

ADEPT[®] Hip Resurfacing System

Clinical Rationale

Delivering Results
Through Performance

Forever **Active**

Contents

1	Introduction	3
2	Development of Modern-Day Hip Resurfacing	3
3	Benefits of Hip Resurfacing	4
4	Long-term Outcomes of Hip Replacement	5
5	Hip Resurfacing Brands	7
6	PROMs Data	8
7	Maturing Data and Use of ADEPT®	9
8	Orthopaedic Data Evaluation Panel (ODEP)	10
9	Summary	11
10	Key Literature	12
11	References	13
12	Notes	14

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1 Introduction

Hip Resurfacing arthroplasty is intended for patients with failure of the hip joint who are likely to outlive or outperform a traditional total hip replacement (THR). The ADEPT® Hip Resurfacing System evolved from successful very-low-wear metal-on-metal (MoM) bearing THR devices that lasted 35 years+ and following successful implementation of modern-day hip resurfacing. With more than 14 years of supporting clinical data, the evidence demonstrates that the ADEPT® Hip Resurfacing is the best treatment option for many patients.

2 Development of Modern-Day Hip Resurfacing

Modern-day hip resurfacing was developed following observations of patients with large diameter metal-on-metal (MoM) total hip prostheses such as the McKee-Farrar and the Ring Hip (Figure 1), who retained functioning hips with very little wear for more than 30 years after their operation¹. Based on knowledge gained from the successful devices and the application of modern manufacturing techniques, the desirable resurfacing concept was revisited. The Birmingham Hip Replacement (BHR) was first used in 1997, and since then many thousands of successful hip resurfacing procedures have been performed around the world.

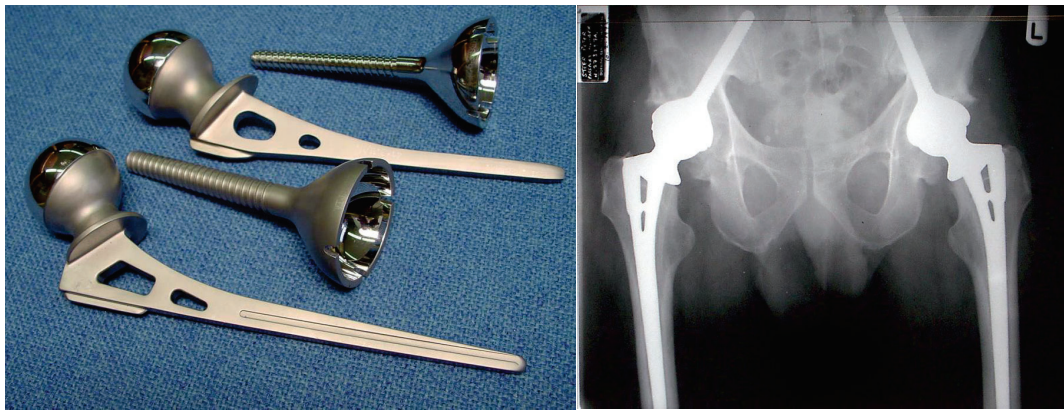


Figure 1 Historical MoM prosthesis: the Ring Hip implanted 1964–1979.

Development of the ADEPT® Hip Resurfacing System built on the knowledge gained by Finsbury (now MatOrtho®) through its direct involvement in the BHR's development and the extensive research of historical MoM devices, and as the original manufacturer of the BHR¹, manufacturing over 200,000 BHR devices.

The ADEPT® introduced a small number of advancements including consistent angle of coverage for all implant sizes, smaller increments between sizes and advanced instrumentation for its reliable implantation.

The ADEPT® Hip Resurfacing was first used in 2004.



Figure 2 The ADEPT® Hip Resurfacing and *in situ*.

3 Benefits of Hip Resurfacing

The benefits of hip resurfacing include:

- a viable treatment for younger, more active patients;
- early intervention;
- bone conserving procedure;
- more reliably restored native hip joint biomechanics²;
- lower infection rates³;
- lower incidence of dislocation²;
- improvements in activity levels and hip scores, particularly in younger patients^{2,4};
- ease of femoral revision.

Surgeons allow their hip resurfacing patients to return to wider variety of sport and leisure activities without restriction as compared to total hip replacement.

Resurfacing of the femoral head allows for better restoration of the anatomy^{2,5} and a more natural gait^{5,6}. Expert surgeons agree that they allow their hip resurfacing patients to return to wider variety of sport and leisure activities without restriction as compared to total hip replacement and return to activity is commonly much earlier in the postoperative recovery phase^{2,6,7}. Patients report a high level of activity including running^{2,4,8,9,10} and these levels of activity are maintained into the second decade after primary surgery¹⁰.

Hip resurfacing significantly reduces the risk of dislocation as compared to total hip replacement.

Hip resurfacing allows the safe use of large-diameter head components and this offers an immediate advantage for the patient in terms of stability and significantly reduces the risk of dislocation as compared to total hip replacement². In the UK National Joint Registry (NJR) the incidence rate of revision for dislocation within the first postoperative year is estimated at 3 to 5 times less for hip resurfacing as compared to total hip replacement and remains low at later time points³.

Hip resurfacing is a more conservative procedure than total hip replacement.

Hip resurfacing is a more conservative procedure than total hip replacement and this may be beneficial in terms of exposure to bacteria. The UK NJR shows that a hip resurfacing procedure is 2.1 to 2.6 times less likely to be revised for infection than a total hip within one year post surgery³. Unlike a resurfacing procedure, a total hip replacement reams deep into the femoral shaft to make a cavity for the hip stem leaving the patient more vulnerable to infection. Revision for infection is associated with double the costs and twice the length of stay in hospital as compared to revision for aseptic causes¹¹. Infection is associated with a higher level of complication, reoperation and morbidity¹¹ and so the benefits of reducing the risk of infection are far-reaching. There is also evidence that hip resurfacing has a lower risk of mortality when compared to total hip replacement^{12,13}.

Revision following a conventional total joint replacement is invariably more challenging than the initial total joint replacement. Numerous specialist techniques address the problems at revision surgery but all are more expensive and take longer than primary surgery.

Given the use of a thin-shelled acetabular component, retention of the femoral neck and uncompromised femoral shaft, revision of a hip resurfacing is essentially conversion to a total hip replacement with similar technology, expense and postoperative recovery to a conventional primary total joint replacement. This is more appealing to younger patients who are more likely to require repeat surgery in their lifetime.

Revision of a hip resurfacing is essentially a primary total hip replacement.

4 Long-term Outcomes of Hip Replacement

Data from the registries confirms that although THR is a highly successful procedure in many patients, younger patients are more likely to require revision surgery in the early years after their primary surgery than older patients (Figures Figure 3 and Figure 4).

Figures Figure 3 and Figure 4 also show an increasing *rate* of revision beyond 10 years in younger patient groups (the graphs become steeper), illustrating that a large number of younger total hip replacement recipients will face a more complex and expensive revision operation in their lifetime.

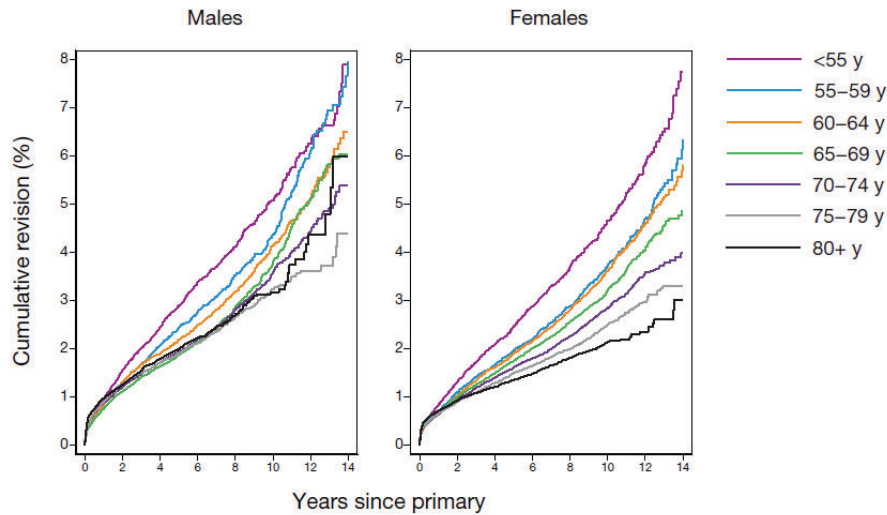


Figure 3 Kaplan-Meier estimates of cumulative revision of all hip replacements excluding metal-on-metal total hip replacement and resurfacings in the NJR³. Note that for males and females the number of revisions in categories <65 years old showing a non-linear increase beyond 10 years.

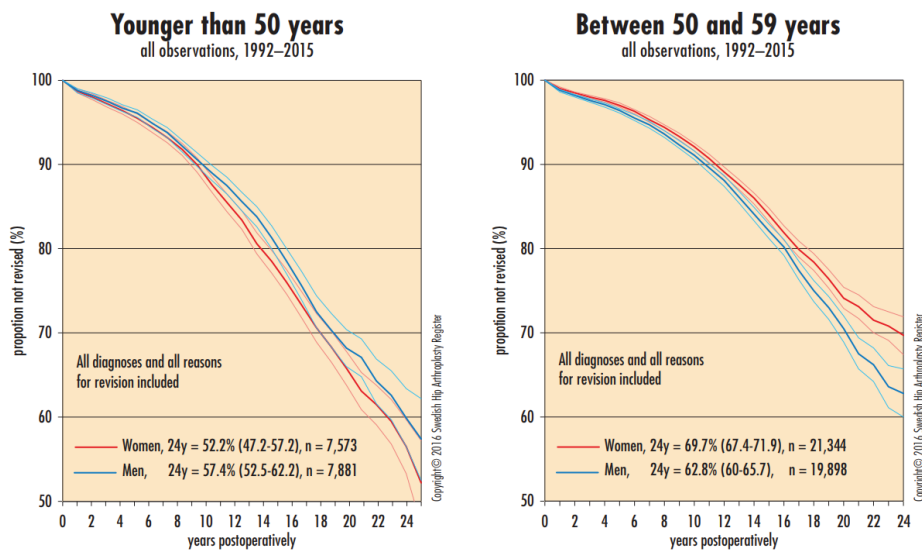


Figure 4 Survivorship of total hip replacements in Sweden for younger patients showing that 30-50% of patients will have required revision surgery within 25 years of their primary operation¹⁴ (presentation of survivorship is a direct 'inverse' of revision rates).

Registry data shows a different trend for hip resurfacing to that seen for THR. Data differs for individual devices and bearing options, however a revealing trend is evident in younger males for whom hip resurfacing is most often prescribed (79% of the NJRR-recorded hip resurfacing patients were male with average age 53.4 years, SD: 9.0)¹³. Beyond the early years, and having remained constant from 2 to 14 years, the rate of revision decreases. Fifteen years after their primary operation, these patients have not only benefitted from the return to activity offered by hip resurfacing, they become less likely to have required a revision surgery than similarly aged THR patients overall (Figure 5).

In the longer term, young male hip resurfacing patients are less likely to have required a revision surgery than similarly aged THR patients.

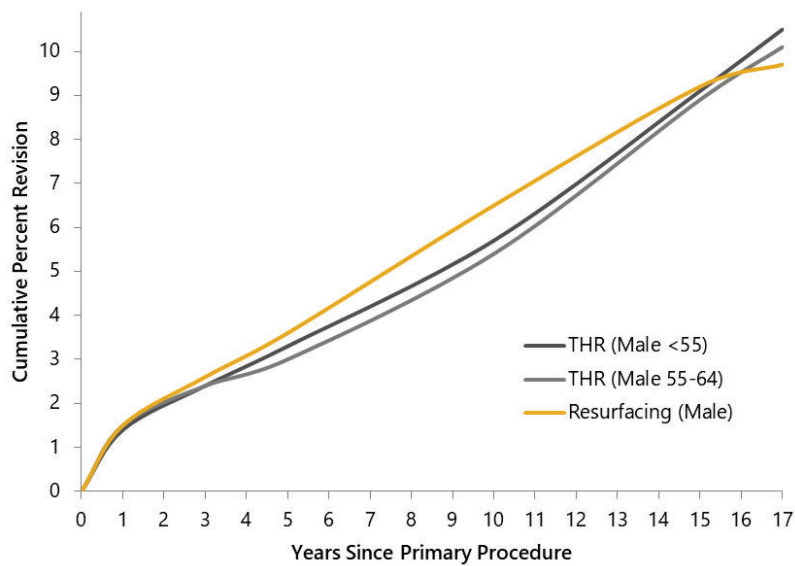


Figure 5 Cumulative revision rates for younger male hip replacement patients in the AOA NJRR showing that beyond 15 years after their primary operation those who received a hip resurfacing are less likely to have required a revision operation than those that received a total hip replacement¹³.

5 Hip Resurfacing Brands

For the resurfacing hip category, appropriate device design is an essential factor for the device performance. Different metallurgy, clearance, geometry and fixation are proven to affect clinical outcome and consequently, results have differed greatly between devices (Figure 6). Of the devices shown in Figure 6, only the ADEPT® (MatOrtho®), Mitch (Stryker) and BHR (Smith & Nephew) have clearance, metallurgy, geometry and fixation based on analysis of the clinical performance of the successful early MoM devices. Finsbury (now MatOrtho®) manufactured all three devices. Only the ADEPT® and BHR are still available and only the ADEPT® remains fully supported and provided by the original manufacturers.

The success of MoM hip resurfacing is brand-specific.

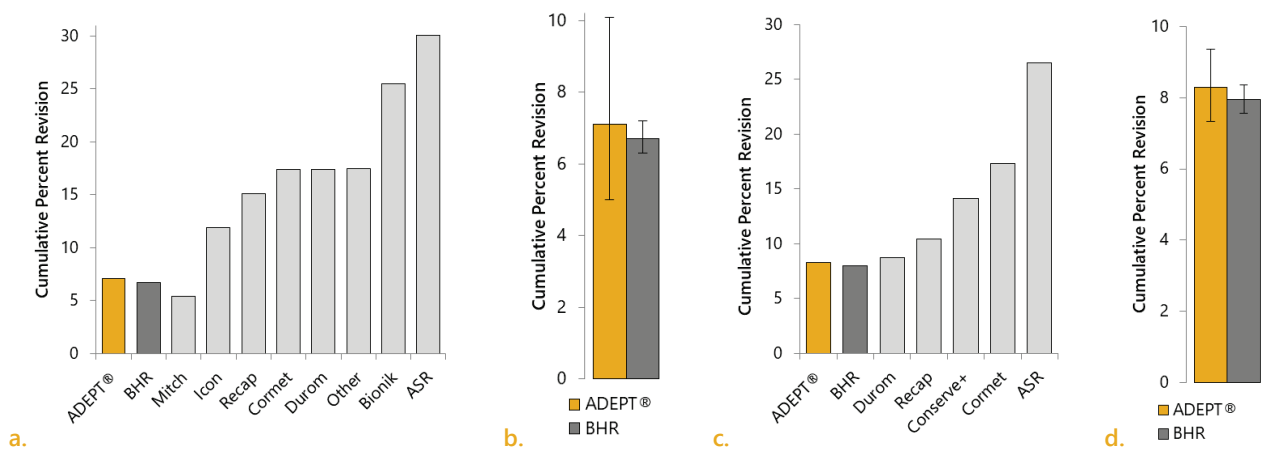


Figure 6 Cumulative Revision Rates 10 years after primary operation for brands of hip resurfacing device in the UK and Australian registries: **a.** resurfacing brands in the NJRR¹³; **b.** no significant difference in revision rates for the ADEPT® and BHR in the NJRR¹³; **c.** resurfacing brands in the NJR³; **d.** no significant difference in revision rates for the ADEPT® and BHR in the NJR³.

6 PROMs Data

The mean postoperative hip score for hip resurfacing is reported to be in the 'excellent' category in numerous published studies^{2,4,15,16,17}

Based on up to date systematic review of peer-reviewed literature published in 2019, MoM hip resurfacing is associated with superior outcomes when compared to THR². The review includes findings such as decreased thigh pain⁴, less limp with walking⁴, improved function¹⁰, superior UCLA activity scores^{18,19}, quality of life^{18,19} and return to manual labour work¹⁸, moderate/heavy activity¹⁹, sport¹⁸ and long distance walking and running⁴.

The ADEPT® Hip Resurfacing System in particular has excellent results in well-selected patients²⁰:

- Oxford scores for hip resurfacing patients were high compared to total hip replacement patients;
- WOMAC scores indicated excellent function;
- the UCLA Activity Scale showed that patients were regularly participating in moderate activity, with 10% regularly participating in high-impact sports;
- metal ion levels just 14% (cobalt) and 19% (chromium) of the limit used for the ASR recall and published guidelines by the MHRA (cobalt 119 nmol/L, chromium 135 nmol/L);
- no failures associated with wear or increased metal ions in the resurfacing group.

Hip resurfacing is as equally valuable an operation as total hip replacement, which is considered to be one of the most successful and cost-effective interventions in medicine.

Patient reported outcomes recorded by the NJR show that overall ADEPT® Hip Resurfacing patients have significantly higher scores than total hip replacement patients (Figure 7)²¹. This is likely to be influenced by the relatively younger age of resurfacing patients, and when adjusted for patient variables using a casemix-adjustment model, patient scores six-months post operation are not significantly different to THR patients²¹.

When asked "Overall, how are your problems now, compared to before your operation?" about 95% of ADEPT® Hip Resurfacing patients respond that their problems are better, and when asked "How would you describe the results of your operation?" about 95% of patients respond 'good', 'very good' or 'excellent'²¹.

In other words, in terms of health gain and patient satisfaction following a hip operation, hip resurfacing is as equally valuable an operation as total hip replacement, which is considered to be one of the most successful and cost-effective interventions in medicine.

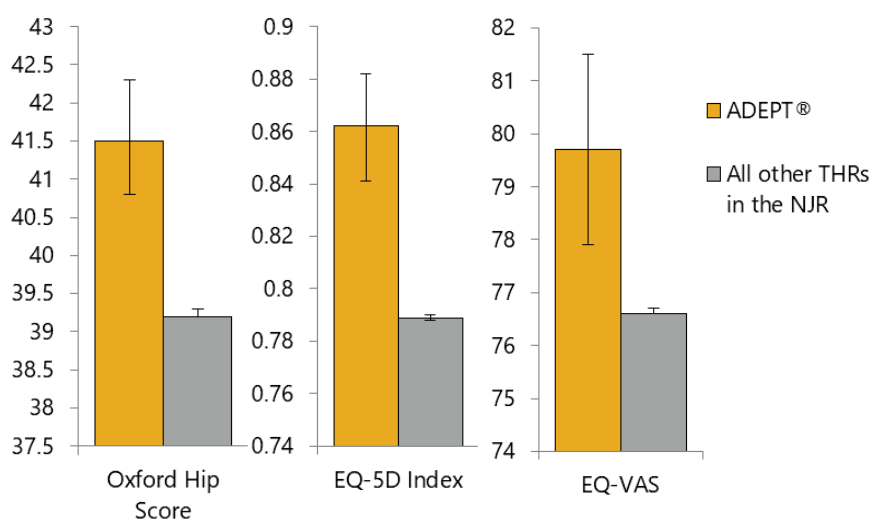


Figure 7 Six-month postoperative PROMs scores for ADEPT® Hip resurfacing and THR patients recorded by the NJR²¹.

7 Maturing Data and Use of ADEPT®

Probability estimations for survivorship of ADEPT® Hip Resurfacing are improving over time as the cohorts of patients on whom the estimations are based mature. Figure 8 shows the difference in estimated probability of survivorship in May 2004, based on a starting cohort of over 3,000 patients recorded in the NJR from 2004 onwards²², compared to the estimated probability of survivorship in November 2018²¹. The probability of revision is less than the lower confidence limits or previous estimate for the same cohort (Figure 8). The difference is simply that in early estimates few patients had reached >5 years post operation.

Fewer ADEPT® MoM Hip Resurfacings are requiring revision than was previously expected and the long term implications of this particularly for the younger patients are good and support the principals of resurfacing outlined (Section 3).

Fewer ADEPT® MoM Hip Resurfacings are requiring revision than was previously expected.

In the UK, 92.3% of all patients with maximum implantation time 13.8 years (mean 8.5 years) who have received an ADEPT® Hip Resurfacing (males and females, 38-58mm bearing sizes) have not required a revision operation and the 10-year cumulative revision rate is 8.4% (7.4-9.4%)²¹. Considering the current available size range (males and females, 48-58mm bearing sizes), 94% of UK patients have not required a revision operation and the 10-year cumulative revision rate is 6.5% (5.5-7.7%). Twelve years after primary operation the cumulative revision rate is 8.8% (7.1-10.9%)²³.

Based on the growing evidence for its success in well-selected patients and the ongoing support from the device manufacturer, use of the ADEPT® has been growing in recent years. This is evident in the NJR³ and NJRR¹³. The ADEPT® Hip Resurfacing is now the most-used resurfacing device in Australia, accounting for over 68% of all hip resurfacings in the last reported year¹³.

Use of the ADEPT® has increased in recent years.

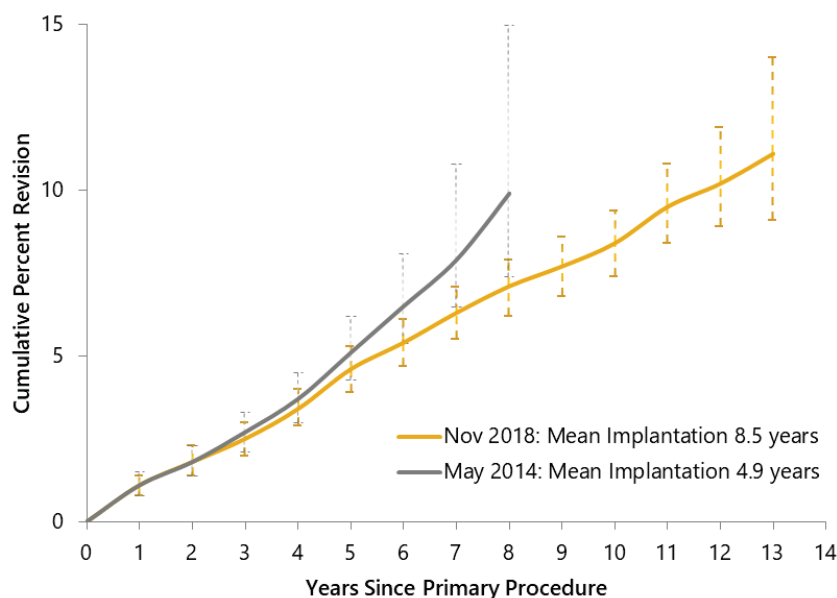


Figure 8 Cumulative percent revision rate of the ADEPT®, including all bearing sizes 38-58mm, males and females) for essentially the same patient cohort, reported in May 2014 (data from 2004 to December 2013)²² and November 2018 (data from 2004 to Sept 2018)²¹.

8 Orthopaedic Data Evaluation Panel (ODEP)

The NICE guidance for MoM hip resurfacing recommends the procedure as 'one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement'²⁴. The British Orthopaedic Association (BOA) guide to good practice in primary hip replacement states that metal-on-metal resurfacing implants remain an acceptable option for well-selected patients²⁵.

The Orthopaedic Data Evaluation Panel (ODEP) was set up to monitor the National Institute for Health and Care Excellence (NICE) guidance on primary hip implants in 2002 and hip resurfacing in 2004. The Panel provides on-going assessment of hip implants to benchmark both hip femoral stems and hip acetabular cups against the NICE guidance, providing a benchmark rating for implant survivorship and data submission quality.

The current range of ADEPT® Hip Resurfacing implants has been awarded an ODEP 10A rating based on the panel's independent review of the survivorship associated with the device and on the quality of data supporting the device²⁶.



Figure 9 ODEP rating for the ADEPT® Hip Resurfacing²⁶.

For those interested in ODEP ratings, further information on ODEP criteria and use of ratings by hospitals can be found on the ODEP website²⁷.

9 Summary

Metal-on-metal (MoM) bearing hip replacement has the longest clinical history of any articular couple in use today²⁸. Although hip resurfacing was first attempted in 1948 and later in the 1970s with metal on poly bearings²⁹, it was not until the 1990s that the availability of long-term data on the early MoM THR devices and the highly specialised manufacturing techniques developed by Finsbury (now MatOrtho®) enabled a revival of resurfacing¹.

The ADEPT® Hip Resurfacing design was based on experience gained from analysis of successful historical devices and development and manufacture of the most successful modern day hip resurfacing devices. It has been shown to meet the demands of patients who, due to their relatively younger age or increased activity level, are likely to outlive or outperform a traditional total hip replacement.

As the available data matures, fewer patients are requiring revision surgery than was previously expected. Further to this, with changing demographics and patients expecting more from their procedure, aspects of returning to a normal active lifestyle are just as important as revision data. This means that many young and active people continue to benefit from having received a hip resurfacing instead of a standard total hip replacement.

- The ADEPT® Hip Resurfacing is available for younger and more active patients who require it,
- Hip resurfacing patients are free to return to work and active lifestyles^{2,6,7} without compromised function and with all options maintained for further treatment if required.
- Survivorship for the ADEPT® is excellent^{3,13,21,23} and the device is awarded an ODEP 10A rating²⁶.
- Clinical data for the ADEPT® shows good outcomes and better long-term prospects are retained when compared to young, active patients who receive a THR¹³.

10 Key Literature

Mid-Term Review of ADEPT Metal-On-Metal Hip Prosthesis. Functional, Radiological and Metal Ion Analysis.

Plant JGA, Prosser GH, Burston BJ, Edmondston SJ, Yates PJ. Open Journal of Orthopedics. 2014; 4: 38-43.

Abstract

Background: There is much interest regarding metal-on-metal implants in medical and general media. Much of this has been regarding failure of specific implant systems and metal ion toxicity. We present our early mid-term experience of the ADEPT metal-on-metal system which has both modular and non-modular hip options.

Methods: Functional assessment, blood metal ion quantification, and radiographic analysis were performed for the modular and non-modular ADEPT variants. Fifty implants were implanted with a mean follow up time of 28 months. Unpaired t-tests were used to compare modular and resurfacing groups, standardised hip scores were used to compare function to conventional total hip arthroplasty.

Results: Metal ion levels were significantly higher in modular prostheses compared to resurfacing implants, but not at "harmful" levels (as determined by a previous metal-on-metal implant recall). Functional outcomes were excellent and revision rates were lower than expected.

Conclusions: At our institution we have good outcomes with the ADEPT hip prosthesis. Though patient selection and implant position are crucial, poor performance of metal-on-metal hip replacements is implant specific.

11 References

- 1 McMinn D. The History of Hip Resurfacing.
- 2 Hellman MD, Ford MC, Barrack RL. Is there evidence to support an indication for surface replacement arthroplasty? A systematic review. *Bone Joint J.* 2019; 101-B (1 suppl A): 32-40.
- 3 National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 15th Annual Report, 2018: Surgical data to 31 December 2017. www.njrreports.org.uk.
- 4 Barrack RL, Ruh EL, Berend ME, Della Valle CJ, Engh A Jr, Parvizi J, Clohisy JC, Nunley RM. Do Young, Active Patients Perceive Advantages After Surface Replacement Compared to Cementless Total Hip Arthroplasty? *Clin Orthop Relat Res.* 2013; 471: 3803–3813.
- 5 Lombardi AV Jr, Skeels MD, Berend KR, Adams JB, Franchi OJ. Do large heads enhance stability and restore native anatomy in primary total hip arthroplasty? *Clin Orthop Relat Res.* 2011; 469(6): 1547-53.
- 6 Van Der Straeten C, De Smet KA. Current expert views on metal-on-metal hip resurfacing arthroplasty. Consensus of the 6th advanced Hip resurfacing course, Ghent, Belgium, May 2014. *Hip Int.* 2016; 26 (1):1-7.
- 7 Girard J. Femoral head diameter considerations for primary total hip arthroplasty. *Orthop Traumatol Surg Res.* 2015; 101 (1 Suppl): S25-9.
- 8 Aqil A, Drabu R, Bergmann JH, Masjedi M, Manning V, Andrews B, Muirhead-Allwood SK, Cobb JP. The gait of patients with one resurfacing and one replacement hip: a single blinded controlled study. *Int Orthop.* 2013; 37 (5): 795-801.
- 9 Plate JF, Issa K, Wright C, Szczech BW, Kapadia BH, Banerjee S, Mont MA. Patient activity after total hip arthroplasty: a comparison of three different bearing surfaces. *J Long Term Eff Med Implants.* 2013; 23(4): 315-21.
- 10 Haddad FS, Konan S, Tahmassebi J. A prospective comparative study of cementless total hip arthroplasty and hip resurfacing in patients under the age of 55 years A Ten-Year Follow-Up. *Bone Joint J.* 2015; 97-B: 617–22.
- 11 Vanhegan IS, Malik AK, Jayakumar P, Ul Islam S, Haddad FS. A financial analysis of revision hip arthroplasty: the economic burden in relation to the national tariff. *J Bone Joint Surg Br.* 2012; 94 (5):619-23.
- 12 Kendal AR, Prieto-Alhambra D, Arden NK, Carr A, Judge A. Mortality rates at 10 years after metal-on-metal hip resurfacing compared with total hip replacement in England: retrospective cohort analysis of hospital episode statistics. *BMJ.* 2013; 347: f6549.
- 13 Australian Orthopaedic Association National Joint Replacement Registry. Hip, Knee & Shoulder Arthroplasty: 2018 Annual Report. Adelaide: AOA. 2018. <https://aoanjrr.sahmri.com>.
- 14 The Swedish Hip Arthroplasty Register. Annual Report 2015. <https://registercentrum.blob.core.windows.net/shpr/r/Annual-Report-2015-H19dFINOW.pdf>. Accessed 6 Dec 18.
- 15 Holland JP, Langton DJ, Hashmi M. Ten-year clinical, radiological and metal ion analysis of the Birmingham Hip Resurfacing: from a single, non-designer surgeon. *JBJS- Br.* 2012. 94(4):471.
- 16 Hing CB, Back DL, Bailey M, Young DA, Dalziel RE, Shimmin AJ. The results of primary Birmingham hip resurfacings at a mean of five years: An independent prospective review of the first 230 hips. *J Bone Joint Surg (Br).* 2007; 89-B:1431-1438.
- 17 Khan M, Kuiper JH, Edwards D, Robinson E, Richardson JB. Birmingham Hip arthroplasty five to eight years of prospective multicenter results. *J Arthroplasty*, 2008. Article in press.
- 18 Pollard TC, Baker RP, Eastaugh-Waring SJ, Bannister GC. Treatment of the young active patient with osteoarthritis of the hip. A five- to seven-year comparison of hybrid total hip arthroplasty and metal-on-metal resurfacing. *J Bone Joint Surg (Br).* 2006; 88-B: 592-600.
- 19 Vendittoli PA, Lavigne M, Roy AG, Lusignan D. A prospective randomized clinical trial comparing MoM total hip arthroplasty and MoM total hip resurfacing in patients less than 65 years old. *Hip Intl.* 2006; 16 (Suppl 4): 73-81.
- 20 Plant JGA, Prosser GH, Burston BJ, Edmondston SJ, Yates PJ. Mid-Term Review of ADEPT Metal-On-Metal Hip Prosthesis. Functional, Radiological and Metal Ion Analysis. *Open Journal of Orthopaedics*, 2014, 4: 38-43.
- 21 National Joint Registry. Implant Summary Report for ADEPT® Hip Resurfacing. November 2018. Ref: Summary.Report.HP_Head_Adept Resurfacing Head_All.22/11/2018.22:10
- 22 National Joint Registry. Implant Summary Report for the ADEPT® Hip Resurfacing. May 2014. Ref: IQMSummary.Adept Resurfacing Head.15/05/2014.17:14
- 23 National Joint Registry. Implant Summary Report for the ADEPT® Hip Resurfacing (Sizes 48-58 only). November 2018. Ref: Summary.Report.HP_Head_Adept Resurfacing Head (Sizes 48 - 58 only)_All.22/11/2018.22:08
- 24 National Institute for Clinical Excellence. Guidance of the use of Metal-on-Metal hip resurfacing arthroplasty. Technology appraisal guidance no 44, 2002 (revised in 2005).
- 25 British Orthopaedic Association (BOA). Primary Total Hip Replacement: a guide to good practice. 2012. <https://www.britishhipsociety.com/uploaded/Blue%20Book%202012%20fsh%20nov%202012.pdf>. Accessed 7 Dec 18.
- 26 Orthopaedic Data Evaluation Panel (ODEP). Latest ODEP ratings can be found at www.odep.org.uk
- 27 For ODEP statement on use of ratings by hospitals see: www.odep.org.uk/ODEPExplained/toHospitals.aspx.
- 28 Cuckler JM. The Rationale for Metal-on-Metal Total Hip Arthroplasty. *Clin Orthop and Rel Res*, 2005, 441: 132-136.
- 29 Schachter AK and Lamont JG. Surface Replacement Arthroplasty of the Hip. *Bulletin of the NYU Hospital for Joint Diseases* 2009; 67(1): 75-82.

12 Notes

Notes



CE₀₀₈₈ TGA Health Safety Regulation
ARTG209647 ARTG209656
ARTG209655 ARTG214708

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