



CERVICAL AND LUMBAR DISC ARTHROPLASTY

30 Aug 2019

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Ortho San Antonio

Cervical Disc Arthroplasty



Background/History/Wear Rates



Indications



Long Term Results



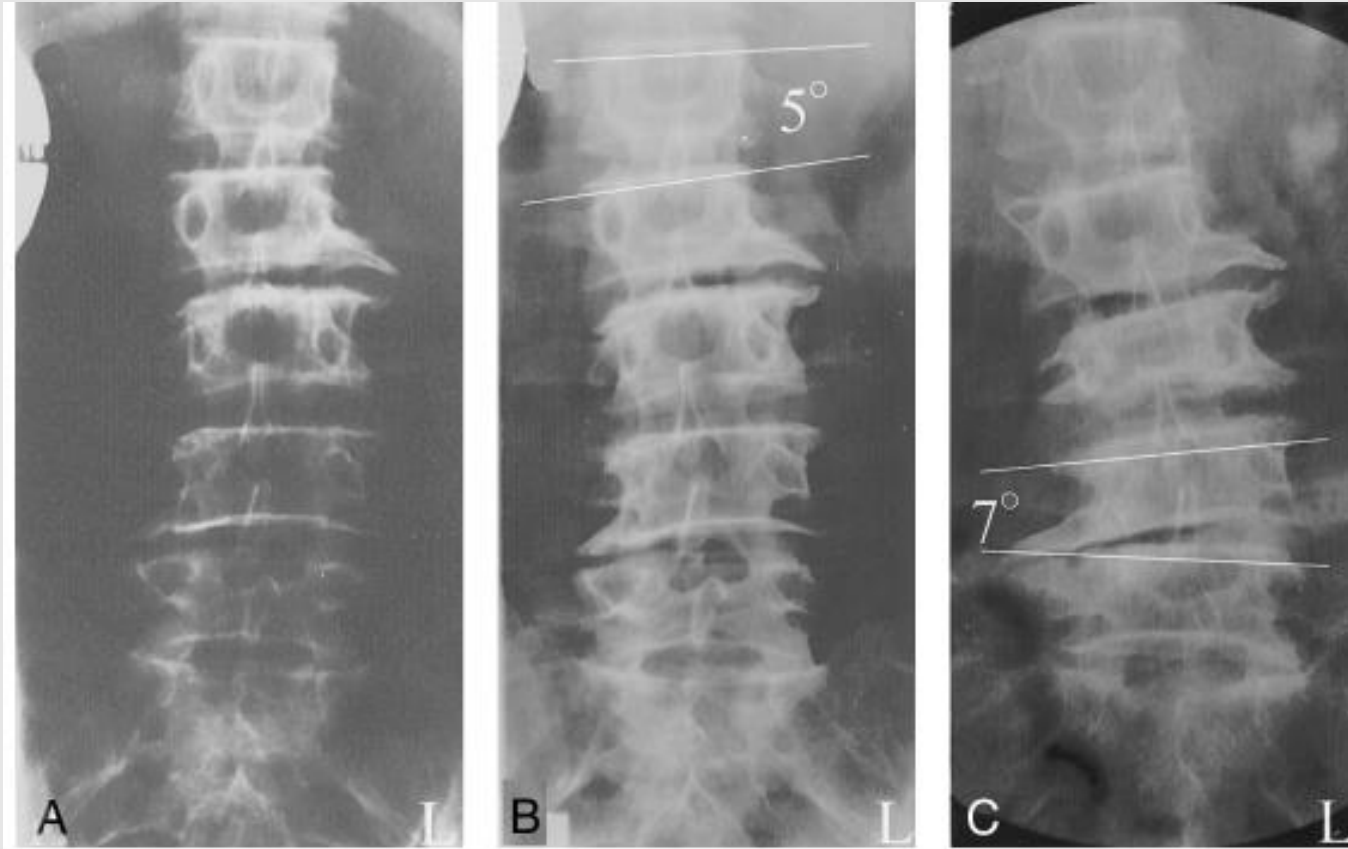
1 and 2 level Arthroplasty



Hybrid Arthroplasty

Background/spine degeneration

- Disc Degenerates First
 - Loss of proteoglycans and water content of discs (black disc)
 - Loss of disc height
 - Scoliosis/Spinal Stenosis with advanced disc degeneration
 - Increased loading of facet joints - *Facet joints degenerate last*



- A – 66 years old w/ 3 deg wedging at L1-2
- B – 70 years old w/ L wedging at L1-2 and compensatory wedging at L4-5
- C – 78 years old further compensatory wedging to the R at L4-5 (Murata et al. 2002)

Traditional Treatment

- Cervical spine
 - ACDF
- Lumbar spine
 - Anterior or posterior spinal fusion

Background

- Anterior Cervical Discectomy and Fusion
 - Long Term Results Excellent
 - Pseudoarthrosis
 - Adjacent Segment Disease

Bohlman 1993 classic long term ACDF

- 120 patients/6 year fu
- Non instrumented ACDF
- 81/120 had no arm or neck pain
- 24/195 levels had pseudoarthrosis
- *Overall Clinical Results Excellent*
- ACDF considered “gold standard”



FIG. 2-E

Lateral roentgenogram made six years postoperatively, showing a solid fusion. The patient had no pain in the neck or arm, and triceps strength returned to normal by two months after the operation.

ACDF – Failure to Fuse

- Increasing risk of pseudoarthrosis with increasing levels fused (Brodke 1992)
- 1 level fusion rate excellent 94% / 3 level fusion rate 83%
- Results confirmed by Bohlman (73% fusion rate with multilevel ACDF)
- **Increased ACDF levels -> greater failure rates**

■ **Modified Smith-Robinson Procedure for Anterior Cervical Discectomy and Fusion**

ACDF – adjacent level disease

- Increased stresses and degeneration at levels above and below a fusion



FIGURE 1. A, A 6-week postoperative plain radiograph in lateral projection of a patient operated on for soft disc herniation at C5–C6. B, A 9-year postoperative plain radiograph in lateral projection of the same patient: progressed degenerative changes at C3–C4, C4–C5, and C6–C7. At C4–C5, there is a decrease of disc height to 50–75% of the normal height: “moderate degeneration.” At C6–C7, there is a decrease of disc height to <50% of the normal height: “severe degeneration.”

ACDF – adjacent level degeneration

- Minimum 5 year fu 180 patients (Goffin 2003)
- **92% radiographic adjacent level changes**
 - Osteophytes
 - Loss of disc height
 - Sclerosis
 - Kyphosis
- 34% non-operated patients develop radiographic changes over 10 years (Gore 2001)



FIGURE 2. An 8-year postoperative plain radiograph in lateral projection of a patient operated on for soft disc herniation at C5–C6. At C4–C5, anterior osteophytes extend anteriorly over a distance of more than one-fourth of the AP diameter of the corresponding vertebral body: “severe degeneration.”

ACDF – symptomatic adjacent level disease

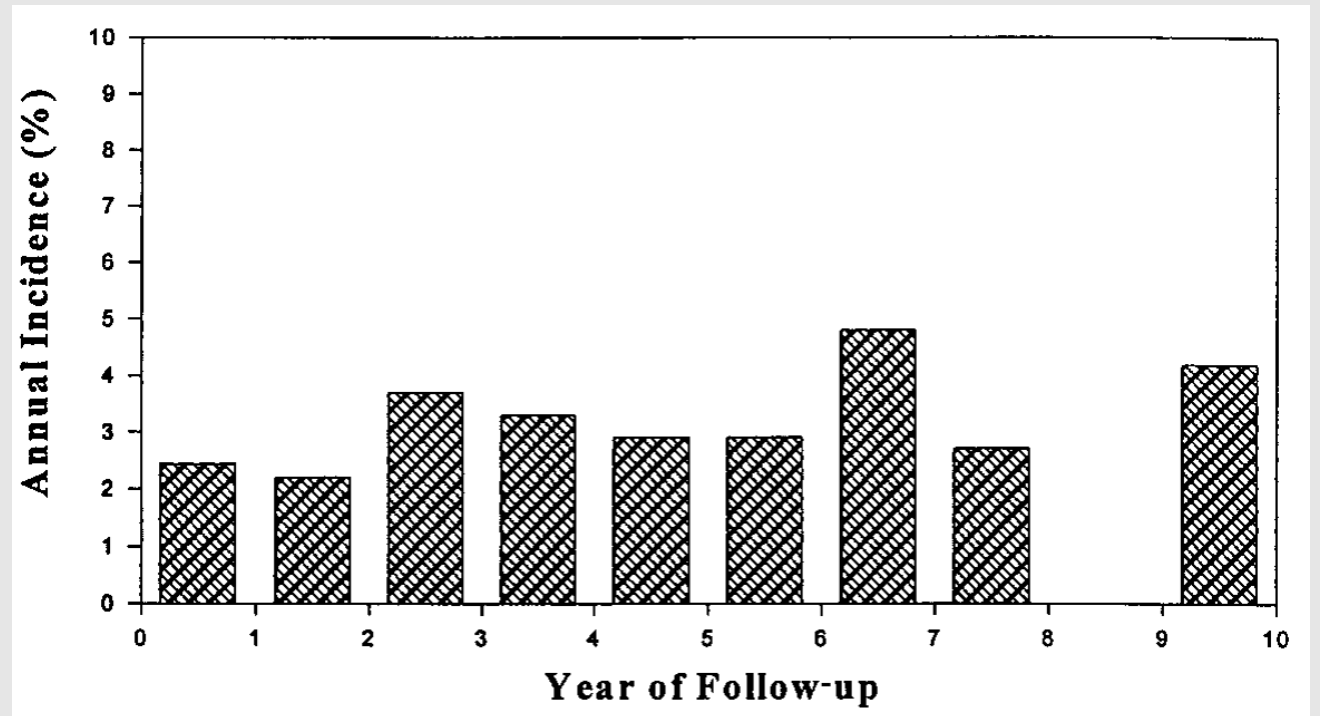
- 374 patients 10 yr fu (Hillibrand 1993)
- ***Symptomatic*** adjacent level degeneration
 - **2.9% per year**
 - **25.6% after 10 years**



18 year fu 2 level ACDF w/ ASD C6-7 (Hillibrand 1993)

ACDF – symptomatic adjacent level disease

- 374 patients 10 yr fu (Hillibrand 1993)
- ***Symptomatic*** adjacent level degeneration
 - **2.9% per year**
 - **25.6% after 10 years**



Lumbar Spine Fusion

Adjacent Segment
Degeneration >50%
after 10 years

Arthroplasty may have
less adjacent segment
changes

Clin Spine Surg • Volume 29, Number 1, February 2016

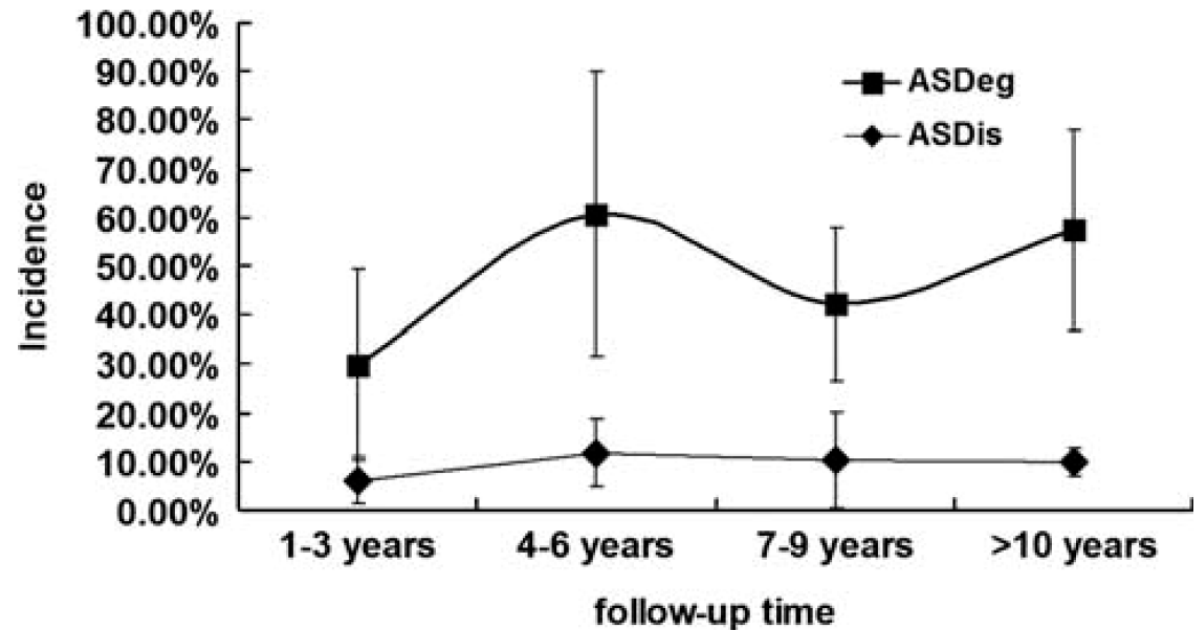
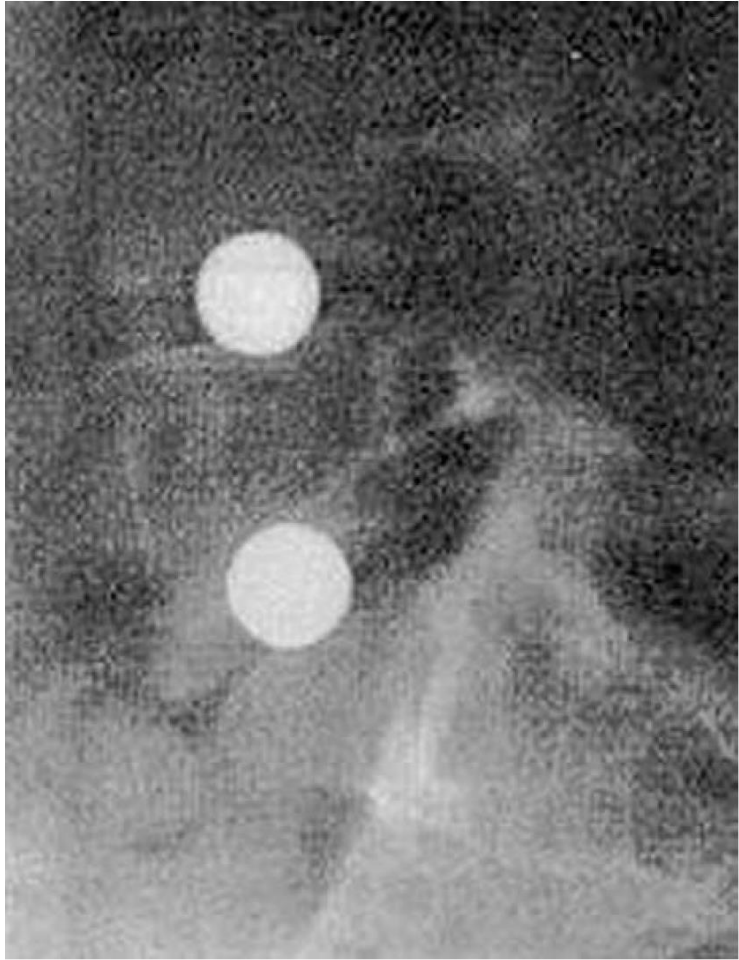


FIGURE 4. Average incidence of ASDeg and ASDis along with follow-up duration. ASDeg indicates adjacent segment degeneration; ASDis, adjacent segment disease.

Rationale for Arthroplasty

- Increasing Failure Rates with Increasing Levels Fused
- Adjacent Segment Disease
 - $\frac{1}{4}$ develop symptomatic disease within 10 years
- Arthroplasty designed in response to the limitations of fusion



Two of the first disc replacement devices, Fernström's steel balls, showing subsidence into the vertebral body end plates.

Arthroplasty History

- Fernstrom Ball
 - Disc excision
 - Steel ball placed at the border of the posterior 1/3rd disc space
 - Center of rotation was physiologic
 - High subsidence rates

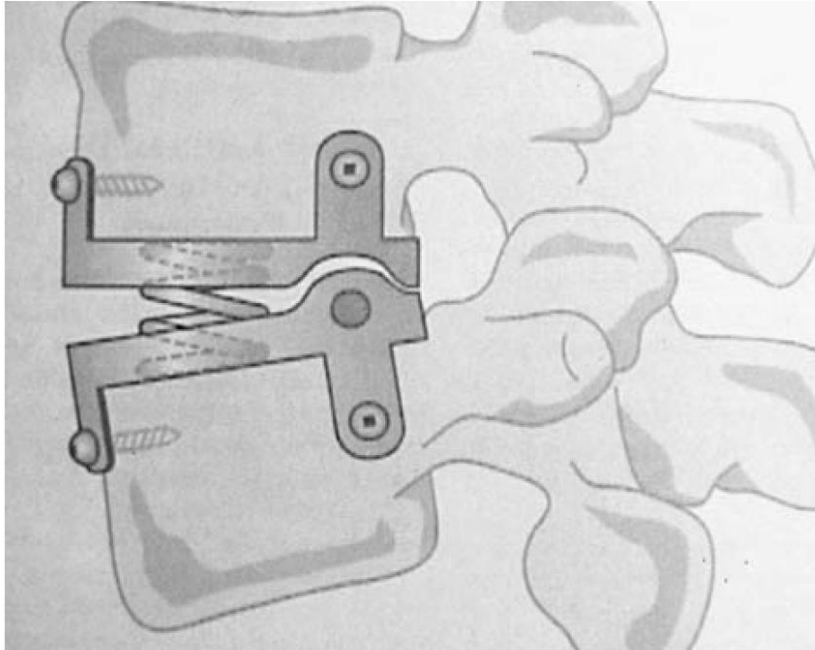


Fig. 2. Kostuik's design relied on a posterior hinge within the disc space to recreate an axis of rotation. A spring interposed between the metal implants attempted to provide axial shock absorption.

Arthroplasty History

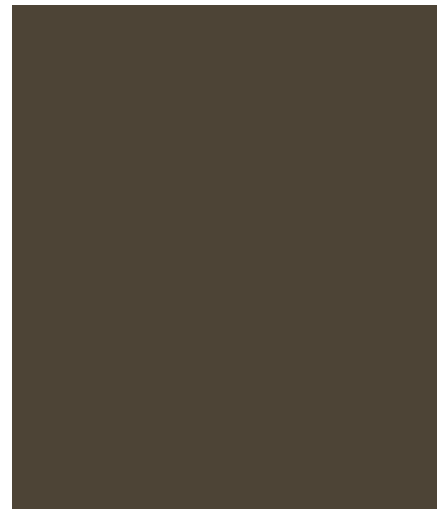
- Kostuik elastic arthroplasty
 - Animal implantation failures
 - Never underwent human trials

Acroflex rubber core disc

- Titanium endplates with a rubber core
- Catastrophic failures with shear and separation of the rubber



Figure 4. Failed acetabial cup.



Arthroplasty Design Lessons Learned from Early Failed Designs

Maximum contact
between implant and
host bone to prevent
subsidence

Articulating surfaces
should be a synthetic
material on a synthetic
material
(Bono/Garfin 2004)

Modern Arthroplasty Designs

- Large surface area endplates and synthetic material articulating surfaces
 - Metal on Metal articulations
 - Metal on polyethylene articulations

Volumetric Wear Rates Compared to Total Hip Arthroplasty

TABLE 1
Results of wear in cohorts of hips with various acetabular-femoral head articulations

Follow-up Period Cohorts	Linear Wear Mean (mm/year)	Linear Wear Standard Deviation	Volumetric Wear Mean (mm ³ /year)	Volumetric Wear Standard Deviation
5 Year				
22-mm machined	0.12	0.07	45.22	27.14
22-mm molded	0.11	0.12	40.91	46.97
28-mm molded	0.14	0.13	89.27	79.70
28-mm molded metal back	0.11	0.07	64.70	45.83
7–8 Year				
28-mm cementless metal back	0.11	0.06	65.78	39.01
10 Year				
22-mm machined	0.12	0.06	48.36	24.51
22-mm molded	0.08	0.06	32.71	24.59
28-mm molded	0.12	0.10	70.88	59.61
15 Year				
22-mm machined	0.11	0.07	41.20	25.79
22-mm molded	0.09	0.06	34.59	22.65
20–22 Year				
22-mm machined	0.10	0.07	40.69	26.24

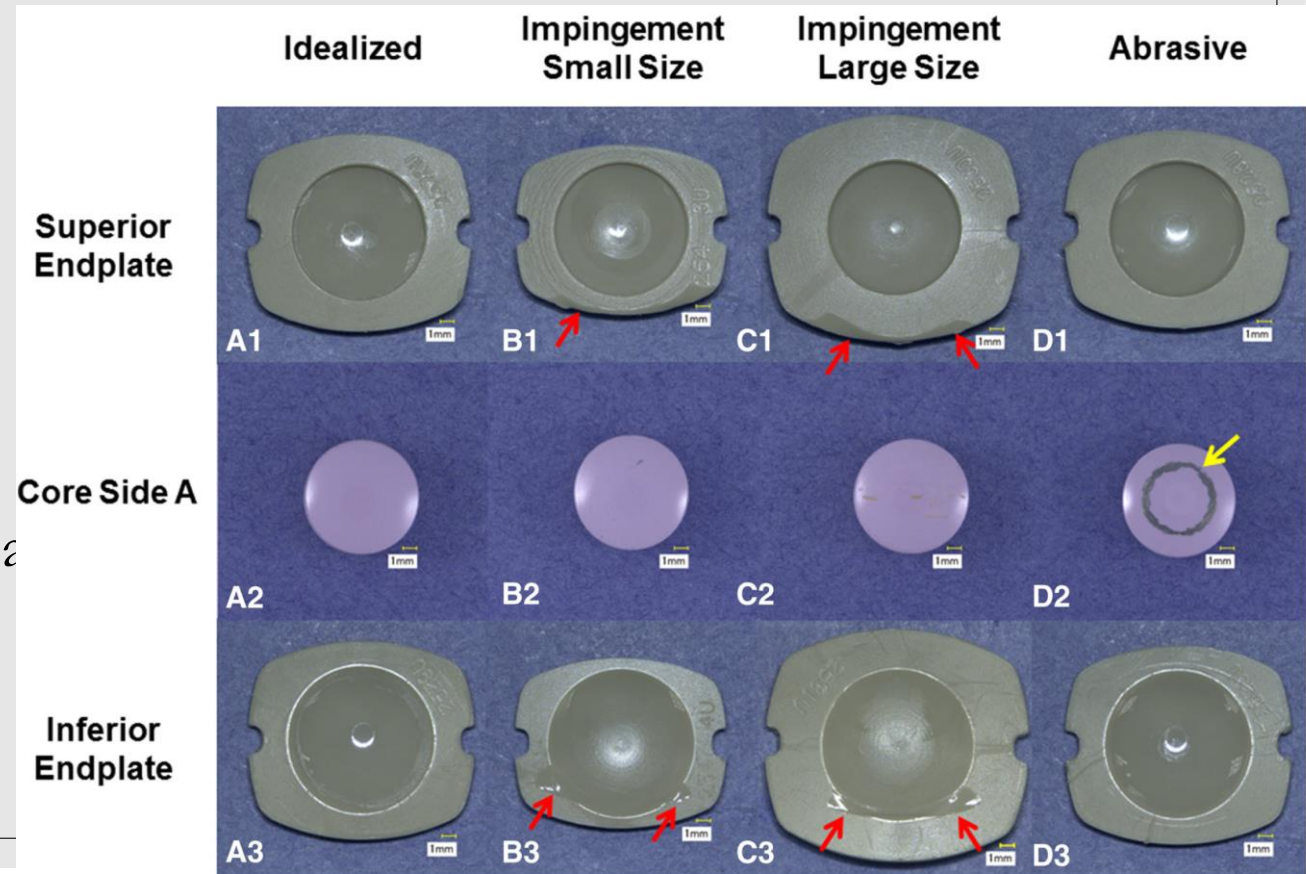
(Pedersen et al., ASTM 1994; Callaghan et al., CORR 1995)

- Direct Comparison Not Possible
- THA volumetric wear rates published between 30 – 70 mm³/year
- Linear wear rates approx. 0.1 mm/year

Wear Cervical Arthroplasty

1 million cycles corresponds to 5-10 years of wear (Anderson 2004)

- Prodisc-C Poly on CoCr wear rates
 - 2.8 mm³/million cycles (FDA 2007)
- Mobi-C poly on CoCr
 - 1.6 mm³/million cycles (FDA 2013)
- PCM poly on CoCr
 - 6.7 mm³/million cycles (FDA 2012)
- Prestige LP titanium carbide on titanium case
 - 0.3 mm³/million cycles (FDA 2014)
- Simplify disc PEEK on Ceramic
 - 1.5 mm³/million cycles (Siskey 2016)



1-2 order of magnitude difference

1 million cycles corresponds to 5-10 years of wear (Anderson 2004)

- Prodisc-C Poly on CoCr wear rates
 - 2.8 mm³/million cycles (FDA 2007)

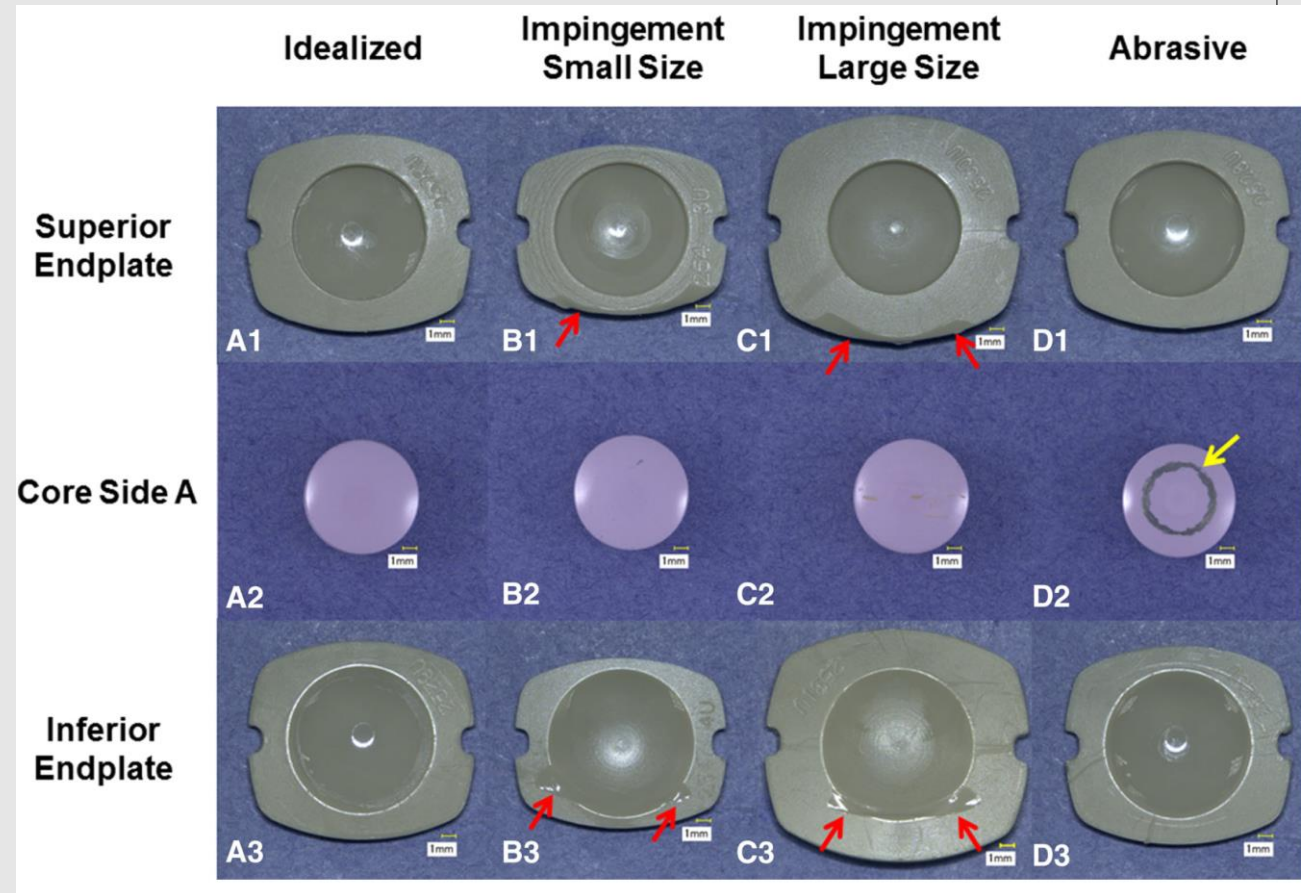
Wear cervical vs hip arthroplasty

1-2 orders of magnitude less

Wear studies suggest cervical arthroplasty implants should last

Decades

Similar findings for lumbar



FDA indications

◦ INDICATIONS

- Degen disc disease
- Soft disc herniation
- Failure of conservative care

◦ CONTRAINDICATIONS

- Osteoporosis/osteopenia
- Facet degenerative changes
- Bony foraminal stenosis or bony central stenosis
- Metal allergy
- Infection
- Tumor

Early Clinical Trials Data Cervical

- Modern designs all have 1 level PRCT, early studies documented 2 year results
 - Non-inferiority to ACDF at 2 years
 - Arm pain and Neck pain improvements

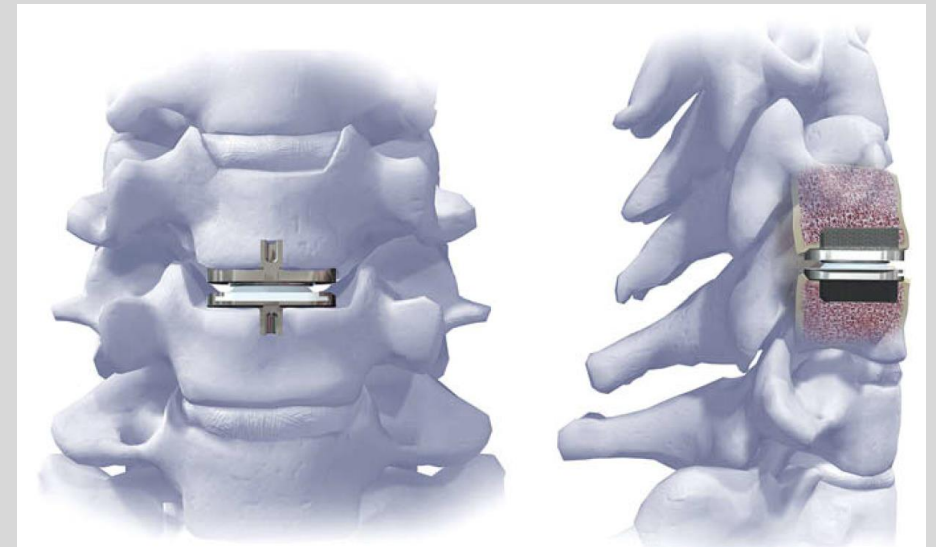
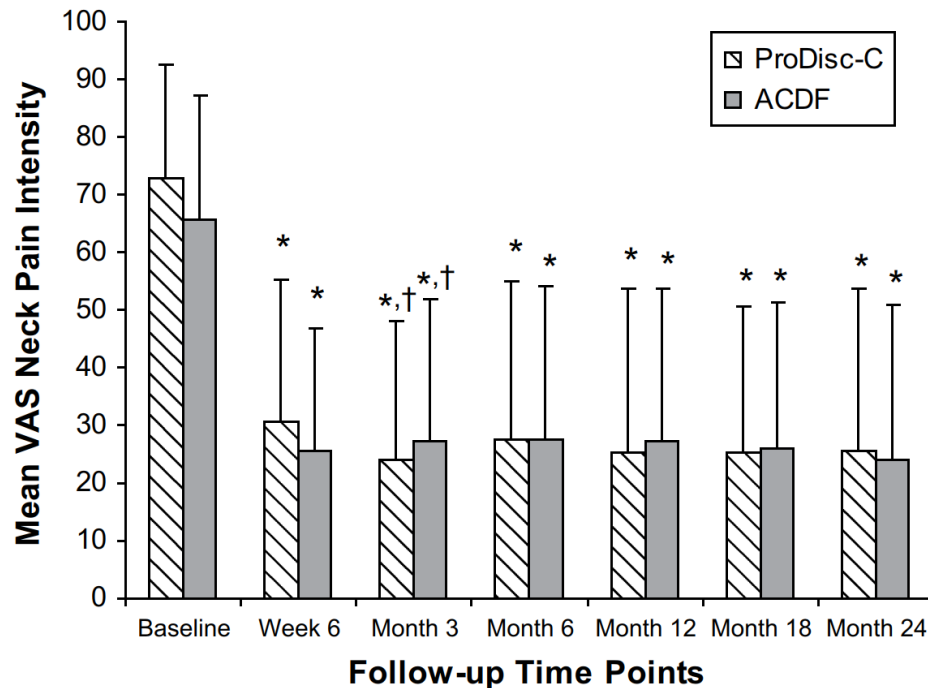
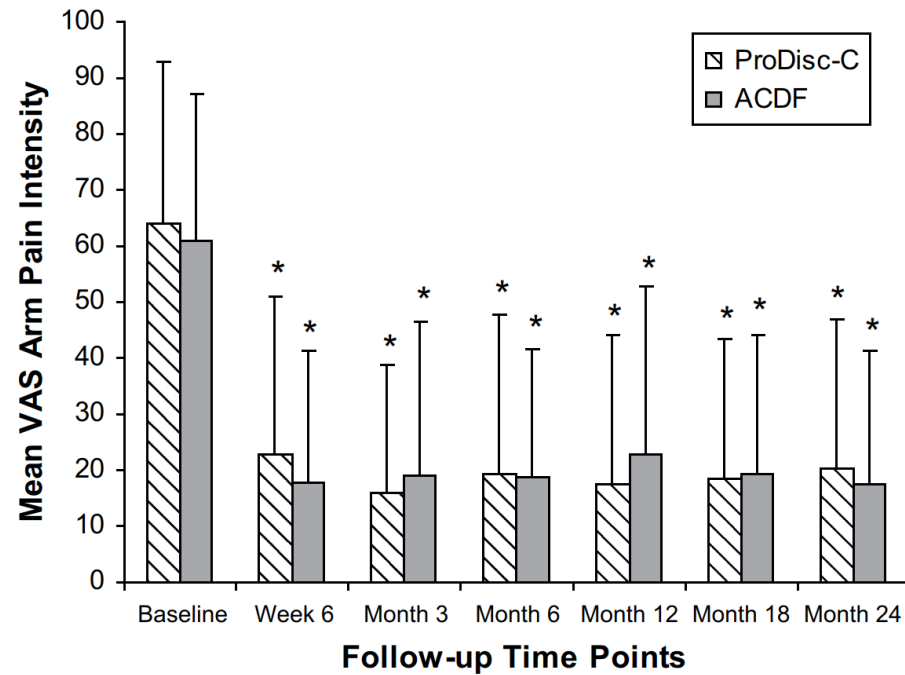


Fig. 2. Illustrations of the anterior and lateral views of the ProDisc-C in the cervical spine.

2 level studies Cervical

- FDA IDE trial mobi-C cervical arthroplasty
 - 225 patients 2 level arthroplasty, 105 patients ACDF
 - Neck pain and arm pain non-inferior or superior in arthroplasty group 2 year fu

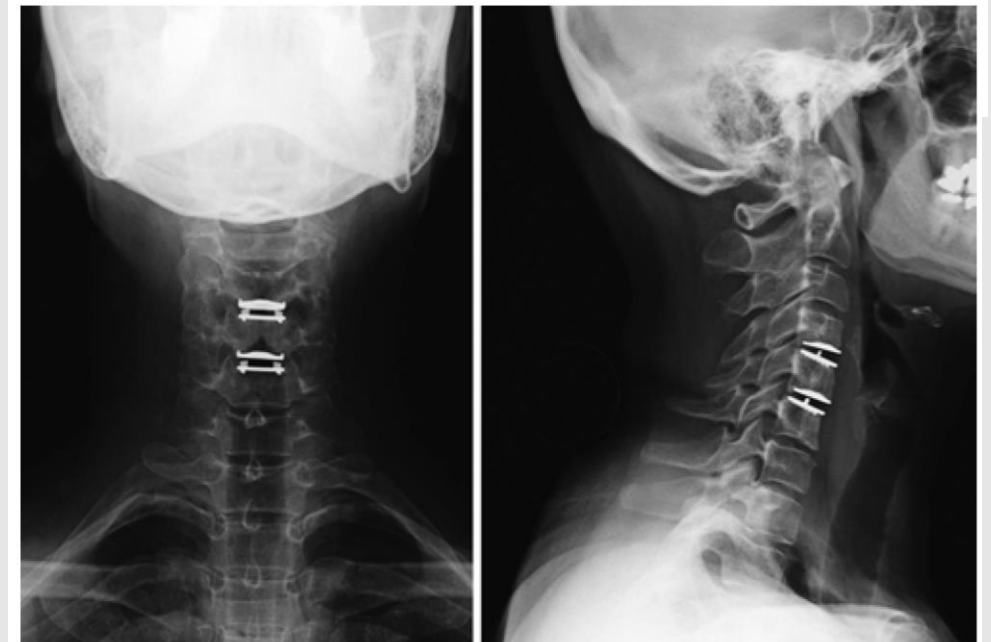
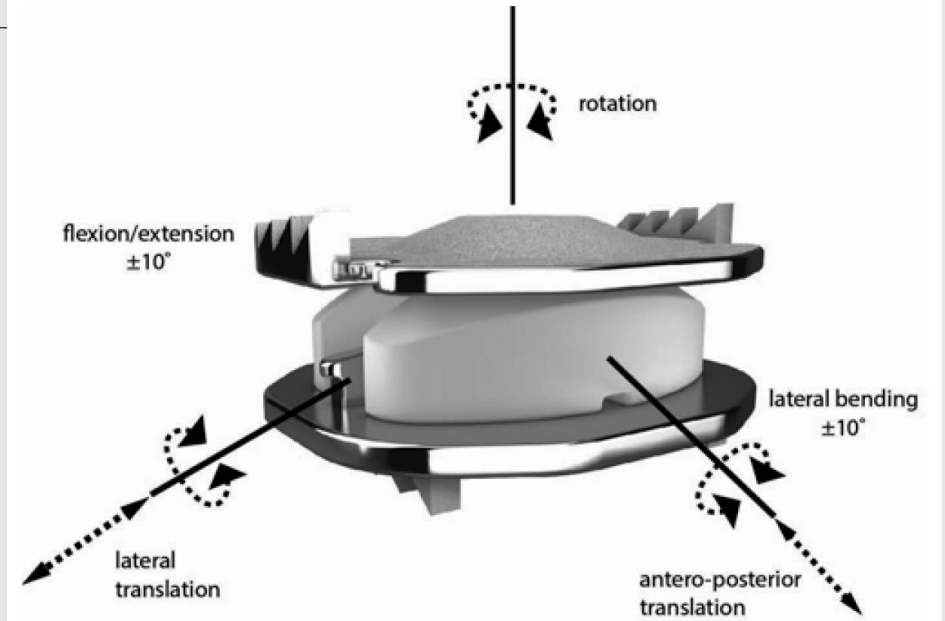
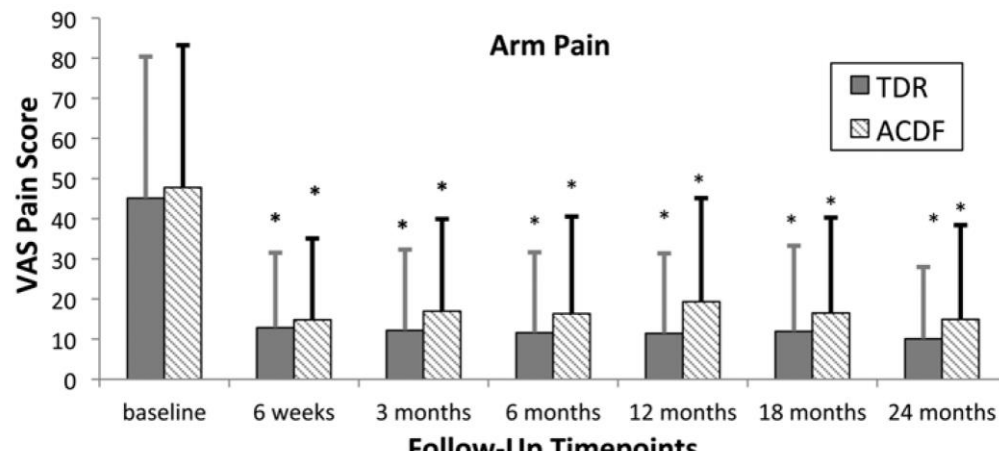
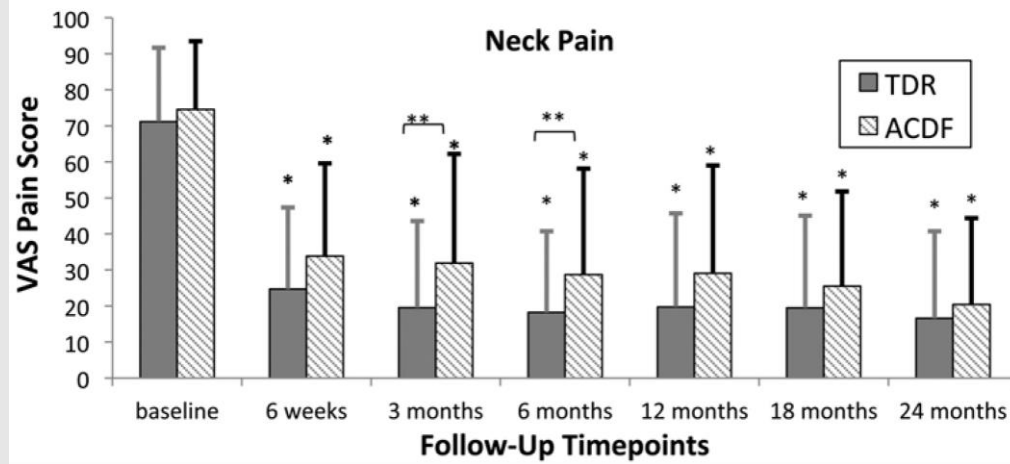


FIG. 2. Anteroposterior (left) and lateral (right) radiographs showing the TDR devices.

2 level mobi-C
cervical 5-year fu
FDA IDE PRCT

- Adjacent segment degeneration 71% ACDF/ **33%
*arthroplasty***
- Nonunion rate 14% in ACDF group
- Adjacent level reoperations in 11% ACDF/ **3%
*Arthroplasty***
- Overall reoperation rate 21% ACDF/ **7% *Arthroplasty***

2 level arthroplasty superior to ACDF at 5 years in adjacent segment degeneration, adjacent segment reoperation, and index level reoperation

Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial

2 level Prestige
LP 10-year fu
FDA IDE PRCT

- Adjacent level reoperations in 18% ACDF/ **9%
*Arthroplasty***
- Index level reoperation rate 17% ACDF/ **5%
*Arthroplasty***

2 level arthroplasty superior to ACDF at 10 years in adjacent segment reoperation and index level reoperation

J Neurosurg Spine. 2019 Jun 21:1-11. doi: 10.3171/2019.4.SPINE19157. [Epub ahead of print]

Two-level cervical disc arthroplasty versus anterior cervical discectomy and fusion: 10-year outcomes of a prospective, randomized investigational device exemption clinical trial.

Gornet MF¹, Lanman TH², Burkus JK³, Dryer RF⁴, McConnell JR⁵, Hodges SD⁶, Schranck FW⁷.

Multi-level Arthroplasty Cervical

- Multi-level arthroplasty proven safe in 10 year FDA IDE PRCT
- Most studies show *lower reoperation rates at both index level and adjacent level for 2 level arthroplasty*

Neurosurg Focus. 2017 Feb;42(2):E4. doi: 10.3171/2016.10.FOCUS16354.

Multilevel cervical arthroplasty: current evidence. A systematic review.

Joaquim AF¹, Riew KD².

Meta-analysis of all PRCT Cervical

- Cervical arthroplasty superior to ACDF at up to 10 years for
 - Reoperation
 - Implant related adverse events
 - Adjacent segment degeneration
 - Neurological success
- *Level 1 data beyond 10 years not available*

Cervical arthroplasty for patients with radiculopathy and degenerative disc disease without contraindications *may* be the “gold standard”

RESEARCH ARTICLE

Mid- to Long-Term Outcomes of Cervical Disc Arthroplasty versus Anterior Cervical Discectomy and Fusion for Treatment of Symptomatic Cervical Disc Disease: A Systematic Review and Meta-Analysis of Eight Prospective Randomized Controlled Trials

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Hybrid fusion and arthroplasty surgery

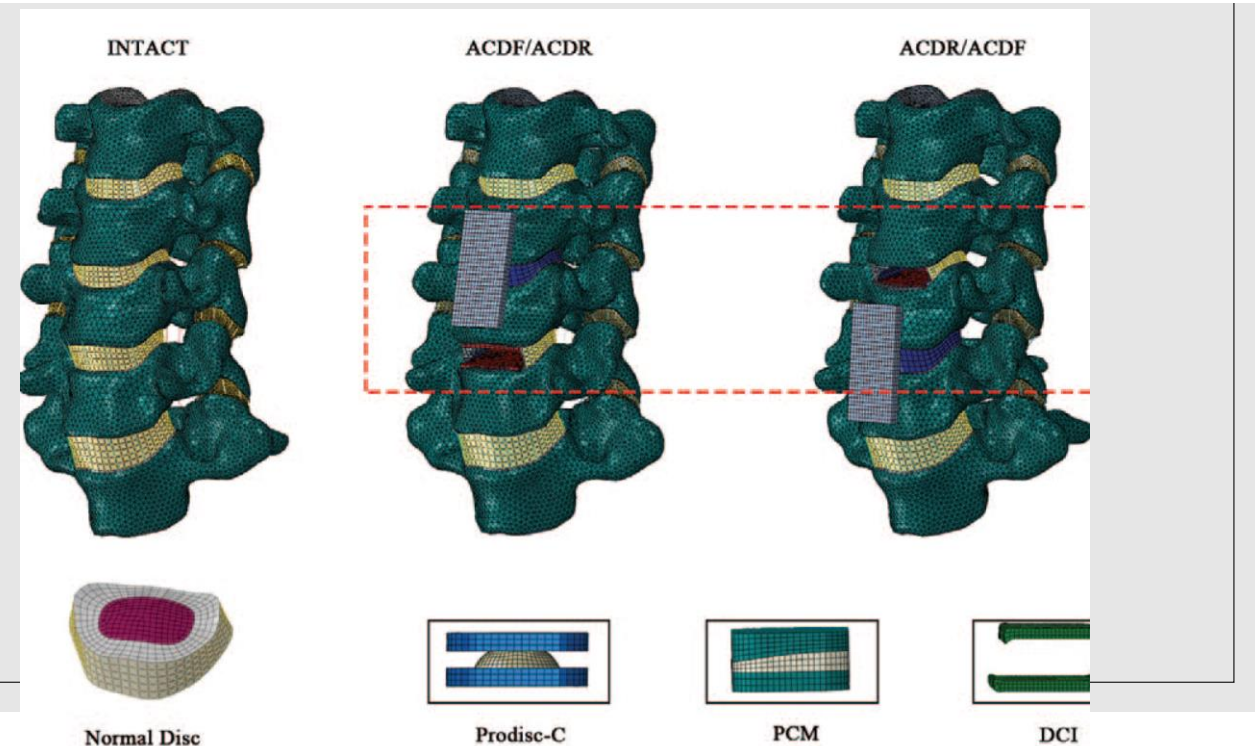
- Finite Element Models
 - Arthroplasty has lower adjacent level stresses compared to multilevel ACDF
 - Incorporating arthroplasty into multilevel fusions safe

Finite element model predicts the biomechanical performance of cervical disc replacement and fusion hybrid surgery with various geometry of ball-and-socket artificial disc

Yang Li^{1,2} · Guy R. Fogel³ · Zhenhua Liao⁴ · Weiqiang Liu^{1,4}

Prosthesis and Hybrid Strategy Consideration for Treating Two-level Cervical Disc Degeneration in Hybrid Surgery

Yang Li, PhD,^{*,†} Guy R. Fogel, MD,[‡] Zhenhua Liao, PhD,[§] Rajnesh Tyagi, PhD,^{||} and Weiqiang Liu, PhD[¶]



Greater than 2 level and hybrid surgery

- Retrospective review (Jang 2017)
- N=30 3 level hybrid arthroplasty ACDF
- N=19 3 level ACDF
- ACDF group had a lower fusion rate
- Arthroplasty group less adjacent segment degeneration at 2 years fu

A Comparison of Anterior Cervical Discectomy and Fusion versus Fusion Combined with Artificial Disc Replacement for Treating 3-Level Cervical Spondylotic Disease

Seo-Ryang Jang, M.D., Sang-Bok Lee,
Department of Neurosurgery, Uijeongbu St. I

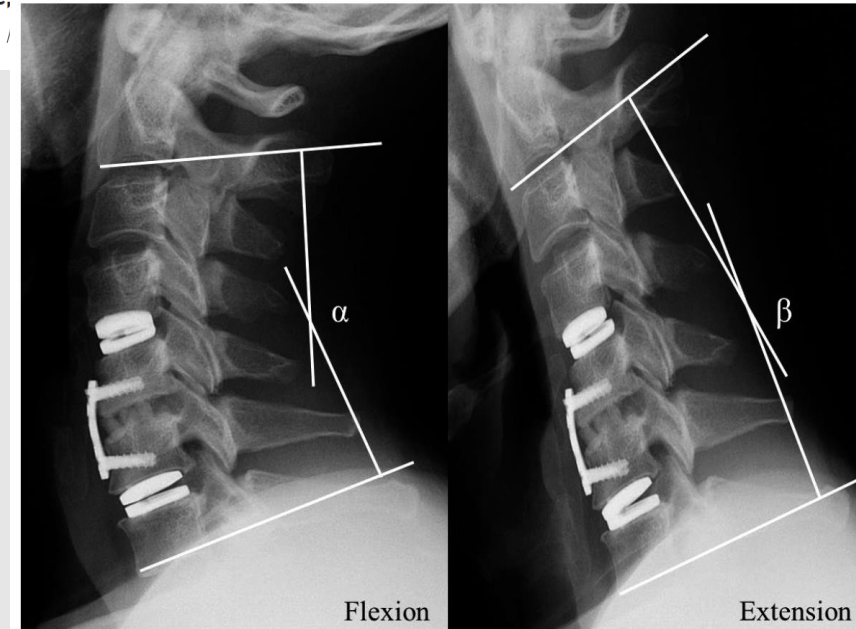


Table 3. Radiological changes of adjacent segment after surgery

	ACDF group (n=30)	HS group (n=19)	p-value
Increased disc space narrowing	3 (10)	1 (5.2)	
New osteophyte formation or enlargement	7 (23.3)	1 (5.2)	
New or enlargement of calcification of ALL	1 (3.3)	0 (0)	
Total of new radiological changes	11 (36.6)	2 (10.5)	0.04

Values are presented as number (%). ACDF : anterior cervical discectomy and fusion, HS : hybrid surgery, ALL : anterior longitudinal ligament

Δ is defined as the difference in the Cobb angle on (C2–C7 Cobb, α) and extension (C2–C7 Cobb, rotation).

Greater than 2 level and hybrid surgery

- Retrospective review (Ding 2014)
 - N=13 3 level hybrid arthroplasty ACDF
 - N=15 3 level ACDF/ACCF
 - Trend towards less adjacent segment degeneration in arthroplasty group

Fusion-Nonfusion Hybrid Construct Versus Anterior Cervical Hybrid Decompression and Fusion

A Comp

Fan Ding
Dike Rua

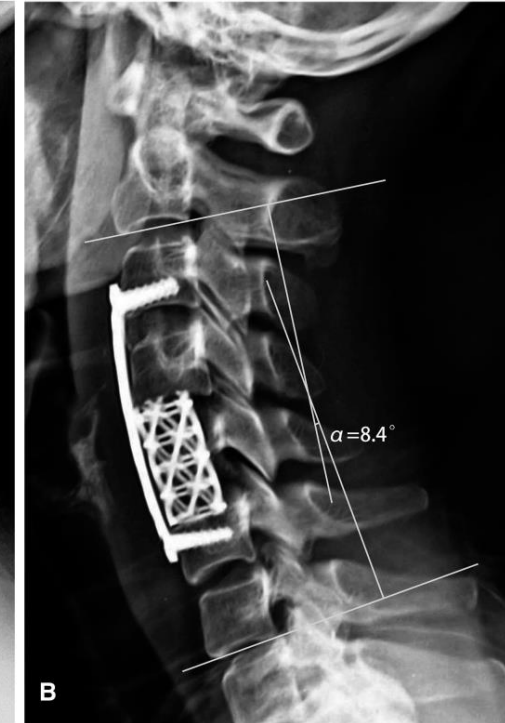


TABLE 4. Radiological Evidence of Adjacent-Level Changes

	HC (n = 13)	ACHDF (n = 15)	Statistical Value	P
New disc herniation	2/13	2/15		
New osteophyte formation	0	2/15		
New narrowing of disc space	0	0		
New ALL calcification	0	0		
Total*	2/13	4/15	0.526	0.655

*Fisher exact test.

HC indicates hybrid construct; ACHDF, anterior cervical hybrid decompression and fusion; ALL, anterior longitudinal ligament.

Lumbar Spine Arthroplasty

- 10 year fu results published in 55 patients
 - Zero implant failures
 - 41/55 excellent or good results
 - 14/55 with continued back pain

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LUMBAR TOTAL DISC REPLACEMENT

SEVEN TO ELEVEN-YEAR FOLLOW-UP

BY PATRICK TROPICANO, MD, RUSSEL C. HUANG, MD, FEDERICO P. GIRARDI, MD,
FRANK P. CAMMISA JR., MD, AND THIERRY MARNAY, MD

Investigation performed at the Department of Orthopaedic Surgery, Clinique du Parc, Castelnau-le-Lez, France

Lumbar Spine Arthroplasty

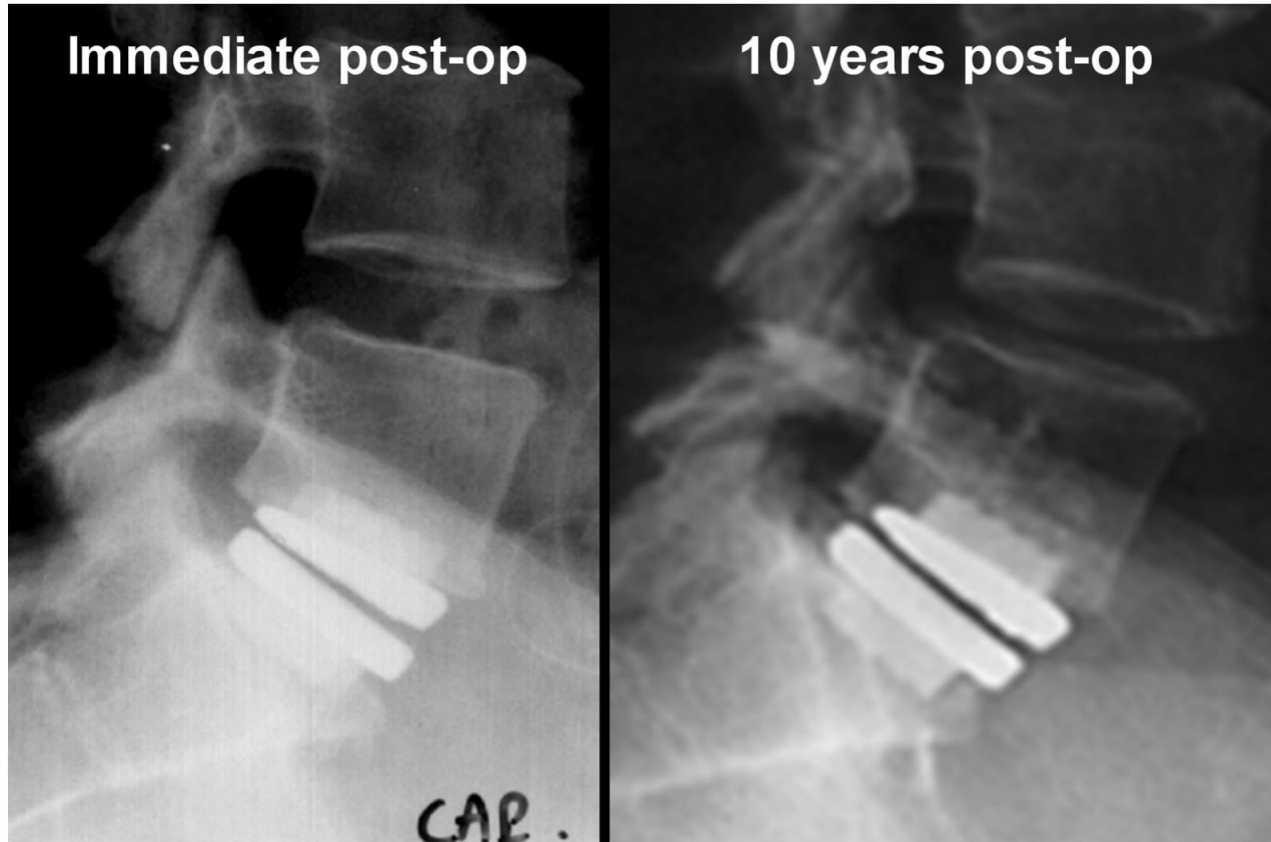


Fig. 5
Immediate postoperative and ten-year follow-up lateral radiographs after L5-S1 disc replacement in a forty-eight-year-old woman.

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LUMBAR TOTAL DISC REPLACEMENT

SEVEN TO ELEVEN-YEAR FOLLOW-UP

BY PATRICK TROPANO, MD, RUSSEL C. HUANG, MD, FEDERICO P. GIRARDI, MD,
FRANK P. CAMMISA JR., MD, AND THIERRY MARNAY, MD

Lumbar Arthroplasty 20 year series


- 20 year series 32 patients
 - Average fu 14 years
 - 10% revision surgery/failure rate

European Spine Journal
<https://doi.org/10.1007/s00586-019-06100-3>

ORIGINAL ARTICLE



Total disc replacement for lumbar degenerative disc disease: single centre 20 years experience

Carlo Formica¹ · Andrea Zanirato² · Stefano Divano² · Marco Basso² · Luca Cavagnaro² · Mattia Alessio Mazzola² · Valerio Gaetano Vellone³ · Maddalena Mastrogiacomo^{4,5} · Pedro Berjano¹ · Lamberto Felli² · Matteo Formica² 

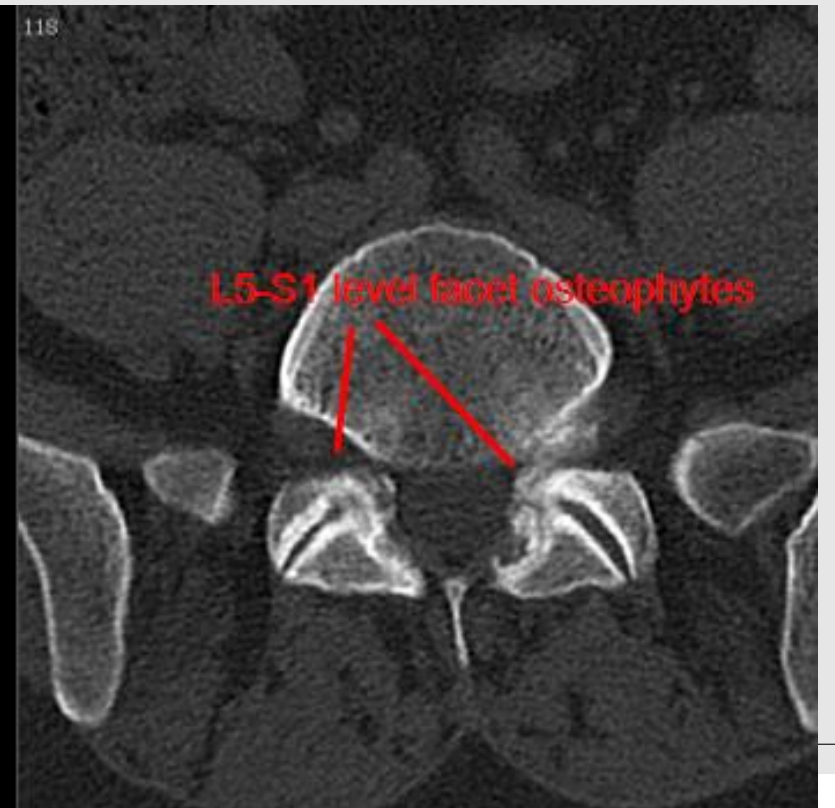
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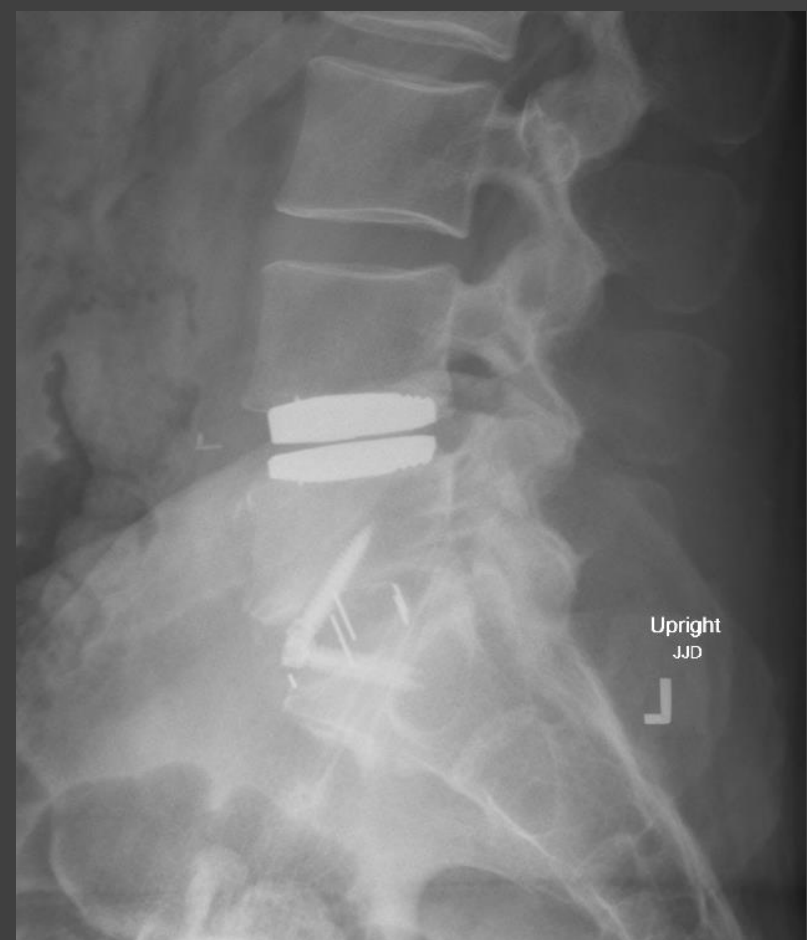


MULTI LEVEL AND HYBRID CERVICAL ARTHROPLASTY

- PRESERVES MOTION
- SUPPORTED BY CLINICAL DATA
- MAY REDUCE ADJACENT SEGMENT REOPERATIONS

Lumbar case





CONSIDER ARTHROPLASTY WHEN POSSIBLE
WITH BAD FACETS THEN FUSION

Closing thoughts

FDA PRCTs 10 year fu for cervical arthroplasty have

- lower Adjacent Segment Degeneration
- lower Adjacent Segment Reoperations
- lower Index Level Reoperations

Lumbar arthroplasty mean 14 year long term studies show low revision rates

Wear studies suggest implants should last decades

Long term surveillance is required