Correspondence

Nationwide review of mixed and non-mixed components from different manufacturers in total hip arthroplasty

Sir,—I read with great interest the recent paper by Peters et al. (2016) "Nationwide review of mixed and non-mixed components from different manufacturers in total hip arthroplasty: a Dutch Arthroplasty Register study." In this study the authors used the data of a nationwide database to compare the revision rate of primary total hip arthroplasty (THA) with components of the same or different manufacturers. Overall, they found similar medium-term revision rates for both groups.

Currently, surgeons implanting not approved mixed combinations do so under their own liability (Michel 2009). However, some mixed combinations used in high numbers have a similar revision rate compared with matched combinations. In cemented THA, the overall implant survivorship is even better in the mixed group than in the matched group (Tucker et al. 2015). The hip implant in the National Joint Registry for England, Wales and Northern Ireland that has the best performance is the Exeter stem (Stryker) in combination the Elite Plus Cemented Cup (DePuy Synthes) (National Joint Registry - Annual Report 2014).

Interestingly, Peters et al. (2016) found a lower risk of revision in patients that had a mixed stem-head THA before adjustment of confounders (hazard ratio = 0.78, 95% CI: 0.62–0.98). These findings are in contrast to those of Tucker et al. (2015). In the latter study, using a mixed stem-head THA resulted in a higher failure rate. There are different hypotheses for this higher failure rate. Firstly, it could be due to variation regarding the exact dimensions of the trunnion, eg. differences in taper length, taper angle, manufacturing tolerances, and surface finish (Rajpura and Board 2015). Secondly, in mixed alloy couples more fretting and corrosion at the head-neck junction can be found (Goldberg et al. 2002). Do the authors have any explanation for the conflicting findings regarding the revision rate in THA with a mixed stem and head in their study compared with Tucker et al.?

Another point merits consideration. The authors state that there is a difference in the frequency of mixing different components. The study by Malcolm et al. (2015) refers to off-label use of THA in patients with contraindicated comorbidities (obesity, neurological or mental disease and derangement of metabolism or bony integrity) and does not refer to the mixing of components of different manufacturers. The overall prevalence of mixing THA components seems to be similar in The Netherlands and the UK (11% versus 15%).

Some mixed combinations used in high numbers have similar revision rates and some even outperform matched combinations. Regulatory bodies should allow these specific combinations in future guidelines to make sure that we can offer the best available combination to our patients even if this means mixing and matching implants from different manufacturers.

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Sir,—We thank Mr. Meermans for his enriching comments on our study (Peters et al. 2016).

Our unadjusted survival analysis demonstrated that patients with a femoral stem and femoral head component from different manufacturers (mixed stem-head THA) had a slightly lower risk of revision compared to those with non-mixed THAs. However, after adjustment for confounding variables, revision rates were similar. As pointed out rightly, these findings are in contrast to the study of Tucker et al. (2015). Using the National Joint Registry for England, Wales and Northern Ireland, a higher failure rate was found in mixed stem-head THAs compared to non-mixed THAs. We agree that this might be caused by variations in the trunnion. Both studies compare mixed stem-head THA with non-mixed THA. However, these mixed stem-head subgroups contain different combinations of stem and head in the 2 countries. Both publications report findings from observational data and not from experimental designs controlling for known and unknown factors; thus any conclusion should be made with caution.

The second issue raised by Mr. Meermans is the statement concerning variation in the prevalence of off-label arthroplasty worldwide. We want to emphasize that there is no unified definition of off-label arthroplasty. Malcolm et al. (2010) referred to off-label arthroplasty as use of medical devices outside the scope of indications or population subgroups specifically approved by the United States (US) Food and Drug Administration (FDA). The contraindicated total joint arthroplasty criteria used in their study were conditions inherently predisposed to falling, infection, implant loosening, noncompliance, and inadequate fixation such as obesity, neurological disorder and metabolic diseases (Malcolm et al. 2010).

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The United States does not have an Arthroplasty Register with nationwide coverage. We used a definition for off-label use similar to Tucker et al. (2015) but differing to Malcolm et al; THAs composed of components made by different manufacturers, despite manufactures recommendation that implants were not designed, tested, or validated to be combined (Michel 2009). We agree that this definition does not refer to patients with contraindicated comorbidities for THA as referred by Malcolm et al. Subsequently, the prevalence's in these 2 studies should not be compared.

Lastly, we completely agree that some mixed combinations might have similar revision rates and some even outperform matched combinations. When nationwide register studies demonstrate superior results for some specific mixed combinations of components used in THA, future guidelines should allow these combinations in order to offer the best available combination for our patients. However, our study compared mixed and non-mixed THA as groups and does not include statements about specific combinations of component. To find definitive answers observational data may be insufficient. Randomized controlled trials nested within registries may overcome the shortcomings of observational data.

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