Five Year Results of Two-level Cervical Total Disc Replacement Compared with Anterior Discectomy and Fusion: An Independent Review of a Prospective, Randomized, Controlled Multicenter Investigational Device Exemption Clinical Trial

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Introduction

The purpose of this study is to independently review and report the five year results of an Investigational Device Exemption study of TDR (Mobi-C) versus ACDF for the treatment of two level, contiguous, symptomatic cervical degenerative disc disease.

Methods

This study reports the 5 year results of a prospective, US FDA IDE pivotal trial of the Mobi- C cervical artificial disc for the treatment of contiguous two level cervical disease. The comparative control treatment was ACDF. A total of 330 patients were enrolled. The primary clinical outcome was an FDA-defined composite measure of study success at 60 months involving improvement in NDI =15 points, avoidance of reoperation, and absence of device related adverse events or neurological complications. Validated outcomes measures including NDI, VAS and SF-12 were utilized.

Results

A total of 225 patients received the Mobi-C TDR device and 105 patients received ACDF. The Mobi-C and ACDF follow-up rates were 90.7% and 88.6%, respectively. Both groups showed significant improvements in all outcome scores relative to baseline at each time point up to 60 months. There was a significantly increased percentage of successful TDR patients (61%) versus ACDF patients (31%) at 60 months. The TDR patients had significantly more improvement than ACDF patients in NDI score, SF12 PCS, and overall satisfaction with treatment at 60 months. Finally, the overall reoperation rate was significantly higher in the ACDF group at 16% compared with 4% in the TDR group.

Conclusions

Anterior cervical surgery for contiguous two level pathology was safe and effective in improving patient outcome and quality of life at five years in both groups. There were fewer incidences of index level and adjacent level reoperation in the disc replacement group. Overall, we conclude that TDR was superior to ACDF for treatment of two level contiguous pathology at five years.

Learning Objectives

Critically evaluate the clinical outcomes of cervical artificial disc and ACDF for the treatment of two level symptomatic cervical spondylosis.

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