Anterior cervical disc arthroplasty case series

2021

A study included 35 patients (14 men and 21 women; mean age: 42.5 years; mean follow-up: 57.8 months). There was a significant decrease in VAS neck and VAS arm scores, which went from 7.2 and 6.9 preoperatively to 2.2 and 1.7 postoperatively, 2.2 and 1.6 at 6 months, 2.0 and 1.8 at 1 year, and 2.1 and 1.3 at the last follow-up, respectively. The mean NDI score was 58.0 preoperatively, 19.4 postoperatively, 17.0 at 6 months, 16.1 at 1 year, and 16.2 at the last follow-up. Radiologic studies revealed a preserved range of motion in 33 of 35 patients. No ASD occurred and no reoperation was required.

Cervical disc arthroplasty with a keel-less prosthesis can be a safe and effective alternative to fusion for degenerative disk disease in selected patients, with a possible reduction of ASD $^{1)}$

2020

253 Patients were included in two randomized, double-blinded trials comparing anterior cervical disc arthroplasty (ACDA), with intervertebral cage (ACDF), or without intervertebral cage (ACD) for onelevel cervical disc herniation. Neutral lateral radiographs were obtained preoperatively, at 1- and 2year follow-up after surgery. Radiological ASD was evaluated on X-ray and defined by a decrease in disc height and the presence of anterior osteophyte formation on both the superior and the inferior level in relation to the target level.

Radiological ASD was present in 34% of patients at baseline and increased to 59% at two-year followup in the arthrodesis groups (ACD and ACDF combined), and to 56% in the arthroplasty group. Progression of radiological ASD was present in 29% of patients in the arthrodesis group and in 31% of patients in the arthroplasty group for 2-year follow-up.

Radiological ASD occurs in a similar manner in patients that were subjected to arthrodesis in cervical radiculopathy and in patients that received arthroplasty to maintain motion. Current data tend to indicate that the advantage of cervical prosthesis in preventing radiological ASD is absent²⁾.

Patients that underwent anterior cervical disc arthroplasty for cervical radiculopathy due to a herniated disc from the NECK and PROCON trial were analyzed for HO at 12 and 24 months postoperatively. Heterotopic Ossification (HO) was scored according to the McAfee-Mehren classification. The index ROM was defined by a custom developed image analysis tool, and global cervical ROM was measured by Cobb angle. Clinical outcome was evaluated by means of the Neck Disability Index and SF-36.

The occurrence of HO was 60% at 1 year, and it increased to 76% at 2-year follow-up. 31% of patients was scored as high grade HO at one-year follow-up, and this percentage increased to 50% at two-year follow-up. Clinical outcome does not correlate to HO grade, and no risk factor for high grade HO could

be identified. The ROM at the index level was significantly higher in low grade HO group than those patients with high grade HO, but in 15-38% HO grade does not correspond to ROM.

Heterotopic ossification occurs in three-fourths of the patients after anterior cervical disc arthroplasty at two years after surgery, but does not necessarily correspond to clinical outcome, nor loss or preservation of ROM. The McAfee-Mehren classification should be combined with ROM evaluation to properly study HO³.

MacDowall et al., from Sweden performed a randomized controlled trial with 153 patients (mean age 47 years) undergoing surgery for cervical radiculopathy. Eighty-three patients received an Artificial disc replacement (ADR) and 70 patients underwent fusion surgery. Outcomes after 5 years were assessed using patient-reported outcome measures using the Neck Disability Index (NDI) score as the primary outcome; motion preservation and heterotopic ossification by radiography; adjacent segment pathology (ASP) by MRI; and secondary surgical procedures.

Scores on the NDI were approximately halved in both groups: the mean score after 5 years was 36 (95% confidence interval [CI] 31-41) in the ADR group and 32 (95% CI 27-38) in the fusion group (p = 0.48). There were no other significant differences between the groups in six other patient-related outcome measures. Fifty-four percent of the patients in the ADR group preserved motion at the operated cervical level and 25% of the ADRs were spontaneously fused. Seventeen ADR patients (21%) and 7 fusion patients (10%) underwent secondary surgery (p = 0.11), with 5 patients in each group due to clinical ASP.

In patients with cervical degenerative disc disease and radiculopathy decompression as well as Artificial disc replacement, surgery did not result in better clinical or radiological outcomes after 5 years compared with anterior cervical discectomy and fusion. Clinical trial registration no.: 44347115 (ISRCTN)⁴⁾.

2017

As part of an FDA IDE trial, a single center collected prospective outcomes data on 47 patients randomized in a 1:1 ratio to ACDF or arthroplasty.

Success of both surgical interventions remained high at the 10-year interval. Both arthrodesis and arthroplasty demonstrated statistically significant improvements in neck disability index, visual analog scale neck and arm pain scores at all intervals including 7- and 10-year periods. Arthroplasty demonstrated an advantage in comparison to arthrodesis as measured by final 10-year NDI score (8 vs. 16, P = 0.0485). Patients requiring reoperation were higher in number in the arthrodesis cohort (32%) in comparison with arthroplasty (9%) (P = 0.055).

At 7 and 10 years, cervical arthroplasty compares favorably with ACDF as defined by standard outcomes scores in a highly selected population with radiculopathy ⁵).

2016

A total of 200 subjects underwent single-level activC® (Aesculap AG) implantation between C-3 and C-7 for the treatment of symptomatic degenerative disc disease. Clinical and radiographic assessments were performed preoperatively, intraoperatively, at discharge, and again at 6 weeks, 6 months, 1 year, 2 years, and 4 years. Radiographic evaluations were done by an independent core laboratory using a specific software for quantitative motion analysis.

Neck Disability Index (NDI) and visual analog scale (VAS) score for neck and arm pain decreased significantly from baseline to the 4-year follow-up. The mean improvement for NDI was 20, for VAS severity and frequency of neck pain 26.4 and 28, and for VAS severity and frequency of arm pain 30.7 and 35.1, respectively. The neurological situation improved for the majority of patients (86.4%); 76.1% of cases were asymptomatic. Subsequent surgical interventions were reported in 7% of the cases, including device removals in 3%. In 2.5% a subsidence greater than 3 mm was recorded; 1 of these cases also had a migration greater than 3 mm. No device displacement, expulsion, disassembly, loose or fractured device, osteolysis, or facet joint degeneration at the index level was observed. Segmental lordotic alignment changed from -2.4° preoperatively to -6.2° at 4 years, and postoperative height was maintained during the follow-up. Advanced HO (Grade III and IV) was present in 27.1% of the cases; 82.4% showed segmental mobility. A progression of radiographic adjacent-segment degeneration occurred in 28.2%, but only 4.5% required surgical treatment.

The activ C is a safe and effective device for cervical disc replacement confirming the encouraging results after cTDR. Clinical trial registration no.: NCT02492724 (clinicaltrials.gov) ⁶⁾

A total of 225 patients received the Mobi-C cervical total disc replacement device and 105 patients received ACDF. The Mobi-C and ACDF follow-up rates were 90.7% and 86.7%, respectively (p = 0.39), at 60 months. There was significant improvement in all outcome scores relative to baseline at all time points. The Mobi-C patients had significantly more improvement than ACDF patients in terms of Neck Disability Index score, SF-12 Physical Component Summary, and overall satisfaction with treatment at 60 months. The reoperation rate was significantly lower with Mobi-C (4%) versus ACDF (16%). There were no significant differences in the adverse event rate between groups.

Both cervical total disc replacement and ACDF significantly improved general and disease-specific measures compared with baseline. However, there was significantly greater improvement in general and disease-specific outcome measures and a lower rate of reoperation in the 2-level disc replacement patients versus ACDF control patients. Clinical trial registration no. NCT00389597 (clinicaltrials.gov)⁷⁾.

Twenty patients (12 females, 8 males; median age 45.6 ± 6.9 years) treated by ACDA (BryanDisc[®], Medtronic, Minneapolis, USA) underwent plain functional radiography and kinematic MRI of the cervical spine at 3T before and 6 and 24 months after surgery.

A sagittal T2-weighted (T2w) 2D turbo spin echo (TSE) sequence and a 3D T2w dataset with secondary axial reconstruction were acquired. Signal intensity of all nonoperated discs was measured in regions of interest (ROI). Disc heights adjacent to the operated segment were measured. Range of motion (ROM) was evaluated and compared to plain functional radiographs. Clinical outcome was evaluated using the visual analog scale (VAS) for head, neck and radicular pain, and the neck disability index (NDI).

Mean ROM of the cervical spine on functional plain radiographs was 21.25 ± 8.19 , 22.29 ± 4.82 and

 26.0 ± 6.9 degrees preoperatively and at 6-month and 24-month follow-up, respectively. Mean ROM at MRI was 27.1 ± 6.78 , 29.45 ± 9.51 and 31.95 ± 9.58 degrees, respectively. There was good correlation between both techniques. Follow-up examinations demonstrated no signs of progressive degenerative disc disease of adjacent levels. All patients had clinical improvement up to 24 months after surgery.

After ACDA, kinematic MRI allows evaluation of the ROM with excellent correlation to plain functional radiographs. Mid-term follow-up after ACDA is without evidence of progressive DDD of adjacent segments⁸⁾.

A prospective, multicenter, randomized, unblinded clinical trial. Patients with symptomatic degenerative disc disease were enrolled to receive 1- or 2-level treatment with either TDR as the investigational device or ACDF as the control treatment. There were 260 patients in the 1-level study (179 TDR and 81 ACDF patients) and 339 patients in the 2-level study (234 TDR and 105 ACDF patients). RESULTS At 5 years, the occurrence of subsequent surgical intervention was significantly higher among ACDF patients for 1-level (TDR, 4.5% [8/179]; ACDF, 17.3% [14/81]; p = 0.0012) and 2-level (TDR, 7.3% [17/234]; ACDF, 21.0% [22/105], p = 0.0007) treatment. The TDR group demonstrated significantly fewer index- and adjacent-level subsequent surgeries in both the 1- and 2-level cohorts.

Five-year results showed treatment with cervical TDR to result in a significantly lower rate of subsequent surgical intervention than treatment with ACDF for both 1 and 2 levels of treatment. Clinical trial registration no.: NCT00389597 (clinicaltrials.gov) 9 .

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