

Hothi H, Henckel J, Shearing P, et al. Assessment of the equivalence of a generic to a branded femoral stem. *Bone Joint J* 2017;99-B:310-316.

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Sir,

We read this paper with interest and agree that manufacturing variances exist for branded products, generic products, and between branded and generic products.¹

However, we question the broad conclusions reached given the methodology used and wider variances seen in a separate comparison of the OptiStem and Exeter stems.

One of the most significant conclusions from this paper is that the trunnion surface of the OptiStem is rougher than that of the Exeter stem. An independent comparison^{2,3} of the taper roughness of the Exeter and OptiStem stems found that the roughness for 107 OptiStems tapers was well within the range of seven Exeter stem tapers (Fig. 1 below). Orthimo shared these data at a British Orthopaedic Association (BOA) breakfast meeting in 2015. The blue lines in Figure 1 show the interquartile range (IQR) values for trunnion roughness taken from the Hothi et al paper¹: these are clearly within the distribution of the independent measurement. One can easily see how a comparison of the two blue lines, rather than the green bars, could erroneously lead to the conclusion that these stems are different.

Interestingly, the roughness of the seventh Exeter stem at 1.41 Ra (μm) was more than eight times that of the first stem at 0.17 Ra (μm). Despite this large variance, the Exeter stem performs very well, as confirmed by the 11th Annual National Joint Registry (NJR) Report⁴ which stated: "It was interesting to note that one of the lowest revision risks was that of an Exeter V40 with an Elite Plus cemented cup with a rate of just 1.36%. This represents a construct where the stem is made by one manufacturer and the socket another, a so-called mix and match system."

Given the variation seen with the Exeter stems in Figure 1, there would have needed to be a much larger sample size than the five stems from each manufacturer to draw the conclusion that the OptiStem is significantly different to the Exeter design. The maximal allowable conclusion should be that there are some differences between the ten specific stems measured, not that these results could be extrapolated to all OptiStem and Exeter stems.

We would like to pose several questions to the authors. Was the study sufficiently powered to draw the conclusion that the stems were different?

The measurement of trunnion roughness in one set of five Exeter stems yields different results to the roughness measurement for another set of seven Exeter stems. How were the implants randomly selected to avoid bias?

Why were medians reported instead of means for the *t*-tests? In particular, why were medians used when there were no reported outliers and all stems were within the accepted Exeter tolerances? Were standard deviations calculated and taken into consideration?

What is the evidence to support the authors' claim that it is not feasible that orthopaedic implants can be manufactured predictably to guarantee the same performance as generic drugs when this hypothesis was not within the scope of topics explored or tested?

This paper shows that variances exist for both branded and generic products within a small sample size. However, drawing conclusions from a small sample size and extrapolating to all prostheses is debatable, especially given the wide variation seen with the Exeter stem.

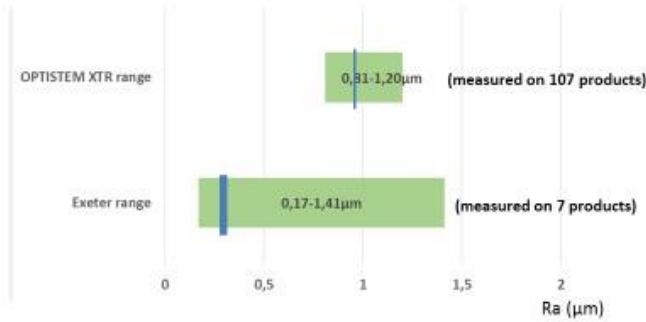
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1. **Hothi H, Henckel J, Shearing P, et al.** Assessment of the equivalence of a generic to a branded femoral stem. *Bone Joint J* 2017;99-B:310-316.
2. **No authors listed.** Independent testing for Orthimo R&D was performed by CRITT MDTS (Centre Régional d'Innovation et de Transfert de Technologie). www.critt-mdts.com (date last accessed 10 April 2018).
3. **No authors listed.** Independent testing for Orthimo R&D was performed by CRT Morlaix (Centre de Ressources Techniques). www.crt-morlaix.com (date last accessed 10 April 2018).
4. **No authors listed.** NJR 11th Annual Report – page 18. National Joint Registry. <http://www.njrcentre.org.uk/njrcentre/Reports,PublicationsandMinutes/tabid/85/Default.aspx> (date last accessed 10 April 2018).

Conflict of Interest: All authors are Orthimo employees.

Figure 1: OptiStem versus Exeter – Comparison of Taper Roughness

OptiStem® vs. Branded Reference – Taper Roughness



Ra is the result of a measurement which characterises roughness.

As shown at BOA meeting in 2015

Shows the IQR value for trunnion roughness, taken from the H Hothi et al., paper (OptiStem 0.924µm, Exeter 0.274µm). The range of values are within the distribution Orthimo measured.

Manufacturing variances exist across:

- branded,
- generic
- generic and branded

Orthimo measurements show that variances for OptiStem are within those of the branded stems (e.g., taper roughness on the left)

Standards for equivalence and manufacturing variances need to be established for both branded and generic medical devices