

**Abstract: 55**

**A Prospective Randomized Comparison of Cervical Disc Replacement and Anterior Cervical Fusion: Combined Results from Five FDA IDE Trials from a Single Site**

J.E. Ziegler<sup>1</sup>, S.L. Blumenthal<sup>1</sup>, R.D. Guyer<sup>1</sup>, M.S. Hisey<sup>1</sup>, A.M. Atanasov<sup>2</sup>, D.D. Ohnmeiss<sup>2</sup>

<sup>1</sup>Texas Back Institute, Plano, TX, USA, <sup>2</sup>Texas Back Institute Research Foundation, Plano, TX, USA

**Introduction:** Traditionally anterior cervical fusion (ACF) has been used to treat cervical radiculopathy and neck pain. In more recent years, total disc replacement (TDR) has been developed with the goals of pain relief and motion of the operated segment. The purpose of this study was to compare cervical TDR to ACF in a prospective randomized format.

**Methods:** Data were combined for patients participating in one of five FDA IDE trials at a single spine clinic and who were randomized to receive cervical TDR or ACF in each of the studies. All studies had very similar inclusion/exclusion criteria and all included use of the NDI as an outcome measure. All patients were treated for pathology between C4 and C7, with the majority of cases performed at C5-6. The group included a total of 100 patients (66 TDR and 34 ACF). Peri-operative data were compared for the two groups. Clinical outcome was based on the Neck Disability Index (NDI), which assessed functional disability. Follow-up data were collected pre-operatively and post-operatively at 6 weeks and 3, 6, 12, 24 months and annually thereafter. The mean follow-up was 26.7 months, ranging from 12 to 60 months.

**Results:** The mean blood loss, operative time, and length of hospital stay were similar in the two groups (Table 1). The mean NDI score improved significantly in both groups ( $p < 0.01$ ).with no significant difference between groups pre- or post-operatively.

	TDR	ACF
Operative time (min)	83.5	83.7
Blood loss (cc)	31.5	26.8
Length of hospital stay (days)	1.2	1.0
NDI:		
Pre-op	51.0	52.7
Post-op*	14.3	19.4

\*improved significantly in both groups ( $p < 0.01$ )

[Table 1. No significant difference between groups.]

Table 1. No significant difference between groups.

Re-operation was undertaken in one TDR patient (1.5%) which involved the implantation of a TDR at the adjacent segment for the treatment of a herniated disc. Re-operation was performed in three ACF patients (8.8%; trend for greater than TDR group  $0.05 < p < 0.08$ ). Two of these patients underwent posterior cervical fusion due to pseudoarthrosis of the ACF. In the third patient, disc herniation occurred at the two segments adjacent to the ACF and was treated with TDR at one level and ACF at the other. In only one patient was the study-assigned treatment aborted. This was an ACF patient whose anatomy did not allow adequate access to the disc space and re-operation was not attempted.

**Conclusions:** This study, based on patients enrolled in five different cervical TDR IDE trials at a single center, found no significant differences between ACF and cervical TDR in blood loss, operative time, or length of stay. Both groups showed significant improvement in NDI scores. One patient in each group underwent re-operation at the adjacent segment; however, two additional ACF patients underwent re-operation for symptomatic pseudoarthrosis. This study found that cervical TDR is similar to ACF with respect to operative factors and clinical outcome. A larger sample is needed to determine if the re-operation rate is significantly less with TDR due to avoiding pseudoarthrosis.