Editorial on “Long-term clinical outcomes of cervical disc arthroplasty: a prospective, randomized, controlled trial” by Sasso et al.

Heeren S. Makanji, Kenneth Nwosu, Christopher M. Bono

Department of Orthopaedic Surgery, Brigham and Women’s Hospital, Boston, MA 02115, USA

Correspondence to: Heeren S. Makanji, MD. Department of Orthopaedic Surgery, Brigham and Women’s Hospital, 75 Francis St., Boston, MA 02115, USA. Email: hmakanji@partners.org or heeren.makanji@gmail.com.


Submitted Oct 06, 2016. Accepted for publication Oct 11, 2016.
doi: 10.21037/jss.2016.12.10
View this article at: http://dx.doi.org/10.21037/jss.2016.12.10

In the paper entitled “Long-term clinical outcomes of cervical disc arthroplasty: a prospective, randomized, controlled trial”, Sasso et al. present seven and ten-year single center data from patients enrolled in the initial FDA Investigational Device Exemption trial of the BRYAN® cervical arthroplasty device. The authors should be commended on the quality of their investigation, as prospective randomized trials with such long term follow-up are a rarity in spine surgery.

The authors present seven and ten-year follow up on 44 and 42 patients, respectively, who underwent anterior cervical discectomy and fusion (ACDF) or cervical disc arthroplasty (CDA) for single level cervical degenerative disease with radiculopathy or myelopathy. Seven years after surgery, the CDA group had lower neck disability index (NDI) scores and VAS neck and arm pain scores. Ten years after surgery, there remained a statistically significant difference in NDI scores favoring CDA, but no difference in VAS arm and neck pain scores. At 10 years, 9% of the CDA group and 32% of the ACDF group had reoperations, which trended towards statistical significance (P=0.55). One of two reoperations in the CDA group and 6 of 8 reoperations in the ACDF group was for adjacent level pathology.

The long-term results presented by Sasso et al. suggest an advantage for CDA for single level cervical spondylosis with associated radiculopathy or myelopathy, in agreement with several prior studies reporting shorter follow-up (1–6). Some intermediate follow-up has also echoed similar benefits for CDA, while other studies have suggested convergence of clinical results, with maintained advantage in terms of range of motion and reoperation for CDA (7-12). Indeed, larger registry studies, application of this technology outside of the U.S., and investigations of Worker’s Compensation patients have made these conclusions even more generalizable (13-15). Meta-analyses have shown mixed results. A Cochrane Database Review of 2,400 patients showed a statistically significant difference in arm pain, neck pain, neurological outcome and segmental mobility favoring CDA but no difference in reoperation rates (16). However, other studies have suggested lower rates of reoperation at the index and adjacent levels in CDA (17,18).

This newest study has the strength of a prospective, blinded, randomized design with nearly 90% percent follow up at 10 years and use of validated outcome measures. The statistically significant difference in NDI scores meets the threshold of minimal clinically important difference of 5 points. At final follow-up, there were no reoperations at the index level in the CDA group. However, there are aspects of the study that warrant careful scrutiny. Sample size is small, and the study and randomization process was industry-sponsored without explanation regarding up to 15 patients who were deemed ineligible by the sponsor. Comorbidities and social factors (such as socioeconomic status, mental illness, opioid dependence, smoking etc.) that have been shown to affect clinical outcomes following spine surgery were not compared to determine uniformity between the groups (19,20). Finally, the study reports...
overall reoperation rate for all causes rather than assessing reoperation rates as it relates to index surgery and adjacent segment disease specifically.

In the current healthcare climate, clinical outcomes of new interventions must be interpreted in the context of cost-effectiveness. Several studies have evaluated this metric in CDA. Multiple studies using advanced statistical modeling have suggested CDA is more cost effective than ACDF (21-23). However, in these models, conclusions only hold true if certain assumed survivorship of implants and rate of reoperation are accurate. Radcliff et al. used a database study to evaluate real costs of these interventions and found reduced index and total costs for CDA compared to ACDF (24).

Even with favorable clinical results and cost-effectiveness data, CDA also introduces previously unseen complications to cervical spine surgery. Studies have shown areas of significant osteolysis around CDA implants that may lead to implant malfunction and complicate future surgical interventions (25-27). Case reports have highlighted hypersensitivity to implant metals, implant fracture, and reactions to metal debris (28,29). As the earliest CDA implants now approach 10 years, what other complications may we see? The complications of ACDF are well-documented and catastrophic events are rare. These questions are not yet answered about CDA. Most CDA implants are metal on polyethylene, which can develop wear and may lead to similar immune reactions as seen in hip and knee arthroplasty. The few metal on metal implants form metal debris that can lead to lymphocyte activation and may lead to a pseudotumor-type reaction as seen in metal on metal hip arthroplasty (30,31). If these reactions can lead to problems in large volume areas such as the hip and knee, what can we expect in the small volume area of the cervical spine, near essential structures such as the spinal cord, trachea, and esophagus?

The more widespread adoption of CDA is inevitable as longer term data, such as that reported by Sasso et al., continue to support its clinical benefits. With the potential for new and unexpected complications comes the opportunity to learn from our colleagues in the joint replacement community and perhaps develop a central registry where details of optimal implants, techniques, and complications can be collected.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

References

8. Sasso RC, Anderson PA, Riew KD, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective,


