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Response to Weber and McFarland regarding: "Analysis of 4063 complications of shoulder arthroplasty reported to the US Food and Drug Administration from 2012 to 2016"

In reply:

We thank Drs. Weber and McFarland for their thoughtful discussion of our article and for emphasizing the shortcomings of the US Food and Drug Administration (FDA) MAUDE (Manufacturer and User Facility Device Experience) database. As they point out, (1) MAUDE does not provide a denominator by which the complication rates can be calculated; (2) there is no control on the quality of data put into MAUDE; and (3) it is likely that many, if not most, adverse outcomes are not reported to MAUDE.

Although we also agree that an obligatory national registry would provide much better data than MAUDE, the fact is that neither industry nor our national organizations have been willing to fund such an effort (see, in contrast, the enviable work performed over decades by the Australian Orthopaedic Association, https://aoanjrr.sahmri.com). In the absence of a national registry, we are limited to level IV case series from large centers and reviews of this literature, which do not reflect what goes on in the world of community surgeons, where most shoulder arthroplasties are performed.

Enter MAUDE, which—despite its many faults—provides a view of the relative frequency of different failure modes: For the 1673 anatomic arthroplasties, the most commonly reported failure modes were glenoid component failure (20.4%), rotator

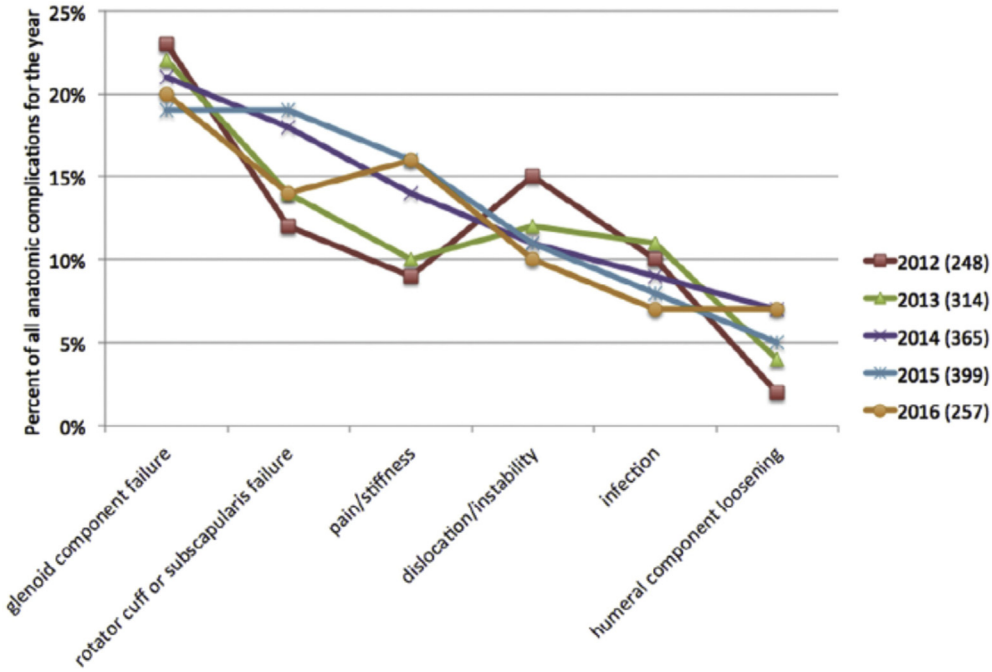

Figure 1 For anatomic shoulder arthroplasty, the percentage distribution of the 6 most common failure modes for each year of surgery remained relatively consistent. Reprinted with permission from Somerson et al.[1]

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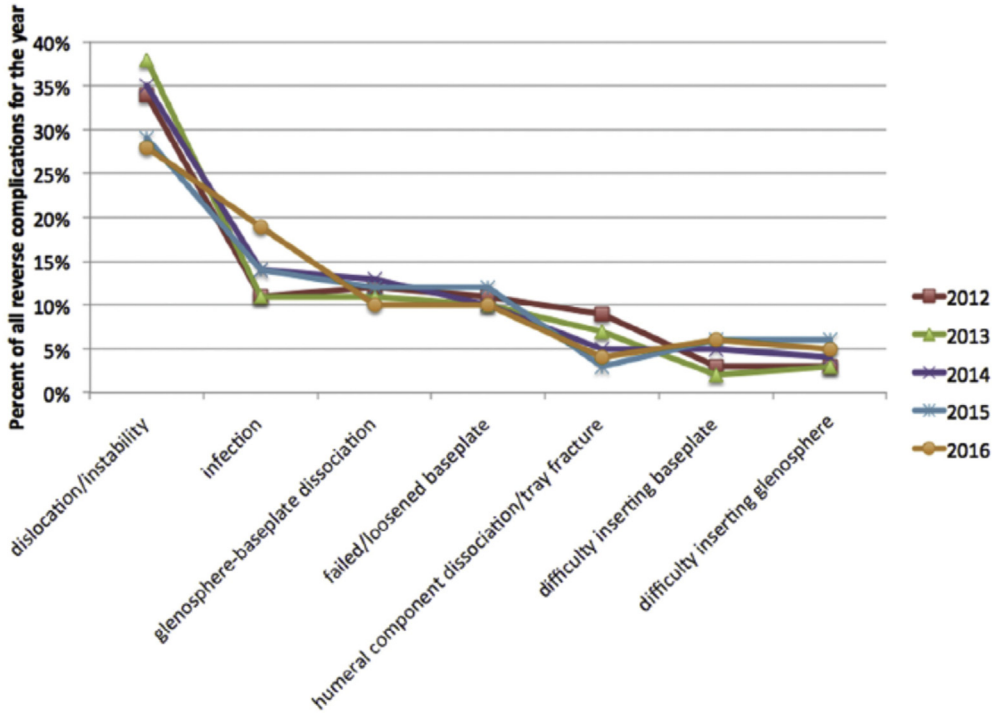

Figure 2 For shoulder arthroplasty, the percentage distribution of the 7 most common failure modes for each year of surgery remained relatively consistent. Reprinted with permission from Somerson et al.[1]

cuff and/or subscapularis tear (15.4%), pain and/or stiffness (12.9%), dislocation and/or instability (11.8%), infection (9%), and humeral component loosening (5.1%) (Fig. 1 [Fig. 4 in original article[1]]). For the 2390 reverse arthroplasties, the most commonly reported failure modes were dislocation and/or instability (32%), infection (13.8%), glenosphere-baseplate dissociation (12.2%), failed and/or loosened baseplate (10.4%), humeral component dissociation and/or tray fracture (5.5%), difficulty inserting the baseplate (4.8%), and difficulty inserting the glenosphere (4.2%) (Fig. 2 [Fig. 6 in original article[1]]). Despite the many shortcomings of MAUDE, there seems to be no reason to disregard these national data that reveal failure modes that are under-represented or unrepresented in case series. There is substantial reassurance that MAUDE data are not willy-nilly from the observation that the percentage distribution among the different failure modes was relatively consistent over the 5 years of this study.

From the analysis of MAUDE data, we concluded that "The Food and Drug Administration database reveals modes of shoulder arthroplasty failure that are not emphasized in the published literature, such as rotator cuff tear, infection, and postoperative pain/stiffness for anatomic total shoulder arthroplasty and implant dissociation and baseplate failure for reverse shoulder arthroplasty. Knowledge of these failure modes may help inform surgical technique and implant design in ways that will lower the risk of implant failure in the future." With the greatest respect for our Baltimore colleagues, we see no reason to back away from these conclusions.

Disclaimer

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Reference

1. Somerson JS, Hsu JE, Neradilek MB, Matsen FA III. Analysis of 4063 complications of shoulder arthroplasty reported to the US Food and Drug Administration from 2012 to 2016. J Shoulder Elbow Surg 2018; 27:1978-86. https://doi.org/10.1016/j.jse.2018.03.025