Two-level Cervical Total Disc Arthroplasty Vs. Anterior Discectomy and Fusion: A Prospective, Randomized, Controlled Multicenter Clinical Trial with 5-year Results

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Introduction

Cervical disc arthroplasty (CDA) is intended to treat symptomatic cervical disc disease (SCDD) while preserving motion. Anterior discectomy and fusion (ACDF) has been the standard treatment, but at the expense of lost motion. Few studies have focused on the results of CDA at 2 levels with 5 year outcomes.

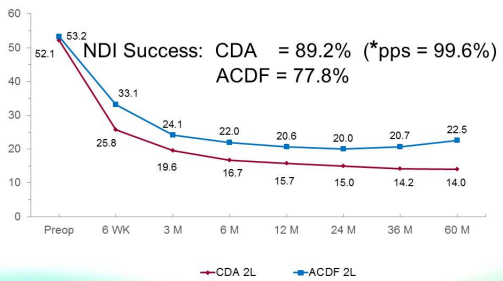
Methods

An FDA IDE trial of the PRESTIGE LP disc was conducted at 30 centers in the US. 397 patients with 2-level SCDD from C3-C7 were randomized and treated with CDA (n=209) or control ACDF (n=188). NDI, numerical pain scales for neck and arm pain, SF36, radiographic outcomes and patient satisfaction were used to analyze clinical effectiveness. Overall clinical success was defined as: Improvement in Neck Disability Index (NDI) $\geq$ 15 points; Maintenance or improvement of neurologic status; No implant or surgical related adverse events (AE); No additional surgical procedures at the index level.

Results

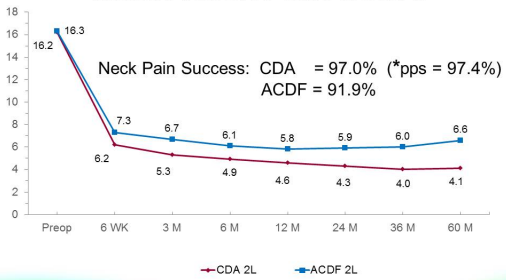
At 5 years CDA patients demonstrated statistical superiority over ACDF patients based on Overall Success, NDI Success, Neck Pain Success and SF-36 PCS Success.

Mean NDI Score



* Statistical Superiority

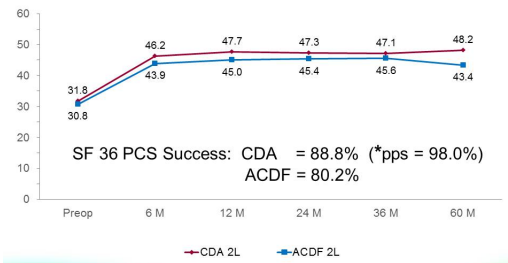
Mean Neck Pain Score



* Statistical Superiority

Mean Arm Pain Score

Mean SF-36 PCS Score



* Statistical Superiority

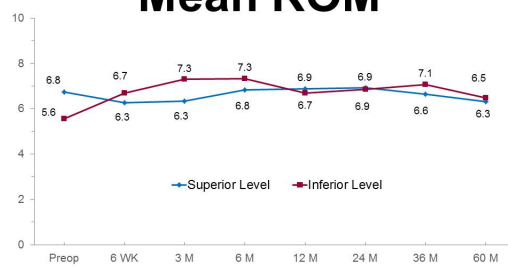
Clinical Success

Criteria	CDA (%)	ACDF (%)	Posterior Probability of Success (%)
NDI Improvement ≥ 15 points	*89.2	77.8	*99.6
Maintenance/Improvement of Neurologic Status	90.4	87.5	
No Implant/Surgical Adverse Events	76.8	75.3	
No Additional Surgery at Index Level	95.8	88.5	
[$] Overall Success	*79.5	65.9	*99.6

[$] Must have success in all 4 criteria

* Statistical Superiority

Mean ROM

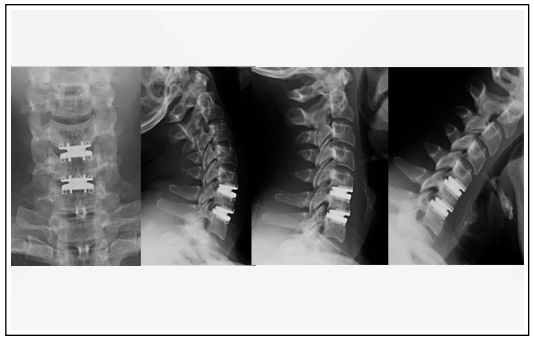


Subsequent Surgeries and H.O.

Result	CDA (%)	ACDF (%)
Subsequent Index Level Surgery	4.2	11.5
Subsequent Adjacent Level Surgery	5.9	9.1
Grade 4 Heterotopic Ossification	8.4	NA

Conclusions

The results of this long term study represent Level I clinical evidence in support of cervical disc arthroplasty at two contiguous levels for the treatment of symptomatic cervical disc disease in appropriately selected patients. Motion preservation with cervical disc arthroplasty is a viable alternative to ACDF.



References

Burkus JK, Traynelis VC, Haid RW Jr, Mummaneni PV. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: Clinical article. J Neurosurg Spine. 2014 Oct;21(4):516-28.