Response to Negenborn et al, 2018: Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial

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Dear Sirs,

We read with great interest the latest results from the BRIOS[1] randomised controlled trial of one-stage versus two-stage implant-based breast reconstruction (IBBR). We would like to congratulate the authors for publishing the primary outcome of the study.

Although implant loss rates were significantly higher in patients receiving single-stage mesh-assisted direct-to-implant reconstruction than those undergoing two-stage expander-implant procedures (29% versus 7%), there were no significant differences in patient satisfaction between the groups irrespective of whether those with complications were included in the analysis.

Two potential hypotheses could explain these findings.

Firstly, the primary outcome was assessed at 17 months following placement of the definitive implant rather than at one year as planned. Reasons for this are unclear but notably almost all (18/21) patients who experienced implant loss in the BRIOS study went on to have secondary reconstruction within the study period. Did the seven-month delay therefore reflect the need for additional surgery and the time-frame for achieving a successful reconstruction? May this also explain why complications do not appear to impact patient satisfaction as patients with a successful reconstruction were satisfied with the end-result, irrespective of how it was achieved? This is an important finding and would be consistent with findings from the National Mastectomy and Breast Reconstruction Audit that suggest that short-term implant-based complications do not affect longer-term quality of life[2]. Complications, however, are likely to impact patients' short-term well-being and longitudinal assessment of patient satisfaction may be a more appropriate method for assessing the true impact of an intervention; an important learning-point for future studies.

The apparent discrepancy in contralateral symmetrisation surgery performed in the two groups may be another contributory factor. 20% (13/62) of the patients in the two-stage group underwent a

symmetrising procedure, but no symmetrising procedures were reported in the one-stage group. Were patients “opportunistically” more likely to undergo contralateral surgery where a second-stage was planned?

While the BRIOS study adds significantly to the evidence-base, we believe uncertainty remains regarding the role of acellular dermal matrix in IBBR. We hope that the results of the iBRA study[3] will help inform this debate.

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On behalf of the iBRA Steering Group

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We declare no competing interests

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