Evidence-based orthopaedic surgery

WHAT TYPE OF RESEARCH WILL BEST IMPROVE CLINICAL PRACTICE?

Surgical research is often maligned. Nevertheless, clear improvements in the surgical management of disorders of bone and joint have occurred since the advent of evidence-based medicine 30 years ago. Examples include joint replacement or arthroplasty surgery, internal fixation of fractures and arthroscopic or ‘minimally invasive’ surgery. Refinements and improvements continue to emerge further reducing complications and morbidity. Could we do better? Much of the published research associated with these changes is, according to the system suggested by the Oxford Centre for Evidence-based Medicine Framework, of poor or low quality. A recent review of published evidence for shoulder surgery revealed that, during a ten-year period to 2002, only 19 (3.1%) papers in mainstream orthopaedic journals described randomised, controlled trials (RCTs) and 538 (88.2%) were single-centre case series offering low levels of evidence according to this system. Most of the RCTs involved non-surgical treatments such as physiotherapy or drugs. A similar picture is probably true for most other areas of published orthopaedic research. What are the reasons for this deficiency? Some would say that orthopaedic surgeons have, at least in part, failed to embrace modern methods of research and design of trials. To a certain extent, this is true but the essence of surgical innovation and improvement has not been by clinical trials but by reliance on individual surgeons inventing new techniques or new implants and reporting their results as a case series to see if improved clinical outcomes have ensued. The fundamental issue is that the surgeon is part of the treatment and is, generally speaking, responsible for its innovation and development. The surgeon, not a third party such as a pharmaceutical company or a university researcher in a laboratory, is the inventor. His or her decision making and technical skill are intimately bound up in its success or failure. To expect an individual surgeon to be equally expert at a number of different techniques is unrealistic. With RCTs, the consent process has proved particularly troublesome and many surgeons find it difficult to participate in the randomisation process without bias. Many surgical RCTs have high rates of exclusion or withdrawal. It is perhaps not surprising that conventional RCTs of surgical treatments have proved very difficult to set up and complete. This ‘expertise bias’ is well recognised.

The influence of surgical expertise on outcome may well be one of the most important areas requiring investigation. Recent studies of total hip replacement have linked surgeon and centre volumes to outcome. The ‘surgical learning curve’ and technical difficulty associated with the new paediatric cardiac surgical procedures performed in Bristol and other centres in the United Kingdom in the 1980s and 1990s, were of worldwide media interest. Arguably these and other similar cases have changed forever the scrutiny required of new surgical procedures.

A variety of alternative designs of trials have been suggested to cope with those aspects which differentiate surgical from other forms of treatment. For example, high quality multicentre observational studies and expertise-based RCTs where the patient is randomised to the different operations in the trial and then allocated to a surgeon expert at that procedure. The practical difficulties of organising such trials, particularly in health systems where there are a variety of providers and funding systems, should not be underestimated. Trials of many orthopaedic treatments, such as joint replacement surgery, will require long-term follow-up of large numbers of cases.

A further issue is funding. Surgical trials are often expensive and difficult to run. Research councils and charities have not proved to be strong supporters of surgical trials. Most importantly, the regulation of new surgical techniques and implants is nowhere near as rigorous as exists for new drug treatments. The implant industry is not compelled to introduce new products with phased trials. Without sponsorship and financial support surgical tri-
als are simply impractical. An alternative to trial-based research is a register, but these have proved difficult to establish even for high profile treatments such as hip replacement. The success of the National Joint Register in the United Kingdom has yet to be shown, but it is a good example of how levels of evidence could be improved in orthopaedic surgery.

Whilst not wanting to quash surgical innovation published as case studies by over regulation, there is no doubt that some questions cannot be answered by such means. Our aim must be both to improve and add to this type of research. Surgeons should be encouraged to work together and participate in well-designed studies. Such organised groups are far more likely to persuade charities, research councils and industry that funding is worthwhile. Government could also improve the environment by requiring stricter regulation of new implants and thereby increase industrial funding of clinical trials. Imposing levels of evidence based on those used to assess drug treatment is unrealistic and probably wrong; surgical research cannot rely entirely on RCTs. The answer must be to devise levels of evidence appropriate for surgical research. The ideal result would be both a wider participation in research and an improvement in published evidence upon which to base best practice.

References