

Non Fusion Spinal Technology (in the lumbar spine)



Dr M J H McCarthy
Spinal Fellow

Aims and Objectives

- Basic science
- Non Fusion Spinal Technology
 - Classification
 - Indications
- What is the Evidence
- Overall aim of this talk...
 - You can give an answer to the patient who says...

Biomechanics of Back Pain

- Bone, Joints, Ligaments, Disc, Muscles, Nerves
- Anterior Strut and Posterior Tension Band
- Motion Segment Tripod – Complex
- Anatomical variation within normal spine, within patient and between patients
- Spinal Balance – Sagittal and Coronal
- Effects of Age and other diseases
- Spine is complex! No simple solution...

Spinal Pathology In General

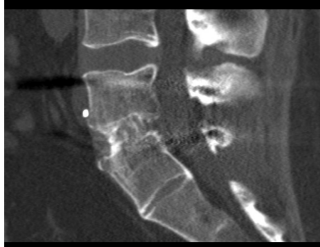
- Arthrosis / Spondylosis
 - Spinal Stenosis
 - Degenerative Spondylolisthesis
 - Black Disc Disease
 - Instability / Imbalance
 - Osteoporosis
- Diagram illustrating the relationship between spinal pathology and clinical outcomes:
- A bracket groups Arthrosis / Spondylosis, Spinal Stenosis, Degenerative Spondylolisthesis, Black Disc Disease, and Instability / Imbalance, leading to the text **Pain Operation**.
 - An arrow points from Osteoporosis to the text **Concern**.

Three Phase Concept Of Degeneration

1. Disc loses its resistance to rotational and translational forces (unstable phase)
Discogenic Pain
2. Facet joint degeneration; segmental instability
Pain in discs, facets, ligaments, nerve compression etc
3. Stability regained; segment gradually ankylosing

Surgery for Back Pain

1. TRY TO IDENTIFY THE CAUSE
2. CLEARLY DEFINE THE INDICATION FOR THE TYPE OF SURGERY



- Still debate what type of fusion...
- MRC Trial...

Biomechanics of Back Pain

- Surgical Mx of painful lumbar motion segment is imperfect
- Advances in fusion techniques → elevated arthrodesis rates → no equivalent rise in pain relief
- Concept of “instability” resulting in a painful motion segment is difficult to define
- Disc degeneration does lead to altered loads across endplates → load modification / controlled motion techniques may have potential role / benefit...

Non Fusion Spinal Technology

- Not orthobiologics, KP / VP or IDET
- Implants and Instrumentation
- Why has it been developed?
 - Treat pain and maintain motion
- Recent Trends
 - Minimise soft tissue dissection (-LISS)
 - Preserve spinal motion



Problems with Spinal Fusion

1. Permanent / irreversible
2. Loss of motion
3. Pseudarthrosis / Failure
4. Adjacent Segment Disease
5. Deformity
6. Donor Site Morbidity (use alternatives...)
7. ...

Non Fusion Spinal Technology

1. Prevent fusion related sequelae
 - Most widely accepted
 - ASD, fusion in malalignment, pseudarthrosis
2. Pain relief with preservation of motion
3. Neuronal decompression
4. Increased anterior load sharing to augment interbody fusion
 - Growing evidence...

Non Fusion Spinal Technology

5. Controlled motion in the iatrogenically destabilized spine
6. Protection and restoration of degenerated facet joints and intervertebral discs
 - Most controversial and least understood
7. Adaptation of stabilisation techniques to the aging spine
 - Soft stabilization
8. Combination with anterior motion preservation (360 motion segment reconstruction / replacement)
 - Crazy!!!

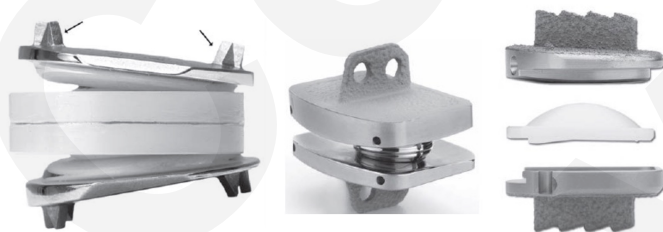
Dynamic Stabilization of the Spine: A New Classification System

Omurganın Dinamik Stabilizasyonu:
Yeni Bir Sınıflandırma Yöntemi

Classification

- Anterior and Lateral
 - TDR
 - Nucleus Pulposus Replacement / Alternatives
 - Nucleus Pulposus Supports / Injectables
- Posterior
 - Transpedicular
 - Pedicle Screw / Rod Based
 - Dynamic rod / rigid screw
 - Dynamic rod / dynamic screw
 - Total Facet Replacement
 - Posterior Interspinous Stabilization

Total Disc Replacement



Imaging Characteristics of Four Major Disk Replacement Devices

Device	Radiolucent Inlay	Keel	Fixation Spikes	Ball-and-Socket Design
ProDisc	Yes	Yes	Yes*	Yes
Charité	Yes	No	Yes†	No
FlexCore	No	No	Yes‡	Yes
Maverick	No	Yes	No	Yes

*Has a single small spike on either side of the keel on both the superior and the inferior end plates.
†Has a transverse row of three spikes on the anterior and posterior aspects of both end plates.
‡Has an anteroposterior row of three short spikes on the lateral aspects of both end plates.

NP Replacements + Supports



Figure 1
Dehydrated PDN-SOLO®



Figure 2
Hydraflex device



Figure 3
NewCue

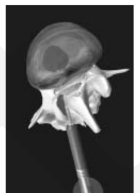


Figure 4
NuCore

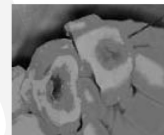


Figure 5
BioDisc

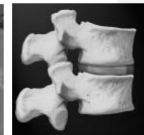


Figure 6
DASCOR



Figure 7
NuBac



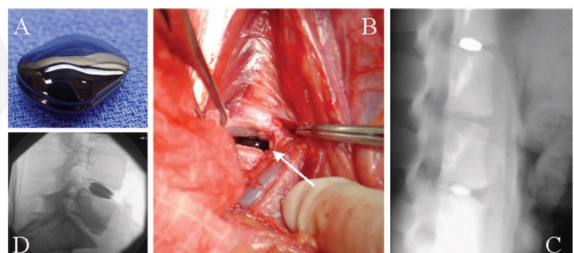
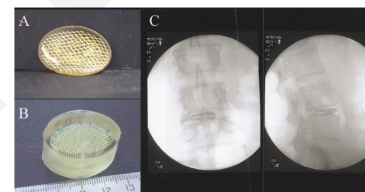
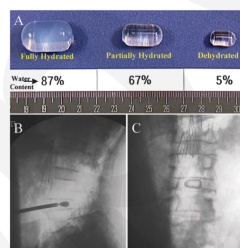
Figure 8
Regain

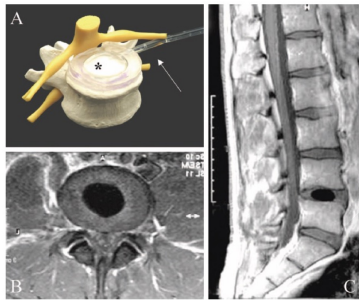
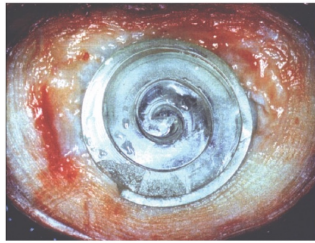
- Restore biomechanical function of annulus by placing fibres under tension
- Maintain and recreate disc characteristics

1. Elastomers

- Hydrogels and non hydrogels

2. Mechanical Devices





Dynamic Rod Rigid Screw

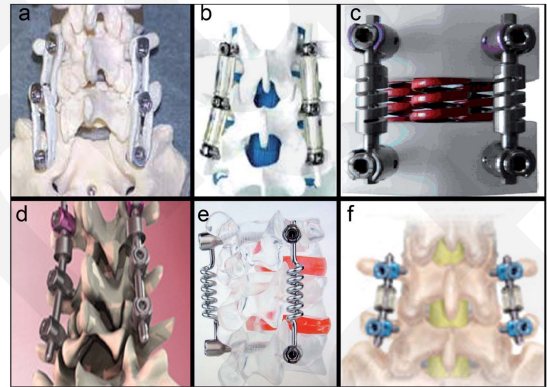
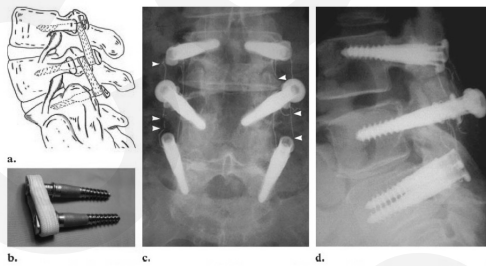


Figure 5: Posterior transpedicular stabilization: A) Graf system, B) Dynesys, C) Tiltis rod, D) Scient'X Isobar, E) Bioflex, F) CD horizon Agile.

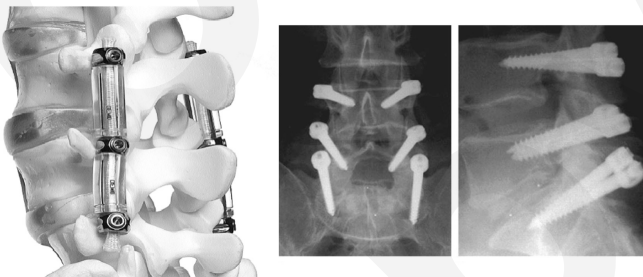
Graf



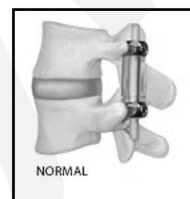
Graf

- Designed to control rotation
- Posterior tensioning may unload disc → redistribute load transmission across painful disc
- Concept of Dynamic stability
 - Mechanical constraint of spinal motion that allows selective motion of the functional spinal unit (– therefore reducing pain...?)

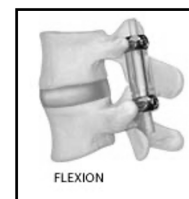
Dynesys



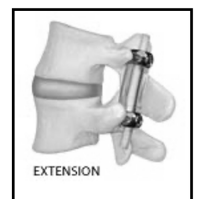
DYnamic NEutralisation SYstem for the Spine (Zimmer)



At rest: The Dynesys System supports an intervertebral joint



Flexion: The Dynesys System supports the affected joint as the spine bends forward (rope)

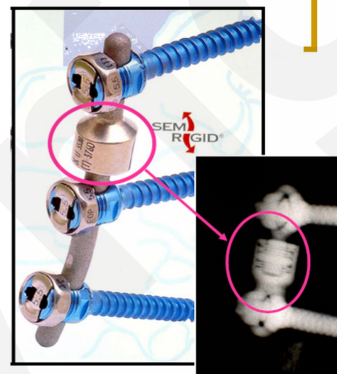


Extension: It also supports the joints as the spine bends backwards (bumper)

Three Phase Concept Of Degeneration

1. Disc loses its resistance to rotational and translational forces (unstable phase)
Discegenic Pain
 2. Facet joint degeneration; segmental instability
Pain in discs, facets, ligaments, nerve compression etc
 3. Stability regained; segment gradually ankylosing
- “They say” Dynesis – alters stage 1 and covers the mechanical aspects of stage 2

Isobar



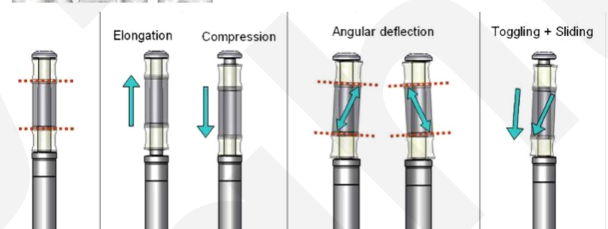
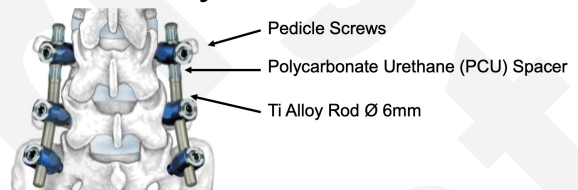
- Concept of
 - “Topping off”
 - Transition zone to prevent / reduce ASD



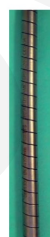
Stabilimax NZ is a scientifically validated posterior dynamic stabilization device designed to support the spine at a single level or multiple levels while preserving range of motion (ROM).

Stabilimax NZ offers numerous advantages over current spinal fixation products and new artificial disc products: (1) a less invasive, less traumatic implant procedure; (2) maintenance of normal spine motion and disc function; and (3) potential to prevent or slow adjacent-level segment disease.

NFlex Dynamic Stabilization



- Semi Rigid Rods
 - PEEK
 - Nitinol
 - Specialty cut
 - Articulated cords



Dynamic Rod Dynamic Screw

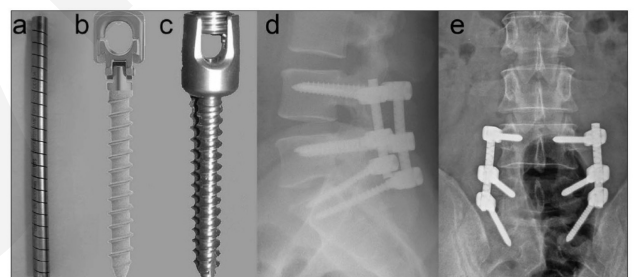


Figure 6: Dynamic Rod-Dynamic Screw: A) Dynamic rod, B) Cosmic screw, C) Safinaz screw, D) lateral X-ray, E) AP X-ray.

Total Facet Replacement

Facet pain = Replace it!

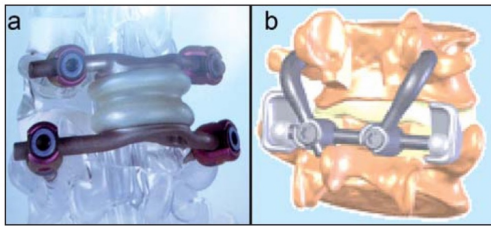


Figure 7: Total Facet Replacement Devices: A) TOPS, B) TEAS.

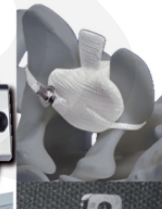
- Total Posterior Arthroplasty Implant
- Total Facet Arthroplasty System

Interspinous Stabilisation

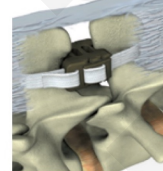
Spacer rigid
Material stiff



Spacer semi rigid (↓↓↓)
Material flexible
(greater elasticity)



Spacer rigid (↓)
Material flexible
(greater elasticity)



Spacer semi rigid (↓↓)
Material stiff



Neuronal decompression

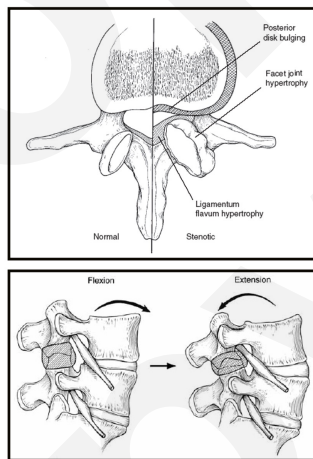
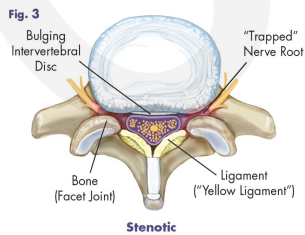
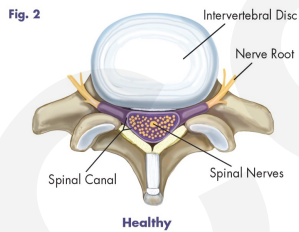


Fig. 10

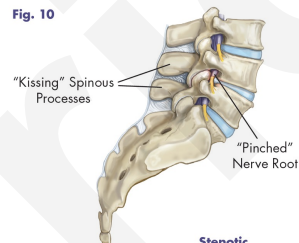
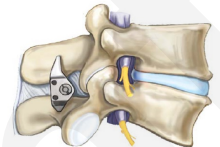
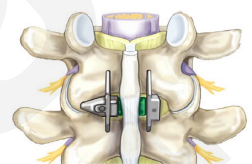
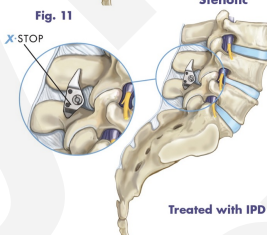
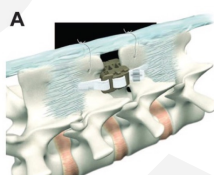
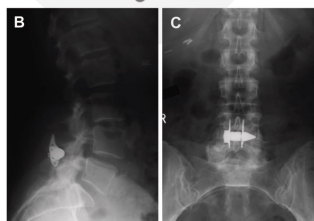
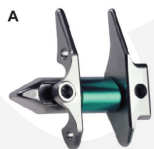


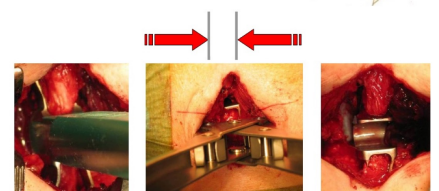
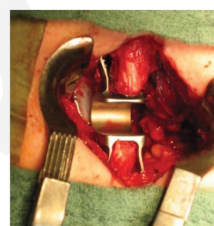
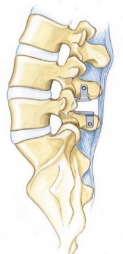
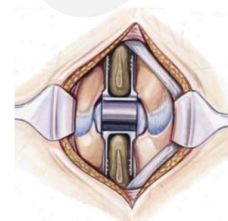
Fig. 11

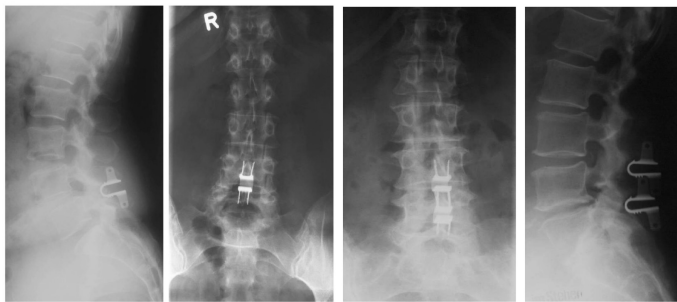


Does not work at L5/S1



coflex™
Interspinous Implant





Nothing to do with the talk but very funny

So far:

- We have seen lots of new technology
- What are the indications?
- Then the evidence...

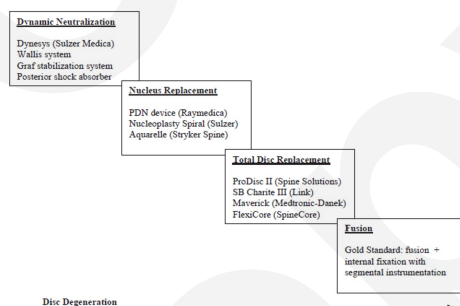
Table I: Dynamic Stabilization of the Spine: Indications and Contraindications (6,22,24,33,39,45,48,61,65,68,69)

Devices	Indications	Contraindications
Anterior Disc Prosthesis Limited	- patients between 18-60 ages (optimally below age 50 years) - single level or two level - pain due to symptomatic degenerative disc disease - absence of facet joint degeneration changes - existence of intervertebral disc height of at least 4 mm - nonradicular leg pain or back pain - postlaminectomy syndrome - patient with positive discogram	- deformations and spondylolysis in the posterior elements - in situ instabilities - the elderly patients who have osteoporosis - morbid obesity - infection - patients with systemic diseases such as allergy to metal
Posterior Dynamic Stabilization Devices Wide Worry? Not understood? Early days...	- degenerative spinal instability, degeneration, facet degeneration, degenerative spondylolisthesis - iatrogenic instability following discectomy / decompressive laminectomy - increased anterior load sharing augment interbody fusion - stabilization of a painful adjacent segment degeneration, adjacent to fusion - complement TDR to achieve anterior disc replacement - second recurrent of a disc herniation	- trauma - infectious - atomic type spondylolisthesis - stabilizations extending beyond two segment
Interspinous Distraction Devices Limited	- central spinal canal stenosis with neurogenic claudication - foraminal stenosis with radicular symptoms - facet joint disease - In one- or two- level stenosis in patients over 50 years	- overt instabilities - Infections

All have LISS potential

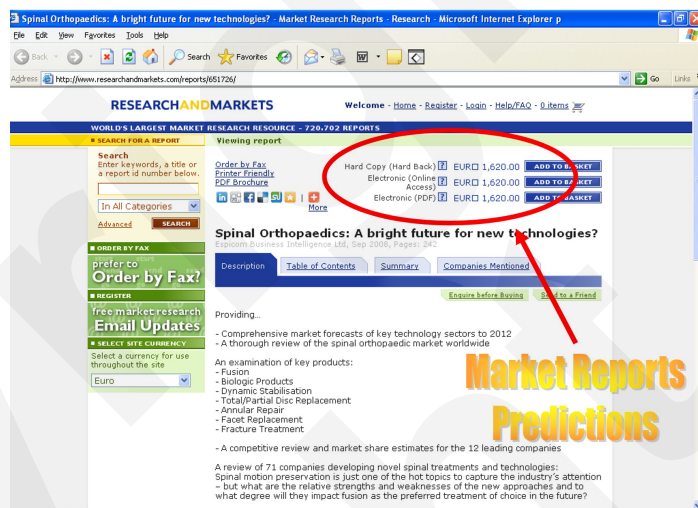
Suggested Surgical Algorithm

- Delamarter et al. OCNA 2005



- All about philosophy and the surgeons beliefs
- Do we really think it works?
- Evidence...

Where is the evidence...?



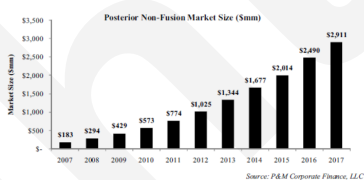
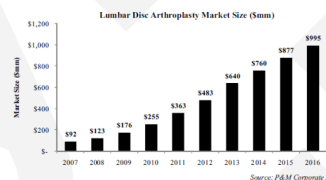
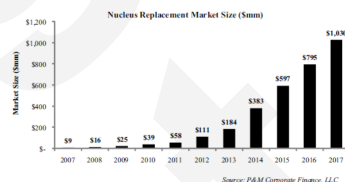
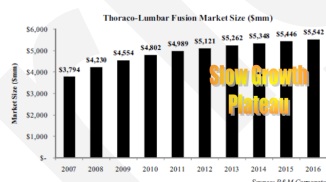
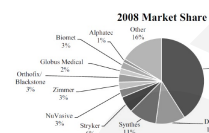
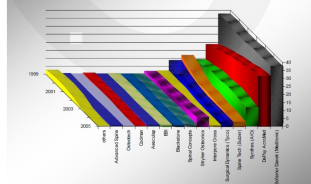
FISCAL FITNESS

Spine Company Count Tops 100; Segment Still on Fire

Author: Shirley A. Engelhardt



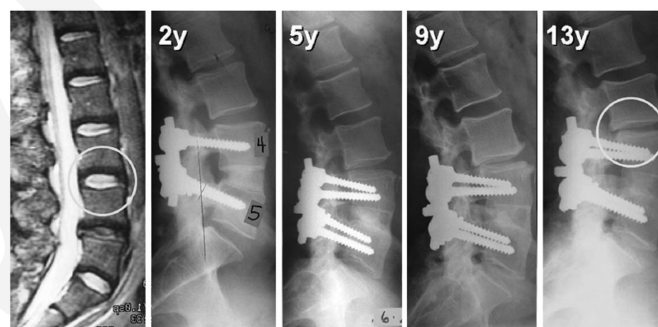
The Players & Their Shares



ADJACENT SEGMENT DEGENERATION IN THE LUMBAR SPINE

BY GARY GHISSELLI, MD, JEFFREY C. WANG, MD, NITIN N. BHATIA, MD, WELLINGTON K. HSU, MD, AND EDGAR G. DAWSON, MD

Investigation performed at the Department of Orthopaedic Surgery, University of California at Los Angeles School of Medicine, Los Angeles, California

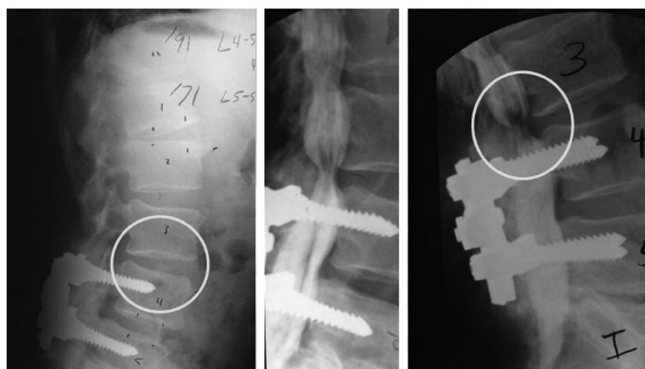


Conclusions: The rate of symptomatic degeneration at an adjacent segment warranting either decompression or arthrodesis was predicted to be 16.5% at five years and 36.1% at ten years. There appeared to be no correlation with the length of fusion or the preoperative arthritic degeneration of the adjacent segment.

The Impact of Adjacent Segment Degeneration on the Clinical Outcome After Lumbar Spinal Fusion

Jun Young Yang, MD, PhD, June-Kyu Lee, MD, PhD, and Ho-Sup Song, MD

- 217 cases fusion with min 2 year follow up
- ASD increased with number fused levels
- Degeneration worse with ↑ levels fused
- Degree of degeneration = worse outcome



SPINE Volume 35, Number 6, pp 625-634
©2010, Lippincott Williams & Wilkins

Adjacent Segment Disease After Interbody Fusion and Pedicle Screw Fixations for Isolated L4-L5 Spondylolisthesis

A Minimum Five-Year Follow-up

Kyeong Hwan Kim, MD, PhD,* Sang-Ho Lee, MD, PhD,† Chan Shik Shim, MD, PhD,† Dong Yeob Lee, MD,† Hyeon Seon Park, MD,‡ Woei-Jack Pan, FRCSE (Ortho),§ and Ho-Yeon Lee, MD, PhD†

Key Points

- Maintaining postoperative L4-L5 segmental lordotic angle at about 20° or more is important to prevention of clinical ASD in single level 360° fusion operation.
- Previously reported risk factor, like older age and female gender, is not a risk factor for ASD, if there was no apparent degenerative change at adjacent segments before surgery.

The lordosis!

SPINE Volume 32, Number 20, pp 2253-2257
©2007, Lippincott Williams & Wilkins, Inc.

Adjacent Segment Disease Following Lumbar/Thoracolumbar Fusion With Pedicle Screw Instrumentation

A Minimum 5-Year Follow-up

Gene Cheh, MD,† Keith H. Bridwell, MD,* Lawrence G. Lenke, MD,* Jacob M. Buchowski, MD,* Michael D. Daubs, MD,‡ Yongjung Kim, MD,§ and Christy Baldus, RN*

Table 2. Prevalence of ASD (n = 188)

Radiographic ASD (no. of patients)	Clinical ASD	
	+	-
+	45	35
-	12	96

Radiographic ASD occurred in 43% of the patients. Clinical ASD occurred in 30% of the patients. Among the patients who had radiographic ASD, 43% had clinical ASD. Twelve patients had clinical ASD without plain radiographic evidence.

SPINE Volume 35, Number 22, pp 1955-1964
©2010, Lippincott Williams & Wilkins

Adjacent Segment Degeneration After Lumbar Spinal Fusion: The Impact of Anterior Column Support

A Randomized Clinical Trial With an Eight- to Thirteen-Year Magnetic Resonance Imaging Follow-up

Tina S. Videbaek, MD,* Niels Egund, MD, DMSc,† Finn B. Christensen, MD, PhD, DMSc,* Anne Grethe Jurik, MD, DMSc,† and Cody E. Bünger, MD, DMSc*

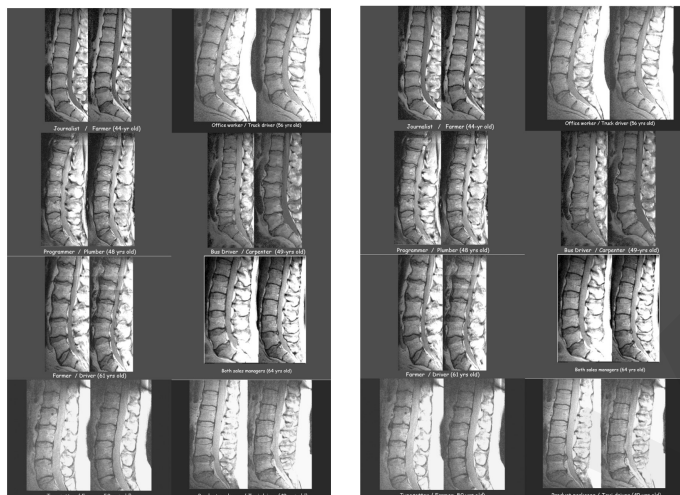
- 148 patients ALIF + PLF vs PLF
- 76% follow up
- ASD not dependent on anterior column support
- ASD due to natural degenerative process...
- ALIF did clinically better ?why

Key Points

- Older patients (>50 vs. ≤50 years) were at higher risk for ASD.
- Longer fusion increased the incidence of ASD in the lumbar spine.
- Fusion up to L1, L2, and L3 increased the risk of ASD compared with L4 and L5.
- Circumferential fusion *versus* posterior only was not a significant risk factor for the development of ASD.
- Some patients had symptomatic spinal stenosis at the ASD level without substantial radiographic changes.

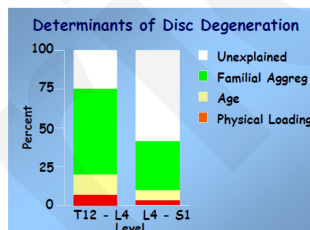
Abnormal motion due to fusion below or destabilised at time of surgery

Short fusion compensates Long fusion does not



Twin Study

Michele C. Battie, PhD^{1,2}, Tapio Videman, MD, PhD^{1,2}, Jaakko Kaprio, MD, PhD²,
Laura E. Gibbons, PhD³, Kevin Gill, MD⁴, Janna Saarela, MD, PhD⁵,
Leena Peltonen, MD, PhD⁶



In Summary

Knowledge gained through the Twin Spine Study and others' efforts over the past decade have substantially enhanced our understanding of disc degeneration and have provided a new paradigm. Disc degeneration is now considered a condition that is genetically determined in large part, with environmental factors, although elusive, also playing an important role. This advance in the understanding of disc degeneration provides a foundation from which to develop new hypotheses and more fruitful research that may help to elucidate the etiology of disc degeneration and associations with pain.

ASD following surgery

...genetic / age...

...deformity / surgical trauma / abnormal motion...



THE
SPINE
JOURNAL

SPINE Volume 30, Number 14, pp 1565-1575
©2005, Lippincott Williams & Wilkins, Inc.

A Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemptions Study

SPINE Volume 32, Number 11, pp 1155-1162
©2007, Lippincott Williams & Wilkins, Inc.

Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the Replacement *Versus* C Treatment of 1-Level I

Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-L Total Disc

SPINE Volume 33, Number 2, pp 123-131
©2008, Lippincott Williams & Wilkins

Prospective, Randomized Trial of Metal-on-Metal Artificial Lumbar Disc Replacement

Initial Results for Treatment of Discogenic Pain

Rick C. Sasso, MD,* David M. Foulk, MD,† and Michael Hahn, MD‡

SPINE Volume 35, Number 22, pp 1991-2003
©2010, Lippincott Williams & Wilkins

The Fate of Facet Joint and Adjacent Level Disc Degeneration Following Total Lumbar Disc Replacement

A Prospective Clinical, X-Ray, and Magnetic Resonance Imaging Investigation

Christoph J. Siepe, MD, PhD,* Piotr Zelenkov, MD,† Jose-Carlos Sauri-Barraza, MD,‡
Ulrike Szimies, MD,§ Thomas Grubinger, MSc,¶ Alexander Tepass, MD,||
Axel Stabler, MD, PhD,§ and Michael H. Mayer, MD, PhD*

Key Points

- After a mean FU of 53.4 months the observed incidence of **ALD following TDR was low** (10.2%; n = 11/108 levels). The degenerative changes were mild, occurred late after surgery and did not reveal a negative effect on postoperative clinical outcome. There was no significant correlation between index-level ROM and the occurrence of ALD ($P > 0.05$).
- Degenerative changes in the facet joints were observed in a considerable number of patients (20.0%; n = 44/220 index level facet joints). FJD occurred significantly more often following TDR at the lumbosacral junction in comparison with the level above the lumbosacral junction ($P < 0.02$), and was observed more frequently at index-levels in comparison to nonindex levels ($P < 0.001$).

ASD Reduced to 10%
but, 20% Incidence
Facet Joint Problems

Eur Spine J (2010) 19:1250-1261
DOI 10.1007/s00586-010-1394-x

REVIEW ARTICLE

A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease

Wu Yajun · Zhu Yue · Han Xinxin ·
Cui Cui

In conclusion, TDR does not show significant superiority for the treatment of lumbar DDD compared with fusion. The benefits of motion preservation and the long-term complications are still unable to be concluded. More high-quality RCTs with long-term follow-up are needed.

NP Replacements + Supports

Table 1. Summary of Prosthesis Currently Under Investigation

Device	Technology	Biomaterial	Studies	FDA Approval
Prosthetic Disc Nucleus	Intradiscal implant	Hydrogel pellet encased in a polyethylene jacket	Implanted in more than 400 patients	Approved in the United States for investigational use only
Aquarelle	Intradiscal implant	Semihydrated polyvinyl alcohol (PVA) hydrogel	Animal experiments (baboon) plus cadaveric spine New Zealand rabbits	—
NeuDisc	Intradiscal implant	Modified hydrolyzed polyacrylonitrile polymer (Aquacryl) reinforced by a Dacron mesh	New Zealand rabbits	—
NewNucleus	Intradiscal implant	Polycarbonate urethane (PCU) elastomer curled into a preformed spiral	Implanted in 5 patients	—
Regain	Intradiscal implant	Modular intervertebral prosthetic disc	Implanted in few patients	United States Investigational Device Exemption to start
IPD	Intradiscal implant	Modular intervertebral prosthetic disc	Tested in an animal experimental model in cow	—
DASCOR Disk Arthroplasty Device	In situ curing polymer	Injectable polyurethane	Implanted in 16 patients	—
BioDisc	In situ curing polymer	Protein hydrogel	Tested on animal models	—

Nucleus Pulposus Replacement

Basic Science and Indications for Clinical Use

Alberto Di Martino, MD,*† Alexander R. Vaccaro, MD,‡ Joon Yung Lee, MD,†
Vincenzo Denaro, MD,* and Moe R. Lim, MD†

Conclusions. Although some of the newly designed prosthesis have shown some promising results in preclinical studies, rigorous short- and long-term clinical evaluations will be critical in evaluating their true efficacy.

Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine

Surgical and Patient-Oriented Outcome in 50 Cases After an Average of 2 Years

Dieter Grob, MD,* Arnoldo Benini, MD,* Astrid Junge, PhD,* and Anne F. Mairion, PhD*†

- 30/31 patients with > 2 years follow up completed a postal questionnaire
- Multitude of indications
- 35% had previous surgery
- Multiple levels instrumented in most cases
- Not all had decompression- only if indicated
- Only 50% rated surgery a success
- 19% reoperation rate
- Semirigid fixation does not result in better patient-oriented outcomes as compared to typical fusion

Dynamic Stabilization in Addition to Decompression for Lumbar Spinal Stenosis with Degenerative Spondylolisthesis

Klaus John Schmake, MD,* Stefan Schaefer, MD,† and Bernard Jeanneret, MD†

- Prospective clinical study (Dynesys)
- 26 consecutive patients (4 at L3/4; 22 at L4/5)
- 24/26 patients followed up for 2 years
- Mean leg pain decreased & walking distance increased significantly
- 21/24 would undergo the same procedure again
- No significant progression of spondylolisthesis detected on xray
- 17% implant failure- none clinically significant

Conclusions. In elderly patients with spinal stenosis with degenerative spondylolisthesis, dynamic stabilization with the Dynesys system in addition to decompression leads to similar clinical results as seen in established protocols using decompression and fusion with pedicle screws. It maintains enough stability to prevent further progression of spondylolisthesis or instability. With the Dynesys system, no bone grafting is necessary, therefore, donor site morbidity can be avoided.

- Dynamic stabilisation was NOT found to prevent adjacent segment degeneration

Adjacent Segment Mobility After Rigid and Semirigid Instrumentation of the Lumbar Spine

Balkan Cakir, MD,* Charles Carazzo, MD,‡ René Schmidt, MD,‡ Thomas Mattes, MD,*
Heiko Reichel, MD,* and Wolfram Käfer, MD*

- 26 pts, LBP + stenosis, L4/5 degen "instability"
- 11 Decompression + Dynesys
- 15 Decompression + Fusion
- Min F/U 2 yrs
- Dynamic XRs

Table 2. Preoperative and Postoperative ROM in Degrees (°) After Monosegmental Fusion and Dynesys Instrumentation at Level L4-L5

	Fusion			Dynesys		
	Preoperatively	Postoperatively	P	Preoperatively	Postoperatively	P
ROM L2-S1	23.6 ± 16.2	12.7 ± 7.1	0.02	14.4 ± 9.7	18.3 ± 8.4	0.05
ROM L4-L5	6.3 ± 5.6	1.6 ± 1.2	0.001	4.0 ± 4.0	4.1 ± 3.7	0.72
ROM L3-L4	7.1 ± 7.0	4.2 ± 4.2	0.35	3.3 ± 3.4	3.9 ± 2.5	0.72
ROM L5-S1	5.2 ± 4.1	5.1 ± 4.7	0.91	5.4 ± 4.2	5.0 ± 3.9	0.79

Values given as mean ± standard deviation.

P was calculated with the Wilcoxon matched-pairs signed-rank tests.

Table 3. Number of Patients With Preserved Motion Preoperatively and Postoperatively (Defined as ROM >3.2°) After Monosegmental Fusion and Dynesys Instrumentation at Level L4-L5

	Fusion			Dynesys		
	Preoperatively	Postoperatively	P	Preoperatively	Postoperatively	P
L4-L5	10/15	2/15	<0.01	5/11	3/11	0.66
L3-L4	7/15	8/15	1.0	3/11	6/11	0.39
L5-S1	10/15	9/15	1.0	7/11	6/11	1.0

P was calculated with the Fisher exact test.

■ Key Points

- Contrary to monosegmental fusion, the semi-rigid lumbar posterior stabilization system Dynesys does not alter *in vivo* range of motion (ROM) at the index level in a monosegmental L4–L5 instrumentation.
- Neither monosegmental instrumented fusion nor monosegmental posterior dynamic stabilization with Dynesys lead to significant changes of both cranial and caudal adjacent level ROM.
- With regard to potential adjacent level effects, monosegmental posterior dynamic stabilization with Dynesys has no beneficial effect on adjacent segment mobility compared to monosegmental fusion.



■ Dynamic Stabilization in the Surgical Management of Painful Lumbar Spinal Disorders

Russ P. Nockels, MD

Conclusions. Posterior dynamic stabilization systems may provide benefit comparable to fusion techniques, but without the elimination of movement. Further study is required to determine optimal design and clinical indications.

SPINE Volume 30, Number 12, pp 1351-1358
©2005, Lippincott Williams & Wilkins, Inc.

■ A Multicenter, Prospective, Randomized Trial Evaluating the X STOP Interspinous Process Decompression System for the Treatment of Neurogenic Intermittent Claudication Two-Year Follow-Up Results

James F. Zucherman, MD,* Ken Y. Hsu, MD,* Charles A. Hartjen, MD,† Thomas F. Mehalic, MD,‡ Dante A. Implicto, MD,§§ Michael J. Martin, MD,¶ Donald R. Johnson II, MD,|| Grant A. Skidmore, MD,** Paul P. Vessa, MD,†† James W. Dwyer, MD,†† Stephen T. Puccio, MD,§§§§ Joseph C. Cauthen MD,¶¶ and Richard M. Ozuna, MD|||

- 191 patients block randomised
- 9 US centres from May 2000-July 2001
- Inclusion criteria:
 - age >50 years
 - leg, buttock, or groin pain +/- LBP relieved by flexion
 - walking distance >50 feet (moderate symptoms)

- 91 Controls:
 - min 1 epidural steroid injection
- 100 X STOP:
 - 64 single level
 - 36 double level

Results. At every follow-up visit, X STOP patients had significantly better outcomes in each domain of the Zurich Claudication Questionnaire. At 2 years, the X STOP patients improved by 45.4% over the mean baseline Symptom Severity score compared with 7.4% in the control group; the mean improvement in the Physical Function domain was 44.3% in the X STOP group and –0.4% in

No trials comparing X Stop to Laminectomy

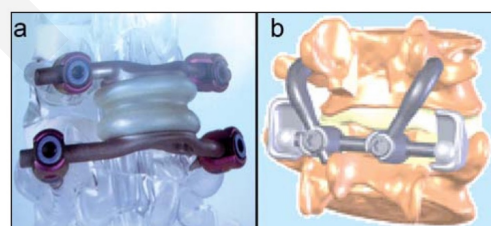
SPINE Volume 30, Number 16S, pp S73-S78
©2005, Lippincott Williams & Wilkins, Inc.

■ Dynamic Interspinous Process Technology

Sean D. Christie, MD, FRCSC, John K. Song, MD, and Richard G. Fessler, MD, PhD

Conclusions. These devices continue to be evaluated in clinical trials. Early results suggest a possible role in the management of degenerative disorders of the lumbar spine.

Total Facet Replacement



- Phase 3 and 4 Clinical Trials...

Wear

- Moving systems are prone to wear
- Biological systems can adapt to an extent
- Mechanical systems cannot
- Both subject to wear
 - Fusion is not!
- Approx 100million load cycles over 40 years



Bone Healing / Fusion

- Wolff's law states that every change in form and function of a bone, or in its function alone, is followed by certain definite changes in its internal architecture and equally definite secondary alteration in its mathematical laws
- Form follows function – bone heals in compression
- Anterior compression vs posterior tension band?
 - Which operation?

SPINAL STABILIZATION AND DECOMPRESSION DEVICES

Stabilization systems, such as the Dynesys[®] Dynamic Stabilization System or the DSS Stabilization System, are **unproven** for the treatment of degenerative spondylolisthesis. The available evidence does not establish the efficacy of the system and contains design flaws such as inclusion of patients without degenerative spondylolisthesis and/or had other surgical procedures and the lack of long term follow-up.

Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation, or the use of posterior intrafacet implants is **unproven**. There is insufficient evidence in the peer reviewed literature that use of total facet joint arthroplasty will improve health outcomes. The Total Facet Arthroplasty System[™] (TFAS) has not been approved by the U.S. Food and Drug Administration (FDA). A single clinical trial is in progress, but no results have been published.

Interspinous process decompression (IPD) systems, such as the X STOP[®] are **unproven** for the treatment of spinal stenosis. Clinical evidence is limited to small studies with lack of blinding and long-term follow-up. The available evidence shows no significant difference between use of interspinous process decompression systems and conservative management.

Proprietary Information of UnitedHealthcare. Copyright 2010 United HealthCare Services, Inc.

Dynamic Constructs for Spinal Fusion: An Evidence-Based Review

Orthop Clin N Am 41 (2010) 203–215

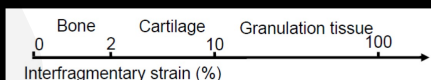
Michael P. Kelly, MD^{a,*}, James M. Mok, MD^b,
Sigurd Berven, MD^a

- The role of “dynamic” stabilisation in augmenting fusion...
- Evolving...

Perren's interfragmentary strain theory (1979)

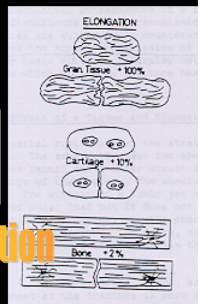
“a tissue which ruptures or fails at a certain strain level can not be formed in a region of precursor tissue which is experiencing strains greater than this level”

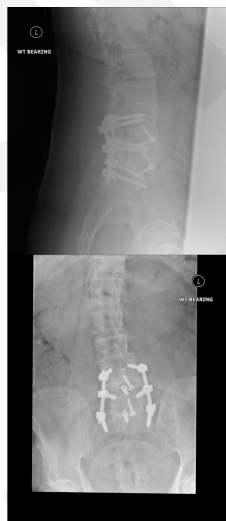
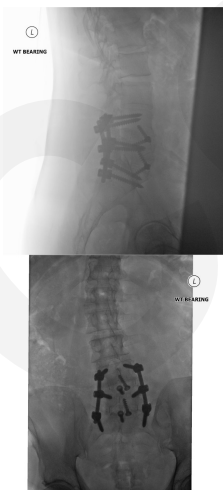
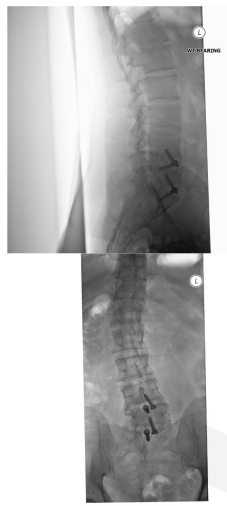
But, if too stiff - no tissue forms



Micromotion helps bone formation

Perren S.M. Clin. Orthop. Rel. Res. 138:175-196, 1979





Conclusion

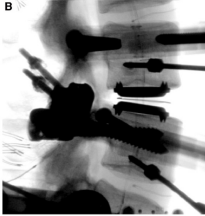
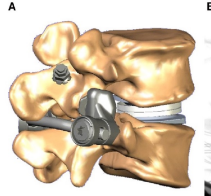
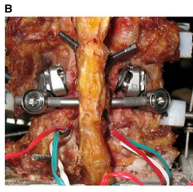
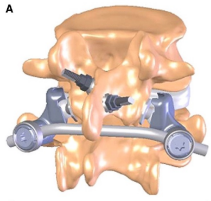
- The role of non fusion spinal technology is unknown / unproven
- Potential role in augmenting spinal fusion?
- ASD?
- Early Stenosis?
- LISS?

Orthopaedic Analogies

- Stenosis
 - Laminectomy **Reducing pathology**
 - Laminotomy **Increasing LISS**
 - Interspinous Spacer
- Knee Arthritis **Complex hinge**
 - TKR (still debate which...)
 - Uni
 - Osteotomy
- THR taken off over the last 60 years
 - Prior to this - fusion or Girdlestones **Ball and socket**
- Spine **Very complex**
 - Fusion vs. other emerging technologies...
 - Perhaps there will be something else...



If all else fails...



make the spine
completely
unstable
and prone
to wear

- Or get one of these...

