Cervical Total Disc Replacement vs. Anterior Cervical Fusion: Data from Four Prospective, Randomized, Multicenter Trials

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Introduction: Cervical total disc replacement (TDR) has emerged as an alternative to fusion in patients with radiculopathy or myelopathy with disc involvement. Food and Drug Administration (FDA) investigational device exemption (IDE) studies have been performed to compare arthroplasty devices to fusion. The purpose of this study was to perform a meta-analysis of the FDA IDE studies of four different cervical TDRs.

Methods: The inclusion and exclusion criteria were similar in the IDE studies for the Bryan Cervical Disc, Prestige, ProDisc-C, and Kineflex|C, and all used the same version of the Neck Disability Index (NDI) as an outcome instrument. Each study used a multi-component definition of overall success, although there were differences in the components used. However, all studies used a minimum of a 15 point improvement in NDI score as a success criterion, and three of the four studies included the criterion of maintained or improved neurological status. In addition to combining these factors across the four studies, the mean NDI score at each time period and across each study was evaluated.

Results: NDI scores through 24-month follow-up followed the same pattern of change in all 8 treatment groups (the TDR and ACF groups from each of the four studies; Figure 1).

Figure 1. NDI scores were consistent in the TDR and ACF control groups across multiple studies. With respect to success criteria, NDI success (greater than 15 point improvement) was achieved in 84.1% (417/496) of patients in the pooled arthroplasty group compared with 80.5% (364/452) of patients in the pooled fusion group. In three of the four studies, neurological success was defined as maintenance or improvement in neurological function. In the arthroplasty group, 93.0% (357/384) of patients were classified as having neurological success compared to 89.0% (306/344) of the fusion group.

Conclusions: This study found that the results of the four TDR vs. ACF trials produced very consistent results with respect to the mean NDI scores during 24-month follow-up. The percentage of patients achieving at least a 15 point improvement in the NDI score as well as the percentage of patients achieving neurological success were both approximately 4% greater in the TDR group.