

# Comparison of 7-Year Results of One-Level versus Two-Level Cervical Disc Arthroplasty and Fusion

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## Introduction

- Clinical trials have directly compared single-level ACDF to single-level CDA, and multi-level ACDF to multi-level CDA
- The original 1-level IDE trial for a titanium ceramic composite cervical artificial disc reported similar improvement for CDA and ACDF patients at 2 and 7 years, but a greater proportion of CDA patients reached overall success than ACDF patients at both time points (7 years: 74.9% CDA vs 63.2% ACDF)

## Introduction

- The original 2-level IDE trial for the same device also reported a higher proportion of CDA patients reaching overall success at 2 years (81.4% vs 69.4%) and 7 years (78.6 vs 62.7%)
- It is not well known whether increasing the number of treated levels similarly impacts the safety and effectiveness of CDA and ACDF

## Purpose & Method

- The purpose of this study is to compare the long term outcomes of:
  - 1-level CDA to 2-level CDA
  - 1-level ACDF to 2-level ACDF
- Retrospective analysis of prospectively collected 7-year outcomes data from two combined FDA IDE clinical trials for the same cervical artificial disc, comparing CDA to ACDF for the treatment of cervical disc disease at:
  - 1 single level
  - 2 adjacent levels

## Outcomes Measures

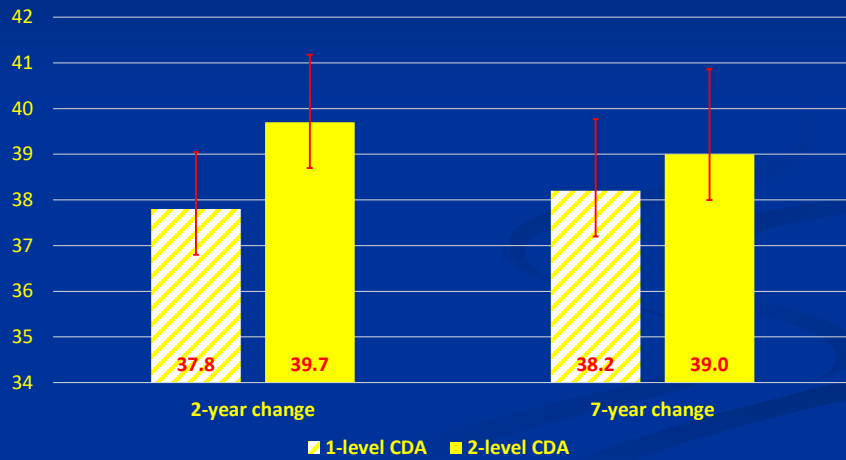
- 2-year and 7-year safety and effectiveness measures:
  - NDI
  - Neck Pain and Arm Pain (0-20 scale)
  - SF-36 PCS
  - Neurological Status
  - Adverse Events
  - Secondary Surgeries at Index Levels
  - Secondary Surgeries at Adjacent Levels

## Sample

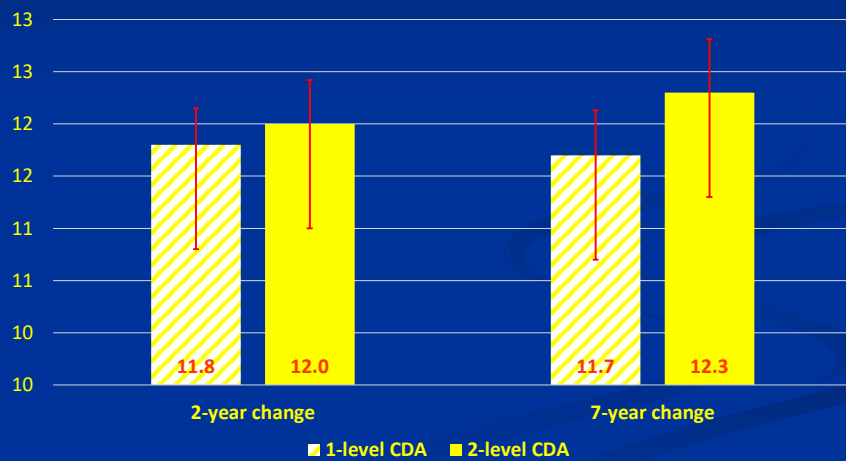
Number of Patients	1-level CDA	2-level CDA	1-level ACDF	2-level ACDF
Preoperative	280	209	265	188
2-year postoperative	270 (96.4%)	199 (95.2%)	220 (83.3%)	159 (84.6%)
7-year postoperative	208 (74.3%)	154 (73.7%)	182 (68.9%)	123 (65.4%)

- Propensity score was used to adjust for the effect of demographic characteristics and preoperative scores

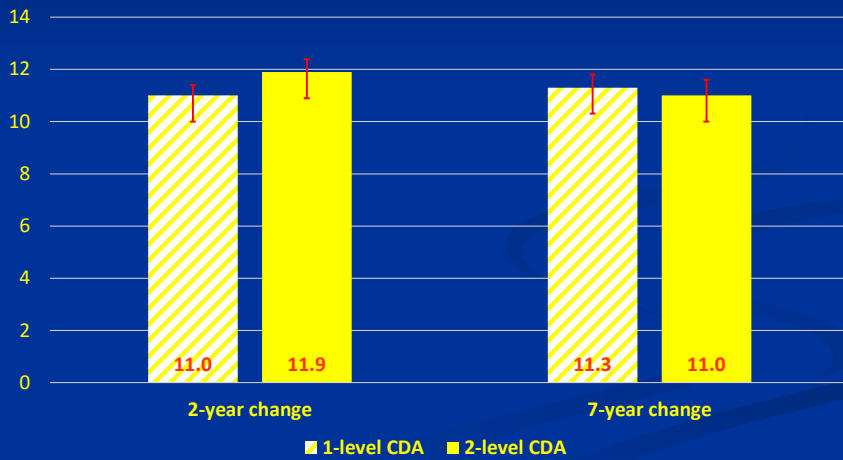
## NDI Improvement (CDA)



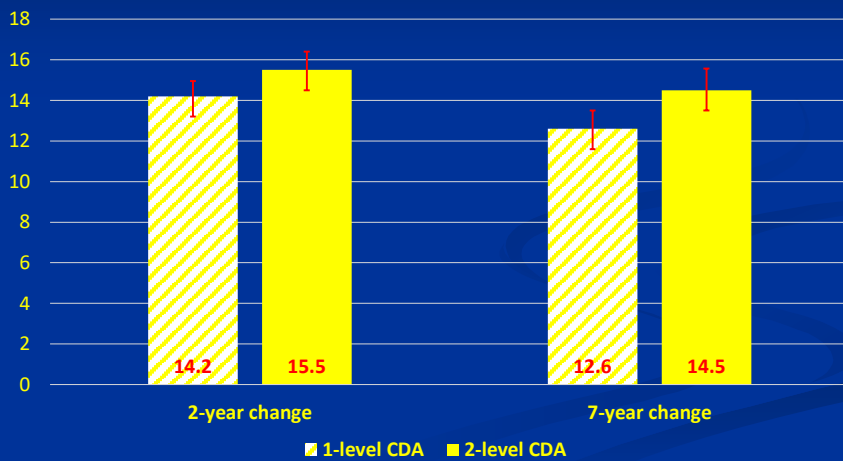
## Neck Pain Improvement (CDA)



## Arm Pain Improvement (CDA)



## PCS Improvement (CDA)



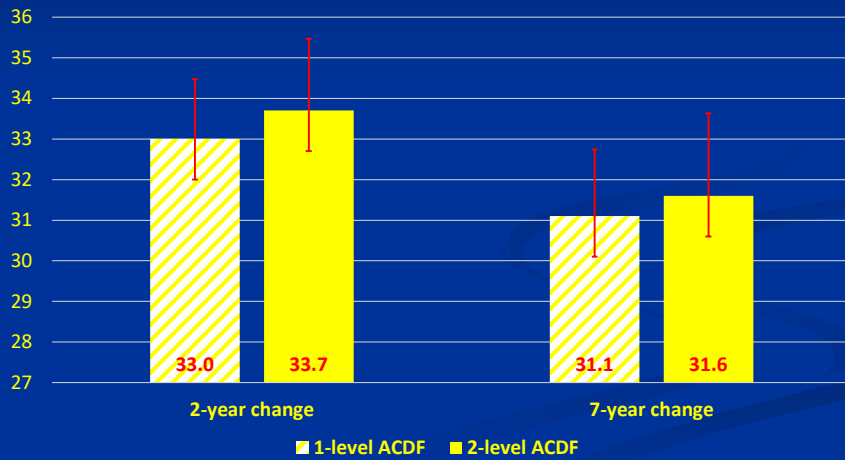
## AEs & Secondary Surgeries (CDA)

	1-level CDA	2-level CDA	P-value
<b>Implant-Related AEs</b>			
2-year postoperative	12.3%	16.1%	0.054
7 year postoperative	21.4%	26.6%	0.067
<b>Serious AEs</b>			
2-year postoperative	45.7%	35.1%	0.011
7 year postoperative	67.8%	56.7%	0.004
<b>Serious Implant-Related AEs</b>			
2-year postoperative	4.7%	2.0%	0.289
7-year postoperative	6.5%	3.2%	0.127
<b>Secondary Surgeries at Index Levels</b>			
2-year postoperative	5.1%	2.5%	0.509
7-year postoperative	7.3%	4.2%	0.566
<b>Secondary Surgeries at Adjacent Levels</b>			
2-year postoperative	2.2%	2.5%	0.916
7-year postoperative	11.6%	6.5%	0.056

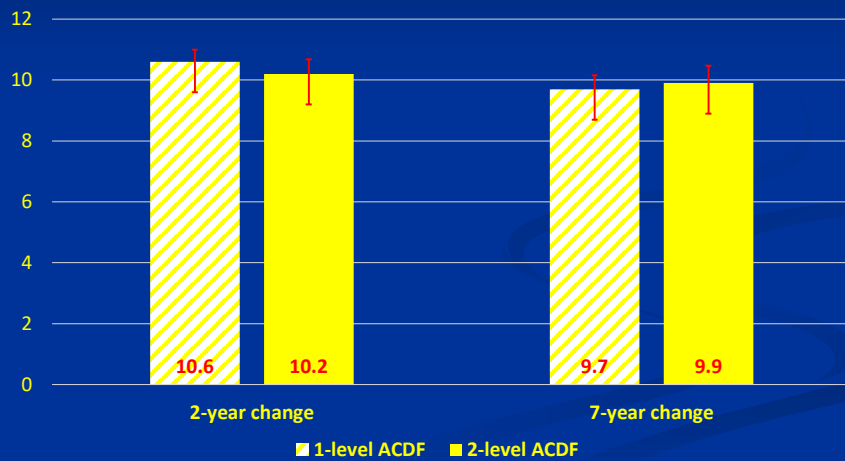
## Overall Success (CDA)

	1-level CDA	2-level CDA	P-value
<b>2-year postoperative</b>			
Overall Success	79.3%	81.4%	0.208
NDI Success	87.8%	87.9%	0.218
Neurological Success	93.3%	91.5%	0.499
2 <sup>nd</sup> Surgery Failure	12	4	
Serious Implant AE	11	2	
<b>7-year postoperative</b>			
Overall Success	74.9%	78.6%	0.332
NDI Success	86.1%	87.0%	0.561
Neurological Success	92.8%	91.6%	0.867
2 <sup>nd</sup> Surgery Failure	16	7	
Serious Implant AE	16	5	

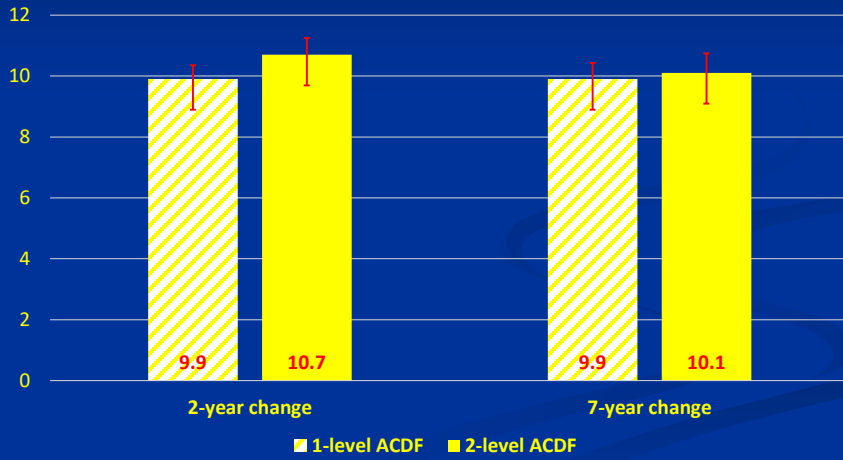
## NDI Improvement (ACDF)



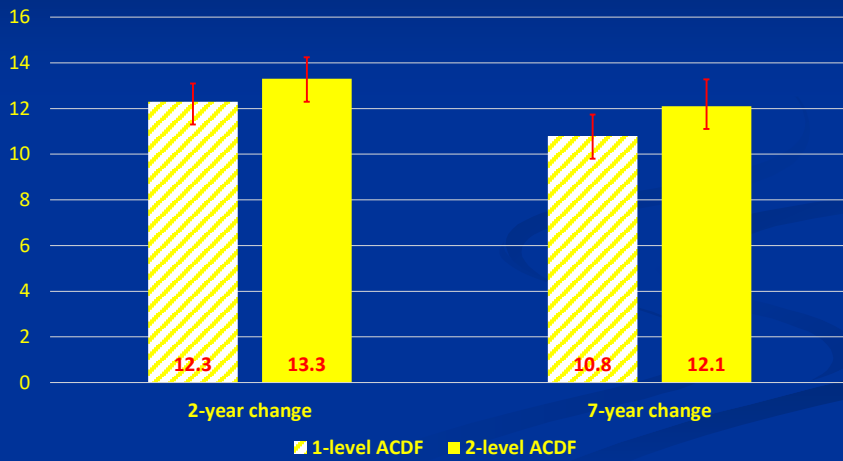
## Neck Pain Improvement (ACDF)



## Arm Pain Improvement (ACDF)



## PCS Improvement (ACDF)





## AEs & Secondary Surgeries (ACDF)

	1-level ACDF	2-level ACDF	P-value
<b>Implant-Related AEs</b>			
2-year postoperative	16.9%	21.1%	0.067
7 year postoperative	18.9%	27.7%	0.036
<b>Serious AEs</b>			
2-year postoperative	39.0%	50.0%	0.026
7 year postoperative	61.8%	68.2%	0.193
<b>Serious Implant-Related AES</b>			
2-year postoperative	5.6%	6.5%	0.263
year postoperative	5.6%	7.2%	0.159
<b>Secondary Surgeries at Index levels</b>			
2-year postoperative	7.9%	8.6%	0.455
7-year postoperative	13.6%	14.7%	0.631
<b>Secondary Surgeries at Adjacent levels</b>			
2-year postoperative	4.2%	3.4%	0.580
7-year postoperative	10.9%	12.5%	0.366

## Overall Success (ACDF)

	1-level ACDF	2-level ACDF	P-value
<b>2-year postoperative</b>			
Overall Success	66.8%	69.4%	0.404
NDI Success	80.8%	79.2%	0.983
Neurological Success	83.6%	86.2%	0.187
2 <sup>nd</sup> Surgery Failure	12	12	
Serious Implant AE	10	11	
<b>7-year postoperative</b>			
Overall Success	63.2%	62.7%	0.951
NDI Success	80.1%	75.6%	0.731
Neurological Success	79.7%	82.1%	0.421
2 <sup>nd</sup> Surgery Failure	15	16	
Serious Implant AE	14	13	

## Conclusions

- Increasing from 1 to 2 surgical levels did not affect the amount of improvement reported by patients for both CDA and ACDF
- Compared to 1-level, 2-level ACDF had a greater proportion of device-related AEs
- 2-level CDA had fewer serious AEs than 1-level CDA

## Disclosures

- Royalties
  - RTI
- Stock
  - Bonovo, Nocimed, OuroBorus
  - Paradigm Spine, Pioneer
- Consulting
  - Medtronic, Aesculap