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SUBSEQUENT SURGERY RATES AFTER TREATMENT WITH TDR OR ACDF AT ONE OR TWO LEVELS: RESULTS FROM AN IDE CLINICAL TRIAL WITH 5-YEARS FOLLOW-UP

Introduction / Aim

Subsequent surgical procedures subject patients to additional risks and continue to be a driving factor for study success rates and treatment cost-effectiveness. Previous results have shown total disc replacement (TDR) to produce lower rates of subsequent surgical intervention than Anterior Cervical Discectomy and Fusion (ACDF) within a 4-year follow-up window. The aim of our study was to evaluate 5-year subsequent surgery rates of one and two-level TDR and ACDF patients.

Materials and Methods

The study was conducted as part of a prospective, multicenter trial with 575 randomized patients in a 2:1 ratio (1-level TDR: 1-level ACDF: 2-level TDR: 2-level ACDF). For the 1-level arm, 179 patients were treated with TDR and 81 with ACDF. For the 2-level arm, 234 patients were treated with TDR and 105 with ACDF. Patients undergoing subsequent surgery were further classified as having a 1) index only, 2) index and adjacent, or 3) adjacent only level surgery. TDR patients were treated with an unconstrained prosthesis with a mobile core. ACDF patients were treated with allograft, anterior plate and screw instrumentation. Outcome measures were collected at baseline, 6 weeks, 3, 6, 12, 18, 24, 36, 46, and 60 months postoperatively.

Results

At 5 years, 4.47% patients had subsequent surgery for one-level TDR, 17.9% for one-level ACDF patients, 6.84% for the two-level TDR and 21.0% of ACDF patients. Differences between the total subsequent surgery rates of TDR and ACDF patients were significant for both one-level ($p=0.0008$) and two-level ($p=0.0002$) treatment. One-level and two-level TDR patients did have a lower rate of surgeries involving both adjacent and index level surgeries ($p=0.032$ and $p=0.0002$ respectively). Both one and two-level TDR patients experienced significantly less subsequent surgeries than ACDF patients with 4.5% vs 17.3% ($p=0.032$) and 7.3% vs 21% ($p=0.0002$) respectively. Moreover, when analyzing causation for secondary surgeries, both one and two-level ACDF patients had a significantly higher rate of adjacent level indications when compared to TDR, 11.1% vs 2.2% ($p=0.004$) and 11.4% vs 3.4% ($p=0.004$) respectively.

Discussion / Conclusion

Treatment with TDR demonstrates significantly lower subsequent cervical surgery rates compared to ACDF for both one and two levels at 5 year follow-up. Additionally, the rate of subsequent surgeries involving both an index and adjacent level was significantly lower in the one and two-level TDR group.

Keywords: TDR, ACDF, cervical arthroplasty