Editorial

Arthroplasty in cervical degenerative disc disease: fulfilling its long-term promise?

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There has been an increasing interest in anterior cervical discectomy with arthroplasty (ACDA) over the past decade. The presumed benefit of ACDA over the more common anterior cervical discectomy with fusion (ACDF) approach is reducing rates of adjacent segment disease, by maintaining mobility in the operated motion segment. Several authors have questioned the role of arthroplasty in actually preventing adjacent segment disease (1,2). In a recent meta-analysis, the authors found a 5.1% incidence of adjacent segment disease 12–24 months after ACDA (3). This is roughly consistent with the yearly incidence of adjacent segment disease after ACDF, which has been reported to be 2.9% (4). If there is indeed a lower yearly incidence of adjacent segment disease in ACDA compared to ACDF, this should become increasingly apparent over time.

Several randomized controlled trials (RCTs) have been performed in the past decade, with long term results finally becoming available. The first 10-year data has been published recently by Sasso *et al*. in Spine in their paper; long-term clinical outcomes of cervical disc arthroplasty: a prospective, randomized controlled trial (5). It addresses the 7- and 10-year clinical outcomes for one of the 30 participating centers in a randomized controlled trial, in which patients with single level cervical degenerative disc disease were treated in a 1:1 ratio with either ACDF or ACDA with the Bryan disc. Results on several outcomes are reported; Visual Analog Scale (VAS) scores for arm pain, VAS scores for neck pain, scores for the Neck Disability Index (NDI), and reoperation rate. To our knowledge, these are the first results at 10-year follow-up from an RCT on this subject.

The authors report a statistically significant benefit for the ACDA group when compared with the ADCF group, with VAS scores for arm pain (0.45 *vs*. 1.88, P=0.0322), VAS scores for neck pain (0.9 *vs*. 2.71, P=0.0146), and for NDI scores (8.6 *vs*. 21, P=0.0138) at 7 years follow-up, and for the NDI scores at 10 years follow-up (8.05 *vs*. 15.48, P=0.0485). The other results were no longer significantly different at 10 years follow-up. Additionally, the authors report on a non-significant difference in re-operation rate in favor of the ACDA group (9% *vs*. 32%, P=0.055).

A few comments can be made on the paper. Regarding the design of the study, it is noteworthy that the reported group of 47 patients is part of the original FDA IDE trial on the Bryan disc (6). As far as we know, this cohort was not intended to be a randomized trial, and is in this respect, is not to be seen as such. It is prospective data, and randomized, but not a trial. A sound statistical hypothesis with a power analysis is lacking. A second remark concerns the inclusion. Originally 62 patents were eligible, of which 15 were not randomized. Ten out of these 15 patients were denied by the study sponsor, the reason for this denial is not stated in the publication. After randomization there was a 10% cross over rate. Exclusion of such a large number of patients can be of influence to the results. It is also remarkable that the ACDF group is still improving after 7 years, in contrast to the ADCA group. The late improvement in the ADCF group may be the result of the larger reoperation rate. In this respect, it is unsatisfactory that it is not shown at what time these reoperations did occur after the index surgery and what their influence was

on the final outcomes.

The result reported above are consistent with other reports concerning mid to long-term clinical outcomes (6-10). Hisey *et al*. reported 4-year results on the Mobi-C FDA IDE trial, which included a total of 265 patients in 23 centers. They found no statistically significant different outcome for VAS scores for arm pain and neck pain, nor for NDI scores. They did report a significant difference in reoperation rate in favor of ACDA (3% *vs*. 9.9%, P<0.05) (8).

Philips *et al*. reported 5-year results for the PCM FDA IDE trial, which included a total of 416 patients in 24 centers, 293 of which reached complete follow up to 5 years. The authors report a statistically significant difference in favor of ACDA for NDI scores (20.4 *vs*. 28.5; P=0.001). They found no significant difference for VAS scores for arm pain, while VAS scores for neck pain were statistically significant in favor of ACDA (actual difference not reported, P=0.002). They found a difference in reoperation rate in favor of ACDA which was not significant (8.1% *vs*. 12%, P=0.237) (10).

Burkus *et al*. reported 5-year results on the Prestige disc FDA IDE trial which included 271 patients in 32 centers, 271 of which reached 5 years of follow up. They report a significant difference for the NDI in favor of ACDA (about 4%, P=0.022), while they found no significant difference for VAS scores for arm and neck pain. They report a significant difference in revision and supplemental fixation at the index level in favor of ACDA, but no significant difference for removal of the implant. Reoperation rate at the adjacent level was 2.9% for ACDA *vs*. 4.9% for ACDF (P=0.376) (7).

Janssen *et al*. reported 7-year follow up on the ProDisc-C FDA IDE trial, in which 209 patients were included in 13 centers, 152 of the these reached 7-year follow up at the time of publication (out of 165). They found no significant difference for NDI scores, or VAS scores for arm and neck pain. They did report a significant difference in secondary surgery in favor of ACDA (7% *vs*. 18%; P=0.0099) (9).

Sasso *et al*., the FDA IDE trial from which the single center 10-year follow up data is discussed above, reported 4-year data on 181 ACDA *vs*. 138 ACDF patients. They found a significant difference in NDI scores in favor of ACDA (improvement of 39.0 *vs*. 31.2; P<0.001). They also report a significant difference for VAS scores for arm pain in favor of ACDA (improvement of 55.5 *vs*. 50.3; P=0.028), as well as for VAS scores for neck pain (improvement of 54.0 *vs*. 44.7; P=0.001). They found no significant difference in secondary surgery on the index level (3.7% *vs*. 4.5%, P=0.816), or the adjacent level (4.1% *vs*. 4.1%, P=1.0) (6).

In the recently reported study by Sasso *et al*. there is a significant difference in NDI scores between the two groups, amounting to 12.4 at 7 years, and 7.4 at 10 years. The clinical relevance of this effect size is harder to define. If Cohen's three levels of effect size are applied, these effect sizes would be classified as 'medium', and 'small', respectively (11). Sadly, to the best of our knowledge, no minimal important difference [MID, defined as the smallest difference in effect size between treatments that patients perceive as beneficial and would mandate, in the absence of troublesome side-effects and excessive cost, a change in the patients management (12)], has been reported for patients with cervical degenerative disc disease. The differences in effect size for VAS scores at 7 years follow up (1.8 for neck pain and 1.33 for arm pain) are statistically significant, while the difference in effect size can be identified as 'medium' for both.

As stated by Sasso *et al*., arthroplasty is meant to preserve motion at the operated motion segment. Sadly, no information is given whether this goal is actually reached in the arthroplasty patients, and if this correlates with clinical outcome. Since cervical disc arthroplasty was introduced to preserve motion at the index level of surgery and subsequently prevent adjacent disc disease, the reoperation rate is an interesting outcome as well. The reoperation rate was lower in the ACDA group, compared to the ACDF group, with one operation at an adjacent segment in the ACDA group, versus 6 in the ACDF group. When looking at the other long term studies, the reoperation rate is significantly lower in the ACDA groups in several cases, in the others the difference is nonsignificant, albeit with a corresponding direction of effect. It seems that arthroplasty might fulfil its long term promise of reducing secondary surgery. This makes us curious about the long-term results of the other RCTs on this subject and the pooled data in review (13).

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None.

Footnote

Conflicts of Interest: The authors have conducted an investigator initiated, industry sponsored, RCT investigating cervical spine motion in cervical arthroplasty (clinicaltrials.gov identifier: NCT00868335).

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