Introduction: Clinical results of anterior cervical fusion (ACF) are generally good, but there is support for potential accelerated degenerative changes at the adjacent level(s). One potential benefit of cervical total disc replacement (TDR) is motion of the operated segment which may protect adjacent levels from accelerated deterioration. The purpose of this prospective, randomized study was to evaluate a new cervical TDR implant by analyzing radiographic findings of range of motion and deterioration of the adjacent segment and compare those data to ACF.

Methods: The study was a prospective, randomized trial conducted at 21 centers across the United States participating in an FDA-regulated trial. A total of 269 patients, all treated for single-level cervical disc problems, were enrolled and randomly assigned to either cervical TDR using the Kineflex|C (Spinal Motion) (n=136) or to ACF (n=133). Anteroposterior, neutral lateral, and flexion/extension radiographs were made at each study visit. After patients were enrolled in the study they were assigned to undergo cervical TDR or ACF using autograft and an anterior plate. Patients were evaluated radiographically pre-operatively and at 3, 6, 12, and 24 months after surgery. All radiographs were evaluated by a center specializing in spinal radiographic assessment. Range of motion (ROM) was determined by measuring the rotation from flexion/extension images. The extent of adjacent segment degeneration was classified by an independent radiologist as: none, mild, moderate, or severe.

Results: Segmental ROM in the TDR group significantly decreased at 3 months, but was significantly greater than the pre-operative mean at 12- and 24-month follow-up (Figure 1). The ROM in the ACF group was significantly reduced by 3 months and remained so throughout the follow-up.

Pre-operatively, there was no significant difference in the proportions of patients in the disc degeneration categories, when comparing TDR to ACF (Figure 2). However, at 24-month follow-up there was a significant difference (p< 0.01), indicating that more patients in the ACF group had greater grades of adjacent segment disc degeneration than the TDR group.
**Discussion:** This prospective, randomized study found that cervical TDR significantly improved the range of motion of the operated segment. Evaluation of the extent of degeneration of the segment adjacent to the TDR level found that pre-operatively there was no difference in the TDR and ACF groups. At 24-month follow-up, the TDR group had significantly more patients in the less severe degenerative categories, suggesting that adjacent segment degeneration was less common in this group. These findings support that mobility allowed by TDR may facilitate prevention of adjacent segment degeneration which may occur with fusion.