Hip and knee replacement 1

Hip replacement

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This is the first in a **Series** of two papers about hip and knee replacement

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Total hip replacement is a frequently done and highly successful surgical intervention. The procedure is undertaken to relieve pain and improve function in individuals with advanced arthritis of the hip joint. Symptomatic osteoarthritis is the most common indication for surgery. In paper 1 of this Series, we focus on how patient factors should inform the surgical decision-making process. Substantial demands are placed upon modern implants, because patients expect to remain active for longer. We discuss the advances made in implant performance and the developments in perioperative practice that have reduced complications. Assessment of surgery outcomes should include patient-reported outcome measures and implant survival rates that are based on data from joint replacement registries. The high-profile failure of some widely used metal-on-metal prostheses has shown the shortcomings of the existing regulatory framework. We consider how proposed changes to the regulatory framework could influence safety.

Introduction

Modern total hip replacement can improve patient quality of life more than any other elective surgical procedure.[1] Since the pioneering work of Wiles,[2] Charnley, and others in the mid-20th century, implant technology has steadily improved.[3] Now, more than 95% of artificial hip joints survive beyond 10 years, and, despite Charnley's prediction to the contrary, many routinely do so beyond 30 years.[4,5] Although the era of major design innovation is probably over, incremental improvements continue. Research efforts focus on three key goals: extending implant lifespan, improving functional outcomes, and reducing complications. This Series paper is presented as an update of what is new in the specialty of total hip replacement since this topic was last reviewed in *The Lancet* in 2012.[6]

Epidemiology

Worldwide, more than 1 million total hip replacements are done each year.[7] More than 370 000 primary total hip replacements were undertaken in the USA in 2014, and in 2017, 37 000 were done in Australia and 97 000 in the UK.[8–10] The number of primary and revision procedures has historically increased annually in developed countries. Between 2008 and 2017, the number of total hip replacements in the UK rose by 37% (figure 1), with similar increases reported in Sweden, New Zealand, and South Korea.[5,10–12]

During the past decade, global economic downturns has led to questions about the sustainability of growth in joint replacement. In the USA, the growth has proven insensitive to macroeconomic conditions, and the number of primary total hip replacements done annually is projected to reach 512 000 in 2020.[8,13] In the UK, the number of annual primary total hip replacements plateaued for the first time in 2015, before increasing again in 2016.[10] The observed plateau might relate to health-care system factors, including rationing and elective hospital bed availability, rather than a drop in demand.[14]

Search strategy and selection criteria

We searched MEDLINE and PubMed for reports in English published from Jan 1, 1970, to Oct 1, 2018, with the search term "hip" in combination with "replacement", "joint", "arthroplasty", "outcomes", "effectiveness", "epidemiology", and "survivorship". Emphasis was placed on results from randomised trials and registries. We mostly selected publications from 2012, to 2018, but did not exclude common referenced and important older publications. Review articles are cited to provide readers with additional details and references.

Causation

The principal causal indications for total hip replacement are osteoarthritis (which accounted for 90% of procedures in the UK in 2017), fractured neck of femur (5%), avascular necrosis (2%), dysplasia (2%), and inflammatory arthritis (1%).[10] Hip osteoarthritis has multifactorial causes, with biological and mechanical components that are dictated by genetic and environmental factors.[15] Salient patient-specific risk factors include age, sex, trauma, and joint morphology. Femoroacetabular impingement is increasingly recognised as a cause.[16] The association of hip osteoarthritis with obesity is much less strong than that of knee osteoarthritis, for reasons that remain unclear.[17] No strong evidence of an association with diet exists. Worldwide, as populations age, the incidence of osteoarthritis is predicted to rise.

The median age at primary total hip replacement in the UK is 69 years (interquartile range 61–76).[10] The proportion of younger patients undergoing surgery has increased in the USA, and those younger than 65 years are predicted to represent 52% of all patients by 2030.[17] In the UK and Australia, however, the proportion has remained stable: 36% are aged less than 65 years in Australia, and 32% are aged less than 65 years in the UK.[9,10] Total hip replacement remains more commonly

undertaken in women than in men, with a stable ratio of 1·5:1 in the UK, related to discrepancies in osteoarthritis incidence between men and women.[10,15]

Decision making for surgery

The principal clinical indication for total hip replacement is end-stage arthritis, with joint pain and stiffness that is resistant to non-operative treatments. Non-operative treatments include activity modification, physiotherapy, and oral analgesics.[18] Symptoms are not reliably associated with the degree of structural disease on imaging, although surgery is rarely indicated in the absence of full-thickness cartilage loss.[19] In patients with atypical hip pain, intra-articular anaesthetic hip injections have been used as a diagnostic aid; however, whether response to injections predicts outcome from hip replacement remains unclear.[20] Intra-articular corticosteroid injections should be discouraged within 3 months before a planned hip replacement because of a potential increase in risk of infection.[21]

Shared decision making benefits patients and surgeons.[22] Patient-specific predictions of surgery outcomes are central to the decision process, and patients should be provided with clear personalised information. Risk prediction tools, such as the American College of Surgeons' National Surgical Quality Improvement Program risk calculator,[23] which calculates the risk of morbidity and mortality on the basis of preoperative health status, are useful adjuncts. Patient characteristics, including advanced age, obesity, and comorbidities, limit functional improvement after surgery and increase rates of complications.[24] However, the mean improvement in pain and function reported by patients is substantial, regardless of their preoperative state.[25] The presence of patient factors predictive of a poor outcome should not bar patients from surgery; rather, these factors should inform the shared decision-making process.

Operating on patients with high preoperative function and who have spent less time on a waiting list achieves the best functional outcomes after surgery.[26] However, caution should be taken before operating when patients have only early disease, because patients with higher preoperative function are less likely to obtain meaningful functional improvement than those with low preoperative function.[27] Furthermore, age at surgery has a significant effect on revision risk. The lifetime risk of revision for male patients aged 50–54 years is 29·6% (95% CI 26·6–32·6), compared with 7·7% (95% CI 6·9–8·5) for their counterparts aged 70–74 years (figure 2).[4] This large risk differential may lead some patients to delay surgery.

In some countries, the provision of hip replacement relative to the number of people who require the procedure varies geographically. This apparent inequity in access is related to factors of age, sex, deprivation, rurality, and ethnicity.[7,28] Although these factors may influence patient willingness for surgery, differences in provision could be due to variation in practice by general

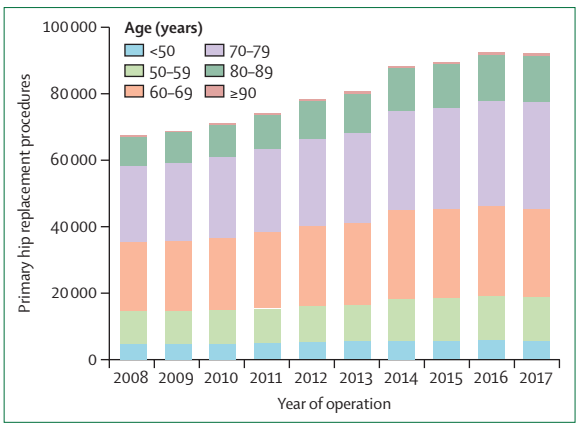

Figure 1: **Distribution of primary hip replacements by age in England and Wales since 2008**
Data are taken from the England and Wales National Joint Registry.[10]

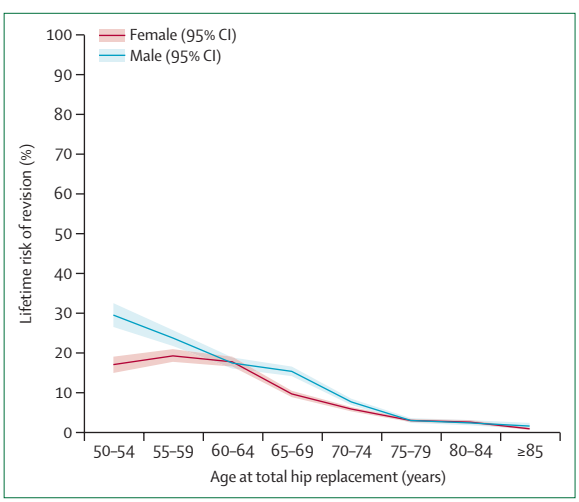

Figure 2: **Lifetime risk of revision after total hip replacement**
Estimates of lifetime risk of total hip replacement revision against age at the time of total hip replacement primary surgery (in 5-year age bands), stratified by sex (results adjusted for lost and censored population). Reproduced by permission of Bayliss and colleagues.[4]

practitioners and surgeons. A study in Canada[29] suggested that the absence of clinical guidelines on when to refer patients for total hip replacement could be responsible for the variation, with 44% of primary care physicians reporting that "lack of clarity regarding surgical indications discouraged them from referral of patients for TJA [total joint arthroplasty]". Although in the UK responsibility to set referral guidelines is deliberately devolved to regional clinical commissioning groups to allow health-care providers to respond to the needs of the local population, harmonising referral guidelines for general practitioners nationwide may minimise variation in practice.

In the UK, the National Institute for Health and Clinical Excellence (NICE) advises that total hip replacement should be done for displaced intracapsular hip fractures in patients who are able to walk independently, are not cognitively impaired, and are medically fit for the

procedure.[30] This advice follows evidence that the operation leads to improved hip function and quality of life compared with hemiarthroplasty in this cohort.[31] However, compliance remains poor, and only 37% of patients meeting the criteria had a total hip replacement and 42% of patients receiving the procedure did not satisfy the criteria.[32]

Assessment of outcome

The primary method used to assess the outcome of surgery is Kaplan-Meier survival analysis with revision surgery as the endpoint. Revision hip replacement refers to the exchange of one or more components of the prosthetic hip. Associated with greater complications and poorer functional outcomes than primary hip replacement, the procedure is only indicated when serious adverse symptoms, including pain or fracture, have occurred or are predicted.[10]

Joint replacement registries are powerful resources for tracking the revision rate of individual implants. Since the first hip arthroplasty registry was established in Sweden 40 years ago, they have proven successful in identifying devices with high failure rates.[33] Geographical coverage has steadily spread, with the International Society of Arthroplasty Registries counting members in 25 countries. In England and Wales, the National Joint Registry (NJR) has gathered data for 1 million hip replacements since 2003; the NJR reports an overall 14-year implant survival of 92·7% (95% CI, 92·6–92·9).[10] Additional data collection enables analysis of the comparative influence of patient, procedure, hospital, and surgeon factors. Revision outcomes are not reported for individual surgeons at present. This is due to the concern that without adequate consideration of patient factors, the publication of these data could influence clinical decisions to operate, for both primary and revision procedures.

Compliance with reporting surgical revision is essential for making robust inferences from registry data. An audit found that 95% of primary and 90% of revision hip replacements done in UK National Health Service (NHS) hospitals were recorded in the NJR;[10] the lower accuracy of recording revisions is concerning because it leads to the overestimation of implant performance. Whether the missing data represent random events or potential bias is under investigation.

The use of revision surgery as the only outcome measure has limitations because patients can have complications, pain, or poor function without having a revision. Indeed, within 5 years of hip replacement, 10% of patients can have continuing pain or poor joint function.[34] Patient-reported outcome scores that measure pain, function, quality of life, and satisfaction are used alongside survival analysis to assess the outcome of hip replacement. Although complications that do not require revision are not recorded by the NJR, two patient-reported outcomes are now routinely recorded: the Oxford Hip Score, which measures pain and functional status, and the EuroQol five-domain score, which assesses quality of life.[35,36]

In the UK, patient-reported outcomes are increasingly used by clinical commissioning groups as criteria for referral to secondary care. Patients with scores higher than a locally set threshold will not be referred, despite scores not being validated for this purpose.[37] Additionally, patient-reported outcomes are influenced by age and comorbidities, making a universal threshold a poor discriminator.[38]

The financial burden of hip replacement on health-care systems is high. In the USA alone, the annual cost is in excess of US$15 billion.[39] The cost per quality-adjusted life-year (QALY) gained with hip replacement is between $1500 and $10 402.[40,41] This value is much less than the threshold of £20 000–30 000 per QALY selected by NICE to guide cost-effectiveness appraisals of new technologies.[42] Furthermore, evidence suggests that in the long term arthroplasty leads to health-care cost savings, with a reduction in cost of $278 every year per patient compared with an increase of $1978 every year per matched, non-operated control patient.[43] In patients who do not have a very limited life expectancy, hip replacement is a cost-effective intervention.

Causes of revision

The most commonly recorded indication for revision is aseptic loosening, accounting for 48% of revision procedures in the NJR.[10] Aseptic loosening is most frequently caused by wear of the bearing surfaces that generates particulate debris within the effective joint space. Macrophages phagocytose the foreign debris and initiate a tumour necrosis factor-α-mediated inflammatory cascade that increases osteoclast activity with net bone resorption and loss of implant fixation.[44]

Dislocation affects 0·2–10% of patients after hip replacement, with 77% of them affected within the first year.[45] Age, muscle tone, non-compliance with avoidance of specific movements, surgical approach, and component position and size influence the dislocation rate.[45] Dislocation accounts for 15% of revision operations.[10]

Periprosthetic joint infection is a devastating complication of arthroplasty, and causes pain, loss of function, systemic illness, or death. The incidence within 2 years of surgery is 1–2%.[46] Microbes create biofilms on implant surfaces, reducing antibiotic penetrance.[47] Surgical intervention is typically required, with debridement and implant retention, or one-stage or two-stage revision, which account for 9% of all revision procedures. Other common indications for revision include periprosthetic fracture (10%) and implant malpositioning (5%).[10]

Indications for revision vary by patient demographic. In patients younger than 55 years at primary surgery, aseptic loosening is the most frequent indication, whereas in patients older than 84 years, dislocation, periprosthetic fracture, and infection are more frequent.[48]

Advances in practice

Adults aged 65–74 years in England spend an average of 6·5 h per week engaged in physical activity.[49] High

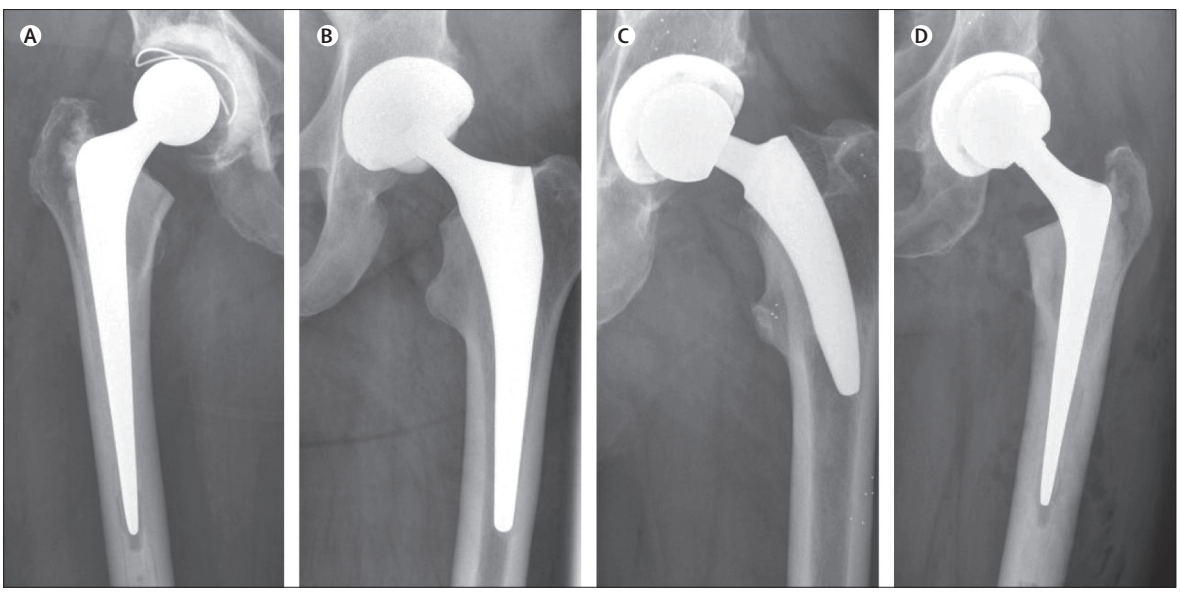

Figure 3: **Total hip replacement with different implant designs and fixation**
Postoperative radiographs of cemented total hip replacement (A); cementless total hip replacement (B), with conventional length femoral stem; cementless total hip replacement, with short length femoral stem (C); and hybrid total hip replacement (D).

demands are placed upon implants, and the development of devices with improved wear characteristics is a key challenge.

The femoral head and acetabular cup articulate at the bearing interface. The ideal bearing interface is chemically inert in vivo, has a low wear rate, produces non-immunogenic wear debris, and is sufficiently tough to resist fracture. In the UK in 2017,[10] implants with metal-on-polyethylene bearings were used in 57% of procedures, those with ceramic-on-polyethylene bearings in 33% of procedures, and those with ceramic-on-ceramic bearings in 9% of procedures.

Early metal-on-polyethylene bearings had high failure rates within 14 years because the softer polyethylene produced wear debris.[9] However, modern highly cross-linked polyethylene is more resistant than the early materials, and registry analysis has found no difference in mid-term revision rates between modern metal-on-polyethylene, ceramic-on-polyethylene, and ceramic-on-ceramic bearings.[9,50] With minimal differences in revision rate, consideration of other factors may guide which bearing to select. Modern ceramic-on-ceramic bearings do not have the increased risk of implant fracture associated with earlier, more brittle, implants, although they are more expensive than other bearings and can make a squeaking sound.[51]

Metal-on-metal prostheses gained popularity 20 years ago because of lower bearing-surface linear wear than metal-on-polyethylene prostheses. Implantation peaked in 2008 at 21% of all prostheses, when analysis of registry data identified much poorer outcomes than for other types of implant.[9] Overall, cementless metal-on-metal total hip replacements have a revision rate of 18·2% (95% CI 17·7–18·8) after 10 years.[10] Since 2011, these types of hip replacements have accounted for less than 1% of all prostheses implanted, and are almost exclusively femoral head resurfacing procedures.

Failure of metal-on-metal implants is due to metal ion debris generated at the bearing surface. The debris can trigger an adverse immunological reaction, resulting in localised bone destruction and soft tissue necrosis. For patients with metal-on-metal implants, the early identification of adverse soft tissue reactions and prompt revision surgery leads to improvement in clinical outcomes. The Medicines and Healthcare Products Regulatory Agency has issued specific recommendations for screening of these patients, which include regular blood metal ion testing, functional assessment, and imaging.[52] Concerns that metal-on-metal implants could be associated with an increased incidence of cancer, through systemic metal ion exposure, remain unproven, with long-term follow-up taking place.[53]

There has been a trend towards larger diameter femoral heads in the past decade.[10] Increased size of femoral heads decreases the incidence of dislocation after hip replacement, because larger heads permit a greater range of movement before impingement occurs than do those of a smaller size.[54] Previous concerns limiting the use of large diameter heads related to evidence that these implants lead to increased volumetric wear of polyethylene; however, with modern generations of highly cross-linked polyethylene, the larger articulations do not appear to increase wear compared with smaller articulations.[55]

continues about the best method of fixation in total hip replacement (figure 3). fixation continues to show revision rates, and

achieves a overall rate of after 14 years than does cementless fixation (figure 4);[9,10,56] higher failure rates of implants with cementless fixation have been proposed to represent failure of early fixation.

fixation, however, may have lower revision rates than cemented fixation e,[57] and lead to rates of in patients than 65 years.[58] The technique also the of cement-related complications.[59] fixation is the method used in , the , and the .

Acetabular aseptic loosening was identified as a major cause of failure of cemented implants in young patients aged less than age 60 years.[60] Hybrid fixation, with cemented femoral and cementless acetabular components, was developed as an alternative, and achieves 14-year outcomes that are superior to cementless but inferior to cemented fixation.[10]

Interest in short cementless femoral stems is growing. These designs preserve proximal bone stock and allow more physiological loading, which is proposed to result in less stress-shielding, thigh pain, and invasive revision surgery. Stem malpositioning and subsidence have been reported with some designs, while other designs have achieved equivalent fixation and functional outcomes to conventional cementless stems after 10 years.[61,62]

Posterior and lateral surgical approaches, which account for 95% of hip replacements in the UK, share excellent outcomes.[10] The use of the posterior approach has increased over the past decade at the expense of the lateral approach. This increase could be explained by increasing evidence that the posterior approach is associated with superior patient-reported outcomes and no increased risk of dislocation.[63,64]

The desire to do hip replacements with less soft tissue disruption has driven interest in minimally invasive surgical approaches. One such technique is the direct anterior approach. Despite early reports promising superior outcomes, systematic reviews found no significant difference in overall complication rate, dislocation rate, gait, and patient function beyond 6 weeks postoperatively compared with traditional approaches. Evidence of the effect on fracture rate and length of stay is conflicting.[65,66] At present, the approach is used in fewer than 5% of procedures in the UK, Sweden, and New Zealand. Other minimally invasive approaches, including the direct-superior, percutaneously-assisted total hip and supercapsular approaches, use a modified posterior incision and allow joint access without disrupting the external rotator muscles. Case series have reported low complication and dislocation rates.[67] However, long-term follow up for all minimally invasive surgical approaches is required.

Malpositioning of acetabular and femoral components can result in impingement, increased bearing surface wear, dislocation, and need for revision.[68] Computer-assisted surgery systems have been developed for use in hip replacement, with the aim of increasing the accuracy

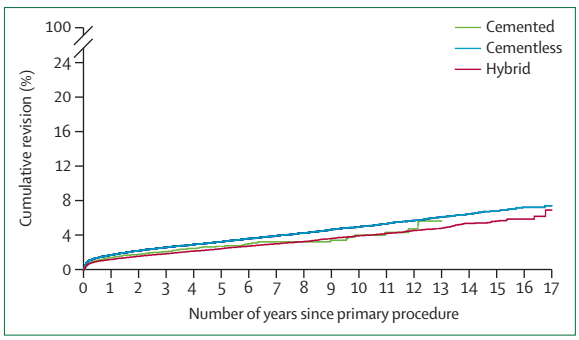

Figure 4: **Cumulative percentage revision of primary total hip replacement by fixation (primary diagnosis of osteoarthritis)**
Reproduced from the Australian Orthopaedic Association's annual report[9] by permission of the Australian Orthopaedic Association National Joint Replacement Registry.

and reliability with which implants are positioned. A spectrum of techniques exists from passive computer navigation, through patient-specific instrumentation, to active robotic-assisted surgery. Interest in the techniques is high, with 20 000 robotic-assisted total hip replacements being done in the USA in 2016.[69]

Computer navigation guides surgeons intraoperatively using anatomic data, from preoperative CT images, intraoperative fluoroscopic images, or imageless intraoperative registration of bony landmarks. A meta-analysis of 473 patients found that computer navigation results in increased precision of acetabular component positioning compared with manual placement.[70] Evidence of superior clinical outcomes, however, has not been shown. By contrast, for knee replacement, data from Australia suggested computer navigation reduces revision rates for patients younger than 65 years.[71] The reasons for this difference remain unclear.

Robotic-assisted surgery systems in orthopaedics make use of strategies distinct from those in soft-tissue surgery. The systems use detailed imaging data and monitor for any deviation from a predetermined surgical plan. Some systems provide haptic feedback to surgeons to prevent bone resection outside planned limits, whereas others terminate bone milling automatically. Improved accuracy of acetabular positioning is achieved, but the effect on clinical outcome is unproven.[72] A single-centre cohort study reported lower dislocation rates after robotic-assisted hip replacement than after manual hip replacement, but further study is required.[73]

Patient-specific instrumentation uses three-dimensional templates printed from preoperative images. The techniques are proposed to improve acetabular positioning, without the substantial time burden associated with robotic surgery.[74] However, as with other computer-assisted surgery systems, appropriately powered studies with long-term follow up are required to establish if there is a benefit in function and survivorship.

Preoperative, perioperative, and postoperative optimisation programmes, collectively termed fast-track surgery

programmes, can be used to reduce complications, and expedite and maximise rehabilitation. A multimodal approach, including medical and nutritional optimisation, pain management, exercise, early mobilisation, and discharge planning, is most successful. A cohort study of patients who had had elective orthopaedic surgery found that comprehensive geriatric optimisation reduced rates of postoperative pneumonia, delirium, pressure sores, and poor pain control, and shortened length of hospital stay compared with routine care.[75]

Spinal anaesthesia is associated with reduced odds of cardiac arrest, stroke, unplanned intubation, and minor adverse events compared with general anaesthesia.[76] Multimodal analgesia regimens allow earlier rehabilitation and improve patient satisfaction than conventional analgesia regimens.[77] Local infiltration analgesia may have equivalent efficacy to epidural analgesia and peripheral nerve blockage, but with reduced side-effects. Local anaesthetic, non-steroidal anti-inflammatory drugs, steroids, adrenaline, and opiates can be used in combination; however, no local infiltration regimen has yet shown superiority.[78]

Balancing the competing risks of venous thromboembolic disease and requirement for blood transfusion is complex. Allogeneic blood transfusion is an independent predictor of in-hospital mortality, and increases the risk of venous thromboembolism, and resulting immunomodulation might increase susceptibility to postoperative infection.[79] NICE recommends tranexamic acid for all hip arthroplasty procedures.[80] This compound reduces transfusion rates with no increase in thromboembolic events.[81] The optimal route, dose, and timing of administration has not been established, although combined topical and intravenous administration might be more effective at reducing blood loss than intravenous administration alone.[82]

NICE recommends mechanical and pharmacological venous thromboembolism prophylaxis after hip replacement.[80] The choice of which agent to use is patient specific. Direct oral anticoagulants have shown superior efficacy than low molecular-weight heparin, but might be associated with an increased bleeding risk.[83] The EPCAT trials[84,85] found that extended prophylaxis with aspirin after total hip replacement was not significantly different from rivaroxaban (5 days after surgery) and low molecular-weight heparin (10 days after surgery) in the prevention of symptomatic venous thromboembolism. The influence of anticoagulation on infection remains unclear. Several single-centre studies have suggested that rivaroxaban increases the risk of surgical site infection after hip replacement compared with other types of pharmacological prophylaxis; however, the RECORD clinical trial programme found no statistical difference.[86,87]

Reduced length of hospital stay after hip replacement seems safe; discharge within 2 days of surgery does not increase the risk of complications or readmission in patients who are risk stratified.[88] There is no consensus about the optimum protocol of postoperative exercise programmes. Evidence suggests that formal outpatient physiotherapy after total hip replacement might not be required, and instead unsupervised home exercise is safe and effective for most patients.[89]

An international consensus on the management of periprosthetic joint infection was published in 2013, with an update due this year, to unify the definition, prevention, and treatment of this complication.[90] Diagnostic challenges remain. Clinical signs are non-specific; inflammatory markers can be raised for 2 months after surgery, and synovial fluid cultures do not identify an organism in 30% of infections. A combination of serological, histological, and microbiological tests are used to support a diagnosis according to the validated international consensus definition.[91] Synovial fluid biomarkers, such as leucocyte esterase and a neutrophil-secreted antimicrobial peptide called α-defensin, may also aid diagnosis with a high sensitivity and specificity.[92,93] Two-stage revision has been seen as the gold standard to eradicate periprosthetic joint infection, although single-stage revision is used routinely in some units, given the reduced operative burden. Registry data showed that the risk of re-revision for infection was two times higher for one-stage revision than for two-stage revision.[94] However, evidence suggests debridement and implant retention can successfully eradicate infection within 6 weeks of the index surgery.[95]

Regulation and surveillance

In the past 10 years, high-profile litigation cases involving several surgical specialties have been brought in response to the insertion of medical devices with unacceptable complication rates. Investigations following the vaginal mesh and the Poly Implant Prothèse silicone breast implant cases, both of which caused enormous distress to thousands of patients, suggested that the regulatory process governing the introduction of these medical devices was inadequate.[96] Within orthopaedics, the discovery of high failure rates of metal-on-metal hip replacements that had been implanted into a million patients worldwide similarly led to calls to reform the regulatory process.[97]

Two pathways exist for a new hip replacement implant to gain approval to use the Conformité Européene (CE) mark and be sold across the EU. Approval can be granted in response to evidence of a successful premarket clinical investigation, showing safety and effectiveness of the device. Alternatively, approval can be granted simply in response to developers showing equivalence of the device to existing approved devices, termed predicates. Premarket clinical investigations require substantial time and resources, hence developers have a strong incentive to identify appropriate predicates. This pathway allows for approval of implants for which the design does not deviate substantially from the predicates; however, even a small design modification can have an important effect on implant performance.[98] Authority to issue CE marking for

medical devices is devolved to private companies, termed notified bodies, with developers being able to apply to any of the 59 bodies that are registered across Europe.

In the USA, two equivalent pathways exist. However, these pathways are regulated centrally by the US Food and Drug Administration (FDA), ensuring consistent standards, but on average the approval process takes longer than in Europe.[99] Unlike in Europe, where the evidence underpinning approval of a device is considered commercially confidential and is not publicly available, the FDA publishes the evidence on its website, permitting external scrutiny.

In an attempt to improve safety, new regulations were published by the EU in 2017, which will apply fully from 2020.[100] Evidence required to show equivalence to a predicate will be stricter than previously, and notified bodies will undergo more rigorous spot checks; after CE approval, devices will have to adhere to a specified postmarket surveillance plan, and premarket clinical investigations and postmarket surveillance plans will be overseen by a central coordination group. Although these improved regulations are welcome, potential weaknesses remain: no minimum cohort size has been defined for the pre-CE clinical investigation, which might allow low-quality studies to be done; applicants can still draw on multiple predicates, which could enable a device to be approved despite substantial design changes; and no requirement exists for stepwise introduction after CE approval, as is the case with medicines.

A key challenge in developing regulations is seeking a balance between promoting innovation and preventing harm to patients. The consensus view is that the safety benefits of stepwise introduction, with several phases of increasing cohort size, outweigh the drawbacks of delaying widespread device implantation. Difficulty arises because the identification of an implant with an inferior lifespan can take many years, even in national registries. Early device assessment could be supported by radiostereometric analysis.[101] The technique detects migration of the implant relative to bone, which permits predictions of long-term implant failure due to aseptic loosening.

Benchmarking

NICE advises that only prostheses with rates (projected or actual) of revision of 5% or less at 10 years are implanted outside clinical trials.[102] To supply the NHS with a list of approved prostheses, the Orthopaedic Device Evaluation Panel (ODEP) was created in 2002. The volunteer-led panel considers data on revision rate from manufacturers, registries, and independent studies, and issues a rating for each device. Implants are first rated once 3-year revision rate data have been obtained, with ratings updated at specified time intervals.

Before the first outcome assessment, a different approach is required. Implants can achieve the top pre-entry ODEP rating if they are registered with the Beyond Compliance scheme, which promotes the safe introduction of implants through close monitoring. ODEP has proved highly successful, and, in the absence of equivalent service evaluation systems, ODEP has been adopted by many health-care systems worldwide.

Health service design

Surgeons doing a high volume of total hip replacements have better outcomes than those who do a low volume of these procedures, including lower risk of dislocation and revision. A threshold of 35 cases per year has been proposed as a minimum cutoff for primary total hip replacement.[103] In the UK, the Getting It Right First Time initiative found that 24% of surgeons do ten or fewer procedures per year.[104] However, the relation between volume and outcomes is complex; there is no evidence that increasing the volume of operations performed by low-volume surgeons to above 35 cases per year would lead to better outcomes. Additionally, hospitals in which a high volume of procedures are done have low rates of complications, including dislocation and mortality.[105] The degree to which services should be regionalised to larger centres requires a balance between outcomes, efficiency, feasibility, and patient preference.

Conclusion

Hip replacement remains one of the most effective surgical interventions. This procedure has enabled millions of patients with severe hip pain and functional limitation to regain a high quality of life. Further advances have been made in implant material and design, surgical technique, and perioperative management. Most patients can expect their prosthesis to function without complications for more than 20 years. Ongoing challenges include further improvements to implant performance for young patients and older patients who are active, ensuring the safe introduction of new implants, and developing strategies to identify osteoarthritis early and slow its progression, to reduce the number of patients requiring major surgery.

Contributors

RJF, AJRP, and SG-J wrote the first draft. All authors reviewed and edited the subsequent drafts.

Declaration of interests

AT has received consultancy fees from Zimmer/Biomet, DePuy, and Corin. HM has received research support from Zimmer/Biomet and DePuy, has received consultancy fees from Zimmer/Biomet, holds stock in RSA Medical, and receives royalties from MAKO/Stryker. SG-J has received consultancy fees from Zimmer/Biomet, Corin, Stryker, and Conmed. RJF, AJRP, and MLP declare no competing interests.

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References

1 NHS Digital. Provisional quarterly patient reported outcome measures (PROMs) in England. 2017. https://digital.nhs.uk/catalogue/PUB23060 (accessed Oct 1, 2018).

2 Wiles P. The surgery of the osteo-arthritic hip. *Br J Surg* 1958; **45:** 488–97.

3 Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. *Lancet* 2007; **370:** 1508–19.

4 Bayliss LE, Culliford D, Monk AP, et al. The effect of patient age at intervention on risk of implant revision after total replacement of the hip or knee: a population-based cohort study. *Lancet* 2017; **389:** 1424–30.

5 Swedish Hip Arthroplasty Register. The Swedish Hip Arthroplasty Register: annual report. 2016. https://shpr.registercentrum.se/shar-in-english/annual-reports-from-the-swedish-hip-arthroplasty-register/p/rkeyyeElz (accessed Oct 1, 2018).

6 Pivec R, Johnson AJ, Mears SC, Mont MA. Hip arthroplasty. *Lancet* 2012; **17:** 1768–77.

7 Organisation for Economic Co-operation and Development. OECD health data. 2017. http://dx.doi.org/10.1787/health-data-en (accessed Oct 1, 2018).

8 Agency for Healthcare Research and Quality, USA. HCUPnet: 2014 national procedures for ICD-9-CM principal procedure code 81.51. 2017. https://hcupnet.ahrq.gov/#setup (accessed Oct 1, 2018).

9 Australian Orthopaedic Association. Australian National Joint Replacement Registry annual report 2018. 2018. https://aoanjrr.sahmri.com/annual-reports-2018 (accessed Oct 1, 2018).

10 National Joint Registry. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man: 15th annual report. 2018. http://www.njrreports.org.uk/ (accessed Oct 1, 2018).

11 Hooper G, Lee AJ-J, Rothwell A, Frampton C. Current trends and projections in the utilisation rates of hip and knee replacement in New Zealand from 2001 to 2026. *NZ Med J* 2014; **127:** 82–93.

12 Yoon PW, Lee Y-K, Ahn J, et al. Epidemiology of hip replacements in Korea from 2007 to 2011. *J Korean Med Sci* 2014; **29:** 852–58.

13 Kurtz SM, Ong KL, Lau E, Bozic KJ. Impact of the economic downturn on total joint replacement demand in the United States. *J Bone Joint Surg Am* 2014; **96:** 624–30.

14 Robertson R, Wenzel L, Thompson J, Charles A. Understanding NHS financial pressures: how are they affecting patient care? 2017. https://www.kingsfund.org.uk/publications/understanding-nhs-financial-pressures (accessed Oct 1, 2018).

15 Glyn-Jones S, Palmer AJR, Agricola R, et al. Osteoarthritis. *Lancet* 2015; **386:** 376–87.

16 Bowler DJM, Flandry F. Prevalence of femoroacetabular impingement in younger patients undergoing total hip arthroplasty. *J Surg Orthop Adv* 2012; **21:** 122–25.

17 Kurtz SM, Lau E, Ong K, Zhao K, Kelly M, Bozic KJ. Future young patient demand for primary and revision joint replacement: national projections from 2010 to 2030. *Clin Orthop Relat Res* 2009; **467:** 2606–12.

18 National Institute for Health and Clinical Excellence. Osteoarthritis: care and management guidelines. 2014. https://www.nice.org.uk/guidance/cg177 (accessed Oct 1, 2018).

19 Kinds MB, Welsing PMJ, Vignon EP, et al. A systematic review of the association between radiographic and clinical osteoarthritis of hip and knee. *Osteoarthr Cartil* 2011; **19:** 768–78.

20 Dorleijn DMJ, Luijsterburg PAJ, Bierma-Zeinstra SMA, Bos PK. Is anesthetic hip joint injection useful in diagnosing hip osteoarthritis? a meta-analysis of case series. *J Arthroplasty* 2014; **29:** 1236–42.

21 Werner BC, Cancienne JM, Browne JA. The timing of total hip arthroplasty after intraarticular hip injection affects postoperative infection risk. *J Arthroplasty* 2016; **31:** 820–23.

22 Bozic KJ, Belkora J, Chan V, et al. Shared decision making in patients with osteoarthritis of the hip and knee: results of a randomized controlled trial. *J Bone Joint Surg Am* 2013; **95:** 1633–39.

23 Bilimoria KY, Liu Y, Paruch JL, et al. Development and evaluation of the universal ACS NSQIP surgical risk calculator: a decision aid and informed consent tool for patients and surgeons. *J Am Coll Surg* 2013; **217:** 833–42.

24 Gordon M, Paulsen A, Overgaard S, Garellick G, Pedersen AB, Rolfson O. Factors influencing health-related quality of life after total hip replacement—a comparison of data from the Swedish and Danish hip arthroplasty registers. *BMC Musculoskelet Disord* 2013; **14:** 316.

25 Judge A, Arden NK, Batra RN, et al. The association of patient characteristics and surgical variables on symptoms of pain and function over 5 years following primary hip-replacement surgery: a prospective cohort study. *BMJ Open* 2013; **3:** e002453.

26 Vergara I, Bilbao A, Gonzalez N, Escobar A, Quintana JM. Factors and consequences of waiting times for total hip arthroplasty. *Clin Orthop Relat Res* 2011; **469:** 1413–20.

27 Berliner JL, Brodke DJ, Chan V, SooHoo NF, Bozic KJ. John Charnley Award: preoperative patient-reported outcome measures predict clinically meaningful improvement in function after THA. *Clin Orthop Relat Res* 2016; **474:** 321–29.

28 Judge A, Welton NJ, Sandhu J, Ben-Shlomo Y. Equity in access to total joint replacement of the hip and knee in England: cross sectional study. *BMJ* 2010; **341:** c4092.

29 Waugh EJ, Badley EM, Borkhoff CM, et al. Primary care physicians' perceptions about and confidence in deciding which patients to refer for total joint arthroplasty of the hip and knee. *Osteoarthr Cartil* 2016; **24:** 451–57.

30 National Institute for Health and Clinical Excellence. Hip fracture: management guidelines. 2017. https://www.nice.org.uk/guidance/cg124 (accessed Oct 1, 2018).

31 Hedbeck CJ, Enocson A, Lapidus G, et al. Comparison of bipolar hemiarthroplasty with total hip arthroplasty for displaced femoral neck fractures: a concise four-year follow-up of a randomized trial. *J Bone Joint Surg Am* 2011; **93:** 445–50.

32 Perry DC, Metcalfe D, Griffin XL, Costa ML. Inequalities in use of total hip arthroplasty for hip fracture: population based study. *BMJ* 2016; **353:** i2021.

33 de Steiger RN, Hang JR, Miller LN, Graves SE, Davidson DC. Five-year results of the ASR XL acetabular system and the ASR hip resurfacing system. *J Bone Joint Surg Am* 2011; **93:** 2287–93.

34 Beswick AD, Wylde V, Gooberman-Hill R, Blom AW, Dieppe P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. *BMJ Open* 2012; **2:** e000435.

35 Dawson J, Fitzpatrick R, Carr AJ, Murray D. Questionnaire on the perceptions of patients about total hip replacement. *J Bone Joint Surg Br* 1996; **78–B:** 185–90.

36 Devlin NJ, Brooks R. EQ-5D and the EuroQol Group: past, present and future. *Appl Health Econ Health Policy* 2017; **15:** 127–37.

37 Robb C, McBryde C, Caddy S, Thomas A, Pynsent P. Oxford scores as a triage tool for lower limb arthroplasty lead to discrimination and health inequalities. *Ann R Coll Surg Engl* 2013; **95:** 1–4.

38 Bremner-Smith AT, Ewings P, Weale AE. Knee scores in a 'normal' elderly population. *Knee* 2004; **11:** 279–82.

39 Lavernia CJ, Hernandez VH, Rossi MD. Payment analysis of total hip replacement. *Curr Opin Orthop* 2007; **18:** 23–27.

40 Vogl M, Wilkesmann R, Lausmann C, Plötz W. The impact of preoperative patient characteristics on the cost-effectiveness of total hip replacement: a cohort study. *BMC Health Serv Res* 2014; **14:** 342.

41 Daigle ME, Weinstein AM, Katz JN, Losina E. The cost-effectiveness of total joint arthroplasty: a systematic review of published literature. *Best Pract Res Clin Rheumatol* 2012; **26:** 649–58.

42 National Institute of Health and Care Excellence. Guide to the methods of technology appraisal. 2013. https://www.nice.org.uk/process/pmg9/chapter/foreword (accessed Oct 1, 2018).

43 Hawker GA, Badley EM, Croxford R, et al. A population-based nested case-control study of the costs of hip and knee replacement surgery. *Med Care* 2009; **47:** 732–41.

44 Sundfeldt M, V Carlsson L, B Johansson C, Thomsen P, Gretzer C. Aseptic loosening, not only a question of wear: a review of different theories. *Acta Orthop* 2006; **77:** 177–97.

45 Dargel J, Oppermann J, Brüggemann G-P, Eysel P. Dislocation following total hip replacement. *Dtsch Arztebl Int* 2014; **111:** 884–90.

46 Lindgren V, Gordon M, Wretenberg P, Kärrholm J, Garellick G. Deep infection after total hip replacement: a method for national incidence surveillance. *Infect Control Hosp Epidemiol* 2014; **35:** 1491–96.

47 Gbejuade HO, Lovering AM, Webb JC. The role of microbial biofilms in prosthetic joint infections: a review. *Acta Orthop* 2015; **86:** 147–58.

48 Geneva Joint Arthroplasty Registry. Geneva Joint Arthroplasty Registry: annual report. 2017. http://www.rpa.spot.pt/getdoc/0071e52c-7cdf-4d4e-86f7-5266c8b15bfb/The-Geneva-Hip-Arthroplasty-Registry_E-BOOK_Table-.aspx (accessed Oct 1, 2018).

49 British Heart Foundation Centre on Population Approaches for Non-Communicable Disease Prevention. Nuffield Department of Population Health University of Oxford. Physical activity statistics. 2015. https://www.bhf.org.uk/informationsupport/publications/statistics/physical-activity-statistics-2015 (accessed Oct 1, 2018).

50 Wyles CC, Jimenez-Almonte JH, Murad MH, et al. There are no differences in short- to mid-term survivorship among total hip-bearing surface options: a network meta-analysis. *Clin Orthop Relat Res* 2015; **473:** 2031–41.

51 Massin P, Lopes R, Masson B, Mainard D, French Hip & Knee Society (SFHG). Does Biolox® Delta ceramic reduce the rate of component fractures in total hip replacement? *Orthop Traumatol Surg Res* 2014; **100:** S317–21.

52 Medicines and Healthcare products Regulatory Agency, Medicines & Healthcare products Regulatory Agency. All metal-on-metal (MoM) hip replacements: updated advice for follow-up of patients. 2017. https://assets.publishing.service.gov.uk/media/5954ca1ded915d0baa00009b/MDA-2017-018_Final.pdf (accessed Oct 1, 2018).

53 Smith AJ, Dieppe P, Porter M, Blom AW, National Joint Registry of England and Wales. Risk of cancer in first seven years after metal-on-metal hip replacement compared with other bearings and general population: linkage study between the National Joint Registry of England and Wales and hospital episode statistics. *BMJ* 2012; **344:** e2383.

54 Howie DW, Holubowycz OT, Middleton R, Group LAS. Large femoral heads decrease the incidence of dislocation after total hip arthroplasty: a randomized controlled trial. *J Bone Joint Surg Am* 2012; **94:** 1095–102.

55 Howie DW, Holubowycz OT, Callary SA. The wear rate of highly cross-linked polyethylene in total hip replacement is not increased by large articulations: a randomized controlled trial. *J Bone Joint Surg Am* 2016; **98:** 1786–93.

56 Wroblewski BM, Siney PD, Fleming PA. Charnley low-friction arthroplasty: survival patterns to 38 years. *J Bone Joint Surg Br* 2007; **8989:** 1015–18.

57 Kallala R, Anderson P, Morris S, Haddad FS. The cost analysis of cemented versus cementless total hip replacement operations on the NHS. *Bone Joint J* 2013; **95–B:** 874–76.

58 Hooper GJ, Rothwell AG, Stringer M, Frampton C, Stringer M, Frampton C. Revision following cemented and uncemented primary total hip replacement A seven-year analysis from the New Zealand Registry. *J Bone Joint Surg Br* 2009; **9191:** 451–58.

59 Donaldson AJ, Thomson HE, Harper NJ, Kenny NW. Bone cement implantation syndrome. *Br J Anaesth* 2009; **102:** 12–22.

60 Berry DJ, Harmsen WS, Cabanela ME, Morrey BF. Twenty-five-year survivorship of two thousand consecutive primary Charnley total hip replacements: factors affecting survivorship of acetabular and femoral components. *J Bone Joint Surg* 2002; **84-A:** 171–77.

61 Liang HD, Yang WY, Pan JK, et al. Are short-stem prostheses superior to conventional stem prostheses in primary total hip arthroplasty? A systematic review and meta-analysis of randomised controlled trials. *BMJ Open* 2018; **8:** e021649.

62 Loppini M, Grappiolo G. Uncemented short stems in primary total hip arthroplasty. *EFORT Open Rev* 2018; **3:** 149–59.

63 Jolles BM, Bogoch ER. Posterior versus lateral surgical approach for total hip arthroplasty in adults with osteoarthritis. *Cochrane Database Syst Rev* 2006; **3:** CD003828.

64 Lindgren JV, Wretenberg P, Karrholm J, Garellick G, Rolfson O. Patient-reported outcome is influenced by surgical approach in total hip replacement: a study of the Swedish Hip Arthroplasty Register including 42 233 patients. *Bone Joint J* 2014; **96–B:** 590–96.

65 Meermans G, Konan S, Das R, Volpin A, Haddad FS. The direct anterior approach in total hip arthroplasty: a systematic review of the literature. *Bone Joint J* 2017; **99–B:** 732–40.

66 Maratt JD, Gagnier JJ, Butler PD, Hallstrom BR, Urquhart AG, Roberts KC. No difference in dislocation seen in anterior *vs* posterior approach total hip arthroplasty. *J Arthroplasty* 2016; **31:** 127–30.

67 Chow J, Penenberg B, Murphy S. Modified micro-superior percutaneously-assisted total hip: early experiences & case reports. *Curr Rev Musculoskelet Med* 2011; **4:** 146–50.

68 Grammatopoulos G, Thomas GER, Pandit H, Beard DJ, Gill HS, Murray DW. The effect of orientation of the acetabular component on outcome following total hip arthroplasty with small diameter hard-on-soft bearings. *Bone Joint J* 2015; **97–B:** 164–72.

69 StrykerMako. Stryker sales data 2016. 2017. https://www.stryker.com/content/stryker/us/en/joint-replacement/systems/mako-total-hip.html (accessed Oct 1, 2018).

70 Li Y-L, Jia J, Wu Q, Ning G-Z, Wu Q-L, Feng S-Q. Evidence-based computer-navigated total hip arthroplasty: an updated analysis of randomized controlled trials. *Eur J Orthop Surg Traumatol* 2014; **24:** 531–38.

71 de Steiger RN, Liu Y-L, Graves SE. Computer navigation for total knee arthroplasty reduces revision rate for patients less than sixty-five years of age. *J Bone Joint Surg Am* 2015; **97:** 635–42.

72 Domb BG, El Bitar YF, Sadik AY, Stake CE, Botser IB. Comparison of robotic-assisted and conventional acetabular cup placement in THA: a matched-pair controlled study. *Clin Orthop Relat Res* 2014; **472:** 329–36.

73 Illgen RL, Bukowski BR, Abiola R, et al. Robotic-assisted total hip arthroplasty: outcomes at minimum two-year follow-up. *Surg Technol Int* 2017; **30:** 365–72.

74 Spencer-Gardner L, Pierrepont J, Topham M, Baré JV, McMahon S, Shimmin AJ. Patient-specific instrumentation improves the accuracy of acetabular component placement in total hip arthroplasty. *Bone Joint J* 2016; **98–B:** 1342–46.

75 Harari D, Hopper A, Dhesi J, Babic-Illman G, Lockwood L, Martin F. Proactive care of older people undergoing surgery ('POPS'): designing, embedding, evaluating and funding a comprehensive geriatric assessment service for older elective surgical patients. *Age Ageing* 2007; **36:** 190–96.

76 Basques BA, Toy JO, Bohl DD, Golinvaux NS, Grauer JN. General compared with spinal anesthesia for total hip arthroplasty. *J Bone Joint Surg Am* 2015; **97:** 455–61.

77 Lee K-J, Min B-W, Bae K-C, Cho C-H, Kwon D-H. Efficacy of multimodal pain control protocol in the setting of total hip arthroplasty. *Clin Orthop Surg* 2009; **1:** 155.

78 McCarthy D, Iohom G. Local infiltration analgesia for postoperative pain control following total hip arthroplasty: a systematic review. *Anesthesiol Res Pract* 2012; **2012:** 709531.

79 Ponnusamy KE, Kim TJ, Khanuja HS. Perioperative blood transfusions in orthopaedic surgery. *J Bone Joint Surg Am* 2014; **96:** 1836–44.

80 National Institute for Health and Care Excellence. Venous thromboembolism: reducing the risk for patients in hospital. Guidance and guidelines. https://www.nice.org.uk/guidance/cg92 (accessed Oct 1, 2018).

81 Hallstrom B, Singal B, Cowen ME, Roberts KC, Hughes RE. The Michigan experience with safety and effectiveness of tranexamic acid use in hip and knee arthroplasty. *J Bone Joint Surg Am* 2016; **98:** 1646–55.

82 Sun Y, Jiang C, Li Q. A systematic review and meta-analysis comparing combined intravenous and topical tranexamic acid with intravenous administration alone in THA. *PLoS One* 2017; **12:** e0186174.

83 Russell RD, Hotchkiss WR, Knight JR, Huo MH. The efficacy and safety of rivaroxaban for venous thromboembolism prophylaxis after total hip and total knee arthroplasty. *Thrombosis* 2013; **2013:** 762310.

84 Anderson DR, Dunbar M, Murnaghan J, et al. Aspirin or rivaroxaban for VTE prophylaxis after hip or knee arthroplasty. *N Engl J Med* 2018; **378:** 699–707.

85 Anderson DR, Dunbar MJ, Bohm ER, et al. Aspirin versus low-molecular-weight heparin for extended venous thromboembolism prophylaxis after total hip arthroplasty: a randomized trial. *Ann Intern Med* 2013; **158:** 800–06.

86 Brimmo O, Glenn M, Klika AK, Murray TG, Molloy RM, Higuera CA. Rivaroxaban use for thrombosis prophylaxis is associated with early periprosthetic joint infection. *J Arthroplasty* 2016; **31:** 1295–98.

87 Lassen MR, Gent M, Kakkar AK, et al. The effects of rivaroxaban on the complications of surgery after total hip or knee replacement. *J Bone Joint Surg Br* 2012; **94–B:** 1573–78.

88 Sutton JC, Antoniou J, Epure LM, Huk OL, Zukor DJ, Bergeron SG. Hospital discharge within 2 days following total hip or knee arthroplasty does not increase major-complication and readmission rates. *J Bone Joint Surg Am* 2016; **98:** 1419–28.

89 Austin MS, Urbani BT, Fleischman AN, et al. Formal physical therapy after total hip arthroplasty is not required: a randomized controlled trial. *J Bone Joint Surg Am* 2017; **99:** 648–55.

90 Cats-Baril W, Gehrke T, Huff K, Kendoff D, Maltenfort M, Parvizi J. International consensus on periprosthetic joint infection: description of the consensus process. *Clin Orthop Relat Res* 2013; **471:** 4065–75.

91 Parvizi J, Tan TL, Goswami K, et al. The 2018 definition of periprosthetic hip and knee infection: an evidence-based and validated criteria. *J Arthroplasty* 2018; **33:** 1309–14.

92 Wyatt MC, Beswick AD, Kunutsor SK, Wilson MJ, Whitehouse MR, Blom AW. The alpha-defensin immunoassay and leukocyte esterase colorimetric strip test for the diagnosis of periprosthetic infection. *J Bone Joint Surg Am* 2016; **98:** 992–1000.

93 Lee YS, Koo K-H, Kim HJ, et al. Synovial fluid biomarkers for the diagnosis of periprosthetic joint infection. *J Bone Jointt Surg* 2017; **99:** 2077–84.

94 Cooper HJ, Della Valle CJ. The two-stage standard in revision total hip replacement. *Bone Joint J* 2013; **95–B:** 84–87.

95 Grammatopoulos G, Kendrick B, McNally M, et al. Outcome following debridement, antibiotics, and implant retention in hip periprosthetic joint infection—an 18-year experience. *J Arthroplasty* 2017; **32:** 2248–55.

96 Heneghan C, Aronson JK, Goldacre B, Mahtani KR, Plüddemann A, Onakpoya I. Transvaginal mesh failure: lessons for regulation of implantable devices. *BMJ* 2017; **359:** j5515.

97 Howard JJ. Balancing innovation and medical device regulation: the case of modern metal-on-metal hip replacements. *Med Devices (Auckl)* 2016; **9:** 267–75.

98 Massoud SN, Hunter JB, Holdsworth BJ, Wallace WA, Juliusson R. Early femoral loosening in one design of cemented hip replacement. *J Bone Joint Surg Br* 1997; **79–B:** 603–08.

99 Van Norman GA. Drugs and devices: comparison of European and U.S. approval processes. *JACC Basic to Transl Sci* 2016; **1:** 399–412.

100 UK Government. Medical devices: EU regulations for MDR and IVDR. https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr (accessed Oct 1, 2018).

101 Nelissen RGHH, Pijls BG, Kärrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. *J Bone Joint Surg Am* 2011; **93:** 62–65.

102 National Institute for Health and Care Excellence. Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip: guidance and guidelines. https://www.nice.org.uk/guidance/ta304/ (accessed Oct 1, 2018).

103 Ravi B, Jenkinson R, Austin PC, et al. Relation between surgeon volume and risk of complications after total hip arthroplasty: propensity score matched cohort study. *BMJ* 2014; **348:** g3284.

104 Briggs TWR. A national review of adult elective orthopaedic services in England: getting it right first time. 2015. https://www.boa.ac.uk/wp-content/uploads/2015/03/GIRFT-National-Report-Mar15..pdf (accessed Oct 1, 2018).

105 Laucis NC, Chowdhury M, Dasgupta A, Bhattacharyya T. Trend toward high-volume hospitals and the influence on complications in knee and hip arthroplasty. *J Bone Joint Surg* 2016; **98:** 707–12.