Editorial

Challenging the state of the art

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The recent clinical article, "Replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial", offers a compelling and comprehensive clinical overview comparing cervical total disc replacement with isolated cervical fusion at 5 years follow up. Moreover, the study identified a patient population challenged by 2 contiguous levels of unresponsive degenerative change, and sustained clinical oversight and data collection over that time.

Authored by Kris Radcliff, Domagoj Coric and Todd Albert this clinical trial included 225 patients receiving a cervical TDR (Mobi-C) and 105 patients undergoing an ACDF with a corticocancellous allograft and an anterior cervical plate as a control group.

Although several RCT's have already reported equivalent or superior clinical outcomes of cTDR compared with ACDF (1-4,) a recent Cochrane review (5) claims that mid and long term follow up periods are needed to assess the long term clinical benefit of cTDR.

With their inclusion and exclusion criteria clearly defied, the authors identified a very clinical oriented way to offer the benefits of cervical TDR to their patients; putting neck disability and neck pain, patient satisfaction, and health related quality of life into the focus of their evaluation.

The authors were able to show significantly higher overall success rate for the cTDR meeting superiority and non inferiority criteria (61% *vs.* 31 %). Namely, the neck disability index (NDI) improvement at 5 years was greater in the cTDR group. However, success defined as patient satisfaction in the cTDR group and the ACDF as defined the health related quality of life using SF-12 and MCS scores, were similar in both groups.

The strengths of the study are the rigorous methodology with adequate statistical power, the low drop-out rate and the long follow-up compared to other trials of cervical arthroplasty. The affirming bias on the part of the cTDR patients to access new technology as well as afford an economic buffer to its development and commercialization offer a few concerns that could be addressed (6).

From a European physician's perspective, what made the decision to build this consort analysis so strong—so confident that a technology restricted to the cervical spine but extended to 2 levels would match comparable existing data. The inclusion boundaries of the patient population differ as to number of levels, and historical control *vs.* randomization, but in the extrapolation of the data, performance and patient satisfaction are the key outcomes critical to physician adoption that were attained. Differences were significant by statistical measure, but the control treatment without structural component clouds the comparison (7).

From the European perspective, treating more than 1-level-disease using TDR technologies is met with hesitation by most neurosurgeons. Why is the clinical decision making process and result so different?

This leads to the evaluation of the control group of this clinical article. In the TDR population the authors show a statistically significant lower rate of overall subsequent surgeries (7% cDTR group *vs.* 21% in the ACDF group, P=0.0006). Although the rate and the etiology of reoperation following surgical fusions remains controversial, the study underscores the outcome that fusion predisposes patients to reoperation. The authors surmise that the index level device was removed to access or fixate adjacent level pathology in many cases not performed to correct pathology at the index level. In any case a 21 % revision surgery rate at 5 years follow-up in ACDF is too high for symptomatic cervical degenerative disc disease.

Is it possible that the fixation over three segments is

compromising the adjacent levels through the stiffness of the 3-level-plating? Evidence has been clear for some time to support the expectation that a fused segment predisposes adjacent segments to additional strain and degenerative change.

A final question is leant to the discussion: Does the selection of the control population represent state of the art procedure, and had interbody structural intervention, or autograft been used, would the same inferiority to the cTDR approach be seen?

Yoon *et al*. reported in a recent survey of ACDF graft selection (8) that 64.1 % of surgeons worldwide perform ACDF without plating, and that among interbody spacer, structural use, up to 84 % of the cases utilize a PEEK cage; in most cases not adding either autologous bone or a bone void filler into the cage.

To best balance current clinical practice, future clinical investigations would have to focus on cTDR versus ACDF, with PEEK cages with and without additional bone void fillers. Further discussion also needs to address the high cost of cTDR compared ACDF with stand alone cages. This cost assessment represents one of the main reasons that fewer cTDR procedures are performed in Europe in bi- or multilevel diseases. A final future focus has to be aligned with the long term follow up of our spinal technologies as clinical outcome exposures that maintain long term reconstruction of spinal alignment.

Heterotopic ossification and fusion in CTR technologies must be analyzed in detail as it often exceeds an incidence approaching 25 %.

Summarizing, several points, the need for motion preservation has to be balanced against the high cost of TDR, as well as the assurance that safety paradigms afforded by modern, fast, and secure ACDF are not abandoned prematurely.

The Radcliff, Coric and Albert paper shows that this longed-for discussion has started.

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Footnote

Conflicts of Interest: The author has no conflicts of interest to declare.

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