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Authors' reply:
A response to 'Clarifications on the design and conduct of the PROFHER trial'

9 November 2016

Sir,

We would like to thank Dr Handoll and colleagues for clarifying some of the issues brought up in our editorial,[1] and for the pivotal PROximal Fracture of the Humerus: Evaluation by Randomisation (PROFHER) trial.[2]

We think we can agree that there are a number of patients whose demographics (young, active, no comorbidities) and fracture type (fracture-dislocations, displaced four-part fractures) benefit from surgery. Similarly, other features (advanced age, dementia, multiple comorbidities, minimally displaced fractures) would dictate non-operative treatment. What remains contentious is how to treat the rest, and this is where the PROFHER study and other high-quality randomised controlled trials come into play. We understand that the patient population for the PROFHER trial was explicitly that, for which there is uncertainty and therefore clinical equipoise with respect to surgical *versus* non-operative management. Our editorial pointed to the fact that there are inherently a large number of cases for which there lacks clinical equipoise and therefore we remain in the position of treating a large group of patients for whom surgical management remains the subjective preference of the treating surgeon.

When surgery is involved, a number of factors are important, including surgical decision making, surgical skill (usually related to volume), implant type (i.e. fixation *versus* replacement) and rehabilitation protocols. It is, in fact, our specific point that surgeons in the PROFHER study were allowed to exempt patients from the study whom they felt clearly required surgery, thus the "bad actors" with intrinsically poor outcome following non-operative care were taken out of the equation early. If a casual reader of the article did not recognise this, it could lead to incorrect conclusions about the role of surgery (i.e. it is never indicated in this setting).

Additionally, we stand by our statement that Dean et al are applying recommendations from the PROFHER study (with 4.4% four-part fractures, the worst type) to a population with a six-fold greater rate of four-part fractures (25%).[3] It may well be that a number of patients seen by Dean and colleagues would fall into the group that the PROFHER surgeons felt had 'clear indications for surgery'. We do concede that the actual proportion of four-part fractures may have been higher in the PROFHER study, as the determination of the fracture pattern can be observer- and classification-

dependent, as outlined by Handoll et al's recent publication in *BJR*.[4] Although the PROFHER trial utilized a two-surgeon independent team to classify fracture patterns, evidence exists to support the need for at least four members for an independent adjudication committee to obtain high levels of reliability.[5,6]

Furthermore, the small number of patients per surgeon in the PROFHER trial raises issues more about surgeon engagement than on generalisability of the trial results. Indeed, sensitivity analyses mitigated concerns about the effects of individual surgeon and clinical site on the primary outcome.[2] However, if fewer than one patient is enrolled per surgeon per year, there are likely to be some factors influencing surgeon interest or commitment to patient enrolment. This is a challenge encountered in all surgical specialties, given the many institutional and personal barriers to participation in surgical trials.[7]

Lastly, practice makes perfect, and this is as true in surgery as it is anywhere else. It is quite likely, even probable, that a surgeon performing two or three proximal humeral fracture repairs a month will have superior results to a centre which enrols only one such patient per year.

We would like to again thank Handoll and colleagues for their commitment to this discussion and to the long-term goal of developing evidence-based guidelines for the management of patients with these challenging fractures.

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Conflict of Interest: None declared