

Abstract: 356

Prospective Study of Cervical Arthroplasty: 98 Patients from Three Separate IDE Studies from a Single Investigational Site with Minimum Two Year Follow-up

D. Coric¹, J. Cassis¹, J.D. Carew², M.O. Boltes¹

¹Carolina Neurosurgery and Spine Associates, Charlotte, NC, USA, ²Carolinas Healthcare System, R Stuart Dickson Institute for Health Studies, Charlotte, NC, USA

Object: Cervical total disc replacement (cTDR) was developed to address some of the short-comings associated with anterior cervical discectomy and fusion (ACDF) by preserving motion at the treated level. In order to establish an evidence-based rationale for CTDR to serve as a viable alternative to ACDF, cervical arthroplasty must establish equivalent or superior clinical outcomes while maintaining motion. The authors report on 98 patients from a single investigational site involved in three separate prospective randomized controlled IDE multicenter trials comparing cervical arthroplasty to ACDF with 2 to 6 year follow-up.

Methods: Patients with 1- and 2-level cervical disc disease producing radiculopathy and/or myelopathy were randomized prospectively under three separate IDE pivotal trials to undergo ACDF with plate or artificial disc placement. The three arthroplasty systems evaluated were:

- (a) Bryan Artificial Disc;
- (b) Kineflex/C; and
- (c) Discover Artificial Disc.

The patients were evaluated with pre- and postoperative serial neurological exams, radiographs and clinical outcome indices at 1,3,6,12,24,36,48 and 60 months.

Results: Ninety-eight patients (cervical arthroplasty=57; ACDF=41) were treated at our single investigational site. Minimum 24 month follow-up (f/u) is available for 90 patients (92%) (combined arthroplasty group=53 and combined ACDF group=37) with f/u duration ranging from 24-65 months (mean f/u= 38 months). Clinical success was defined as a composite measure consisting of 5 separate components:

- (1) maintenance or improvement in neurologic evaluations
- (2) minimum of 20% improvement in NDI scores
- (3) no serious adverse events related to the implant or surgical procedure
- (4) no reoperation at the index or adjacent level and
- (5) no narcotic usage at 24 month follow-up. Clinical success was significantly higher in the combined arthroplasty group (85%) compared to the combined ACDF group (70%) (p=0.035).

Clinical indices: Neck Disability Index (NDI) and Visual Analog Scale (VAS) patient self-report were evaluated at 3 to 24 month f/u. All groups showed excellent clinical outcomes. NDI: Bryan (pre=62, 48m=13 with 96% showing >20% improvement); Kineflex/C (pre=63, 24m=22 with 85% showing >20% improvement); Discover (pre=54, 24m=20 with 87% showing >20% improvement); ACDF (pre=62, 24m=23).

Radiographic success: Overall, angular motion was improved by 0.91° in the combined arthroplasty group and reduced by 7.8° in the combined ACDF group (t = 7.33, df = 73, p < 0.0001). Angular motion (degrees): Bryan (pre=7.6°, 24m=8.5°); Kineflex/C (pre=7.9°, 24m=13°); Discover (pre=8.2°, 24m=6.9°); ACDF (pre=8.1°, 24m=0.84°).

In the ACDF group there was a fusion rate of 97% (36 of 37). In the arthroplasty group there 6% incidence of bridging heterotopic ossification (n=4).

Reoperation: There were a total of 4 reoperations (8%) in the combined arthroplasty group with one (1.7%) at the adjacent level. There 3 reoperations in the ACDF group (8.1%), all at the adjacent level.

Conclusion: The prospective, intermediate-term (greater than 3 year average f/u) results of cTDR at our site are encouraging. Patients treated with the artificial discs showed significantly better clinical results, maintained motion at the treated level and trended toward less adjacent level disease.