

Cervical Disc Replacement in Patients with and without Previous Adjacent Level ACDF Surgery

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US IDE Study

- 492 patient – 24 site Study
- Inclusion / Exclusion criteria common to other studies (e.g. radiculopathy / myelopathy, failed conservative therapy, etc.)
- Previous single level fusion allowed
- Control:
 - ACDF with structural allograft
 - Synthes CSLP or DePuy Slimloc
- Investigational Group
 - PCM and PCM-V implants (Cervitech, Inc.)



1^o PCM vs PCM adj. to fusion

- Data from five sites included
- 26 patients had a PCM adjacent to previous single level ACDF at a single "adjacent" level
- 126 patients received the PCM as a "primary" procedure
- Mean time from previous fusion: 7.1 yrs (0.5 to 26.3 yrs)



1^o PCM vs PCM adj. to fusion : Demographics

- No significant differences

Descriptor	Primary	Adjacent to Prior Fusion	p-value
Age (years)	44.4 ± 9.2	46.4 ± 8.4	0.310
Height (inches)	67.7 ± 4.6	66.2 ± 3.7	0.127
Weight (pounds)	182.9 ± 40.9	171.0 ± 44.7	0.189
BMI	27.9 ± 4.2	27.3 ± 5.5	0.547
Gender (M/F)	70/56	10/16	

1^o PCM vs PCM adj. to fusion : Operative Results

- No Significant differences in *Time of Surgery* or *EBL*

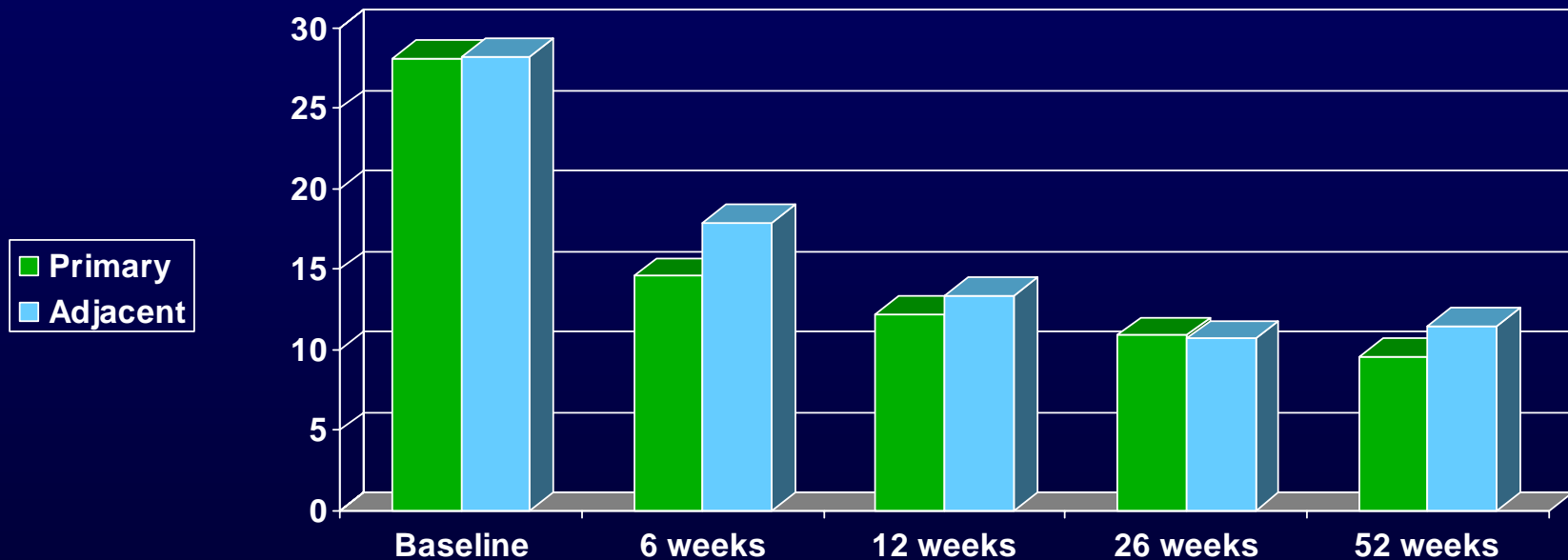
	Primary	Adjacent to Prior Fusion	p-value
Surgery Time (minutes)	95.5 ± 37.5	98.0 ± 32.6	0.761
Estimated Blood Loss (cc)	77.5 ± 59.3	68.8 ± 46.1	0.491

1^o PCM vs PCM adj. to fusion :

	Primary	Adjacent to Fusion
Level Treated		
C3-C4	1	
C4-C5	18	6
C5-C6	68	8
C6-C7	37	11
PCM Location		
Above Fusion		12
Below Fusion		13
PCM Type (Standard / V-teeth)		
	104/20	24/1

1^o PCM vs PCM adj. to fusion

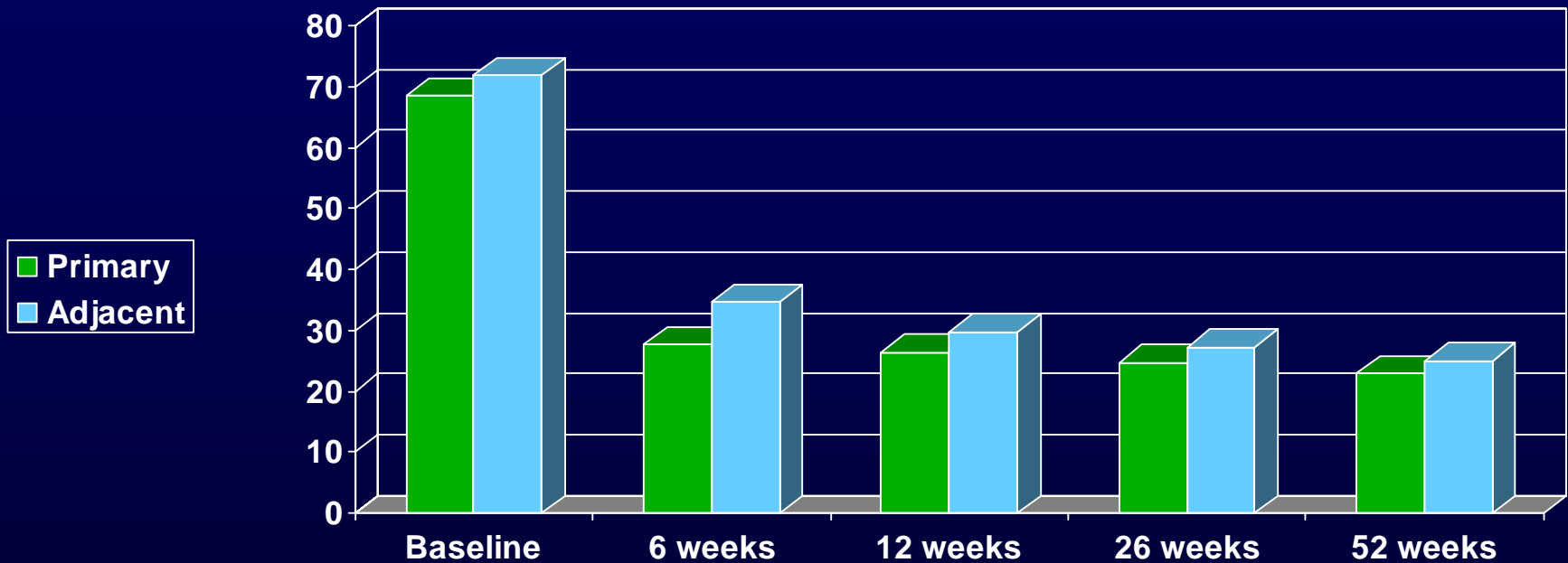
- Neck Disability Index (NDI)



Both groups decreased between baseline and 6 weeks. ($p=0.001$)
Other differences between and within groups not significant.

1^o PCM vs PCM adj. to fusion

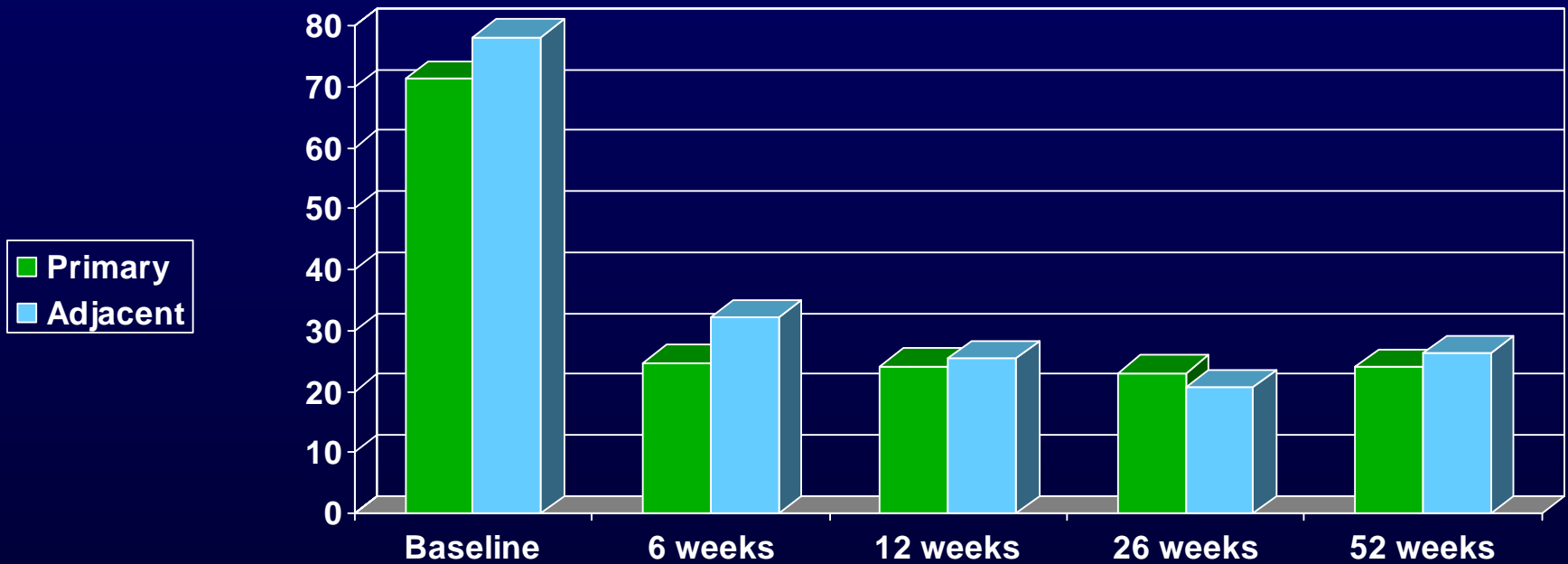
- Neck VAS



Both groups decreased between baseline and 6 weeks. ($p=0.001$)
Other differences between and within groups not significant.

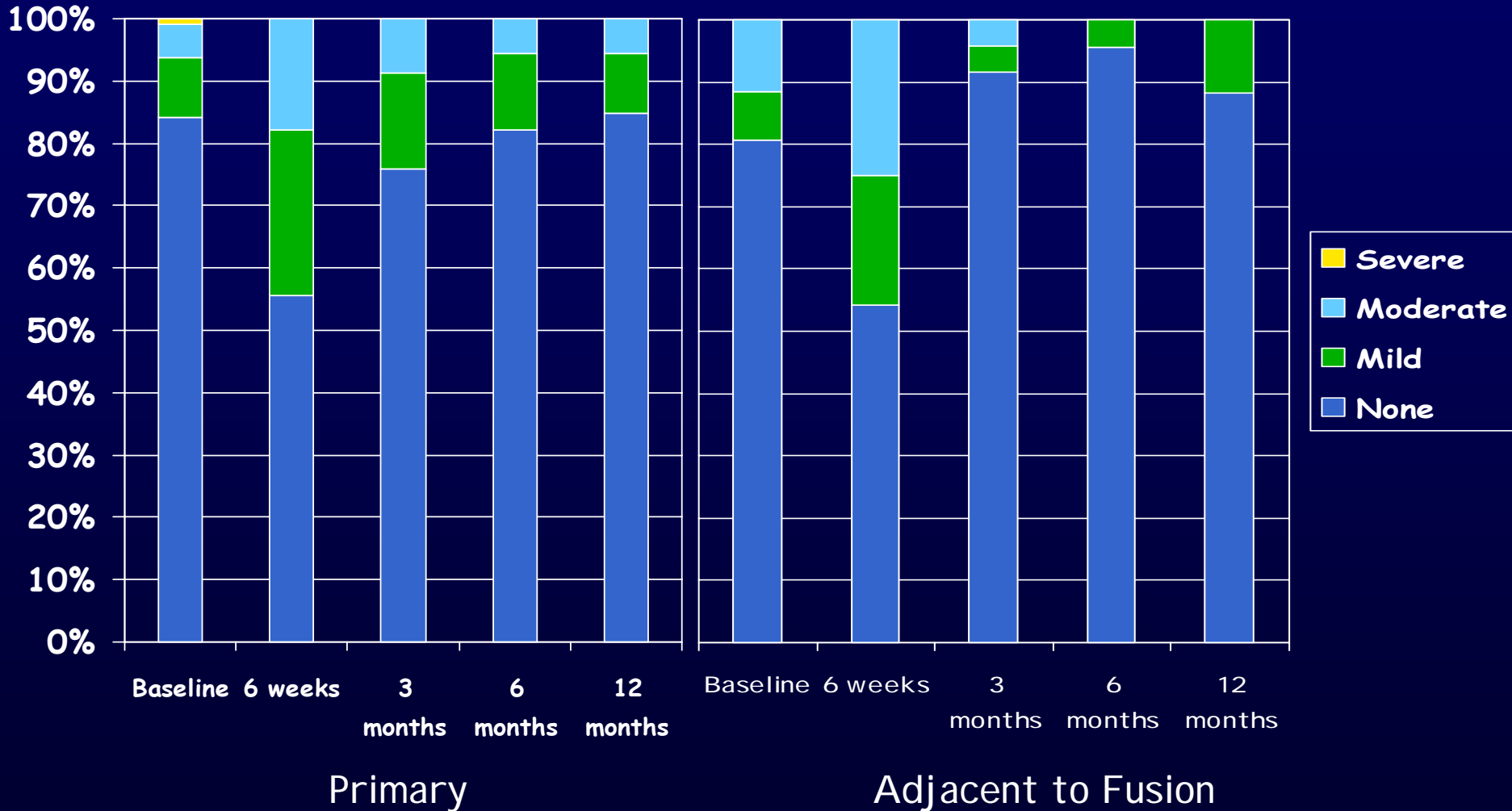
1^o PCM vs PCM adj. to fusion

- Arm VAS (most painful)



Both groups decreased between baseline and 6 weeks. ($p=0.001$)
Other differences between and within groups not significant.

1^o PCM vs PCM adj. to fusion: Dysphagia



Adverse Events: 1^o PCM vs PCM adj. to fusion

	Primary n = 126	Adjacent to Fusion n = 26
Revisions	2 (1.6%)	2 (7.7%)
Device Misalignment / Migration	0	1 (3.8%)
Adjacent Level Issues	2 (1.6%)	1 (3.8%)
Radiolucency	2 (1.6%)	0
Kyphosis	1 (0.8%)	0

CONCLUSION

- PCM cervical TDR resulted in good clinical results and acceptable complication profile when compared to ACDF for the treatment of cervical radiculopathy and/or myelopathy
- First disc to be studied in US IDE trial adjacent to prior ACDF
 - More challenging environment
 - Good clinical results with acceptable complications (though possibly higher than primary PCM)