MOTION PRESERVATION IN SPINE SURGERY

SPINE SYMPOSIUM - JULY 27, 2019

SCOTT HODGES, D.O. - CHATTANOOGA ORTHOPEDIC GROUP
MOTION PRESERVATION-SPINE

DISCLOSURES:

- CONSULTANT - MEDTRONIC SPINE
- EDUCATIONAL SPEAKER - MEDTRONIC SPINE
- SHAREHOLDER - INTERNATIONAL SURGICAL/BB
- PARTNER - COG
MOTION PRESERVATION-SPINE

- CS
  - LAMNIoplasty
  - HEMILAMINOTOMY/FORAMINOTOMY
- LS
  - COFLEX
  - HEMILAMINOTOMY/FACETECTOMY
CERVICAL SPINE-CDA

- ONE LEVEL-MANY (PRESTIGE, MOBIC-C, PRO-DISC, SECURE-C, M-6)
- TWO LEVEL-2 DEVICES (PRESTIGE-LP, MOBIC-C)
Kinematics

- ACDF: Increase of Intra-discal pressure and hyper mobility at adjacent level
- CDA: Normal Intra-discal pressure and no hyper mobility at adjacent levels

- (3) DJ DiAngelo: Neuro Surgery Focus 2007
- (2) Dimitrier: SPINE, May 2005
- (1) J. Eck: SPINE, November 2002
Kinematics

- If ACDF alters adjacent segment disc pressures and causes hyper mobility that can be returned to normal intra-discal pressures with no hyper mobility by CDA-
- Shouldn’t CDA reduce adjacent segment degeneration possibly reducing number of secondary surgeries at adjacent levels?
### Anterior Cervical Surgery

**Evolution of Cervical Disc Arthroplasty (CDA)**

<table>
<thead>
<tr>
<th>Initial Treatment Goals - ACDF</th>
<th>Improvement Goals - CDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Treat neck &amp; arm pain symptoms</td>
<td>• Re-establish disc function</td>
</tr>
<tr>
<td>• Preserve or enhance neurological function</td>
<td>• Maintain motion</td>
</tr>
<tr>
<td>• Provide segmental stability</td>
<td>• Obviate need for bracing</td>
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<td>• Earlier functional recovery</td>
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<td>• Reduce future reoperations</td>
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</tbody>
</table>

**Improvement Goals - CDA**

- Re-establish disc function
- Maintain motion
- Obviate need for bracing
- Earlier functional recovery
- Reduce future reoperations
Both successful surgeries with proven outcomes
At least 14 Level 1 IDE comparisons in all
CDA at least equal to ACDF in ALL studies
More Level 1 data on this subject than any other spine disorder1
Why Do Motion Preservation-CDA

- Avoid Loss of Motion
- Decrease Risk of ASD/Surgery
- Reduce Cost of Treatment
- Faster Recovery
Avoid loss of motion

IDE Studies

- PRESTIGE-LP® Disc: 7.59° (motion varied from 0-22°) at 24-months postoperative)

- BRYAN® Disc: 7.74° (motion varied from 0-20°) at 24-months postoperative

- ProDisc®-C Disc: Maintenance of or gain of 4.5

- PRESTIGE-LP® Disc: 7.51° (motion varied from 0.19-26.43°) at 24-months postoperative
Clinical Data: Non IDE-study data

- A Clinical Analysis of 4 and 6 Year Follow-up Results after Cervical Disc Replacement Surgery Using the BRYAN® Cervical Disc Prosthesis

- 98 patients
- 1 year ROM 7.3°, 2 year ROM 7.7°
- Angular motion outcomes persist after 4 and 6 years
Decreased Risk of Additional Surgery

Long Term Clinical and radiographic Outcomes of Cervical Disc Replacement with the PRESTIGE-LP® Disc8

5 year f/u-276 patients

Statistically significant differences between control and investigational groups in the rate of revision (p=0.028) and supplemental fixation surgeries (p=0.028)

Five Year Re-operation Rates Cervical Total Disc Replacement (ProDisc®-C) versus Fusion, Results from a Prospective, Randomized Clinical Trial9

209 patients, 103 TDR, 106 ACDF, 13 sites

Secondary surgery was re-operation at any level

At 5 years: patients who received ProDisc®-C had a statistically higher probability of no secondary surgery than ACDF (97.1% and 85.5%, respectively with p=0.0079)
Decrease Risk of Additional Surgery

A. Analysis of the three United States Food and Drug Administration investigational device exemption Cervical Arthroplasty Trials


a) Statistically fewer surgeries at index level in Arthroplasty group

b) Fewer adjacent level surgeries in Arthroplasty group using fixed effect model
Decreased Risk of Additional Surgery

- Five Year Re-operation Rates Cervical Total Disc Replacement versus Fusion, Results from a Prospective, Randomized Clinical Trials R.B. Delamarter, J. Zigler SPINE: Nov 2012
- 1) 209 patients, 103 TDR, 106 ACDF, 13 sites
- 2) Secondary surgery was re-operation at any level
- 3) At 5 years: 5x difference in re-operation rates comparing ACDF to TDR
Mean Total Cost over 10 years (based on DRG and Medicare 2010 costs)10
CDA = $14,154; ACDF = $15,340
Cost per Quality Adjust Life Year (QALY)
CDA = $2,353; ACDF = $2,608
QALY vs. Cost to society11
Model assumed a 20 year survival of CDA device
Aim to identify the most critical factors affecting procedural cost.
CDA had higher average QALY; gained at a lower cost to society
CDA: $3,042/QALY vs. ACDF $8,760/QALY
Cervical Disc Arthroplasty Versus Anterior Cervical Discectomy and Fusion for Incidence of Symptomatic Adjacent Segment Disease: A Meta-Analysis of Prospective Randomized Controlled Trials.


Author information

Abstract
STUDY DESIGN: Meta-analysis of randomized controlled trials.

OBJECTIVE: To evaluate the reported rate of adjacent segment disease (ASD) of cervical disc arthroplasty (CDA) compared with anterior cervical discectomy and fusion (ACDF).

SUMMARY OF BACKGROUND DATA: Motion-maintaining technologies such as CDA have developed rapidly because of the concern of ASD. Till date, however, it still has been under debate whether CDA is superior to ACDF regarding the incidence of ASD.

METHODS: We comprehensively searched PubMed, EMBASE, and Cochrane Central Register of Controlled Trials for prospective randomized controlled trials (RCTs) that reported the incidence of ASD between CDA and ACDF. The retrieved results were last updated on November 20, 2015 without language restrictions. Two independent authors selected qualified studies, assessed methodological quality, and extracted requisite data.

RESULTS: Fourteen relevant RCTs involving 3235 individuals with a follow-up period of 2 to 7 years were included in the meta-analysis (1696 in CDA group and 1539 in ACDF group). The outcomes indicated that CDA was superior to ACDF considering the lower rate of ASD (risk ratio, 0.57; 95% confidence interval, 0.37 to 0.87; P=0.009). And compared with ACDF, there were significantly fewer adjacent segment reoperations in the CDA group (risk ratio, 0.47; confidence interval, 0.32 to 0.70; P=0.0002). Subgroup analysis stratified by different types of disc prostheses was also performed.

CONCLUSION: CDA was superior to ACDF regarding fewer ASDs and relative reoperations on the basis of available evidence from a meta-analysis of 14 RCTs. CDA may be a better surgical procedure to reduce the incidence of ASD for patients with cervical disc disease compared with ACDF. Further well-designed studies should continue to pay attention to excellent patients with longer-term follow-up to evaluate the incidence of ASD of these two procedures.

LEVEL OF EVIDENCE: 1.
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; Leeman Th2; Burtis JR3; Dryer RE4; McConnell JR5; Hodges SS0; Schranck FW7

Abstract

OBJECTIVE: The authors assessed the 10-year clinical safety and effectiveness of cervical disc arthroplasty (CDA) to treat degenerative cervical spine disease at 2 adjacent levels compared to anterior cervical discectomy and fusion (ACDF).

METHODS: A prospective, randomized, controlled, multicenter FDA-approved clinical trial was conducted comparing the low-profile titanium ceramic composite-based Prestige LP Cervical Disc (n = 209) at two levels with ACDF (n = 188). Ten-year follow-up data from a postapproval study were available on 148 CDA and 118 ACDF patients and are reported here. Clinical and radiographic evaluations were completed preoperatively, intraoperatively, and at regular postoperative follow-up intervals for up to 10 years. The primary endpoint was overall success, a composite variable that included key safety and efficacy considerations. Ten-year follow-up rates were 86.0% for CDA and 84.9% for ACDF.

RESULTS: From 2 to 10 years, CDA demonstrated statistical superiority over ACDF for overall success, with rates at 10 years of 90.4% versus 82.2%, respectively (posterior probability of superiority [PPS] = 99.9%). Neck Disability Index (NDI) success was also superior, with rates at 10 years of 88.4% versus 76.5% (PPS = 99.5%), as was neurological success (92.6% vs 86.1%; PPS = 95.6%). Improvements from preoperative results in NDI and neck pain scores were consistently statistically superior for CDA compared to ACDF. All other study effectiveness measures were at least noninferior for CDA compared to ACDF through the 10-year follow-up period, including disc height. Mean angular ranges of motion at treated levels were maintained in the CDA group for up to 10 years. The rates of grade IV heterotopic ossification (HO) at the superior and inferior levels were 8.2% and 10.3%, respectively. The rate of severe HO (grade III or IV) did not increase significantly from 7 years (42.4%) to 10 years (39.0%). The CDA group had fewer serious (grade 3-4) implant-related or implant/surgical procedure-related adverse events (3.8% vs 8.1%; posterior mean 95% Bayesian credible interval [BCI] of the log hazard ratio [LHR] -0.92 [-1.88, -0.01]). The CDA group also had statistically fewer secondary surgical procedures at the index levels (4.7%) than the ACDF group (17.6%) (LHR [95% BCI] -1.39 [-2.15, -0.61] as well as at adjacent levels (9.0% vs 17.9%).

CONCLUSIONS: The Prestige LP Cervical Disc, implanted at two adjacent levels, maintains improved clinical outcomes and segmental motion 10 years after surgery and is a safe and effective alternative to fusion. Clinical trial registration no.: NCT00837156 (clinicaltrials.gov)
PRESTIGE-LP vs ACDF (10 year)

- F/U: 86% 84.9%
- Statistical Superiority:
  - Over-all-success: 80.4% 62.2%
  - NDI: 88.4% 76.5%
  - Neurological: 92.6% 86.1%
  - VAS: 2.1 4.6
  - Serious AE: 3.8% 8.1% (implant or surgical related)
  - Secondary Surgery: 4.7% 17.6% (index level)
  - 9.0% 17.9% (adjacent level)
Reduction in opioid (narcotic) medication uses after arthroplasty with Prestige LP™ cervical disc as compared to ACDF in patients with 2-level surgery: a randomized study with 10-year follow-ups

Matthew F. Gornet MD, Todd H. Lanman MD, J. Kenneth Burkus MD, Randall G. Dryer MD, Jeffrey R. McConnell MD, Scott D. Hodges MD, Francine W. Schranck BSN, Guorong Ma PhD
Figure 1. % subjects who used narcotic medication ≥ once a day

<table>
<thead>
<tr>
<th></th>
<th>Preop</th>
<th>6 W</th>
<th>3 M</th>
<th>6 M</th>
<th>1 Y</th>
<th>2 Y</th>
<th>3 Y</th>
<th>5 Y</th>
<th>7 Y</th>
<th>10 Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>2L CDA</td>
<td>47.8%</td>
<td>24.0%</td>
<td>10.8%</td>
<td>9.4%</td>
<td>10.9%</td>
<td>10.2%</td>
<td>7.7%</td>
<td>7.3%</td>
<td>8.6%</td>
<td>7.5%</td>
</tr>
<tr>
<td>2L ACDF</td>
<td>44.4%</td>
<td>38.3%</td>
<td>23.2%</td>
<td>23.8%</td>
<td>18.3%</td>
<td>17.8%</td>
<td>17.0%</td>
<td>21.8%</td>
<td>20.8%</td>
<td>15.0%</td>
</tr>
</tbody>
</table>
LUMBAR SPINE-FUSION

- 30 DAY READMISSION-13%
- 90 DAY READMISSION-24.8%
- 30 DAY ER VISITS-12.8% COST 2/3 OF READMISSION COST
Adjacent Segment Degeneration and Revision Surgery after Lumbar Fusion: Outcomes throughout 15 year F/U

Marueda JT, Barrios C, Garibo F

- 15 year f/u TLIF/PLIF: Evaluation of ASD and Reintervention
- 73 patients (1-3 level fusions)
- Evaluations at 2,5,10,15 years after surgery
- Static and dynamic xray, CT scan, MRI scan
- ODI, VAS, patient self satisfaction questionnaire
- 2 year ODI 72.3 reduced to 30.5 (sever disability to moderate disability)
- 2 year VAS 8.2 reduced to 4.9 (40% reduction)
- 5, 10, 15 ODI, VAS back to pre-operative levels
- 5 year: 9.6% required reoperation secondary to ASD

- 10 year: 24.6% required reoperation, good to excellent satisfaction - 41%

- 15 year: nine patients lost to f/u, 37.5% required reoperation. Good to excellent satisfaction < 30%
Lumbar Adjacent Segment Degeneration and Disease After Arthrodesis and Total Disc Arthroplasty

Harrop, James S., MD; Youssef, Jim A., MD; Maltenfort, Mitch, PhD; Vorwald, Peggy, BS; Jabbour, Pascal, MD; Bono, Christopher M., MD; Goldfarb, Neil, BS; Vaccaro, Alexander R., MD; Hilibrand, Alan S.

Spine: July 1, 2008 - Volume 33 - Issue 15 - p 1701-1707

doi: 10.1097/BRS.0b013e31817bb956

Literature Review
REVIEW OF 28 ARTICLES

- ARTHRODESIS
  - ASDeg: 34%
  - ASDis: 14%

- ARTHROPLASTY
  - ASDeg: 9%
  - ASDis: 1%
MOTION PRESERVATION-SPINE
MOTION PRESERVATION-SPINE
Risk Factors for Poor Patient-reported Quality of Life Outcomes After Posterior Lumbar Interbody Fusion

An Analysis of 2-Year Follow-up

Takahiro Makino, MD, DMSc, Takashi Kaito, MD, PhD, Hiroyasu Fujiwara, MD, Hirotsugu Honda, MD, PhD, Yusuke Sakai, MD, Shota Takenaka, MD, DMSc, Hideki Yoshikawa, MD, PhD, and Kazuo Yonenobu, MD, DMSc
The Kyphosing Cascade at L1-4 and Loss of Lordosis L4-S1

The kyphosing cascade and loss of lordosis of the lumbar spine during flexion. If the spine were to be fuse, the cascade would only be able to occur over the remaining L1 to L3 vertebrae. Further attempts at flexion would result in physiological stress, predominantly at the immediate proximal adjacent level (L3-L4).
Variations of Lumbopelvic Alignment in Standing, Seated, and Slumped Postures: Implications for lumbar fusion surgery


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Edward Hines Jr., VA Hospital, Hines, IL

Department of Orthopaedic Surgery
Loyola University Chicago

No relevant disclosures

www.WindyCityLab.com
Postural Influence on Lumbopelvic Alignment

- L4-Sacrum fusions are most prevalent for degenerative conditions in adults.
- Lordotic fusion alignment duplicating standing lateral radiograph is recommended to allow patients to ambulate postoperatively in upright posture.
- Adults spend increasingly larger amounts of time...

How does L4-S1 fusion in standing alignment affect proximal lumbar segments during post-fusion sitting?

- 10 asymptomatic subjects (9M/1F, 39±12 years)
- EOS images were obtained:
  - Standing erect, Sitting erect, Sitting slumped
Postural Influence on Lumbopelvic Alignment
Postural Influence on Lumbopelvic Alignment

<table>
<thead>
<tr>
<th></th>
<th>Standing Upright</th>
<th>Sitting Upright</th>
<th>Sitting Slumped</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacral Slope</td>
<td>37.2</td>
<td>25.7</td>
<td>11.2</td>
</tr>
<tr>
<td>L1-S1</td>
<td>46.5</td>
<td>33.0</td>
<td>10.2</td>
</tr>
<tr>
<td>L1-L4</td>
<td>17.7</td>
<td>15.6</td>
<td>-2.5</td>
</tr>
<tr>
<td>L4-S1</td>
<td>28.8</td>
<td>17.4</td>
<td>12.7</td>
</tr>
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MOTION PRESERVATION-SPINE

<table>
<thead>
<tr>
<th>Posture Transition</th>
<th>Pre-Fusion L1-L4 compensation</th>
<th>Post-Fusion L1-L4 compensation</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standing to Sitting</td>
<td>2.0 (4.2)° flexion</td>
<td>13.4 (8.8)° flexion</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>Standing to Slumped</td>
<td>20.1 (11.6)° flexion</td>
<td>36.3 (17.0)° flexion</td>
<td>P&lt;0.01</td>
</tr>
</tbody>
</table>
Restoring angular alignment and SVA of L1 vertebra to its values in pre-fusion sitting requires increased compensation from the junctional segment.
Conclusions

- The increased compensatory demand on junctional segment may:
  - Explain patients’ sitting intolerance and pain after lumbar fusion.
  - Increase risk of junctional breakdown over time.
MOTION PRESERVATION-SPINE

- LUMBAR SPINE-TDA
  - ONE LEVEL-2 DISCS
    - ACTIV-L
    - PRO-DISC-L
MOTION PRESERVATION-SPINE
KINEMATICS

- More Difficult-2/3 of body weight crossing disc space.
- Limited materials to manage load. Both constructed using CoCr/Polyethylene-Vit.E enriched, moderate cross-linked
- Guyer et.al. SPINE 1995 found increased intra-discal pressure and hypermobility adjacent to fusion but normal values and no hypermobility adjacent to TDA
LUMBAR TDA

- Only treats discogenic pain
- 5% of patients that need a lumbar surgery
- Over time will develop facet arthropathy
- Can not address nerve compression
Clinical Outcomes of Total Disc Replacement Versus Anterior Lumbar Interbody Fusion for Surgical Treatment of Lumbar Degenerative Disc Disease

Tobias A. Mattei, MD¹, Jennifer Beer, BS², Alisson R. Teles, MD³, Azeem A. Rehman, BS², Jean Aldag, PhD², and Dzung Dinh, MD²
ACTIV-L VS ALIF 1 YEAR

- TDR
  - ALIF
- VAS 2.3
  - ALIF 4.5
- ODI 19
  - ALIF 46
- RTW 90 DAYS
  - ALIF 156 DAYS
- Employed 81%
  - ALIF 28%
MOTION PRESERVATION-SPINE
MOTION PRESERVATION-SPINE
MOTION PRESERVATION-SPINE

THANK YOU