Editorial

Disc replacement or arthrodesis

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In this issue of the *Journal of Neurosurgery: Spine*, Zigler and Delamarter² provided 5-year follow-up data from a randomized clinical trial comparing lumbar total disc replacement ([TDR], ProDisc-L, Synthes Spine, Inc.) versus circumferential fusion (anterior lumbar interbody fusion using femoral ring allograft with subsequent posterolateral fusion using pedicle screws). The original cohort consisted of 161 patients who underwent lumbar TDR and 75 patients who underwent circumferential fusion. The authors reported an overall 81.8% clinical follow-up rate at 5 years. The fusion group had a 74.7% clinical follow-up rate, and the arthroplasty group had an 85.1% clinical follow-up rate. However, only 72.9% of the patients had complete radiographic follow-up. Clinical outcomes as measured by the Oswestry Disability Index, visual analog scale, 36-Item Short Form Health Survey, and neurological success were maintained in both the TDR and fusion groups at 5 years, and improvements in the investigated clinical outcomes were not statistically different between the groups.

The mean flexion and extension range of motion (ROM) in the TDR group remained roughly constant between the 2- and 5-year time points ($7.7^\circ \pm 4.7^\circ$ at 2 years and $7.2^\circ \pm 4.1^\circ$ at 5 years). In this report, 91.9% of the TDR patients had preserved a normal segmental ROM at 5 years. There were no spontaneous fusions in the TDR group. However, it is important to note that approximately one-quarter of the original cohort did not have complete radiographic follow-up.

Moreover, the rates of heterotopic ossification in the TDR group were not reported in this paper. Heterotopic ossification (HO) around the TDR has been described in other FDA clinical trials and has been shown to limit the ROM of an arthroplasty. Guyer et al.¹ reported that 18.9% of lumbar TDR cases utilizing the Charité disc (DePuy Spine, Inc.) showed lack of motion ($< 5^\circ$) and an HO grade > 3 at the 5-year follow-up. Heterotopic ossification is an

issue that spine surgeons will need to monitor in patients undergoing lumbar arthroplasty, and an analysis of the HO rate with the ProDisc-L is still needed.

Another important issue regarding the long-term results of lumbar arthroplasty is device-related failure, which can be assessed using both the radiographic results and index-level secondary surgeries. In this report, 3 of the TDR patients had device migration, all cases occurring within 3 months. There were 2 TDR patients who had device subsidence. For the fusion group, the fusion rate was 95.8% at 5 years, with no cases of migration or subsidence. There were 13 TDR patients (8%) and 9 fusion patients (12%) who underwent a second surgery at the index level during the 5-year follow-up. Of the 13 secondary index-level surgeries in the TDR group, there were 2 cases of polyethylene migration due to “extreme trauma,” 3 additional cases of device failure due to problems with the surgical technique, and 8 cases of unresolved pain requiring supplemental fixation or decompression.

The noninferiority of lumbar TDR as compared with a traditional open circumferential fusion procedure is established by this 5-year report. The advantage of motion preservation with lumbar TDR and its effects on adjacent-level degeneration are still unclear. For patients with lumbar degenerative disc disease, both fusion and arthroplasty appear to be viable choices.

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Disclosure

Dr. Mummaneni is a past consultant for DePuy and receives royalties from DePuy, Quality Medical Publishing, Inc., and Thieme Medical Publishers, Inc.

References

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Response

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We appreciate the comments made by Drs. Tu, Ziewacz, and Mummaneni, as well as the peer review process performed by the *Journal of Neurosurgery*.

Follow-up rates in long-term clinical spine studies within the US vary from 43.4% in the Guyer 2009 study¹ of Charité artificial disc replacement (ADR) outcomes to 68.3% in the Weinstein 2009 fusion/SPORT (Spine Patient Outcomes Research Trial).² We are proud of the 81.8% clinical follow-up the investigators were able to achieve in our study. Although complete radiographic data sets were available in only 72.9% of these patients, this rate is still comparatively high and was largely a function of technique issues related to legibility of film and implant obliquity, making measurement impractical, rather than a clinically biased loss of data. We are quite comfortable with our belief that the radiographs capable of measurement represented a fair sample of the patient populations.

Heterotopic ossification has been a ubiquitously reported problem in cervical arthroplasty studies. In lumbar arthroplasty it was described by Guyer et al.¹ as “longitudinal ossification” occurring in 15.5% of cases using a 3° motion cutoff value, and it was reported in 18.9% of patients using a 5° motion cutoff value in the Charité lumbar ADR 5-year analysis. Heterotopic ossification following lumbar arthroplasty with ProDisc-L has not been reported as a significant clinical issue, with well over 35,000 worldwide implantations. McAfee Grade IV HO (continuous bridging bone) has not been seen in any of the 5-year follow-up ProDisc-L patients, in contradistinction to the Charité experience. The insertion technique

and intrinsic mechanics of the ProDisc-L implant are different from those of the Charité implant and may be factors in explaining the difference in observed pathology.

True device-related failures were very uncommon. Device migration more than 3 mm in 3 ADR patients and subsidence more than 3 mm in 2 ADR patients are more likely related to insertion technique, bone quality, or post-operative trauma. Overall device success was similar in both arthroplasty and fusion groups at 5 years (93.2% and 93.3%, respectively). Nonphysiological traumatic loading did lead to implant failure in 2 patients, requiring (successful) revision surgery in both.

We completely agree that this long-term study clearly supports the use of both fusion and arthroplasty for patients with disabling single-level degenerative disc disease. Both are shown in this multicenter, multisurgeon study to improve clinical outcomes for patients in whom conservative therapy has failed. Additionally, a sparing effect on adjacent-level degeneration has, in fact, been shown in a radiographic analysis of these same patient cohorts, which appears separately in this issue.

References

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