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Letter to the editor

# Letter to the editor on " Survivorship of a modular acetabular cup system: medium- to long-term follow-up"

We are concerned about several claims raised by Drs. Kindsfater and Lesko in their article "Survivorship of a modular acetabular cup system: medium- to long-term follow-up" [1]. Drs. Kindsfater and Lesko wrote that "… record-keeping irregularities did not, in the sponsor's [J&J/DePuy] estimation, affect the integrity of the data" [1]. Data, documents, and testimony from lawsuits against J&J/DePuy shed light on the "record-keeping irregularities" of the underlying study—the "Multi-center, Prospective, Clinical Evaluation of Pinnacle Acetabular Implants in Total Hip Arthroplasty" (PIN Study) [2].

The PIN study protocol called for consecutive and prospective enrollment; without these enrollment measures, investigators could cherry-pick by excluding high-risk patients [3,4]. Drs. Kindsfater and Lesko acknowledged that at least one site enrolled patients into the PIN study retrospectively, but J&J/DePuy included 93 patients total across 10 separate sites, who signed informed consents after their surgery [1,5,6]. Dr. Kindsfater testified about nonconsecutive enrollment at his own site, stating that he would not include "the street person" [7]. Had Dr. Kindsfater enrolled patients consecutively, he would have at least 4 additional revisions [8]. Thus, the "cherry-picking" of healthy survivors was not just a theoretical problem but one which impacted the study findings.

Furthermore, Drs. Kindsfater and Lesko excluded 13 failures among PIN study participants, 10 identified in J&J/DePuy's medical complaints database and 3 reported in PIN investigator testimony [5,8-10]. Drs. Kindsfater and Lesko omitted these failures because including them "… without also including further follow-up on all unrevised hips from a similar search of sources outside data collection methods in this study would have introduced bias [1]." Contradictorily, J&J/DePuy included external data when they transferred 31 patients from a stem study into the PIN study [6,11]. One case report form suggests that J&J/DePuy transferred data from a third source, a company registry called "CaptureWare" [5].

Drs. Kindsfater and Lesko claimed that the inclusion of the additional revisions would have introduced study bias [1]. In an uncontrolled prospective study such as the PIN study in which a data analysis by KM accounts for variable follow-up times, these failures cannot create differential reporting bias. Rather, their exclusion biased the study toward more favorable survivorship results [1,8,10].

Drs. Kindsfater and Lesko reported a data entry cutoff period of January 2013, but J&J/DePuy changed the date retrospectively in 2015 and did not sign the study freeze and lock form until March 2016 [12,13]. Nine of 13 excluded revisions occurred before January 2013; all occurred before March 2016 [1,5]. Drs. Kindsfater and Lesko included one revision that came to their attention in December 2015 [13,14]. This selective reporting constitutes cherry-picking.

Finally, Drs. Kindsfater and Lesko did not report all adverse events. The authors reported no revisions for osteolysis, but PIN investigators recorded 2 such revisions [1,5]. The device-related death of Dr. Kindsfater's patient, who suffered a dislocation and died under anesthesia, and 109 other recorded patient deaths were not disclosed in the article [1,5,15].

We hope that our comments bring greater clarity and transparency to the findings of Drs. Kindsfater and Lesko.

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D.S.E. served as an expert witness in litigation at the request of people who were injured as the result of having a total hip replacement with the Pinnacle Metal on Metal Hip System. J.E.S. and K.J.R. worked for D.S.E. on this litigation. E.A.F. served as a consultant on the same litigation. None of these authors were compensated for work on this article, and the lawyers for the injured plaintiffs did not review this article and had no input into the content of the article. The authors provided J&J/DePuy lawyers a draft copy of the manuscript 1 month before submission with a request for comments and corrections; no response has been received.

Please note that this letter represents an abbreviated version of the original submission, so as to comply with *Arthroplasty Today* publication requirements.

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