Editorial

Two-level total disc replacement *vs*. fusion: any difference in reoperation rate?

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Comment on: Radcliff K, Spivak J, Darden B 2nd, *et al*. Five-Year Reoperation Rates of 2-Level Lumbar Total Disk Replacement Versus Fusion: Results of a Prospective, Randomized Clinical Trial. Clin Spine Surg 2016. [Epub ahead of print].

Received: 24 March 2017; Accepted: 21 April 2017; Published: 16 May 2017.

doi: 10.21037/amj.2017.05.03

View this article at: http://dx.doi.org/10.21037/amj.2017.05.03

In this issue of the *Clinical Spine Surgery*, Radcliff *et al*. report on the results of five-year follow-up of reoperation rates in a prospective and randomized trial comparing 2-level lumbar total disc replacement (TDR) *vs*. fusion. 2-level lumbar TDR is a relatively novel procedure and its role in the surgical treatment of degenerative disc disease (DDD) should be fully scrutinized in comparison to 2-level fusion. However, it should be uncommon for an investigator to hold a well-controlled prospective randomized study with appropriate number of patients in long-term follow-up. Au fond there are few high-level studies reporting long-term reoperation rates in comparison between 2-level TDR and 2-level fusion. The current study comparing 2-level TDR and fusion in many patients is certainly a high-level and rare study despite its limitations, as this study includes well controlled, randomized, and longer-term follow-up research compared to the other relevant studies in the literature. As the authors indicated, this study was based on a US Food and Drug Administration (FDA) investigational device exemption comparing TDR to fusion for the treatment of symptomatic 2-level contiguous lumbar DDD.

In the present study, there was a significantly lower rate of index levels reoperation in the TDR (5.6%) patients compared with circumferential fusion control patients (19.1%). This finding heralds TDR's superiority to fusion in terms of safety. A survivorship analysis revealed that the estimated reoperation free survival at 5 years was 89.8% for all patients. The reoperation-free survival was significantly increased in the TDR (94.1%) versus fusion (80.0%) cohorts (P=0.0020). The most common reason for index levels reoperation was instrumentation removal (9/11=82%) in the fusion population. The overall rate of adjacent segment disease (ASD) requiring surgery was 3.5% (8/229). There were 4 adjacent segment reoperations in the fusion population (4/68=5.9%) and TDR (4/161=2.5%, P=0.24) respectively.

The rate of index level reoperation in TDR population, 5.6%, seems to be rather low but relatively comparable to that of the index level reoperation in other 2-level TDR studies in the literature, which ranges 8.1% to 20% (1-3). In the present study, 2-level TDR has better outcome in terms of reoperation. The reoperation-free survivor was significantly increased in TDR. There were significantly fewer reoperations in 2-level TDR than those of 2-level of fusion (superior to fusion). But the result became insignificantly different, when the instrumentation removal was excluded in the reoperation of the fusion population (non-inferior to fusion). Recently, Siepe *et al*. (4) reported the results of the assessment of the mid- and long-term efficacy and safety of TDR in 151 single-level and 29 2-level TDR cases. In their report, deteriorating clinical results and higher complication rates were observed in the cohort of two-level TDR. They hypothesized the reason of this observation that the latest technique of lumbar TDR may have reached its limits and may not be a viable treatment option for multilevel lumbar DDD with currently available designs of artificial disc. And they explained the reason for worse outcome of two-level report compared to one-level TDR that there was abnormally increased mobility. However, it must be imprudent to compare the reoperation

rate directly between two different cohorts in the literature. These differences between investigational sites might be caused by several factors including small and/or imbalanced cohort sizes, inclusion and exclusion criteria, the inherent variability in the patient population, and differences in the technologies themselves, et cetera.

Whether multilevel TDR reduces incidence of reoperation at adjacent level or not is still on debate. Dooris *et al*. (5) reported that by maintaining motion at the index levels, multilevel TDR may maintain more normal spinal kinematics. Multilevel TDR can reduce the aberrant forces at adjacent levels, thereby lowering the incidence of reoperation compared with multilevel fusion. Meantime, Sariali *et al*. (6) reported that abnormally increased mobility was found at the index segments following bi-segmental L4–L5, L5–S1 TDR in 50% of cases compared with results off healthy volunteers. And, in another study (7), multi-segmental TDR could bring about an increase in biomechanical segmental instability. In such biomechanically unstable and abnormal situations, reoperation at the adjacent level could not be reduced. The effect of multilevel TDR on symptomatic ASD has been undetermined. On the contrary, asymptomatic radiological adjacent segment degeneration (ASDeg), which does not need reoperation, appears to be negatively influenced by lumbar TDR. Thus, the occurrence rate of asymptomatic ASDeg is significantly low in TDR compared to that in fusion (8,9). However, there is no evidence for an eventual change of asymptomatic ASDeg into symptomatic ASD.

Regarding exclusion of the instrumentation removal cases in the fusion population, it is rather absurd that there were nine instrumentation removals in 44 cases of a single cohort of fusion and nine instrumentation removals among 12 index-level secondary surgeries in fusion. In Kim *et al*.'s report (10), only 14 patients of instrumentation removal could be collected in a single institute in Korea between January 2003 and May 2005. As far as I am concerned, there are hundreds of lumbar fusion surgeries annually in this institute (personal communication). Despite some differences between one investigational site and another, instrumentation removal accounted for a considerable part of secondary operation after fusion surgery in the present study. In fact, the removal of spine implants for pain relief in patients with solid fusion has been a matter of debate (11-13). In this regard, the authors could have suggested that the data related to instrumentation removal were excluded. Based on the authors' assertion, the possibility of improper study design and protocol for the fusion control group could be considered in this prospective study. Anyhow, in the present study whether excluding the instrumentation removal is appropriate or inappropriate might remain disputable.

In addition to the biomechanical risks in multilevel TDR mentioned above including junctional degeneration with hypomobility (14), it was observed that increase in pressure on the posterior facet joints leading to symptomatic facet arthropathy at the index segments in postoperative mid-term follow-up of TDR (15,16). Some other investigators cast a doubt on the efficacy and safety of 2-level TDR, based on their own study results (1,3,17). More than 1-level lumbar TDR can no longer be performed and/or reimbursed in some countries including France (18) and South Korea. This might be due to lack of confirmative superiority of multilevel TDR in terms of its efficacy, safety and cost-effectiveness compared to those of multilevel fusion. At all events, the level of the present study must be higher than any other studies dealing with 2-level TDR, if only the merits of the present study are considered. Meanwhile, considering a safety issue including late complications unfamiliar to spine surgeons such as wear debris of implants (9), much longer-term follow-up of TDR is strongly warranted. Finally, the fact that the present study is based on industry-sponsored clinical research could be another matter of concern (19).

Acknowledgements

I thank Miss Soha Park for her sincere secretarial assistance. *Funding:* None.

Footnote

Provenance and Peer Review: This article was commissioned and reviewed by the Section Editor Ai-Min Wu (Department of Spinal Surgery, Zhejiang Spinal Surgery Centre, Orthopaedic Hospital, The Second Affiliated Hospital and Yuying Children's Hospital of Wenzhou Medical University, The Key Orthopaedic Laboratory in Zhejiang Province, Wenzhou, China).

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/amj.2017.05.03). The author has no conflicts of interest to declare.

Ethical Statement: The author is accountable for all

aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References

1. Di Silvestre M, Bakaloudis G, Lolli F, et al. Two-level total lumbar disc replacement. Eur Spine J 2009;18:64-70.
2. McAfee PC, Cunningham B, Holsapple G, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. Spine (Phila Pa 1976) 2005;30:1576-83; discussion E388-90.
3. Siepe CJ, Mayer HM, Heinz-Leisenheimer M, et al. Total lumbar disc replacement: different results for different levels. Spine (Phila Pa 1976) 2007;32:782-90.
4. Siepe CJ, Heider F, Wiechert K, et al. Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up. Spine J 2014;14:1417-31.
5. Dooris AP, Goel VK, Grosland NM, et al. Load-sharing between anterior and posterior elements in a lumbar motion segment implanted with an artificial disc. Spine (Phila Pa 1976) 2001;26:E122-9.
6. Sariali el-H, Lemaire JP, Pascal-Mousselard H, et al. In vivo study of the kinematics in axial rotation of the lumbar spine after total intervertebral disc replacement: long-term results: a 10-14 years follow up evaluation. Eur Spine J 2006;15:1501-10.
7. Steffen T. Biomechanics of disc replacement. 12th Brussels International Spine Symposium: Non Fusion Technologies in Spinal Surgery. Brussels, Belgium, 2005.
8. Zigler JE, Glenn J, Delamarter RB. Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion. J Neurosurg Spine 2012;17:504-11.
9. Park CK. Total disc replacement in lumbar degenerative disc diseases. J Korean Neurosurg Soc 2015;58:401-11.
10. Kim SW, Ju CI, Kim CG, et al. Efficacy of spinal implant removal after thoracolumbar junction fusion. J Korean Neurosurg Soc 2008;43:139-42.
11. Cook S, Asher M, Lai SM, et al. Reoperation after primary posterior instrumentation and fusion for idiopathic scoliosis. Toward defining late operative site pain of unknown cause. Spine (Phila Pa 1976) 2000;25:463-8.
12. Deckey JE, Court C, Bradford DS. Loss of sagittal plane correction after removal of spinal implants. Spine (Phila Pa 1976) 2000;25:2453-60.
13. Hume M, Capen DA, Nelson RW, et al. Outcome after Wiltse pedicle screw removal. J Spinal Disord 1996;9:121-4.
14. Huang RC, Girardi FP, Cammisa Jr FP, et al. Long-term flexion-extension range of motion of the prodisc total disc replacement. J Spinal Disord Tech 2003;16:435-40.
15. Park CK, Ryu KS, Jee WH. Degenerative changes of discs and facet joints in lumbar total disc replacement using ProDisc II: minimum two-year follow-up. Spine (Phila Pa 1976) 2008;33:1755-61.
16. Park CK, Ryu KS, Lee KY, et al. Clinical outcome of lumbar total disc replacement using ProDisc-L in degenerative disc disease: minimum 5-year follow-up results at a single institute. Spine (Phila Pa 1976) 2012;37:672-7.
17. Lee YC, Zotti MG, Osti OL. Operative management of lumbar degenerative disc disease. Asian Spine J 2016;10:801-19.
18. Trincat S, Edgard-Rosa G, Geneste G, et al. Two-level lumbar total disc replacement: functional outcomes and segmental motion after 4 years. Orthop Traumatol Surg Res 2015;101:17-21.
19. Carragee EJ, Weiner BK. Re: The Charite' five-year follow-up study: The editors' response to Dr. Guyer. The Spine J 2010;10:361-3.

doi: 10.21037/amj.2017.05.03
Cite this article as: Park CK. Two-level total disc replacement *vs.* fusion: any difference in reoperation rate? AME Med J 2017;2:55.