

Hyun Bae, MD

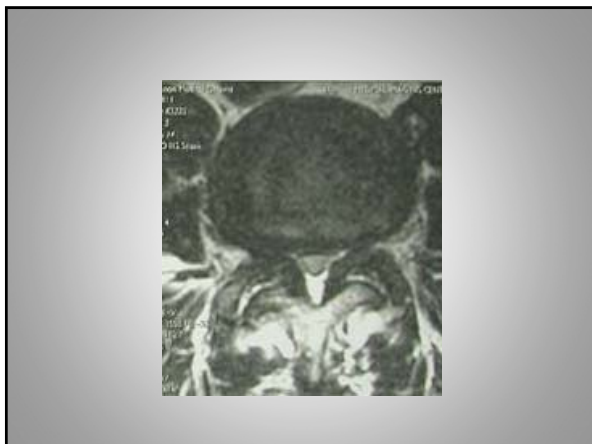


Director of Education
Co-Director of Fellowship
Cedars Spine Center

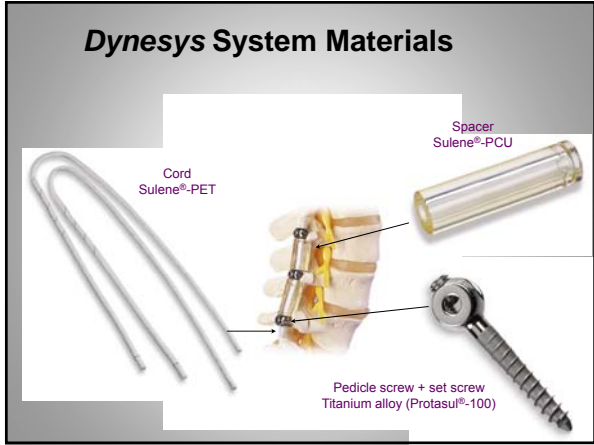


Research Director









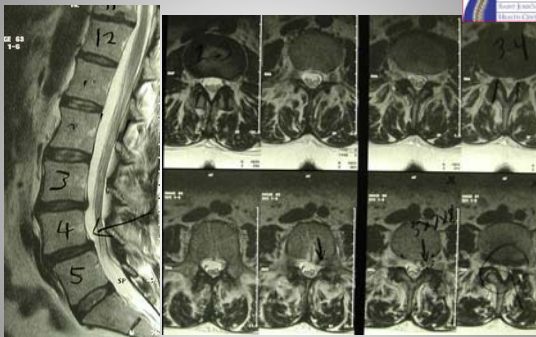


Case History

- MV
 - 49 yo F c/o LBP radiating to L leg x 2 yrs
 - Pain worse after falling down stairs
 - Numbness on plantar surface of L foot
 - Failed PT, epidurals, facet blocks, NSAIDs
 - L4-5 Grade I spondylolisthesis







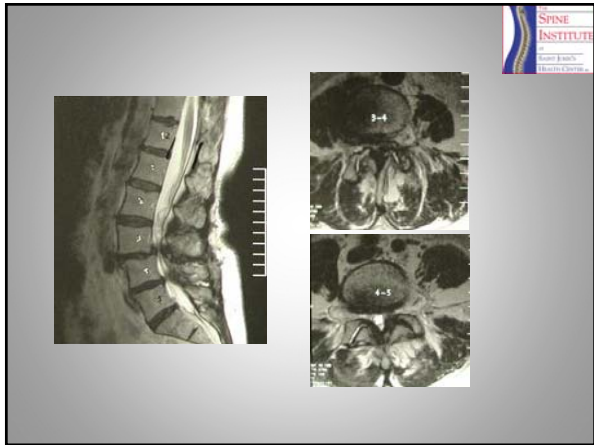


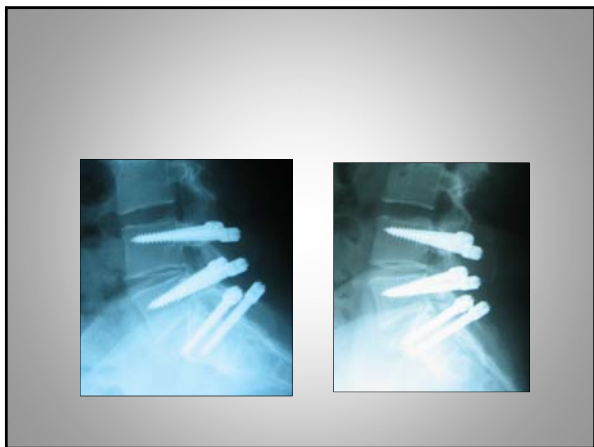


Case History

- PK
 - 73 yo F, c/o 1 yr LBP radiating to L leg
 - Failed PT, epidurals x 4, NSAIDs
 - L EHL 4/5, + SLR on L
 - Sensation intact
 - Grade I slip at L3-4
 - L3-5 decompression, Dynesis



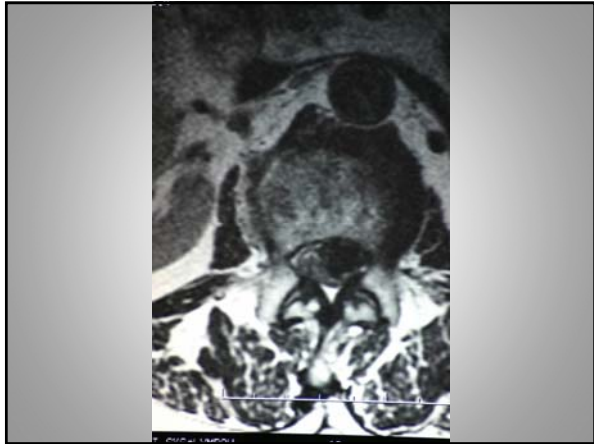






C.D.
75 YEAR OLD FEMALE





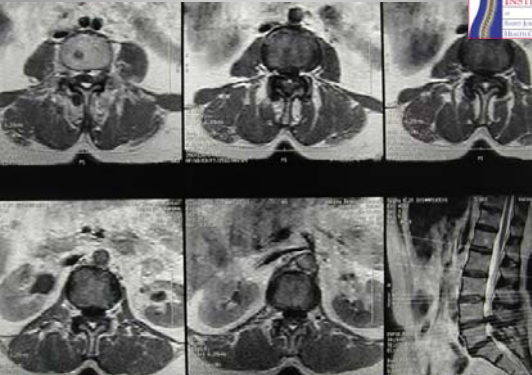




Case History

- BV
 - 66 yo F c/o LBP radiating to R leg x 10 yrs
 - Pain incapacitating over past 6 mos
 - Unable to walk > 2 blocks due to leg pain
 - Failed epidurals, NSAIDs
 - Motor intact, Sensation decreased in R foot/leg
 - + SLR bilaterally
 - Grade I slip at L4-5, L5-S1
 - L4-S1 decompression/Dynesis







Dynesys IDE

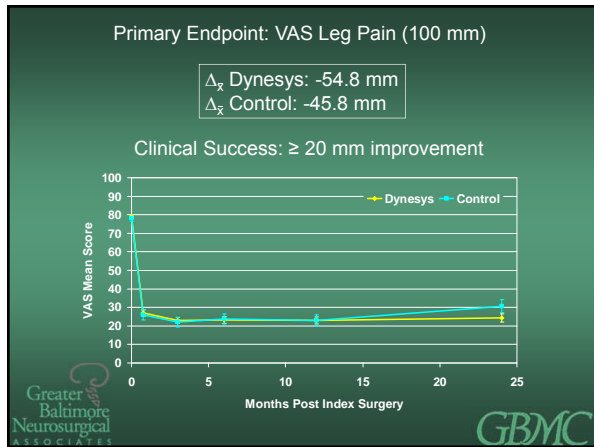
- Prospective RCT Dynesys vs. Fusion
 - 367 patients enrolled 2 Dyn:1 Fus ratio
 - Degenerative Instability with stenosis.
 - 24 month follow up.
 - Endpoints ODI, VAS Back and Leg pain, maintenance of neuro status, no reoper

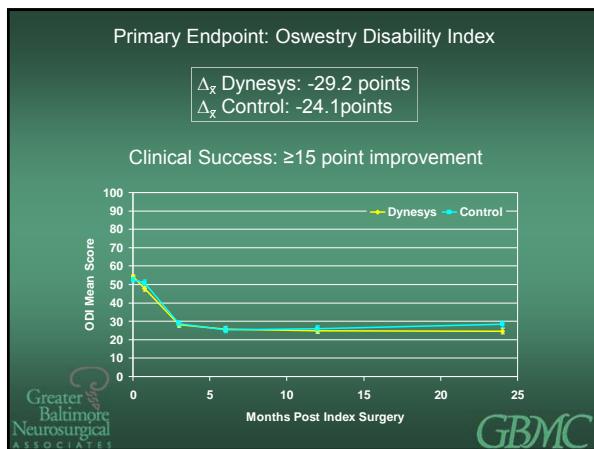
Selected Inclusion Criteria

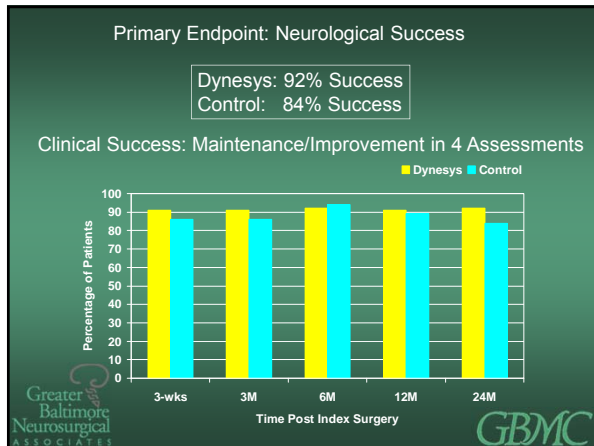
- Spinal stenosis or stenosing lesions, with or without degenerative spondylolisthesis or retrolisthesis (\leq Grade I)
- One or two contiguous levels from L₁-S₁
- VAS leg pain score \geq 40mm
- Oswestry score \geq 30
- Unresponsive to conservative care for \geq 3M
- Subjects were candidates for PLF
- 20-80 years of age

Results at 2 years

- DS had significant increase in patients which had a meaningful decrease in VAS leg pain
- ODI showed similar results at all time points
- Additional procedure DS 9% Fus 11%
- Frequency of screw loosening or breakage
 - DS 2% vs Fus 4%
- FDA composite success DS 52.1% vs 40.4%







Primary Endpoint: Major Complications

Clinical Success: Absence of Major Complications

	Dynesys cohort	Control cohort
Major Complications	1/253 (0.4%)	1/114 (0.9%)
Revisions	28/253 (11.1%)	11/114 (9.6%)

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Primary Endpoint: Device-Related Adverse Events

Clinical Success: No Device-Related Adverse Events

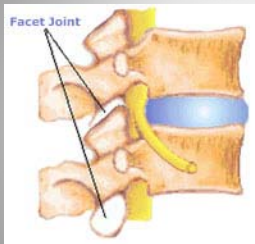
	Dynesys cohort	Control cohort
Device-Related Adverse Events (not including revisions)	9/253 (3.6%)	8/114 (7.0%)
Screw Loosening: Number of cases Number of screws	7/253 (2.77%) 11/1244 (0.88%)	5/114 (4.39%) 9/546 (1.65%)
Screw Breakage: Number of cases Number of screws	1/253 (0.40%) 2/1244 (0.16%)	0/114 (0%) 0/546 (0%)

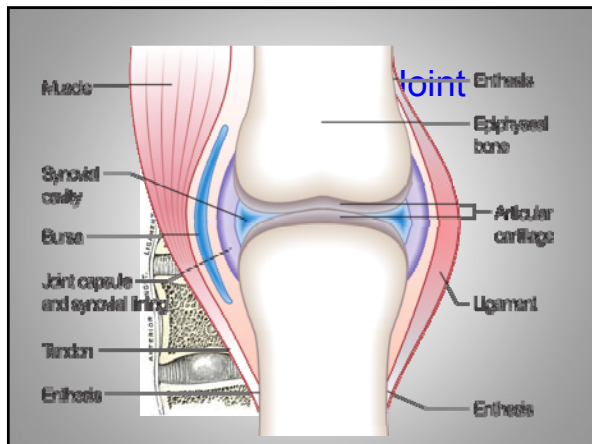
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ROM

- Dynesys 1.8 degrees at 24 months
- Fusion <1.0 degrees at 24 months
- Stability achieved without the biologic demands of fusion.
- Stability achieved with out the additional morbidity of fusion.

Facet Joint- Diarthrodial





Advantages

- Easier mechanically to neutralize segment that provide absolute rigidity
- Decrease Biological Demands- Stability without biological requirement of fusion
- Allows for Improve load transition to adjacent level

Thank You
