Trying to provide better evidence in orthopaedic surgery: RCTs, registries or both?

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Part of a clinician's duty of care is to provide patients with information on "the benefits, risks, burdens, and likelihood of success" when offering surgical treatments. The ease with which placebos can be used in medical randomised controlled trials (RCTs) has put physicians decades ahead of surgeons in providing treatments based on high level evidence. Providing such evidence in surgery has been far more challenging. However recently, funders, surgeons, trial methodologists and ethicists have realised that not only can national multicentre surgical trials be successfully recruited to target, but that placebo surgical trials can also be designed and successfully delivered. [1–3]

As such there is now a growing momentum, enthusiasm, and commitment within surgical communities—particularly in orthopaedic surgery, to address remaining evidence gaps. For the past 10 years the British Elbow and Shoulder Society (BESS) and its members have endorsed and supported nationally funded multicentre trials run by surgical trials units. [3–7] It has also supported priority setting partnerships that identify ongoing treatment uncertainties which are important to patients, in turn helping set the national research agenda in this speciality. [8] One ongoing uncertainty has been around the lack of high quality data on the use of different types of shoulder replacement surgery. [9] While still considered the gold standard of evidence, RCTs in this context are underpowered to reliably detect differences in serious adverse events or longer-term revision surgery risks. It is the latter in particular, that patients wish to have more information on, especially as the incidence of shoulder replacement surgery has risen dramatically and it has become the established treatment for painful end stage glenohumeral joint arthritis. [10] While definitive RCTs are still needed to examine the different design types of shoulder replacement, the use of large observational database cohorts are an important source of generalisable data that can provide better evidence and information than is currently available especially in relation to serious adverse events.

Our analysis of lifetime revision risk and serious adverse events provides information with sufficient clinical detail to be used in a meaningful way with patients of different sexes and age in the context of an individual's life expectancy. [11] While shoulder replacement surgery may provide substantial benefit to many, our findings serve as a reminder that it is a major operation carrying real risks that patients and surgeons need to understand and accept.

Administrative datasets, such as Hospital Episode Statistics, lend themselves well to the analysis of rarer outcomes, benefitting from high procedure volumes, long-term follow-up, and universal coverage of a health system. However, they lack detail on specific technical and implant related details, which are more readily analysed using dedicated joint replacement registries. While providing important and new information on adverse events and risk of revision, our study offers nothing further on the real world benefits of shoulder replacements to patients with regard pain and functional improvements. To address this some national joint registries are now collecting patient reported outcome measures. In time this will provide better data to measure and predict the successful outcomes of joint replacement surgery, over and above the outright failures currently defined by revision surgery.

Joint replacement surgery benefits from rich innovation and frequent new implant designs, each promising improved function and increased longevity. The IDEAL Collaboration lays out a model for evaluation of such changes. We believe that multicentre RCTs that become carefully nested within dedicated joint registries will provide unbiased effectiveness estimates with reliably reported longer-term surveillance data and will offer the most efficient model to measure implant performance and patient outcomes in the future.[12] The design of registries should now consider evolving to routinely support this type of RCT as part of a joined up strategy for the continuous assessment of outcomes of joint replacement surgery.

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