

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

Frank M. Phillips, MD

Rush University Medical Center, Chicago, IL

John J. Regan, MD

Pacific Coast Spine Institute, Beverly Hills, CA

Andrew Cappuccino, MD

Buffalo Spine Surgery, Lockport, NY

John G. DeVine, MD

Madigan Army Medical Center, Ft. Lewis, WA

Jeanette Ahrens, PhD

Pivotal Research Solutions, Allen, TX

Paul C. McAfee, MD

Towson Orthopaedics, Towson, MD

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*

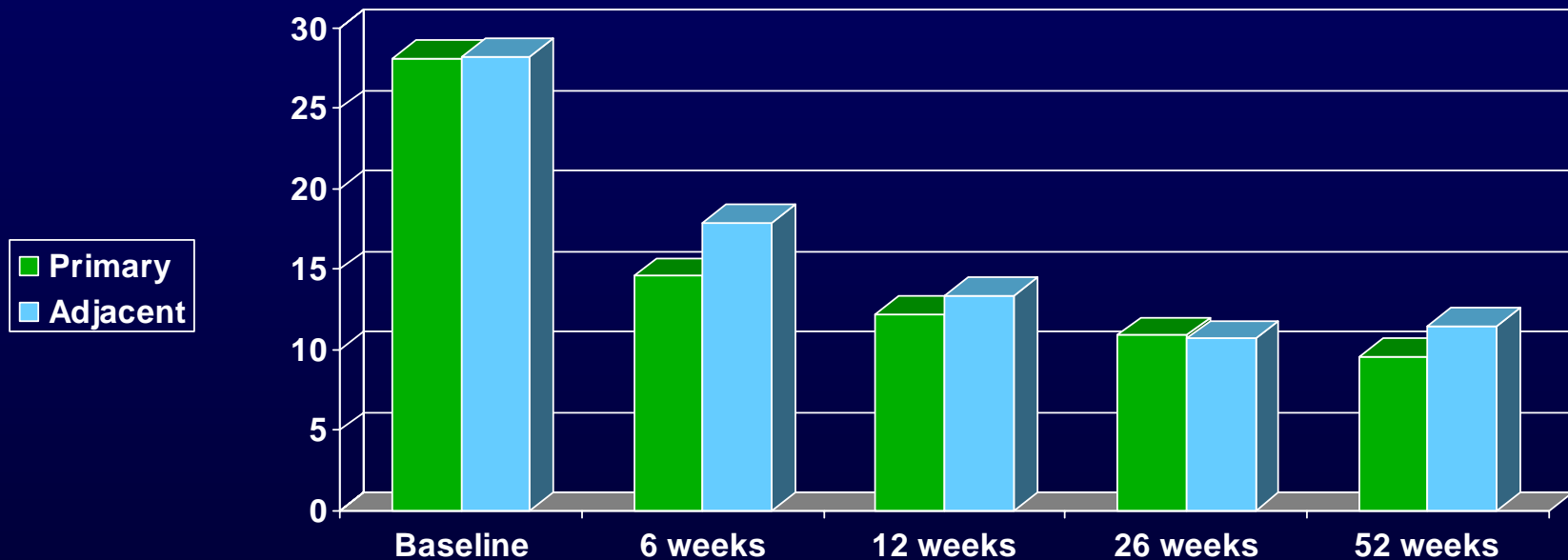
	Primary	Adjacent to Prior Fusion	p-value
Surgery Time (minutes)	95.5 ± 37.5	98.0 ± 32.6	0.761
Estimated Blood Loss (cc)	77.5 ± 59.3	68.8 ± 46.1	0.491

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

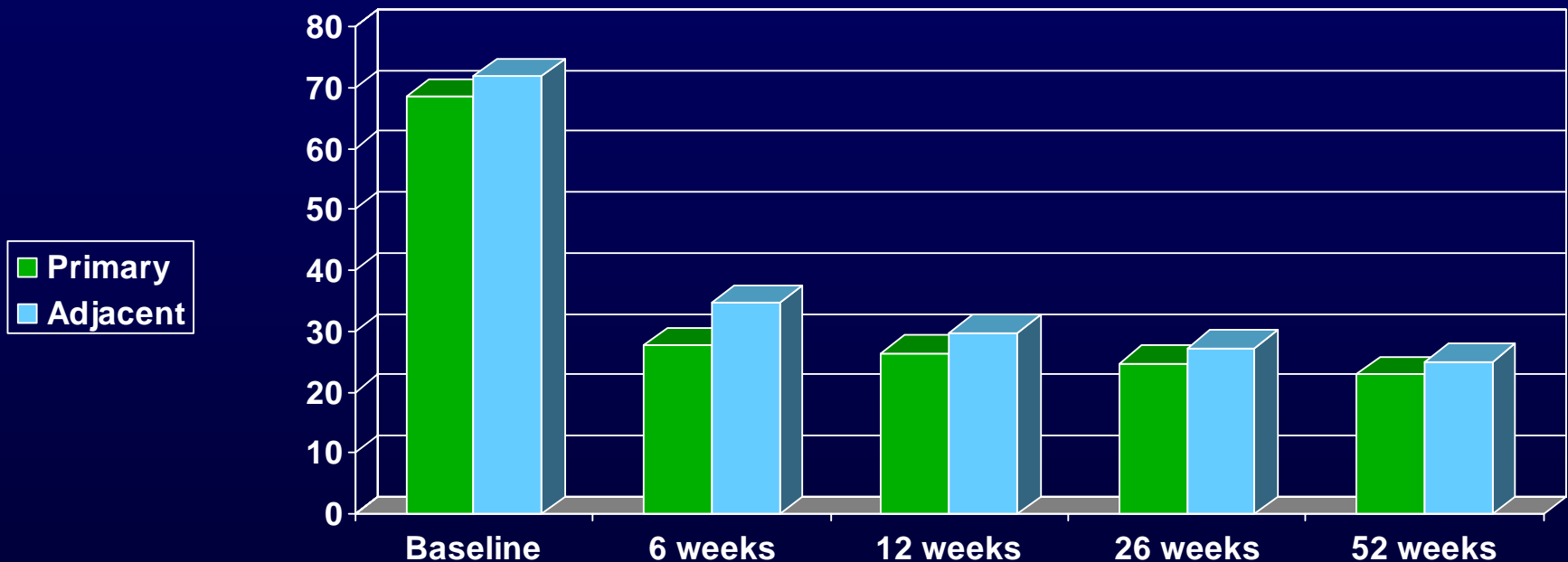
- Neck Disability Index (NDI)



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

1° PCM vs PCM adj. to fusion

- Neck VAS



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Other differences between and within groups not significant.

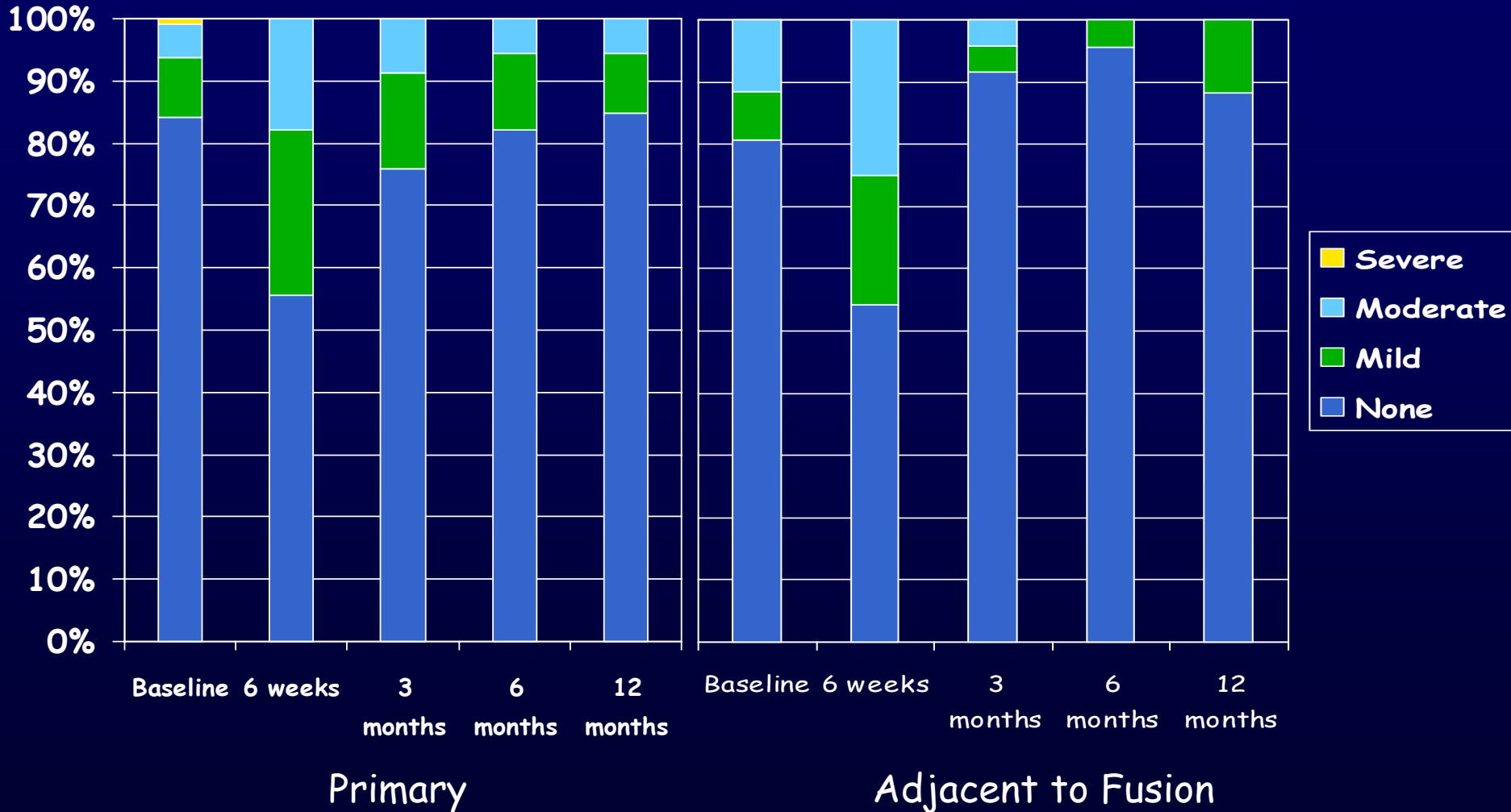
1^o PCM vs PCM adj. to fusion

- 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° 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)