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EDITORIAL

Three orthopaedic operations, over 1,000 randomized controlled trials, in over 100,000 patients

WHAT HAVE WE LEARNT?

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In orthopaedic surgery, the three most commonly performed operations are total knee arthroplasty (TKA), total hip arthroplasty (THA), and anterior cruciate ligament reconstruction (ACLR). The demand for TKA is ever-increasing, with an estimated 700,000 TKAs performed each year in the USA alone, and a projected increase in demand to over 3.48 million procedures by 2030.[1,2] Similarly, THA is one of the most successful and cost-effective interventions in orthopaedic surgery, considered by many as the operation of the century.[3] The demand for THA is also rising worldwide.[4-6] The anterior cruciate ligament (ACL) is the most commonly injured ligament in the knee with an estimated 400,000 ACLRs performed each year worldwide.[7-9] Despite the success of and high demand for these procedures, debate continues on many surgical and technical aspects of these operations.

High-quality randomized controlled trials (RCTs) provide strong evidence for the efficacy of healthcare interventions and help to inform evidence-based practice.[10,11] RCTs show a statistically significant difference in the results of two treatments, or the absence of a significant difference but a narrow confidence interval indicating a positive effect of a treatment.[12,13] Recently, we systematically reviewed all published RCTs of TKA, THA, and ACLR.[14-16] Here, we present an overview of our findings and the lessons learnt from 1,014 RCTs in 107,511 patients.

Total hip arthroplasty

Since the inception of the modern Low Friction Arthroplasty by Sir John Charnley, little has changed in the fundamentals of this operation.[17] However, substantial advances have been achieved in metallurgy and manufacturing processes, particularly with the cross-linking of polyethylene (XLPE and HXLPE), ensuring excellent long-term outcomes of THA.[18] Nonetheless, debate continues over the optimal surgical approach, implant fixation, head sizes, or bearing surfaces. In a comprehensive systematic review of 312 RCTs involving 34,020 patients, 14.5% of trials (n = 41) reported significant differences (excluding metal-on-metal trials with significant differences in ion levels) between the intervention and control groups for the outcome measures used by those trials. The early failures encountered between the 1970s and 1980s had been largely addressed in the 1990s and early 2000s with improved metallurgy and manufacturing processes. The evidence available from high-quality RCTs indicates that for the vast majority of patients, a standard conventional THA with a surgical approach familiar to the surgeon, using standard well-established components and XLPE, leads to satisfactory clinical outcomes.[15]

Total knee arthroplasty

Several studies have found that about one in five patients undergoing TKA are dissatisfied with the results of their surgery.[19,20] Over the years and in an attempt to improve patients' outcomes and satisfaction, surgeons and manufacturers have introduced a number of modifications to TKA from the use of uncemented fixation and mobile bearings to patient-specific instrumentation (PSI) and navigation techniques. In a comprehensive systematic review of 403 published RCTs

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on TKA involving 47,675 patients, only 8.2% of trials (n = 33) reported any significant differences between the intervention and control groups for the outcome measures used by those trials. Some of those trials reported significant differences in radiological but not clinical outcomes. While debates continue on whether to use mobile bearing components, resurface the patellae or adopt more costly techniques such as PSI, navigation technology, or robotics, a number of conclusions can be drawn from this study. For the vast majority of patients, a standard conventional TKA, performed with a surgical approach familiar to the surgeon using well-established components with a good track record, with or without using a tourniquet, will lead to satisfactory long-term clinical outcomes.[16]

Anterior cruciate ligament reconstruction

The modern intra-articular ACLR is largely based on the Hey Groves' operation, which he described in 1917 using a strip of fascia lata passed through a tibial tunnel.[21,22] Over a century later, the debate continues in the literature on many different aspects of ACLR. Applying similar methodology, in a systematic review of 299 RCTs involving 25,816 patients, only 10% of trials (n = 30) reported any statistically significant differences between the intervention and control groups for the outcome measures used by those trials. This evidence has shown that for the vast majority of patients, using standard arthroscopic techniques, a single- or double-bundle ACLR with hamstrings, or bone-patella tendon-bone autografts, implanted using a transportal technique and graft fixation methods familiar to the surgeon, achieve satisfactory and comparable clinical outcomes as reported by the included RCTs.[14]

What have we learnt?

TKA, THA, and ACLR are successful and durable operations that have helped millions of patients worldwide. The early failures encountered have been largely addressed with improved metallurgy and manufacturing processes. Many techniques have seen a cycle of gaining initial popularity before falling out of favour, only to surface again a decade or so later. While new techniques aim to achieve better clinical outcomes, it is important to consider the added costs, particularly with the rising costs of healthcare and the potential complications of adopting new technologies and the associated learning curve.

The evidence from published RCTs indicates that for the vast majority of patients, standard conventional techniques in TKA and THA lead to satisfactory outcomes. Future trials should focus on preoperative interventions and patients' optimization to improve clinical outcomes – an area that is currently lacking. Similarly, ACLR trials showed that for the vast majority of patients, standard techniques are comparable. Most trials have only reported short- to medium-term follow-up; only approximately 5% reported long-term outcomes beyond ten years' follow-up. In those, a high incidence of osteoarthritic changes in the reconstructed knees, ranging from 22% to 100%, was reported. There is a need for further long-term studies of high-quality RCTs, particularly existing ones.

Further, some surgical aspects have been evaluated repeatedly; for example, 47 RCTs compared mobile versus fixed bearing TKA, with only one trial reporting significant differences, and 30 RCTs looked at PSI, with only two reporting significant differences. Numerous examples are found in THA and ACLR trials, with 72 RCTs looking at surgical approaches in THA, and 30 RCTs comparing different bearing surfaces. Similarly, 45 RCTs compared patella versus hamstring grafts and 42 RCTs compared single- versus double-bundle ACLR. Rather than repeatedly asking the same question in the hope of finding a different answer, careful planning is needed if any further trials on these aspects are to be conducted.

Finally, although a recent review has highlighted a lack of RCTs comparing surgery with conservative/placebo treatments in orthopaedics,[23] it is clear that a lack of such trials does not equate to a concern that these procedures lack effectiveness. Our series demonstrate that patients continue to benefit from these surgical interventions worldwide. Over 1,000 RCTs included have focused on surgical and technical aspects of these procedures in an attempt to further improve patients' outcomes.

References

1. **Nguyen LC**, **Lehil MS**, **Bozic KJ**. Trends in total knee arthroplasty implant utilization. *J Arthroplasty*. 2015;30(5):739–742.
2. **Kurtz S**, **Ong K**, **Lau E**, **Mowat F**, **Halpern M**. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am*. 2007;89-A(4):780–785.
3. **Laupacis A**, **Bourne R**, **Rorabeck C**, **et al**. The effect of elective total hip replacement on health-related quality of life. *J Bone Joint Surg Am*. 1993;75-A(11):1619–1626.
4. **Culliford D**, **Maskell J**, **Judge A**, **et al**. Future projections of total hip and knee arthroplasty in the UK: results from the UK Clinical Practice Research Datalink. *Osteoarthr Cartil*. 2015;23(4):594–600.
5. **Ackerman IN**, **Bohensky MA**, **Zomer E**, **et al**. The projected burden of primary total knee and hip replacement for osteoarthritis in Australia to the year 2030. *BMC Musculoskelet Disord*. 2019;20(1):90.
6. **Pabinger C**, **Lothaller H**, **Portner N**, **Geissler A**. Projections of hip arthroplasty in OECD countries up to 2050. *Hip Int*. 2018;28(5):498–506.
7. **Mall NA**, **Chalmers PN**, **Moric M**, **et al**. Incidence and trends of anterior cruciate ligament reconstruction in the United States. *Am J Sports Med*. 2014;42(10):2363–2370.
8. **Rayan F**, **Nanjayan SK**, **Quah C**, **Ramoutar D**, **Konan S**, **Haddad FS**. Review of evolution of tunnel position in anterior cruciate ligament reconstruction. *World J Orthop*. 2015;6(2):252–262.
9. **Granan LP**, **Forssblad M**, **Lind M**, **Engebretsen L**. The Scandinavian ACL registries 2004-2007: baseline epidemiology. *Acta Orthop*. 2009;80(5):563–567.
10. **Altman DG**, **Schulz KF**, **Moher D**, **et al**. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med*. 2001;134(8):663–694.
11. **Evidence-Based Medicine Working Group**. Evidence-based medicine. A new approach to teaching the practice of medicine. *JAMA*. 1992;268(17):2420–2425.
12. **Prescott RJ**, **Counsell CE**, **Gillespie WJ**, **et al**. Factors that limit the quality, number and progress of randomised controlled trials. *Health Technol Assess*. 1999;3(20):1–143.
13. **McCulloch P**, **Taylor I**, **Sasako M**, **Lovett B**, **Griffin D**. Randomised trials in surgery: problems and possible solutions. *BMJ*. 2002;324(7351):1448–1451.

14. **Matar HE**, **Platt SR**, **Bloch BV**, **James PJ**, **Cameron HU**. A systematic review of randomized controlled trials in anterior cruciate ligament reconstruction: standard techniques are comparable (299 trials with 25,816 patients). *Arthrosc Sports Med Rehabil*. 2021;3(4):e1211–e1226.
15. **Matar HE**, **Platt SR**, **Board TN**, **Porter ML**. Overview of randomized controlled trials in primary total hip arthroplasty (34,020 patients): what have we learnt? *J Am Acad Orthop Surg Glob Res Rev*. 2020;4(8):e20.00120.
16. **Matar HE**, **Platt SR**, **Gollish JD**, **Cameron HU**. Overview of randomized controlled trials in total knee arthroplasty (47,675 patients): what have we learnt? *J Arthroplasty*. 2020;35(6):1729–1736.
17. **Charnley J**. Arthroplasty of the hip. A new operation. *Lancet*. 1961;1(7187):1129–1132.
18. **Evans JT**, **Evans JP**, **Walker RW**, **Blom AW**, **Whitehouse MR**, **Sayers A**. How long does a hip replacement last? A systematic review and meta-analysis of case series and National Registry reports with more than 15 years of follow-up. *Lancet*. 2019;393(10172):647–654.
19. **Bourne RB**, **Chesworth BM**, **Davis AM**, **Mahomed NN**, **Charron KDJ**. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? *Clin Orthop Relat Res*. 2010;468(1):57–63.
20. **Gunaratne R**, **Pratt DN**, **Banda J**, **Fick DP**, **Khan RJK**, **Robertson BW**. Patient dissatisfaction following total knee arthroplasty: a systematic review of the literature. *J Arthroplasty*. 2017;32(12):3854–3860.
21. **Snook GA**. A short history of the anterior cruciate ligament and the treatment of tears. *Clin Orthop Relat Res*. 1983;172:11–13.
22. **No authors listed**. The classic. Operation for repair of the crucial ligaments Ernest W. Hey Groves, MD., F.R.C.S. *Clin Orthop Relat Res*. 1980;147:4–6.
23. **Blom AW**, **Donovan RL**, **Beswick AD**, **Whitehouse MR**, **Kunutsor SK**. Common elective orthopaedic procedures and their clinical effectiveness: umbrella review of level 1 evidence. *BMJ*. 2021;374:n1511.

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