Long-Term Safety and Efficacy Outcomes of an Artificial Cervical Disc Replacement at Two Levels: Results from a Level 1 Prospective Randomized Controlled Clinical Trial

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Introduction

Up to 40% of patients treated for cervical degenerative disc disease have two-level treatment, warranting study of use of disc replacement devices at more than one cervical level. The objective of this study was to determine long-term clinical safety and effectiveness outcomes in patients undergoing anterior cervical surgery using an artificial disc replacement (ADR) prosthesis to treat degenerative disease at two adjacent levels. Outcomes at 7 years after surgery were compared to those from a standard treatment, anterior cervical discectomy and fusion (ACDF).

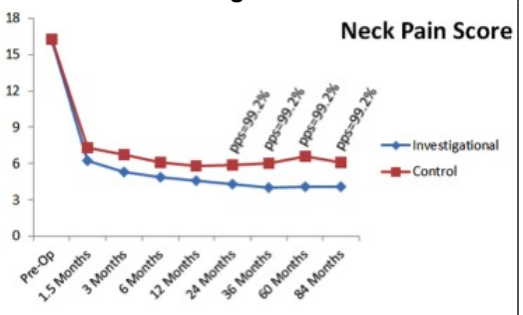
Methods

A prospective, randomized, controlled, multicenter FDA-approved clinical trial was conducted at 30 US centers comparing a low profile titanium ceramic composite based ADR, (Prestige LP, Medtronic, TN)(n=209) at two levels with an ACDF procedure (n=188). Patients were followed at regular intervals to 7 years. The primary endpoint was overall success, a composite variable that included key safety and efficacy considerations.

Learning Objectives

To demonstrate the efficacy and clinical benefits of 2 level total disc cervical arthroplasty.

Figure 1



Neck pain scores in two-level ADR group (blue) compared to control group (red). PPS = posterior probability of superiority

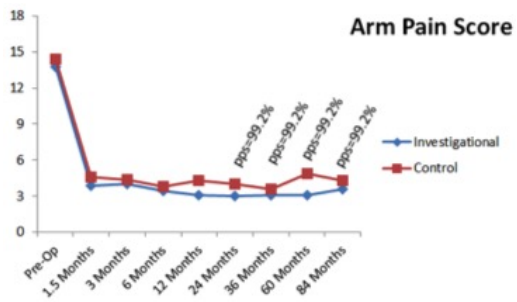
Results

At 7 years, the ADR demonstrated statistical superiority over fusion on overall success, observed rate (78.6 % vs 62.7%, respectively; posterior probability of superiority pps=99.8%), Neck Disability Index success (87% vs 75.6%; pps=99.2%), and neurological success (91.6% vs 82.1%; pps=99.0%). All other study effectiveness measures were non-inferior for ADR compared to ACDF. There was no significant difference in overall rate of implant/surgical procedure-related adverse events up to 7 years (26.6% and 27.7%, respectively), but the ADR group had fewer Grade 3-4 implant/surgical procedure-related adverse events (3.2% vs 7.2%, log hazard ratio (LHR) and 95% Bayesian Credible Interval (BCI): -1.19 (-2.29, -0.15)). The ADR group also had significantly fewer secondary surgical procedures at index level (4.2%) than the fusion group (14.7%) (LHR (95% BCI): -1.29 (-2.12, -0.46)). Angular range of motion at superior and inferior target levels was maintained in the ADR group to 7 years.

Figure 2

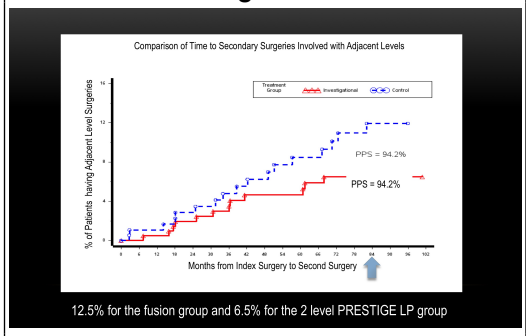
Overall success as defined by the FDA at each time point in the two-level ADR group (dark turqoise) compared to the control group (lite turqoise)

Figure 3



Arm pain scores over time in the two-level ADR group (blue) compared to the control group (red). PPS = posterior probability of superiority

Figure 4



The percentage of patients that underwent adjacent-level surgery was 6.5% in the two -level ADR group (red line) compared to 12.5% in the fusion control group (blue line) at 7 years follow-up

Conclusions

The low profile artificial cervical disc in this study, implanted at two adjacent levels, maintains improved clinical outcomes and segmental motion 7 years after surgery and is an alternative to fusion.