Editorial

Lumbar total disc replacement: does it still need further follow-up?

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In a recent article in *Spine*, Guyer *et al.* reported on the results of a 5-year follow-up results on a prospective, randomized trial comparing two kinds of lumbar total disc replacement (TDR): Charite [metal-on-polyethylene (MoP) TDR, the control] *vs.* Kineflex-L [metal-on-metal (MoM) TDR, the investigational]. To the best of my knowledge, there are few clinical comparison studies between two different artificial discs in the lumbar spine. The present study might be one of the few TDR clinical trials carried out in over 15 years in the U.S. These trials serially report comparison results between an investigational prosthesis and the control at certain time periods of follow-up. The authors had already published the 2-year follow-up results of the comparison study with the identical implants and in identical specimens as an early outcome with those of the present study (1). The current 5-year follow-up study demonstrated similar overall results with the 2-year follow-up. The clinical and radiological results of the investigational implant also appeared to be similar to the results of the control. Furthermore, this investigational implant has evidence of much lower serum ion levels than a proposed threshold and possibly merits of small ball radii. These results may herald a validity of clinical application of the investigational MoM TDR. In consideration of the U.S. experience with another MoM TDR, Maverick, there are concerns on how this MoM prosthesis would go through with the uncertainty and apprehension about MoM, particularly with its metallic wear.

Unlike the 2-year follow-up study, in the present study the authors expressed the concern of metallic wear debris. They monitored pre- and post-operatively the changes of serum ion analysis in 8 patients among 204 patients of the investigational group, MoM TDR. They demonstrated that the results of serum ion analysis had lower serum ion levels compared with the threshold values recommended by van der Straeten *et al.* (2) to predict problems with MoM prosthesis. However, the threshold value the authors referred in the present study might be inconclusive yet. Gornet and his associates (3) reported an elevated postoperative serum ion level even in patients with well-functioning MoM TDR in a prospective study of 24 patients, and insisted that no reliable threshold values were currently available for the clinical results of circulating serum metallic debris following arthroplasty surgery. Whether there is a correlation between serum ion levels and clinical problems may remain undetermined. In light of these observations, clinical implications of the local tissue and systemic ionic concentrations can't be certain. Therefore, the MoM group in the current study can't be free from the potential risk of hypersensitivity and other types of biologic response, because released ionic compounds can trigger an immune reaction anytime, resulting in osteolysis and failure of the prosthesis (4,5), as a process of cell-mediated hypersensitivity, which has been well documented for hip and knee arthroplasty.

Until recently, polyethylene wear was not a clinically relevant issue in TDR in the spine according to the idea that there is no synovial joint in the intervertebral discs and limitation of motion between the lower lumbar segments. These days, it is well known that PE particles may induce osteolysis and aseptic loosening. Punt and his colleagues (6) reported that they could observe PE and chronic

inflammatory reaction in peri-prosthetic tissue collected during reoperation in 15 of 16 patients with MoP. Among 15 with reoperation, two patients received a prosthesis only 3 years ago, and the investigators were able to discover PE and macrophages in their collected peri-prosthetic tissues. Kurtz and his colleagues (7) reported the results of quantitatively analyzing long-term PE damage mechanisms in contemporary TDRs, where increasing wear with implantation time might be accompanied with a potential risk for osteolysis in the spine in long-term follow-up. Recently, highly cross-linked PE has reduced the wear rate, and this result came from a substantial evolution in the understanding of PE in the last 20 years (8). Furthermore, MoP using cobalt-chromium-molybdenum (CoCrMo) and modern ultrahigh molecular weight polyethylene (UHMWPE) is regarded as a reference standard based on its extensive clinical experience as a bearing surface. However, such a development of new materials engineering may not fully protect TDR from wear-related issues. It has been reported that wear debris-induced tissue reaction caused a peri-prosthetic osteolysis in a patient with UHMWPE TDR (9). In the present study, the authors investigated metallic debris in the MoM TDR group, and in the meantime there were no report of tissue reactions of wear debris in either of the two groups, although they had prosthesis-related reoperation cases: 7 cases of prosthesis-related surgery in the MoP group and 2 cases in the MoM group. I wonder if peri-prosthetic tissues have been obtained during the reoperations that are substantially prosthesis-related. In 2014, the authors reported the results of tissue reaction in the last 2 cases of MoM TDR among the reoperation cases along with 2 other TDR cases as a case report in a separate journal, all of which had been salvaged due to peri-prosthetic lymphocytic reaction. However, there might not be an investigational trial for PE particles in the MoP group.

For better surgical outcomes, patient selection and indications for TDR in the lumbar spine are known to be the most important factors to be considered. Most of the patients who have received TDR are expected to be relatively young and have an active lifestyle. Consequently, wear and local tissue responses may become a major issue in these patients at long term follow-up (10). There have been small numbers of wear-related complications reported, which represented a low rate of wear-related complications. Nevertheless, nobody can predict how to maintain the overall low rate of wear-related issues as time passes. Prosthesis wear is usually accompanied with a poor biomechanical status such as subsidence, migration, and undersizing. The wear could adversely affect the outcome.

Because of the evidence shown by the reports dealing with increasing wear with implantation time and substantial osteolysis in the spine as well as the potential for unknown complications, which spine surgeons have never experienced in fusion surgery, regular long-term follow-up and spine surgeons' awareness of these potential complications are warranted, as were concluded in most of TDR review articles.

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Footnote

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