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Prospective, Randomized Study Comparing Cervical Total Disc Replacement to Anterior Cervical Fusion: Results from an FDA-regulated IDE Trial


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Introduction: Anterior cervical fusion has long been the standard of care for symptoms related to cervical disc degeneration. Cervical total disc replacement (TDR) has been developed in recent years as a possible alternative to fusion. The purpose of this study was to provide a prospective randomized comparison of cervical TDR to anterior cervical fusion for the treatment of painful disc degeneration.

Methods: A total of 269 patients from 21 centers participating in the FDA-regulated IDE trial were randomized in a 1:1 ratio to receive the KineflexC (Spinal Motion; n=135) or anterior cervical fusion performed using allograft bone and anterior plate (ACF; n=134). All patients were treated for single-level symptomatic disc degeneration between C3 and C7, with the majority at C5-6. Peri-operative data were compared for the two groups. Clinical outcome was based primarily on the Neck Disability Index (NDI) assessing function and visual analog scales (VAS) assessing pain. Radiographic assessment was used to determine changes in disc space height and flexion/extension range of motion. Currently, 153 patients have reached 24-month follow-up.

Results: The mean blood loss, operative time, and length of hospital stay were not significantly different in the two surgical groups, (blood loss: TDR 40.4 cc vs. fusion 41.4 cc; operative time: TDR 90.0 min vs. fusion 75.0 min) and hospital stays averaged approximately 2 days in both groups (calculated as discharge date minus date of surgery plus one day). The mean NDI scores improved significantly in both groups by 6 week follow-up and maintained the improvement throughout the 24-month follow-up (Figure 1). There were no significant differences between groups at any visit. The VAS pain scores followed a similar pattern, improving significantly in both groups with no significant differences between groups (improved from approximately 76 in both groups pre-operatively to 23 at 24-month follow-up).

Conclusions: The data from this prospective randomized study found that the peri-operative measures are similar between TDR and ACF. Both groups improved significantly based on VAS and NDI scores by 6 week follow-up and maintained the improvement throughout the 24-month follow-up. This study supports that cervical TDR produces clinical outcomes similar to fusion.