Editorial

The real value of cervical arthroplasty?

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In this issue of the Journal of Neurosurgery: Spine, Coric et al.\(^4\) report their experience with cervical arthroplasty derived from a prospective, randomized FDA investigational device exemption (IDE) multicenter trial comparing the safety and efficacy of a metal-on-metal cervical disc replacement device to single-level anterior cervical discectomy with fusion and internal fixation (ACDF) in 269 patients with symptomatic cervical spondylosis. The study appears to have been well done. The minimum follow-up of 2 years appears to have been meticulous. Appropriate outcome measures (the Neck Disability Index, visual analog scale, neurological status, radiological evaluation, and a composite clinical success scale) were used. The authors concluded that cervical arthroplasty with the Kineflex\(^\text{C}\) (SpinalMotion, Inc.) device is safe, with neural decompression and clinical results comparable to ACDF. Furthermore, they found greater overall clinical success with the arthroplasty device (85%) compared with ACDF (71%) (p < 0.05), better self-reports of patient satisfaction, and statistically significantly more severe adjacent-level deterioration in the ACDF group at the 24-month follow-up compared with the arthroplasty group, 24.8% and 9%, respectively (p < 0.0001).\(^3\)

I salute the authors for their work. I have long been an advocate of innovation in surgery and, at the same time, a practicing proponent of evidence-based medicine. I particularly favor the two together. Multiple prospective, randomized clinical trials providing Class I medical evidence on the safety and efficacy of cervical arthroplasty devices have now been published.\(^2,5,8,9,10\) These initial studies appear to be thoughtful, well-administered, and complete comparative trials assessing the short-term outcome of cervical arthroplasty compared with ACDF, but 2 key and integral scientific principles have yet to be sorted out: 1) long-term follow-up; and 2) absence of bias (by investigators and patients).

To date, only one of these commercially supported cervical arthroplasty clinical trials has offered meaningful follow-up beyond 2 years. Burkus et al.\(^2\) reported on 276 cervical arthroplasty patients and 265 control (ACDF with plate) patients. Sixty months of follow-up was offered for 144 arthroplasty patients (52% of the treated arthroplasty population) and 127 ACDF patients (48%). They concluded that cervical arthroplasty with the Prestige device maintained improved clinical outcomes and segmental motion after implantation at 5-year follow-up. They could have added (but did not) that other than segmental motion at the index/treatment level, ACDF-treated patients did just as well statistically (p > 0.05) in 4 of the 5 measured clinical parameters 5 years after surgery (mean neck pain, mean arm pain, mean SF-36 PCS [36-item Short-Form Health Survey Physical Component Summary] scores, and neurological success rates). Only the Neck Disability Index remained statistically significantly favorable in the arthroplasty group at 5 years postoperatively (p = 0.022).

Without sounding like a pessimist (I am not), my real concern with “follow-up” of arthroplasty devices is late follow-up. No mechanical device known to mankind has an infinite lifespan. All fail. We do not know the failure rate, time frame, or consequences of failure of cervical arthroplasty devices. The “fix” or the bailout strategy once this occurs has not been elucidated. I imagine it will be different for different devices, and for no device will the repair, replacement, or revision surgery be minimal or easy (for the surgeon or the patient). Late follow-up will illuminate more than device lifetime. What is the human body’s reaction to nickel, cobalt chrome, various ceramics, or polyurethane over time, particularly when they deteriorate or degrade? Not one industry executive, scientist, or investigational surgeon has definitive answers to these concerns yet. Before the cervical arthroplasty band wagon gets rolling, well before surgeons and the public jump on board, our professional integrity demands more data, many more patients, longer experiences, and unbiased study and cogent interpretation of late outcome evidence.

While it is natural that industry supports the initial study and evaluation of devices it may bring to the public sector, the best medical evidence is that derived from unbiased/unrelated researchers setting out to “disprove the hypothesis” rather than find favor with a device or treatment in which they are intellectually or financially interested. This work has yet to be forthcoming.

From my perspective, cervical arthroplasty as reported in several large clinical trials appears safe and efficacious in the short run.\(^2,5,8,9,10\) There are important rates of complications with arthroplasty (as with any operative implant), including dislodgment, vertical vertebral body frac-
Arthroplasty devices are meant to maintain motion (they typically do compared with fusion) and are touted as less likely to be associated with adjacent-level deterioration (an unproven and speculative theory, given that we do not have a consensus understanding of the cause or even the natural history of that phenomenon). We have a 55+ year experience with anterior cervical fusion. We have learned that 24-month follow-up is the minimal acceptable follow-up for these procedures. I would advise a longer period of scientific scrutiny for these new, potentially better, motion-saving mechanical devices.

Meaningful, “functionally significant” rather than “statistically significant” differences in outcome between the two techniques are hard to find in the literature. The early thoughtful work on this issue with these devices (present study included) needs to continue with a longer perspective and a bias-free focus on late failures and/or late ramifications without failure to define their real efficacy with respect to functional outcome.

I approve of the scientific quality of the majority of these early comparative efficacy studies. Quality work of this kind and unbiased assessment over time will truly define the “real” value of cervical arthroplasty in the treatment of symptomatic cervical spondylisis. I look forward to further innovation, continued study, and persistent scientific diligence on this important issue.

Disclosure

The author reports no conflict of interest.

References


Response

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We would like to thank Dr. Hadley for his insightful commentary. We certainly share Dr. Hadley’s endorsement of evidence-based medicine as well as his concerns regarding long-term follow-up and study bias. A commitment to evidence basis in medical decision making also requires a commitment to incremental information gathering. In the case of cervical arthroplasty, this is a process that proceeds from preclinical testing through pivotal IDE study, minimum 2-year follow-up, and postmarket approval (PMA). This process generally takes a minimum of 6–8 years. To date, over 10 cervical total disc replacement (CTDR) devices have completed the US FDA IDE process, randomizing in excess of 2000 patients in prospective study and amassing a body of Level I data unprecedented in the field of spine surgery. In this setting, it seems reasonable that if multiple devices prove to be safe and efficacious in the short-term (2–4-year) follow-up, that device would no longer be considered investigational. Subsequent intermediate (5–7-year) follow-up should be used to refine ideal indications. Ultimately, long-term follow-up (8–10 years and beyond) is necessary to definitively establish whether a device warrants classification as a gold-standard treatment. However, minimizing or ignoring positive early and intermediate results while awaiting long-term data is counterproductive to establishing an evidence basis for adaptation of new technologies.

Dr. Hadley’s comments concerning bias are well received. Although the multicenter, prospective, randomized