AUTHORS' REPLY TO: Rometsch et al

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Sir,

Thank you for giving us the opportunity to respond to the letter by Rometsch et al about the PROFHER trial.

We note that this AO Foundation-funded 'critical appraisal' of the PROFHER trial has been linked primarily with the report of the five-year follow-up[1] rather than with the main trial report published in JAMA[2] and the comprehensive National Institute for Health Research (NIHR) Health Technology Assessment (HTA) monograph[3]. Perusal by Rometsch et al of both of these reports will address many of their concerns; for example, about the expertise of the operating surgeons and on the availability of topic-specific estimates of the minimal clinically important change (MCID) for the Oxford Shoulder Score (OSS). Further pertinent insights are available in our article on defining the fracture population.[4]

We further refer Rometsch et al to our letter[5] detailing the unsound methods, analyses and conclusions of the meta-analysis conducted by Sabharwal et al.[6] Other unsound methodology is their suggestion for a per-protocol analysis. Such analysis is rarely, if ever, justified.[7]

Finally, we suggest that Rometsch et al examine the systematic approach taken in the critical appraisal of the PROFHER trial in a recent 'User's guide' to the medical literature relating to surgical trials.[8]

We hope that by taking these steps, Rometsch et al will accept that the conclusion of the trial was appropriate and applicable to the majority of patients with displaced proximal humeral fractures involving the surgical neck.

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References

- 1. Handoll HH, Keding A, Corbacho B, et al. Five-year follow-up results of the PROFHER trial comparing operative and non-operative treatment of adults with a displaced fracture of the proximal humerus. Bone Joint J 2017;99-B:383-392.
- 2. Rangan A, Handoll H, Brealey S, et al. Surgical vs nonsurgical treatment of adults with displaced fractures of the proximal humerus: the PROFHER randomized clinical trial. JAMA 2015;313:1037-1047.
- 3. Handoll H, Brealey S, Rangan A, et al. The ProFHER (PROximal Fracture of the Humerus: Evaluation by Randomisation) trial a pragmatic multicentre randomised controlled trial evaluating the clinical effectiveness and cost-effectiveness of surgical compared with non-surgical treatment for proximal fracture of the humerus in adults. Health Technol Assess 2015;19:1-280.
- 4. Handoll HH, Brealey SD, Jefferson L, et al. Defining the fracture population in a pragmatic multicentre randomised controlled trial: PROFHER and the Neer classification of proximal humeral fractures. Bone Joint Res 2016;5:481-489.
- 5. Handoll HH, Brealey SD, Keding A, Rangan A. Going far beyond the evidence (eletter). Bone Joint Res 2016: 20 October 2016. https://online.boneandjoint...
- 6. Sabharwal S, Patel NK, Griffiths D, et al. Trials based on specific fracture configuration and surgical procedures likely to be more relevant for decision making in the management of fractures of the proximal humerus: findings of a meta-analysis. Bone Joint Res 2016;5:470-480.
- 7. Lee YJ, Ellenberg JH, Hirtz DG, Nelson KB. Analysis of clinical trials by treatment actually received: is it really an option? Stat Med 1991;10:1595-1605.
- 8. Evaniew N, Carrasco-Labra A, Devereaux PJ, et al. How to Use a Randomized Clinical Trial Addressing a Surgical Procedure: Users' Guide to the Medical Literature. JAMA Surg 2016;151:657-662.

Conflict of Interest: None declared