

## Advances in hip replacement

### ***Search strategy and selection criteria***

*We searched Medline and PubMed for reports in English published from January 1970 to February 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 2012-18, but did not exclude common referenced and important older publications. Review articles are cited to provide readers with additional details and references.*

### **Abstract**

Total hip replacement is a frequently performed and highly successful surgical intervention. It 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 this paper, we focus on how patient factors should inform the surgical decision-making process. Significant demands are placed upon modern implants, as patients expect to remain more active for longer. We discuss the advances made in implant performance, and the developments in peri-operative practice that have reduced complications. Assessment of surgery outcomes should include patient-reported outcome measures and implant survival rates, based on data from joint replacement registries. The high-profile failure of some widely used metal-on-metal prostheses has demonstrated the shortcomings of the existing regulatory framework. We consider how proposed changes to the regulatory framework may influence safety.

### **Introduction**

Modern total hip replacement offers the ability to improve patient quality of life more than any other elective surgical procedure.<sup>1</sup> Since the pioneering work of Wiles, Charnley and others in the mid-20<sup>th</sup> century, implant technology has steadily advanced.<sup>2</sup> Now, over 95% of artificial hip joints survive beyond 10 years and, despite Charnley’s prediction to the contrary, many routinely survive beyond 30 years.<sup>3,4</sup> 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 lowering complication rates. 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.

### **Epidemiology**

Worldwide, over one million total hip replacements are performed each year.<sup>5</sup> More than 370,000 primary total hip replacements were performed in the USA in 2014, with 93,000 in the UK and 37,000 in Australia performed in 2016.<sup>6-8</sup> The number of primary and revision procedures has historically increased annually in developed countries. Between 2008 and 2016, the number of total hip replacements performed in the UK rose 32% (figure 1), with similar increases reported in Sweden, New Zealand and South Korea.<sup>4,8-10</sup>

During the past decade, global economic downturns led to questions about the sustainability of growth in joint replacement. In the USA, the growth has proven insensitive to macro-economic conditions and the number of primary total hip replacements performed annually is projected to reach 512,000 in 2020.<sup>6,11</sup> In the UK, annual primary total hip replacements decreased for the first time in 2015, before increasing again in 2016.<sup>8</sup> The observed decrease may reflect healthcare system factors, including rationing and elective hospital bed availability, rather than a decrease in demand.<sup>12</sup>

### **Aetiology**

The principal aetiological indications for total hip replacement are osteoarthritis (accounted for 90% of procedures in the UK in 2016), fractured neck of femur (5%), avascular necrosis (2%), dysplasia (2%) and inflammatory arthritis (1%).<sup>8</sup> Hip osteoarthritis has a multifactorial aetiology, with biological and mechanical components that are dictated by genetic and environmental factors.<sup>13</sup> Salient patient specific risk factors include age, gender, trauma and joint morphology. Femoroacetabular impingement is increasingly recognised as a cause.<sup>14</sup> The association of hip osteoarthritis with obesity is much less strong than that of knee osteoarthritis for reasons that remain unclear.<sup>13</sup> There is no strong evidence to suggest an association with diet. 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 62.1-77.2).<sup>8</sup> The proportion of younger patients undergoing surgery has increased in the USA, and those aged under 65 years are predicted to represent 52% of all patients by 2030.<sup>15</sup> In the UK and Australia, however, the proportion has remained stable: 32% and 37% are aged under 65 years respectively.<sup>7,8</sup> Total hip replacement remains more commonly performed in women than in men, with a stable ratio of 1.5:1 in the UK, reflecting gender discrepancies in osteoarthritis incidence.<sup>8,13</sup>

### **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.<sup>16</sup> Symptoms do not reliably correlate with the degree of structural disease on imaging, although surgery is rarely indicated in the absence of full thickness cartilage loss.<sup>17</sup> In patients with atypical hip pain, intra-articular anaesthetic hip injections have been used as a diagnostic tool, however, it is not clear whether response to injections predicts outcome from hip replacement.<sup>18</sup> Intra-articular corticosteroid injections may be discouraged within three months prior to planned hip replacement because of a potential increase in risk of infection.<sup>19</sup>

Shared decision-making benefits patients and surgeons.<sup>20</sup> 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' NSQIP risk calculator, which calculates the risk of morbidity and mortality based on preoperative health status, are useful adjuncts.<sup>21</sup> Patient characteristics, including advanced age, obesity and comorbidities, limit functional improvement after surgery, and increase rates of complications.<sup>22</sup> However, the mean improvement in pain and function reported by patients is substantial, regardless of their preoperative state.<sup>23</sup> The presence of patient factors predictive of a poorer outcome should not bar patients from surgery; rather this should inform the shared decision-making process.

Operating on patients with a higher level of pre-operative function and who have spent less time on a waiting list achieves superior functional outcomes after surgery.<sup>24</sup> Caution should be taken before operating when patients have only early disease, however. This is because patients with better pre-operative function are less likely to obtain meaningful functional improvement.<sup>25</sup> Furthermore, age at surgery has a significant influence on revision risk. The lifetime risk of revision for male patients aged 50-54 years is 29.6% (95% confidence interval, 26.6-32.6%), compared with 7.7% (95% CI, 6.9-8.5%) for their counterparts aged 70-74 years (figure 2).<sup>3</sup> This significant risk differential may lead some patients to delay surgery.

In some countries, there is geographical variation in the provision of hip replacement relative to the number of people who require it. This apparent inequity in access is related to factors of age, gender, deprivation, rurality and ethnicity.<sup>5,26</sup> Whilst these factors may influence patient willingness for surgery, differences in provision may be due to variation in practice by general practitioners and surgeons. A study in Canada suggested that a lack of clear guidelines may be responsible, with 44% of primary care physicians reporting the "lack of clarity regarding surgical indications discouraged them from referring patients for arthroplasty".<sup>27</sup> Although responsibility to set referral guidelines in the UK is deliberately devolved to regional clinical commissioning groups in order to permit healthcare 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 total hip replacement should be performed for displaced intracapsular hip fracture in patients who were able to walk independently, are not cognitively impaired, and are medically fit for the procedure.<sup>28</sup> This follows evidence that the operation leads to superior hip function and quality of life compared to hemiarthroplasty in this cohort.<sup>29</sup> Compliance remains poor, however: only 37% of patients meeting the criteria underwent total hip replacement and 42% of patients receiving the procedure did not satisfy the criteria.<sup>30</sup>

**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 significant adverse symptoms, including pain or fracture, have occurred or are predicted.<sup>8</sup>

Joint replacement registries are powerful tools in tracking the revision rate of individual implants. Since the first hip arthroplasty registry was established in Sweden forty years ago, they have proven successful in identifying devices with higher failure rates.<sup>31</sup> Geographical coverage has steadily spread, with the International Society of Arthroplasty Registries now counting members in 25 countries. In England and Wales, the National Joint Registry (NJR) has collected data on one million hip replacements since 2003; it reports an overall 13-year implant survival rate at 93.2% (95% CI, 93.0-93.3%).<sup>8</sup> Additional data collection enables analysis of the comparative influence of patient, procedure, hospital and surgeon factors. Revision outcomes are not reported at individual surgeon level at present. There are concerns 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 94.5% of primary and 91.3% of revision hip replacements performed in NHS hospitals were recorded in the NJR.<sup>8</sup> The lower accuracy of recording revisions is concerning because it may lead to the overestimation of implant performance. Investigation into whether the missing data represent random events or potential bias is ongoing.

The use of revision surgery as the only outcome measure has limitations as patients may suffer with complications, pain or poor function without undergoing revision. Indeed, within five years of hip replacement, 10% of patients may suffer ongoing pain or poor joint function.<sup>32</sup> Patient-reported outcome scores that measure pain, function, quality of life and satisfaction are now used alongside survival analysis in assessing the outcome of hip replacement. Although complications not requiring revision are not recorded by the NJR, two patient-reported outcomes are now routinely collected: the Oxford Hip Score, which measures pain and functional status, and the EuroQol five domain (EQ-5D) score, which assesses quality of life.<sup>33,34</sup>

In the UK, patient-reported outcomes are increasingly used by clinical commissioning groups as criteria for referral to secondary care. Patients with scores above a locally set threshold will not be referred,

despite scores not being validated for this purpose.<sup>35</sup> In addition, patient-reported outcomes are influenced by age and comorbidities, making a universal threshold a poor discriminator.<sup>36</sup>

The financial burden of hip replacement on healthcare systems is significant. Worldwide, the annual cost is in excess of US\$7 billion.<sup>5,37</sup> The cost per quality-adjusted life-year (QALY) gained with hip replacement is between \$1,500 and \$10,402.<sup>38,39</sup> This value is significantly less than the threshold of £20,000-30,000 per QALY selected by NICE to guide cost effectiveness appraisals of new technologies.<sup>40</sup> Furthermore, evidence suggests that in the long-term arthroplasty leads to healthcare cost savings, with a reduction in cost of \$278 every year per patient compared with an increase of \$1,978 every year per matched, non-operated control patient.<sup>41</sup> In patients that 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.<sup>8</sup> 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 TNF-alpha-mediated inflammatory cascade that increases osteoclast activity with net bone resorption and loss of implant fixation.<sup>42</sup>

Dislocation affects 0.2-10% of patients after hip replacement, with 77% of patients affected within the first year.<sup>43</sup> Age, muscle tone, non-compliance with avoidance of specific movements, surgical approach, and component position and size influence the dislocation rate.<sup>43</sup> Dislocation accounts for 14% of revision operations.<sup>8</sup>

Periprosthetic joint infection is a devastating complication of arthroplasty, and may cause pain, loss of function, systemic illness or death. The incidence within two years of surgery is 1-2%.<sup>44</sup> Microbes create biofilms on implant surfaces, reducing antibiotic penetrance.<sup>45</sup> Surgical intervention is typically required, with debridement and implant retention, or one- or two-stage revision, which account for 8% of all revision procedures. Other common indications for revision are periprosthetic fracture (10%) and implant malpositioning (5%).<sup>8</sup>

Indications for revision vary by patient demographic. In patients under 55 years, aseptic loosening is the most frequent indication, while in patients aged over 84 years, dislocation, periprosthetic fracture and infection are more frequent.<sup>46</sup>

## **Advances in practice**

### *Implants*

Adults aged 65-74 years in England spend an average of 6.5 hours per week engaged in physical activity.<sup>47</sup> Significant 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. Implants with metal-on-polyethylene bearings were used in 58% of procedures, with ceramic-on-polyethylene in 29%, with ceramic-on-ceramic in 11% in the UK in 2016.<sup>8</sup>

Early metal-on-polyethylene bearings had high failure rates within 14 years because softer polyethylene produced wear debris.<sup>7</sup> However, modern highly cross-linked polyethylene is more resistant, and registry analysis has found no difference in mid-term revision rate between modern metal-on-polyethylene, ceramic-on-polyethylene and ceramic-on-ceramic bearings.<sup>7,48</sup> With minimal differences in revision rate, consideration of other factors may guide which bearing to select. Modern ceramic-on-ceramic bearings may not have the increased risk of implant fracture associated with earlier, more brittle, implants, although they are more expensive than other bearings and may squeak.<sup>49</sup>

Metal-on-metal prostheses gained popularity twenty 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 significantly poorer outcomes.<sup>7</sup> Overall, uncemented metal-on-metal total hip replacements have a revision rate of 18.2% (95% CI, 17.7-18.8%) after ten years.<sup>8</sup> Since 2011 they have accounted for less than 1% of all prostheses implanted and these 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 may trigger an adverse reaction in which localised bone destruction and soft tissue necrosis occurs. For patients with metal-on-metal implants, the early identification of adverse soft tissue reactions and prompt revision surgery leads to superior 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.<sup>50</sup> Concerns that metal-on-metal implants may be associated with an increased incidence of cancer, through systemic metal ion exposure, remain unproven, with longer-term follow up ongoing.<sup>51</sup>

There has been a trend towards larger diameter femoral heads in the last decade.<sup>8</sup> Increased size of femoral heads decreases the incidence of dislocation after hip replacement, because they permit a greater range of movement before impingement occurs.<sup>52</sup> Previous concerns limiting the use of larger diameter heads related to evidence that they lead to increased volumetric wear of polyethylene; however, with modern generations of highly cross-linked polyethylene, the larger articulations do not appear to increase the wear rate compared with smaller articulations.<sup>53</sup>

### *Fixation*

Debate continues regarding the best method of fixation in total hip replacement (figure 3). Cemented fixation continues to demonstrate excellent long-term revision rates, and achieves a lower overall rate of revision after 13 years compared with cementless fixation (figure 4).<sup>7,8,54</sup> It is proposed that the higher failure rates of implants with cementless fixation may represent failure of early fixation.

Cementless fixation, however, may have lower revision rates beyond the first decade,<sup>55</sup> and lead to lower rates of revision in patients aged under 65 years.<sup>56</sup> The technique also avoids the risk of cement-related embolic complications.<sup>57</sup> Cementless fixation is now the most common method used in the UK, USA and Australia.

Acetabular aseptic loosening was identified as a major cause of failure of cemented implants in younger patients. Hybrid fixation, with cemented femoral and cementless acetabular components, was developed as an alternative, and achieves 13-year outcomes superior to cementless but inferior to cemented fixation.<sup>8</sup>

There is growing interest in short cementless femoral stems. These designs preserve proximal bone stock and allow more physiological loading, which may result in less stress-shielding, thigh pain and invasive revision surgery. Stem malpositioning and subsidence have been reported with some designs, whilst others have reported no differences from conventional cementless stems in fixation or function after ten years.<sup>58</sup>

### *Surgical approach*

Posterior and lateral approaches, which account for 95% of hip replacements in the UK, share excellent outcomes.<sup>8</sup> The use of posterior approach has increased over the last decade at the expense of the lateral approach. This may be explained by increasing evidence that the posterior approach is associated with superior patient-reported outcomes and no increased risk of dislocation.<sup>59,60</sup>

The desire to perform hip replacement 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, recent systematic reviews found no significant difference in overall complication rate, dislocation rate, gait, and patient function beyond six weeks post-operatively compared with traditional approaches. Evidence of the effect on fracture rate and length of stay is conflicting.<sup>61,62</sup> 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, utilise a modified posterior incision and permit joint access without disrupting the external rotator muscles. Case series have reported low complication and dislocation rates.<sup>63</sup> However, long-term follow up for all minimally invasive surgical approaches is required.

#### *Computer-assisted surgery*

Malpositioning of acetabular and femoral components may result in impingement, increased bearing surface wear, dislocation and need for revision.<sup>64</sup> Computer-assisted surgery systems have been developed for use in hip replacement, with the aim of increasing the accuracy 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 performed in the USA in 2016.<sup>65</sup>

Computer navigation guides surgeons intraoperatively using anatomic data, either from pre-operative CT images, intraoperative fluoroscopic images or imageless intraoperative registration of bony landmarks. Meta-analysis of 473 patients found that this results in increased precision of acetabular component positioning compared with manual placement.<sup>66</sup> Evidence of superior clinical outcomes, however, has not been demonstrated. By contrast, for knee replacement, data from the Australian National Joint Replacement Registry suggested computer navigation reduces revision rate for patients less than sixty-five years of age.<sup>67</sup> The reasons for this difference remain unclear.

Robotic-assisted surgery systems in orthopaedics use 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, whilst others terminate bone milling automatically. Improved accuracy of acetabular positioning is achieved, but the effect on clinical outcome is unproven.<sup>68</sup> A single-centre cohort study reported lower dislocation rates after robotic-assisted hip replacement, but further study is required.<sup>69</sup>

Patient specific instrumentation uses three-dimensional templates printed from preoperative images. The techniques may lead to improved acetabular positioning, without the significant time burden associated with robotic surgery.<sup>70</sup> 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.

### *Enhanced recovery*

Pre-, peri- and post-operative optimisation programmes, collectively termed fast-track surgery programmes, can be employed 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 elective orthopaedic patients found comprehensive geriatric optimisation reduced rates of post-operative pneumonia, delirium, pressure sores and poor pain control, and shortened length of stay compared with routine care.<sup>71</sup>

Spinal anaesthesia is associated with reduced odds of cardiac arrest, stroke, unplanned intubation and minor adverse events compared with general anaesthesia.<sup>72</sup> Multimodal analgesia regimes permit earlier rehabilitation and improve patient satisfaction.<sup>73</sup> Local infiltration analgesia may have equivalent efficacy to epidural analgesia and peripheral nerve blockage, but with fewer side effects. Local anaesthetic, nonsteroidal anti-inflammatory drug, steroid, adrenaline and opiate may be used in combination, however, no local infiltration regimen has yet demonstrated superiority.<sup>74</sup>

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 may increase the risk of venous thromboembolism, and resulting immunomodulation may increase susceptibility to postoperative infection.<sup>75</sup> NICE recommends tranexamic acid for all hip arthroplasty procedures.<sup>76</sup> This has been shown to reduce transfusion rates with no increase in thromboembolic events.<sup>77</sup> The optimal route, dose, and timing of administration has not been determined, although combined topical and intravenous administration may be more effective at reducing blood loss than intravenous administration alone.<sup>78</sup>

NICE recommends mechanical and pharmacological venous thromboembolism prophylaxis after hip replacement.<sup>76</sup> The choice of which agent to use is patient specific. Direct oral anticoagulants have demonstrated superior efficacy to low molecular-weight heparin, but may have an increased bleeding risk.<sup>79</sup> The EPCAT trials found that, from 10 days after surgery, extended prophylaxis with aspirin after total hip replacement was not significantly different from rivaroxaban and low molecular-weight heparin in the prevention of symptomatic venous thromboembolism.<sup>80</sup> The influence of anticoagulation on infection remains unclear. A number of single-centre studies have suggested that rivaroxaban increases the risk of surgical site infection after hip replacement compared to other pharmacological prophylaxis, however, the RECORD trial found no statistical difference.<sup>81,82</sup>

Reduced length of stay following hip replacement appears to be safe: discharge within two days of surgery does not increase the risk of complications or readmission in risk-stratified patients.<sup>83</sup> There is no consensus on the optimum protocol of postoperative exercise programmes. Recent evidence suggests that formal outpatient physiotherapy after total hip replacement may not be required, and instead unsupervised home exercise is safe and efficacious for a majority of patients.<sup>84</sup>

### *Management of infection*

An international consensus on the management of periprosthetic joint infection was published in 2013, to unify the definition, prevention and treatment of this complication.<sup>85</sup> Diagnostic challenges remain. Clinical signs are non-specific, inflammatory markers can be elevated for two months after surgery and synovial fluid cultures fail to grow an organism in 30% of infections. A combination of serological, histological and microbiological tests are used to support a diagnosis, and findings may be scored in keeping with the most recent validated international consensus definition.<sup>86</sup> Synovial fluid biomarkers, such as leucocyte esterase and a neutrophil-secreted antimicrobial peptide called alpha-defensin, may also aid diagnosis with a high sensitivity and specificity.<sup>87,88</sup> 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 the risk of rerevision for infection was 2.0 times higher for one-stage revision compared with two-stage revision.<sup>89</sup> However, recent evidence suggests debridement and implant retention can successfully eradicate infection, within six-weeks from index surgery.<sup>90</sup>

### **Regulation & surveillance**

In recent 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 PIP silicone breast implant cases, both of which caused enormous distress to thousands of patients, suggested that the regulatory process governing the introduction of the medical devices was inadequate.<sup>91</sup> Within orthopaedics, the discovery of high failure rates of metal-on-metal hip replacements that had been implanted into one million patients worldwide similarly led to calls to reform the regulatory process.<sup>92</sup>

Currently 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 may be granted in response to evidence of a successful pre-market clinical investigation, demonstrating safety and effectiveness of the device. Alternatively, approval may be granted simply in response to developers demonstrating equivalence of the device to existing approved devices, termed predicates. Pre-market clinical investigations require significant time and resources, hence developers have a strong incentive to identify appropriate

predicates. This pathway allows for approval of implants where the design does not deviate significantly from the predicates, however, even a small design modification can have a significant effect on implant performance.<sup>93</sup> Authority to issue *CE* marking for medical devices is devolved to private companies, termed Notified Bodies, with developers able to apply to any of the 59 registered across Europe.

In the USA, two equivalent pathways exist, however, they are regulated centrally by the Food and Drug Administration (FDA), ensuring consistent standards but on average taking longer than in Europe.<sup>94</sup> 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.<sup>95</sup> Evidence required to demonstrate equivalence to a predicate will be stricter and Notified Bodies will undergo more rigorous spot checks; after *CE* approval, devices will have to adhere to a specified post-market surveillance plan, and pre-market clinical investigations and post-market surveillance plans will be overseen by a central coordination group. Whilst these improved regulations are welcome, potential weaknesses remain: there is no minimum cohort size defined for the pre-*CE* clinical investigation, which may permit low quality studies to be conducted; applicants may still draw on multiple predicates, which may enable a device to be approved despite significant design changes; and there is no requirement for stepwise introduction after *CE* approval, as there is 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 it may take many years before an implant with an inferior lifespan may be identified, even in national registries. Early device evaluation may therefore be supported by radiostereometric analysis.<sup>96</sup> 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 of clinical trials.<sup>97</sup> 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 there are three-year revision rate data, with ratings updated at specified time intervals.

Prior to the first outcome evaluation, a different approach is required. Implants may 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, it has been adopted by many healthcare systems worldwide.

### **Health service design**

Surgeons performing a higher volume of total hip replacements have better outcomes, including lower risk of dislocation and revision. A threshold of 35 cases per year has been proposed as a minimum cut off for primary total hip replacement.<sup>98</sup> In the UK, the Getting It Right First Time initiative found 24% of surgeons perform 10 or fewer procedures per year.<sup>99</sup> The relationship between volume and outcomes is complex, however: there is no evidence that increasing the volume of low volume surgeons would improve their outcomes. Hospitals, too, performing a higher volume of procedures have lower rates of complications, including dislocation and mortality.<sup>100</sup> 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. It 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 peri-operative management. Now, the majority of patients can expect their prosthesis to function without complications for over twenty years. Ongoing challenges include further improvements to implant performance for young patients and more active older patients, ensuring the safe introduction of new implants, and developing strategies to identify osteoarthritis earlier and slow its progression, to reduce the number of patients requiring major surgery.

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### Authors contributions

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

### **Declarations 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 that they have no conflicts of interest.

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