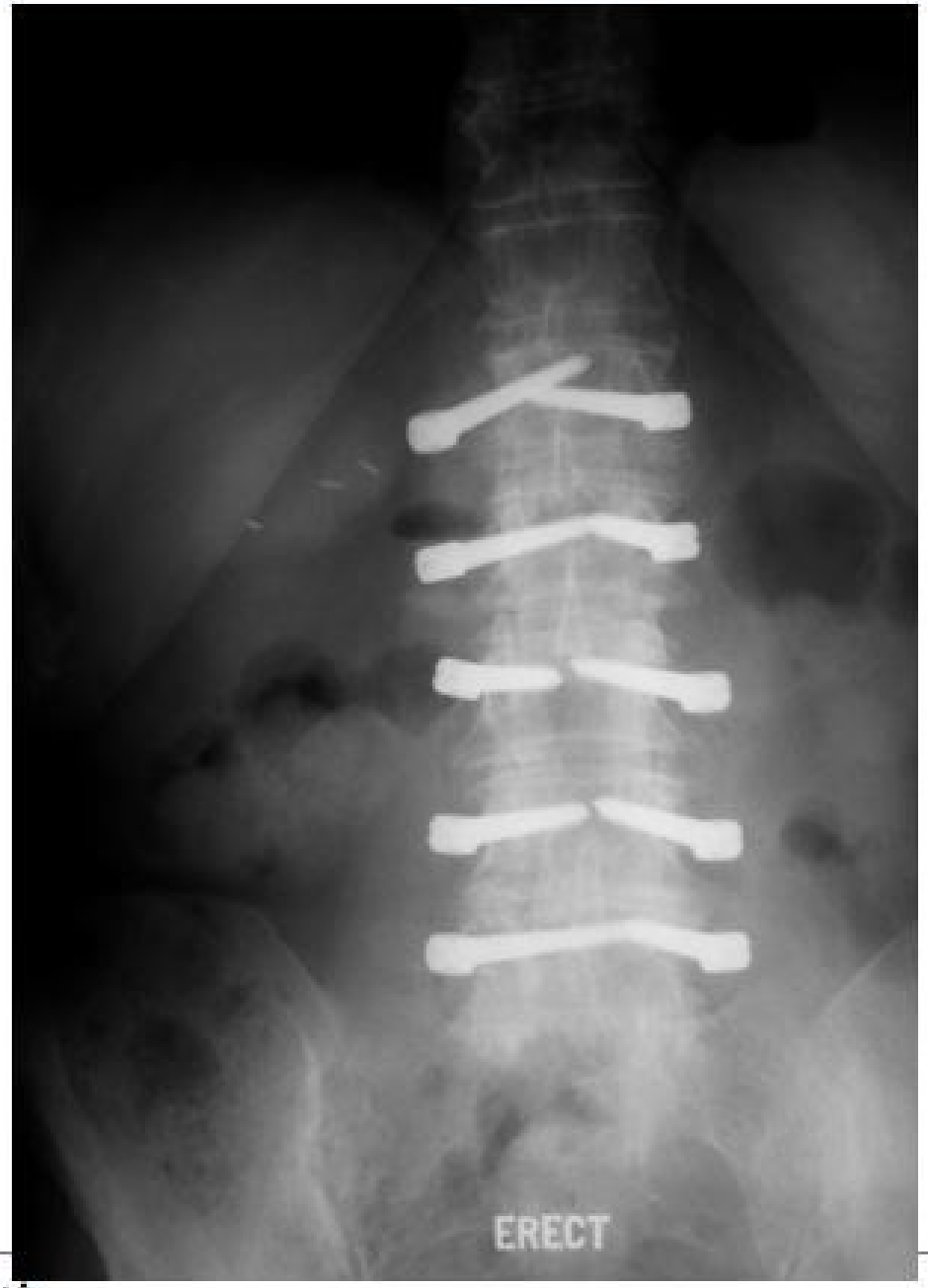
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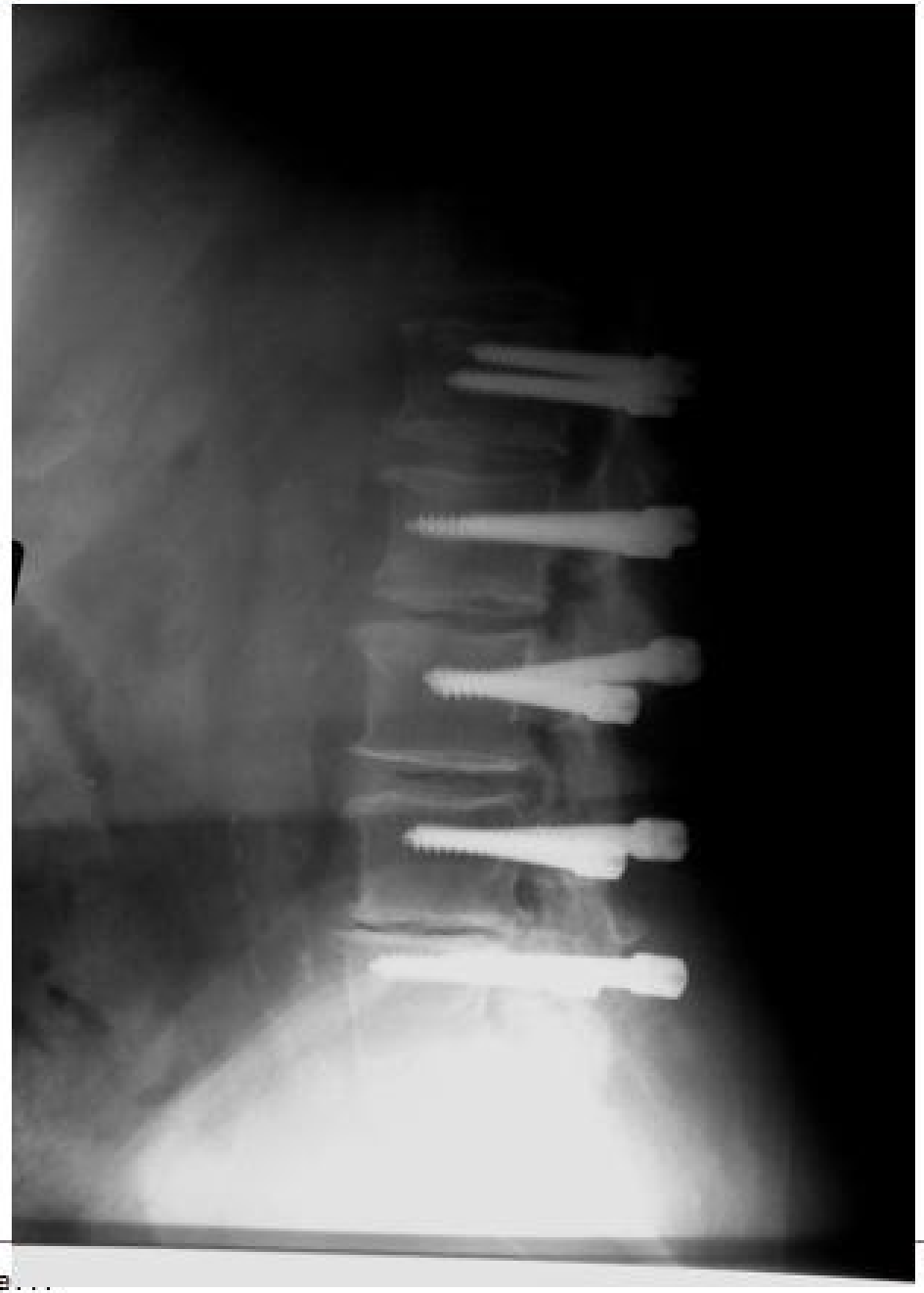

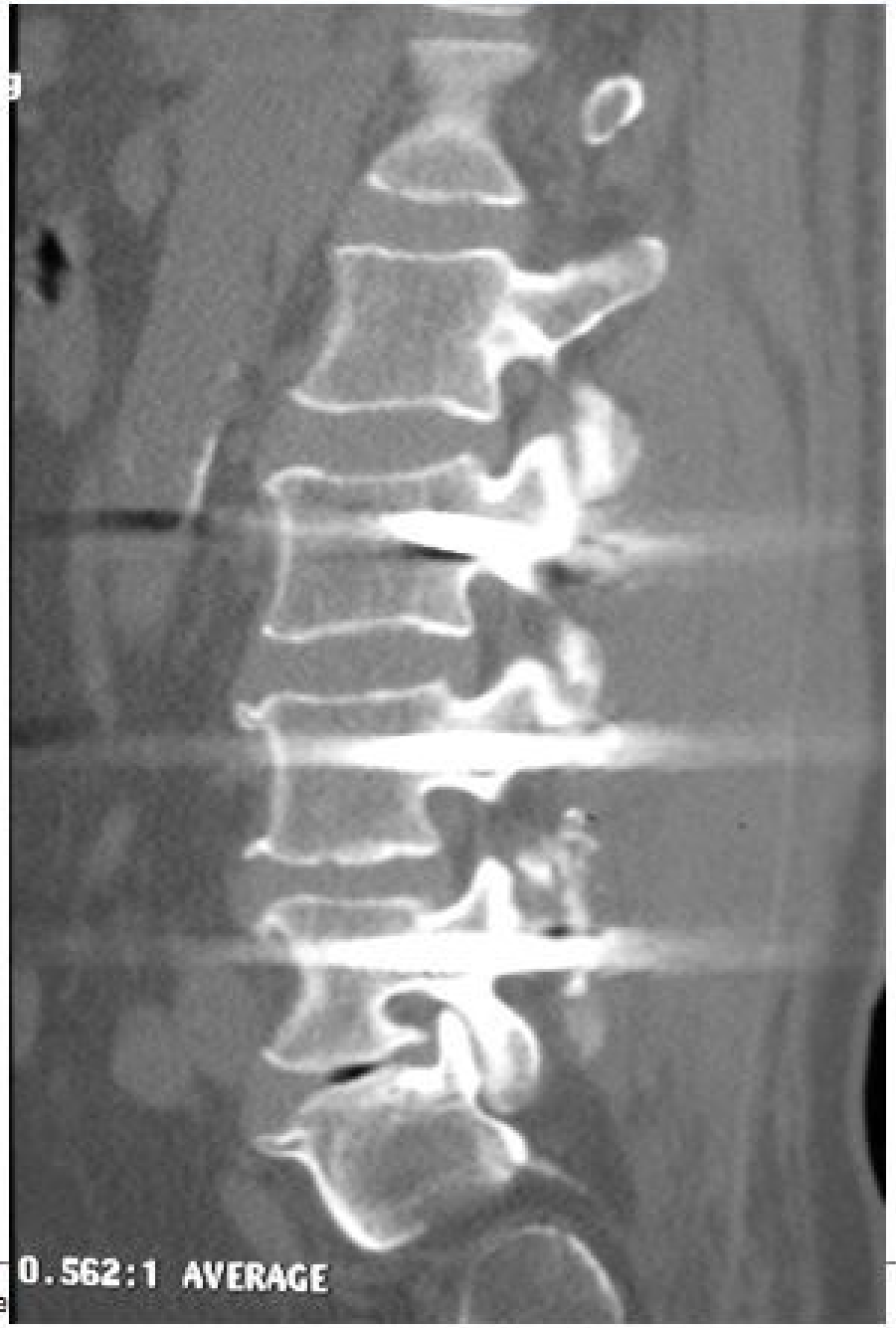
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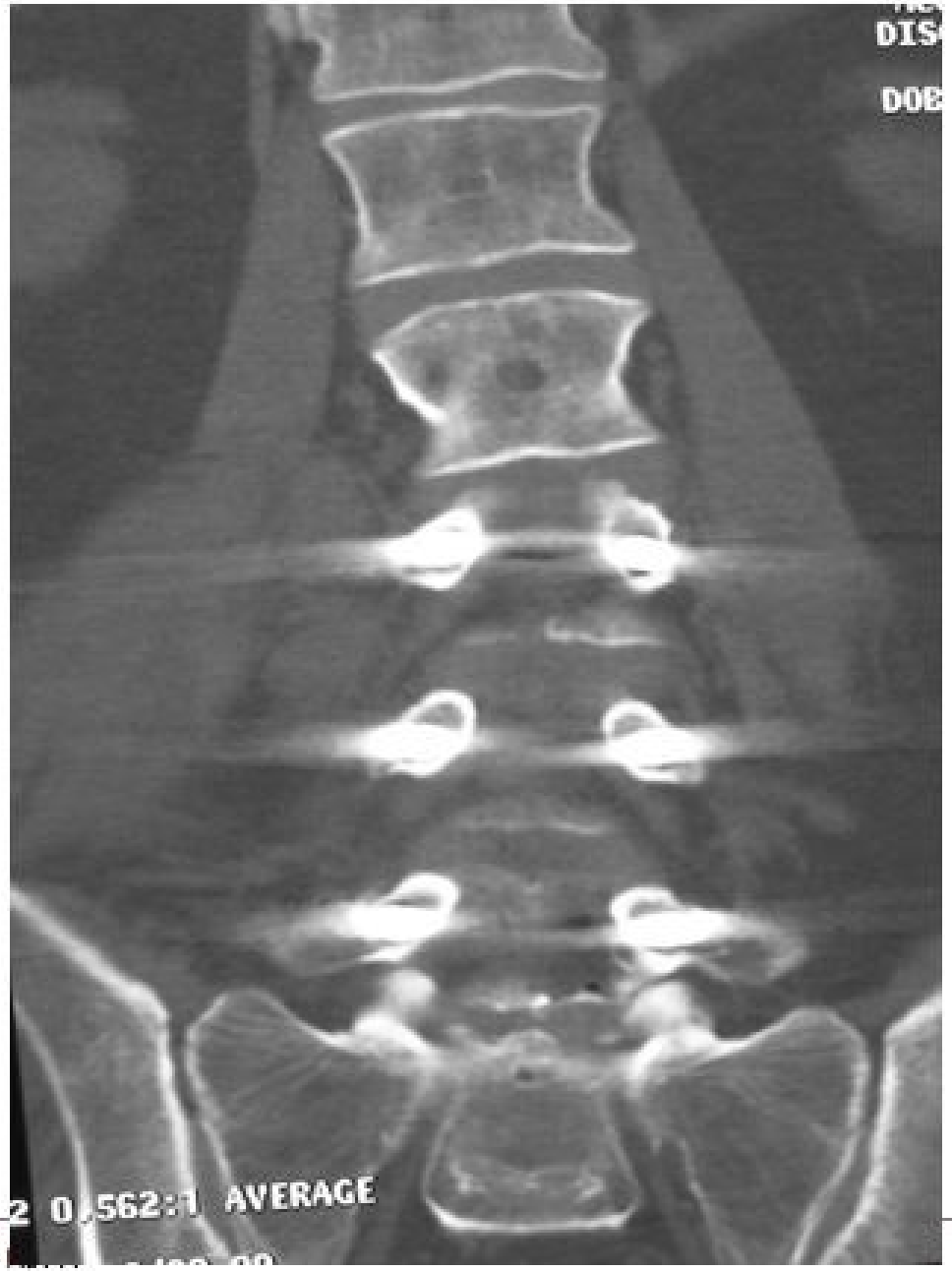
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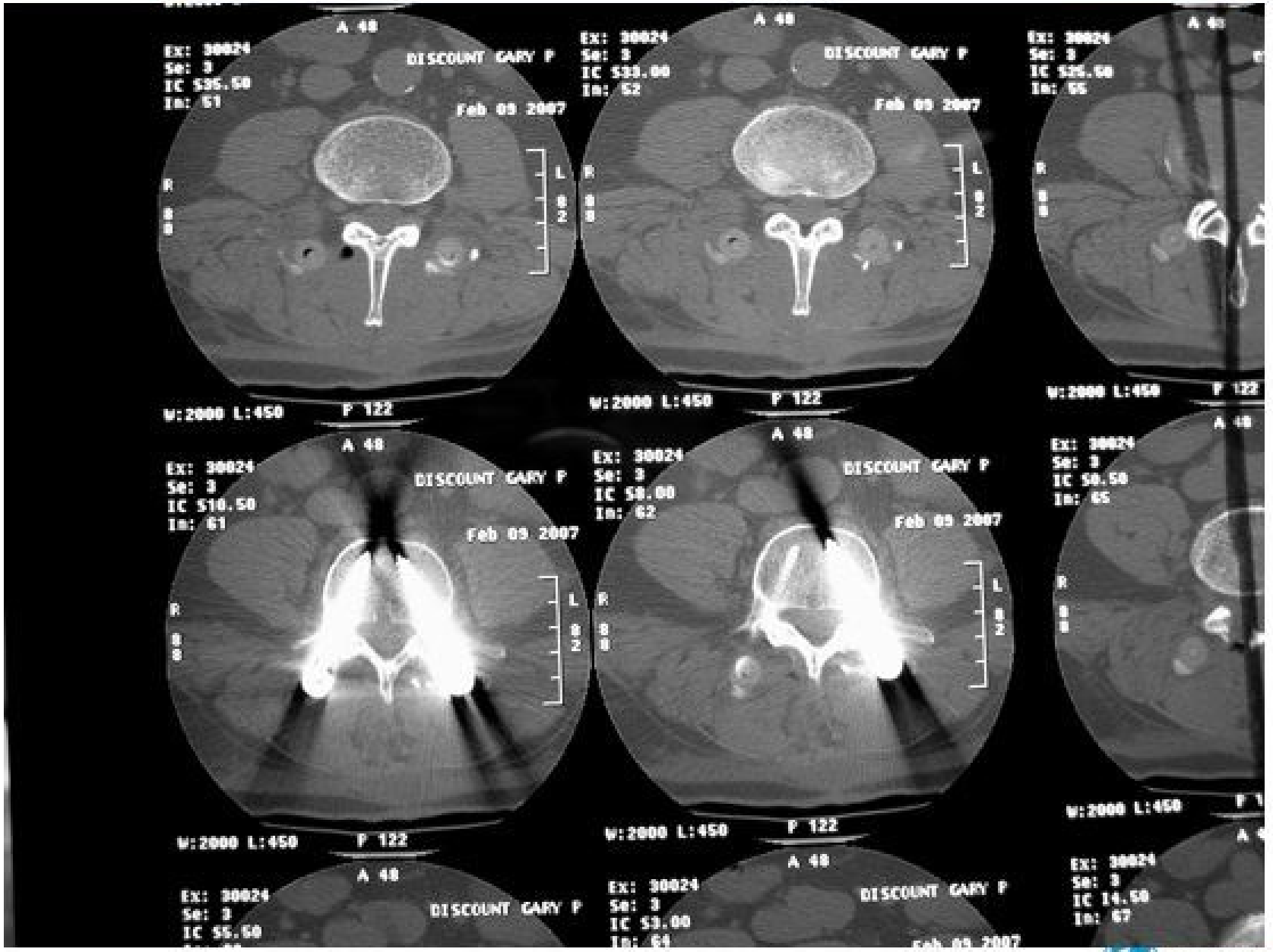
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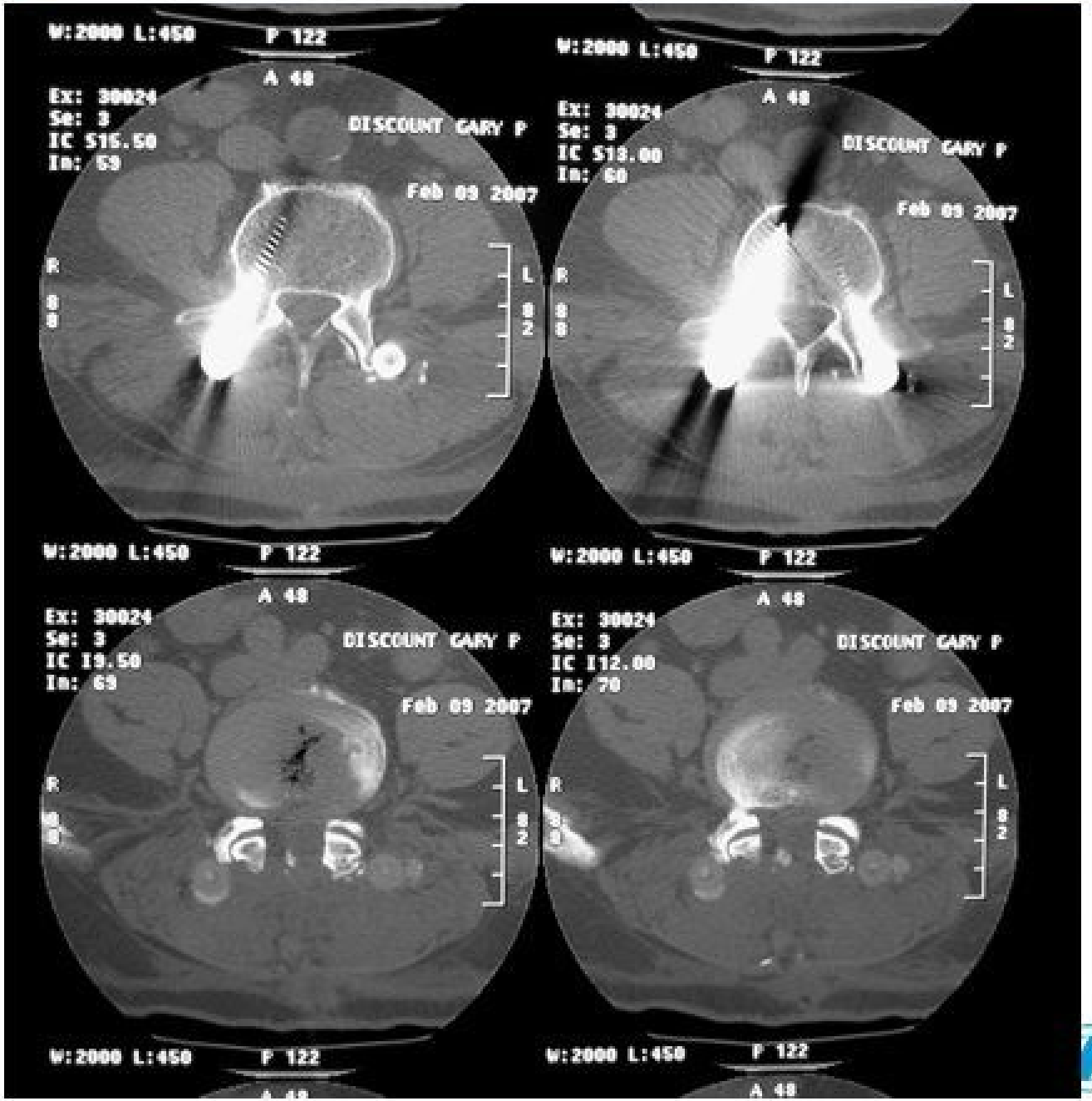
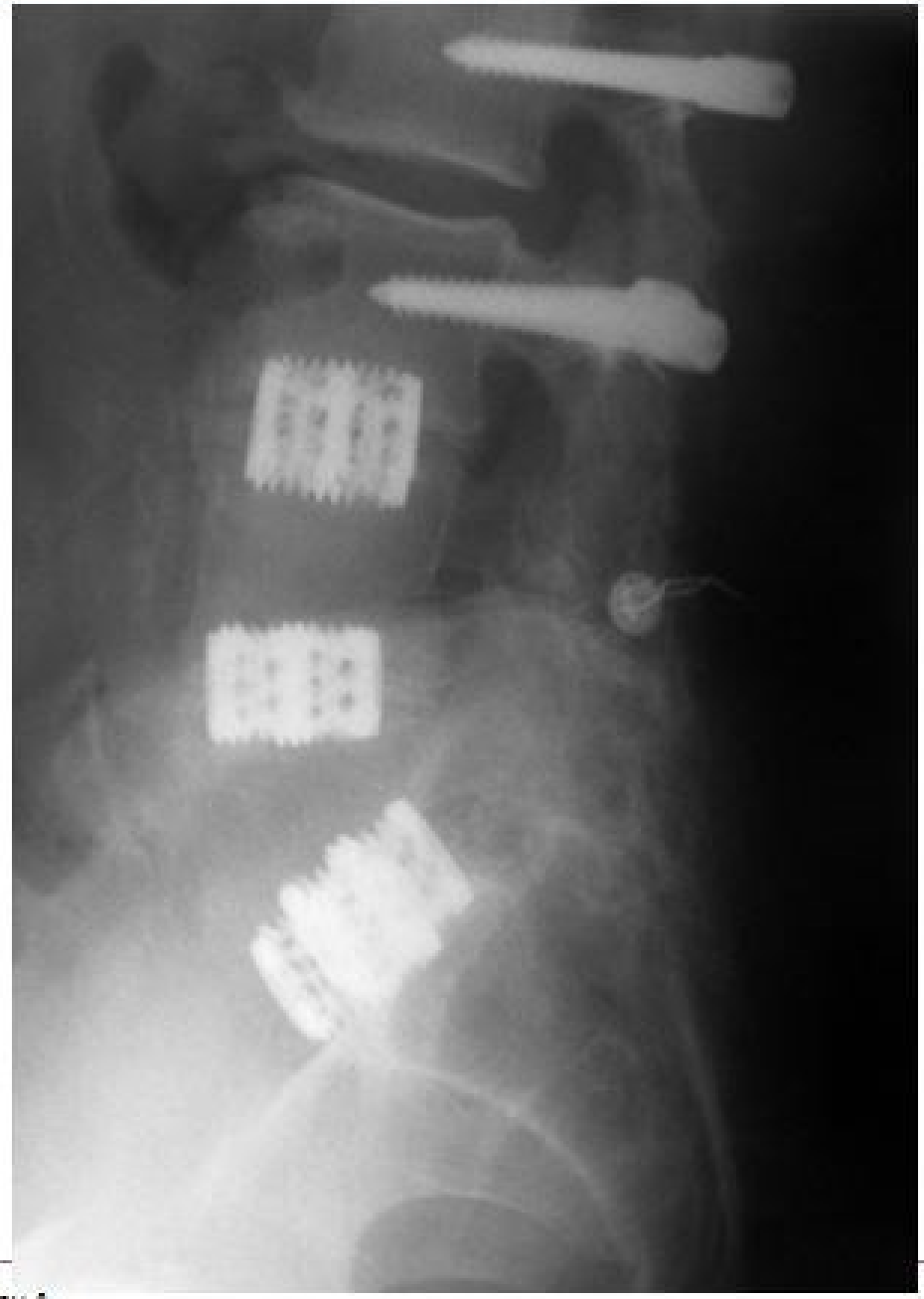
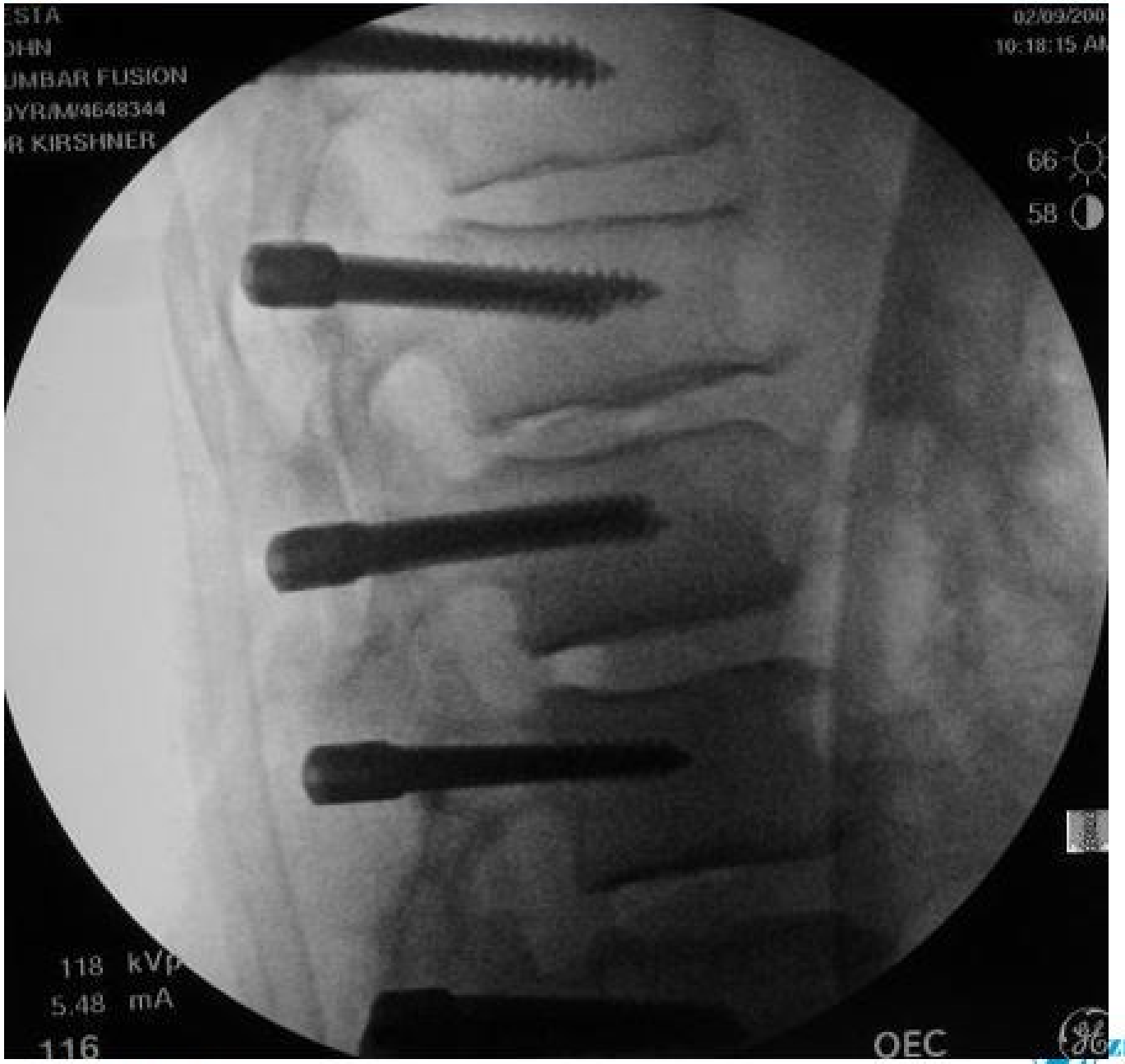


zimmer | spine





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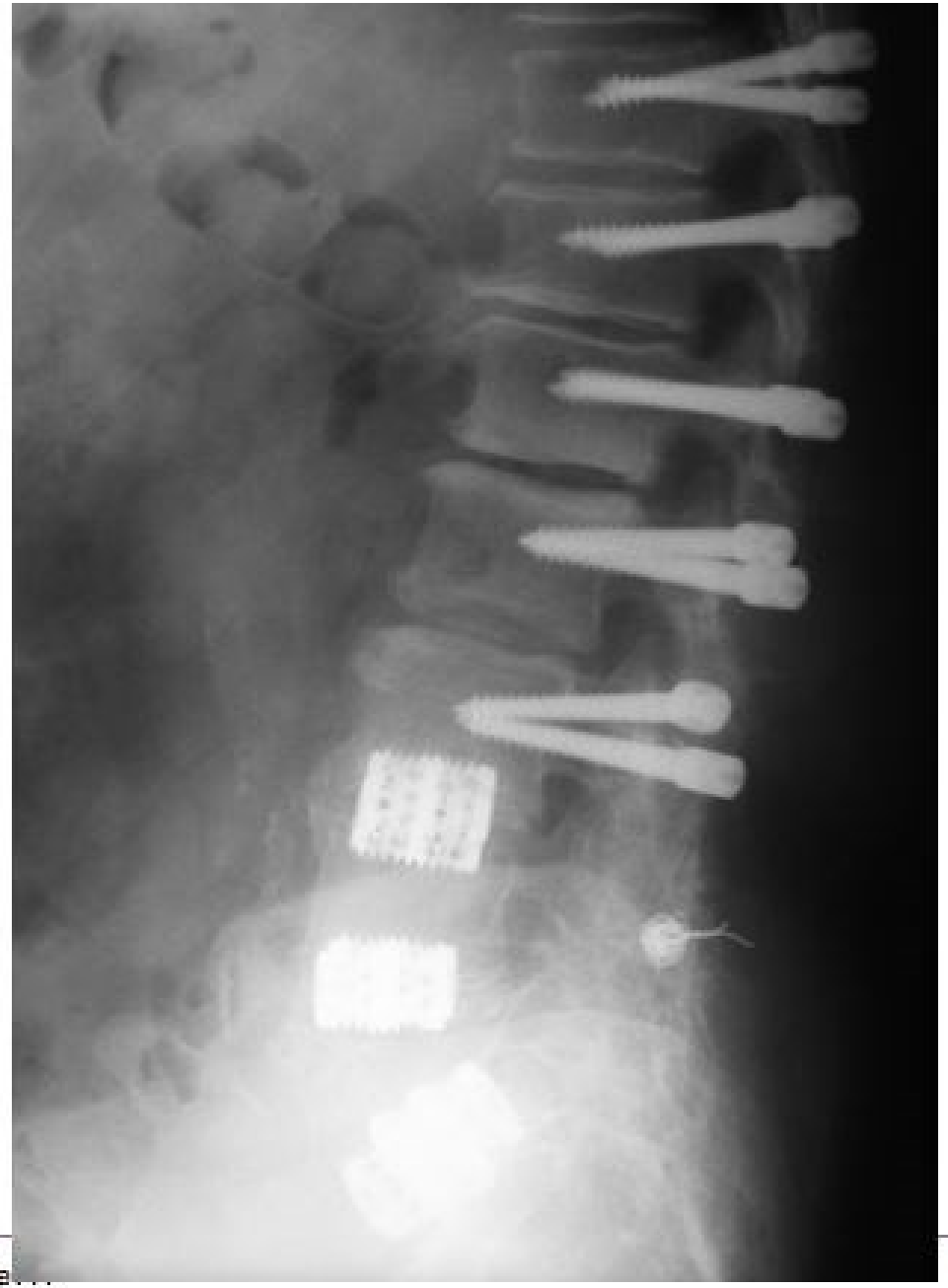
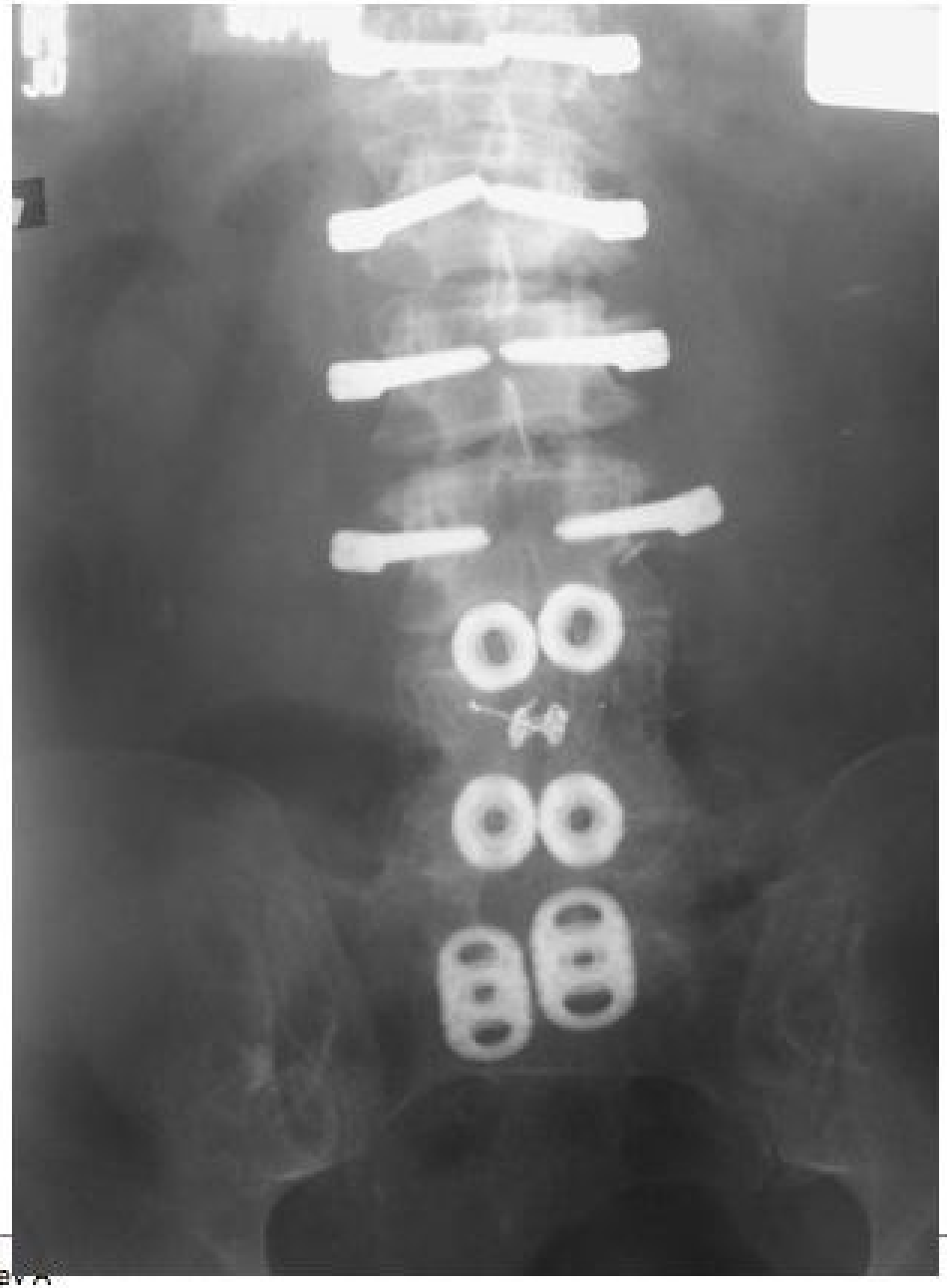
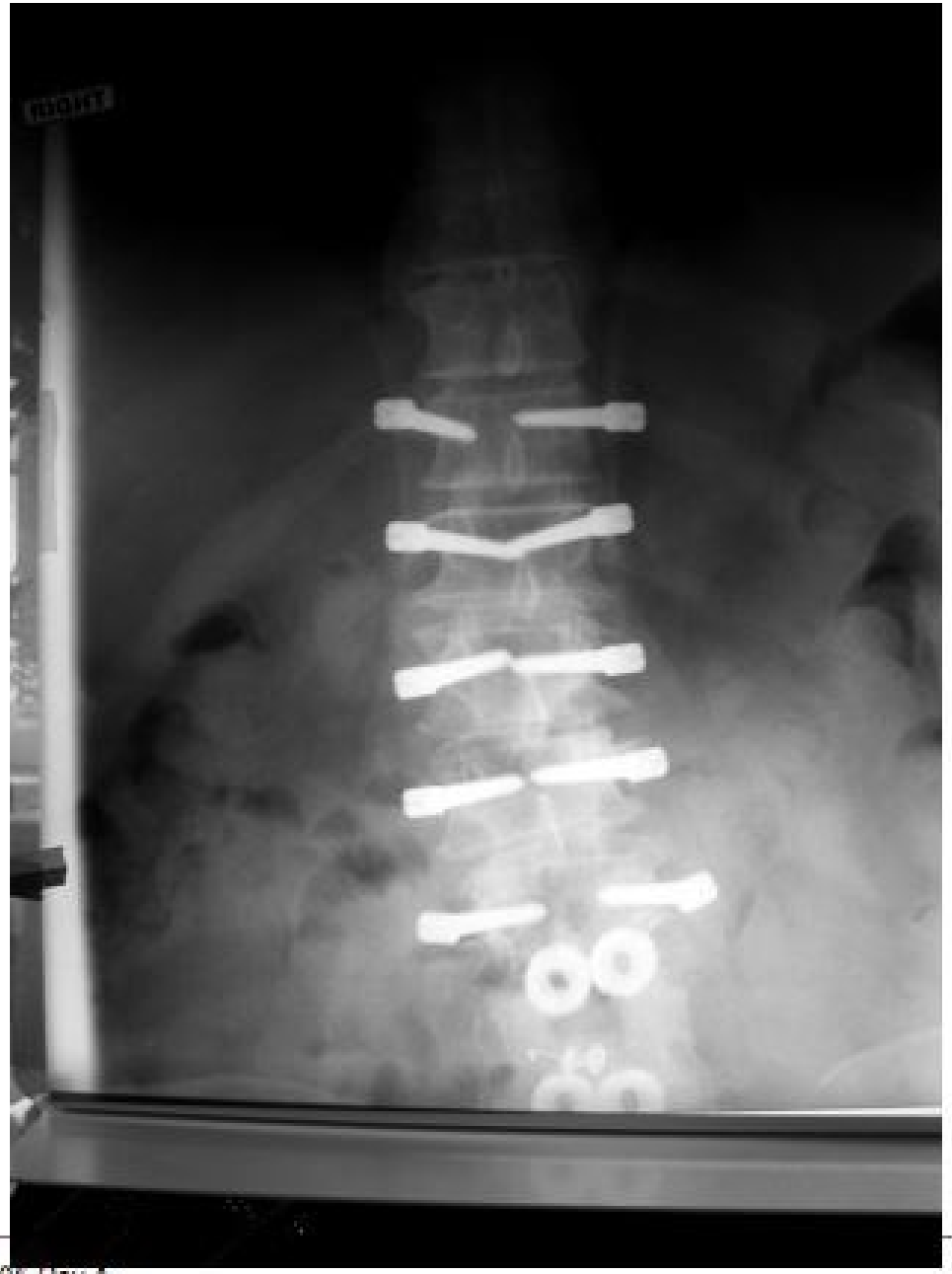
zimmer | spine







Dynesys Clinical Investigation

Reginald Davis, Greater Baltimore Medical Center, Baltimore, MD
Rick Delamarter, Saint John's Health Center, Santa Monica, CA
James H. Maxwell, Scottsdale Spine Care, Scottsdate AZ
John Sherman, Institute for Low Back and Neck Care, Edina, MN
William Welch, University of Pittsburgh, Pittsburgh, PA
Jeffrey K. Wingate, spine., Mt. Pleasant SC

Study Design

- Prospective, randomized, multi-center study
- 368 total patients were implanted at 28 centers
- The Dynesys® Spinal System (Investigational)
  PLF with The Silhouette™ Fixation System (Control)
- 2 Investigational:1 Control
- Each site completed 1 non-randomized Dynesys procedure
- Study visits
  - Pre-op
  - Operative/Post-Op
  - 3 weeks
  - 3 month
  - 6 month
  - 12 month
  - 24 month

IDE Indication Statement

The Dynesys Spinal System is indicated to provide alignment and stabilization in skeletally mature patients at one or two contiguous levels from L_1-S_1. Patients have radiculopathic symptoms including leg pain, muscle weakness, and/or sensation abnormality as evidenced by patient history and diagnostic studies. Patients may have a narrowing of the lateral or central canal and/or neurogenic claudication. These signs and symptoms are caused by:

- Degenerative spondylolisthesis or retrolisthesis (Grade I)
  AND/OR
- Spinal stenosis or stenosing lesions

Patients may require decompression at the levels considered for treatment. Dynesys is intended to be used without bone graft.

Inclusion Criteria

- Candidate for single-level or contiguous two-level PLF between L1-S1;
- Patients have a predominate component of leg rather than back symptoms; symptoms include pain, muscle weakness, and/or sensation abnormality
- Leg pain score ≥ 40 mm
- Unresponsive to conservative management for at least 3 months;
- Pre-operative Oswestry score ≥ 30
- Age between 20 and 80
- Must be willing and/or able to comply with study requirements

Exclusion Criteria

- Primary diagnosis of discogenic back pain
- Degenerative scoliosis >10°
- Greater than Grade I spondylolisthesis or retrolisthesis
- Previous lumbar fusion attempt(s) at index level(s)
- previous total facetectomy or trauma at index level(s);
- Gross obesity
- Advanced osteoporosis women over 50 and men over 60 should have a DEXA scan of <-2t (age corrected)
- Any significant medical conditions which would substantially increase surgical risk
- Titanium alloy, PET or PCU allergy, or intolerance;
- Current chemical dependency or significant emotional and/or psychosocial disturbance
- Pathology or deformity to the spine that would compromise the system

Primary Study Objectives

- Safety:
  - Neurological maintenance or improvement
  - Freedom from further surgical intervention
- Effectiveness
  - Leg pain relief (100 mm VAS)
  - Functional improvement (Oswestry Disability Index)
- Dynesys and PLF compared in a non-inferiority paradigm

Radiographic Criteria

- Stability:
  - £ 15° Angular Motion at L_1-L_4
  - £ 20° Angular Motion at L_4-L_5
  - £ 25° Angular Motion at L_5-S_1
  - £ 4.5 mm Translation Motion
- Fusion:
  - £ 5° Angular Motion
  - £ 3.0 mm Translational Motion
  - Clear Evidence of Bridging Bone
- **Radiographic Success**
  - Dynesys = Stability NOT Fusion
  - PLF = Stability AND Fusion

Study Status

- Follow-Up Ongoing
  - Primary comparison at 24 months post-surgery
- Randomized Subjects Implanted
  - 247 Dynesys implants
  - 111 Silhouette implants
- Needed for adequate comparisons
  - 184 Dynesys implants
  - 92 Silhouette implants
- Last Patient Last Visit:
  - Last procedure preformed on 29 June 2005
  - Last Visit ± 2 Month from 29 June 2007

The Dynesys® Spinal System Summit Data A Preliminary Analysis:

- Pooled observations from 6 non-systematically chosen investigative sites

The Summit Cohort

- 101 Subjects pooled form 6 investigative sites

Maximum sample size at indicated assessment points

Preoperative	3 Week	3 Month	6 Month	12 Month	24 Month
101	**92**	**96**	**94**	**80**	**27**

Individual sample sizes vary slightly due to

- Missing Data
- Non Verified Data
- Follow-up visit not completed
- Etc.

In all cases error bars indicate 1 Standard Error of Measure (SEM)

The Summit Cohort

	Age (yrs)	Height (In)	Weight (lb)	Symptom Duration (yrs)
Mean	56.3 (1.2)	66.7 (0.4)	178.6 (3.3)	5.3 (0.6)
SEM	1.2	0.4	3.3	0.6
n	99	100	101	95

Gender	Male	Female	Total
n	48	53	101
Percent	47.5%	52.5%	100.0%

The Summit Cohort

Primary Indication

	Lateral Stenosis	Central Stenosis	Spondy-lolisthesis	Retro-listhesis	Other	Total
n	40	26	20	3	4	93
Percent	43.0%	30.0%	21.5%	3.2%	4.3	100.00%

The Summit Cohort

Operative Levels

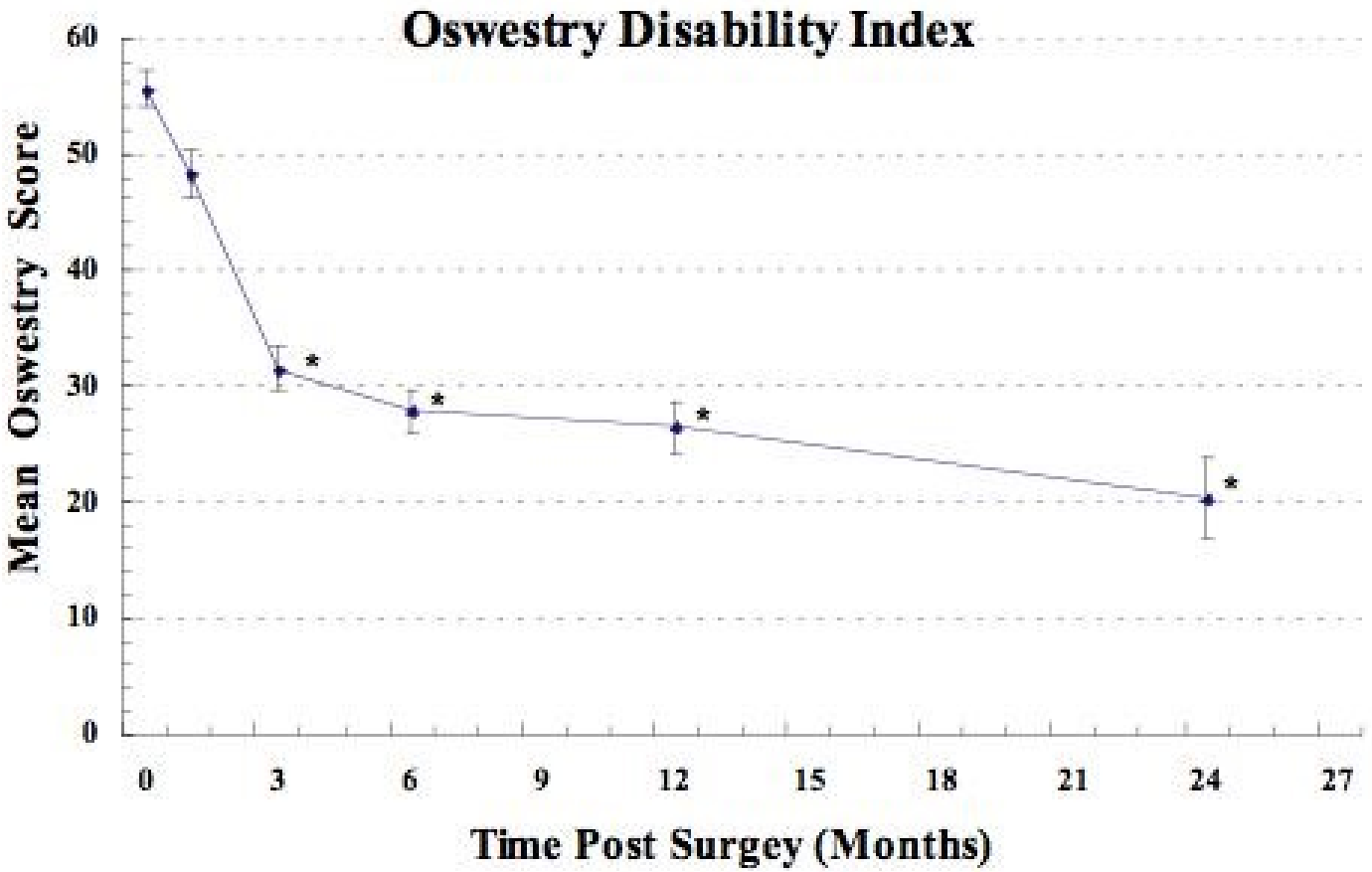
		n	% of Group	% of Total
1-Level	L2-L3	3	5.4%	3.0%
	L3-L4	7	12.5%	6.9%
	L4-L5	38	67.9%	37.6%
	L5-S1	8	14.3%	7.9%
	Group Sub Total	**56**	**100.0%**	**56.0%**
2-Level	L2-L3, L3-L4	1	2.3%	1.0%
	L3-L4, L4-L5	20	45.5%	19.8%
	L4-L5, L5-S1	23	52.3%	22.8%
	Group Sub Total	**44**	**100%**	**44.0%**
TOTAL		**100**		**100%**

The Summit Cohort

Operative Variables

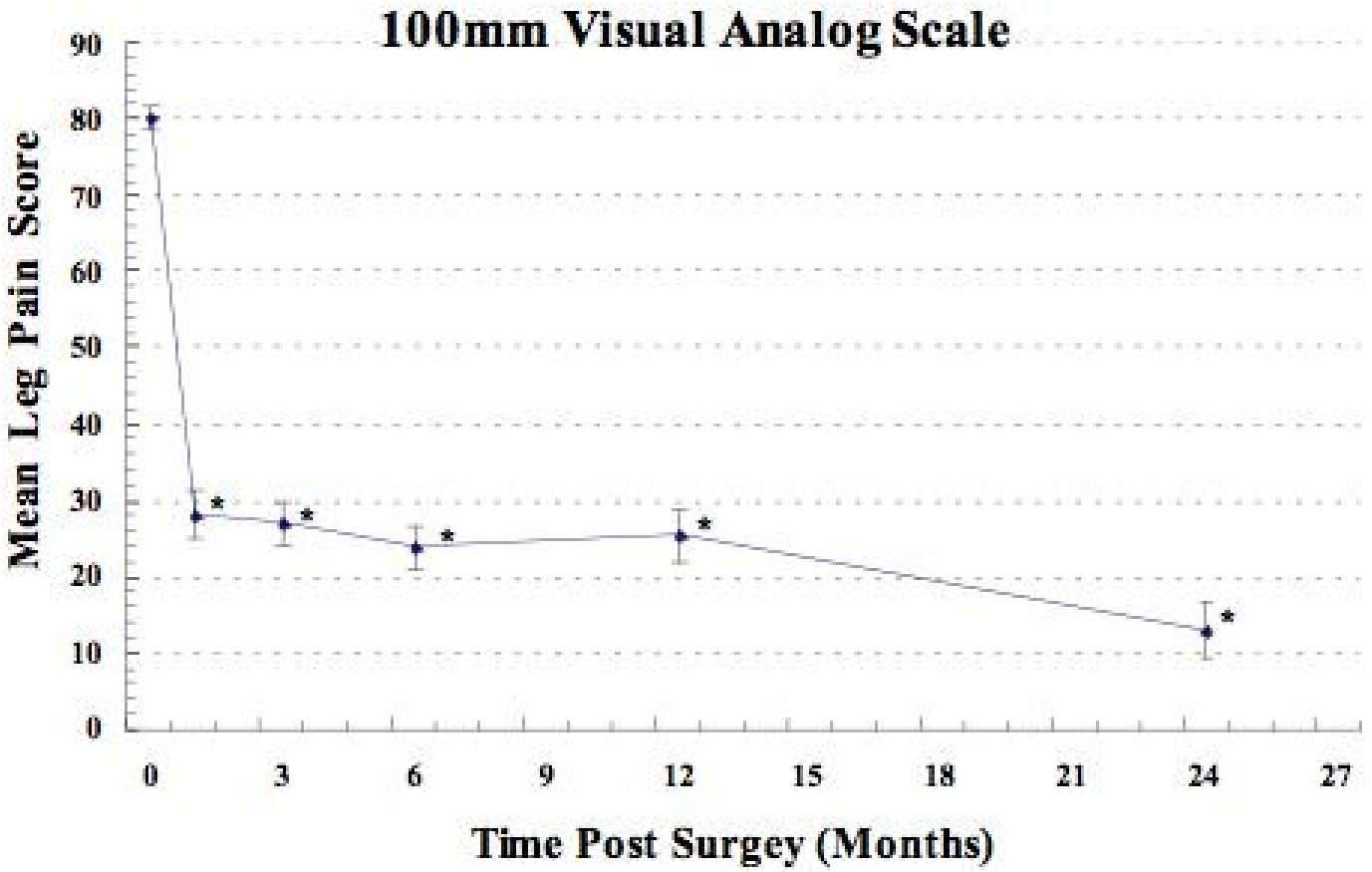
		Surgery Time (min)	Hospital Stay (days)	EBL (cc)
1 Level	Mean	167	4.1	400
	SEM	4.9	0.2	50.8
	n	56	56	56
2 Levels	Mean	205.6	4.7	516
	SEM	8.2	0.3	52.2
	n	44	43	44
All Subjects	Mean	184	4.4	451
	SEM	4.9	0.1	36.9
	n	100	99	100

Function



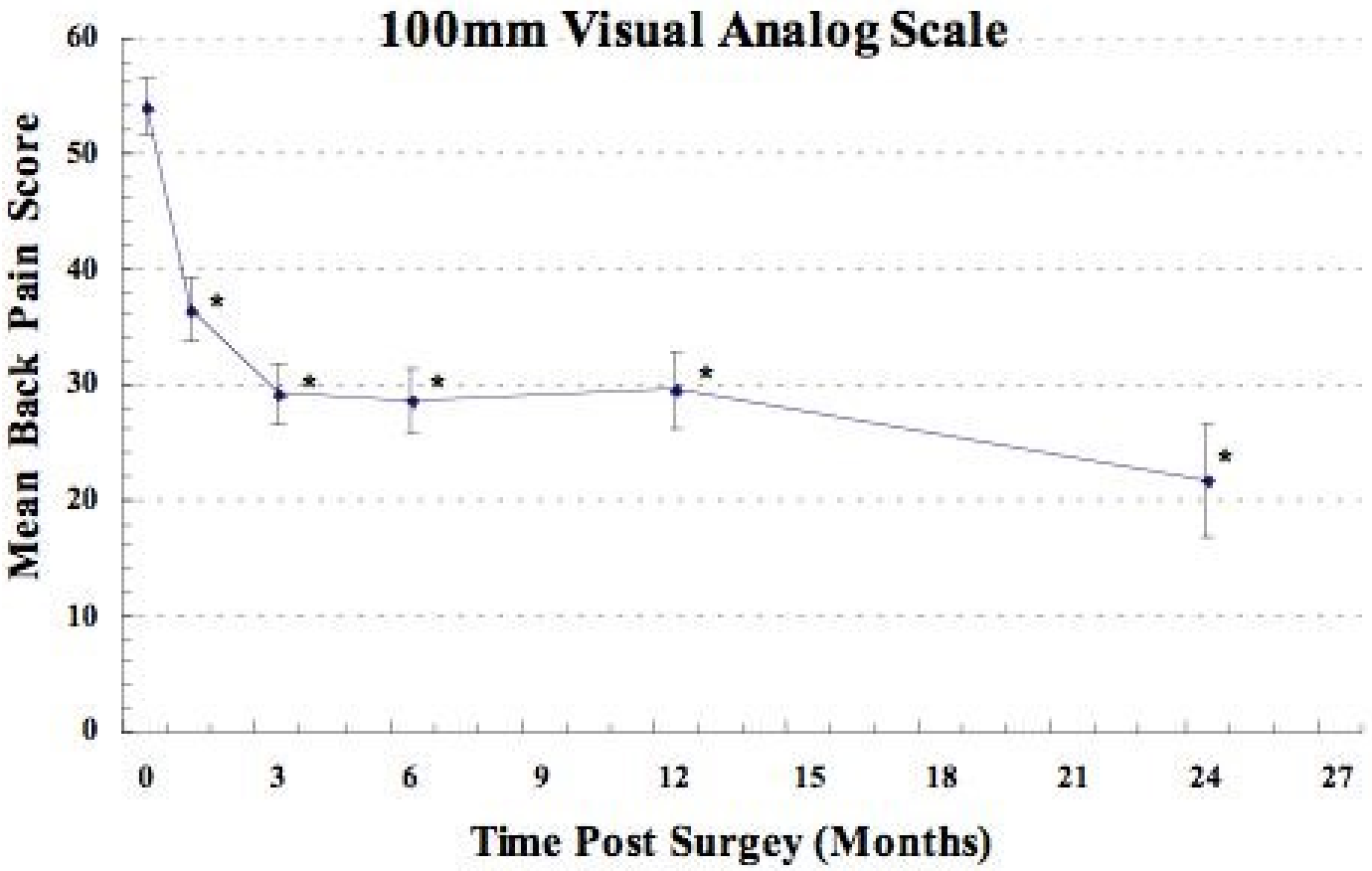
* Indicates Significant Difference From Preoperative Baseline
$p < 0.01$, Wilcoxon Signed Rank Test

Leg Pain



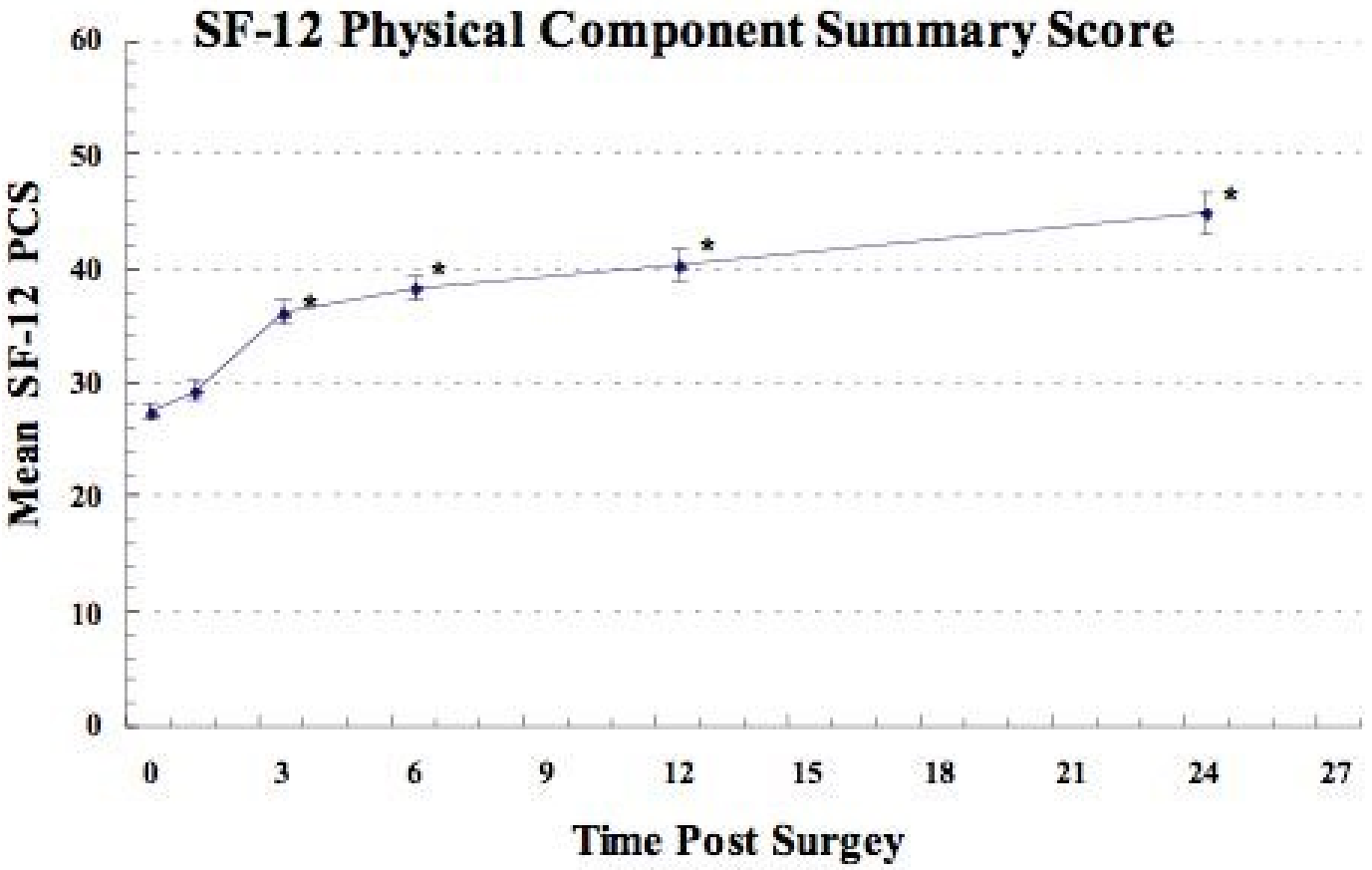
* Indicates Significant Difference From Preoperative Baseline
$p < 0.01$, Wilcoxon Signed Rank Test

Back Pain



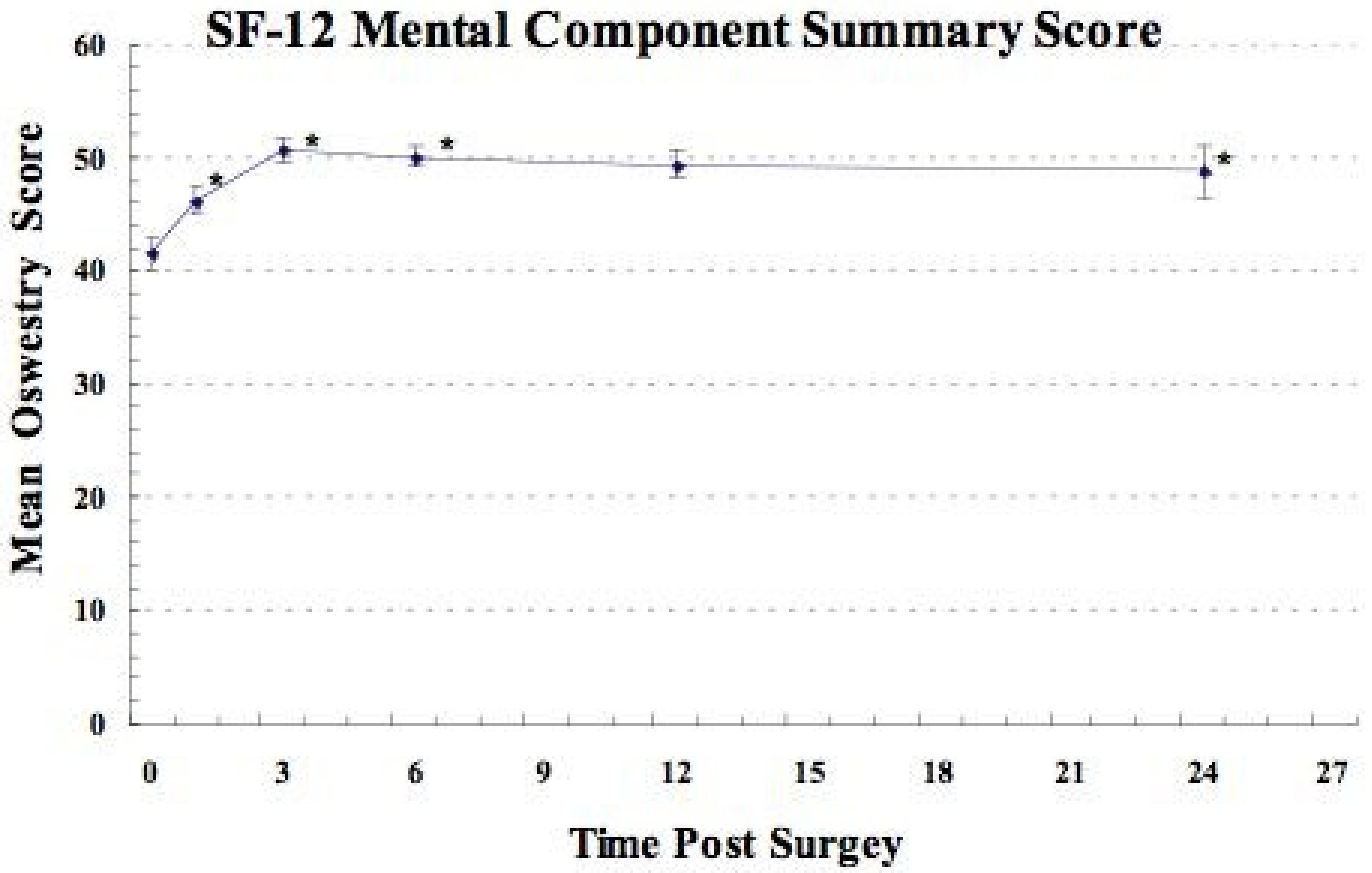
* Indicates Significant Difference From Preoperative Baseline
$p < 0.01$, Wilcoxon Signed Rank Test

General Health



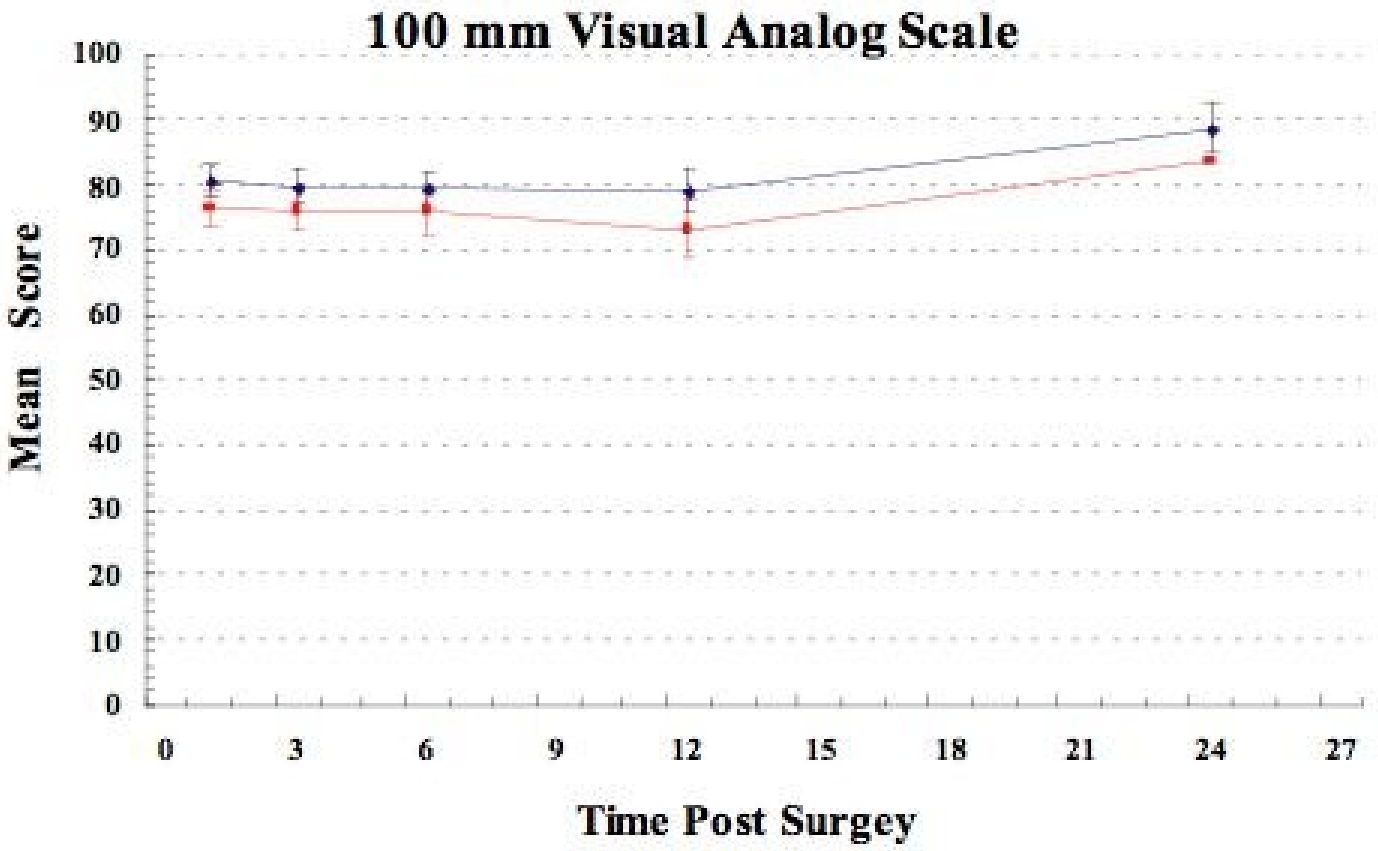
* Indicates Significant Difference From Preoperative Baseline
$p < 0.01$, Wilcoxon Signed Rank Test

General Health



* Indicates Significant Difference From Preoperative Baseline
$p < 0.05$, Wilcoxon Signed Rank Test

Patient Perception



The Summit Cohort

Device Related A/Es

	n	Percent of Cohort
Device Failure Fracture		
Device Migration		
Device Misplacement		
Screw Failure Fracture	1	1.0%
Screw Misplacement		

The Summit Cohort

Additional Surgical Procedures

	Total Procedures	Total Patients	% Patients experiencing Additional Surgical Procedure
Spine Related	13	10	10%
Surgery Related	1	1	1.0%
Non-Spine Related	5	4	4.0%
Total	19	15	15%

In Conclusion

- There were significant reductions in pain
- There was a significant improvement in function
- There was only 1 device related A/E
- There was essentially no change in lordosis
- There was no change in disc height

THANK YOU