



■ EDITORIAL

The truths we seek and the randomised trial in orthopaedic surgery

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Research is, in essence, the search for the truth. We ask ourselves clinical questions and we seek to find truthful answers: is streptomycin effective in the management of pulmonary tuberculosis? Is the combination of conservative surgery and radiation as effective as the radical mastectomy in local control of breast cancer? These questions have been definitively answered and have had an impact on clinical practice to the extent that millions of lives have been saved, and the morbidity of the most common cancer surgery in women has plummeted. These landmark discoveries, and many others, were realised by randomised controlled trials (RCTs).^{1,2}

Before the turn of the millennium, the term 'RCT' was not in the verbiage of the orthopaedic surgeon. However, our research culture has shifted towards higher-level evidence and more and more studies published in the orthopaedic literature are RCTs, ranging from single, and smaller multicentre studies,³⁻¹⁵ to large multicentre national and international collaborative RCTs.¹⁶⁻²¹ Orthopaedic journals, including *The Bone & Joint Journal* and *Bone & Joint Research*, are now publishing at least one, if not several, RCTs per month. The methodology of the RCT is designed to minimise bias in answering research questions. As bias can be defined as systematic deviation from the truth, the least bias in the study design, the closer we will come to the truth when answering our research questions.

So why not answer all of our clinical research questions with an RCT? There are many barriers to conducting methodologically sound RCTs. Some are applicable to all medical specialties, and some are specific to surgical specialties. The former include cost and lack of expertise, infrastructure and clinical equipoise (the belief that treatment arms may in fact be equal in efficacy, and if they are not equal, the more efficacious could be either one). Although these barriers apply

to all medical specialties, as surgeons we are further challenged by difficulty, if not impossibility, of blinding the patient and surgeon to treatment allocation, strong surgeon-specific preference and expertise, and the unwillingness of patients to be randomised.

Despite these barriers, the RCT has surfaced in orthopaedic research and is gaining momentum. What has made this possible despite the barriers? The reasons are likely multifactorial. Expanded education of the importance of RCTs in orthopaedic research, increased awareness, and the impetus to overcome barriers may be playing a role. Several orthopaedic surgeons have led by example and have developed collaborative research groups to work together to run multicentre RCTs.²² Surgeons have obtained advanced degrees in clinical research and have developed prospective research programmes at their own institutions. Orthopaedic surgeons are running and participating in RCTs more and more.

Models of innovative approaches to overcome the challenges of conducting RCTs abound in research in orthopaedic surgery. Feasibility has been addressed with several strategies. Surgeons have administered surveys to determine clinical equipoise and willingness to participate in a RCT.^{23,24} Small pilot studies address issues of recruitment and adherence to protocol.^{25,26} Even the publication of a well-designed protocol will increase awareness and interest in RCTs and inspire collaboration.²⁷⁻²⁹ In order to ensure adequate patient accrual, surgeons have conducted studies at multiple centres,^{30,31} or have even completed both arms in the same patient with two different procedures for bilateral hallux valgus.³² In order to ensure adequate follow-up and decrease study costs, others have designed and conducted studies in which the primary outcome requires only weeks or a few months of follow-up.³³

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Orthopaedic surgeons must be even more innovative in addressing issues of blinding and outcomes assessment. Visibly identical placebo arms can be used for regional anaesthetic injection, allowing for double-blind treatment allocation.¹¹ Blinding can also be accomplished with a placebo arm in the evaluation of pulsed ultrasound efficacy in scaphoid fracture healing.³⁴ Outcomes assessment can be blinded, independent and unbiased, particularly with respect to radiographic outcomes.^{18,35,36} Subtle differences in the type of implant available allow for blinding and, therefore, unbiased patient and outcomes assessment.³⁷ Finally, the use of patient-centred outcomes can be independent of the opinion of the clinical practitioner and, as a result, provide an unbiased assessment of treatment efficacy.³⁸

Despite the remarkable advances in research in orthopaedic surgery, there remain many challenges to overcome with respect to the conduct of RCTs. The majority of published orthopaedic research continues to be retrospective and non-comparative in nature. However, the ball is rolling, the inertia of low-level evidence is dissipating, and orthopaedic surgeons have the opportunity to join the ranks of other medical specialties in producing evidence that will truthfully guide our clinical practices. Keep on the 'look out' for upcoming volumes of *The Bone & Joint Journal* and *Bone & Joint Research* as we continue to publish orthopaedic RCTs and play our part in the research revolution in orthopaedic surgery.

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