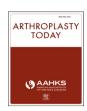
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Letter to the editor

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].

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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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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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