NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Total hip replacement and resurfacing arthroplasty for the treatment of pain or disability resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44)

Final scope

Appraisal objective/remit

To appraise the clinical and cost effectiveness of total hip replacement and surface replacement within their CE marked indications for the treatment of pain or disability resulting from end stage arthritis of the hip.

Background

Arthritis is a group of diseases that affect joints, leading to pain and disability. Osteoarthritis is the most common form of arthritis, where there is loss of cartilage within the joint and accompanying changes in the associated bone. Osteoarthritis is more common in women than men and the risk of developing osteoarthritis increases with age. In 2006 it was estimated that 414,900 men and 760,400 women consulted their GP with osteoarthritis. Rheumatoid arthritis is an autoimmune disease causing inflammation of joints and is the second most common form of arthritis with approximately 400,000 people affected in the UK. Rheumatoid arthritis is approximately three times more common in women than men.

Osteoarthritis of the hip is the most common reason for having a hip replacement. In 2011, 57,745 hip procedures were carried out in the NHS in England and Wales, with a further 25,138 carried out in independent hospitals, and 93% of primary hip replacements were of hips that were affected by osteoarthritis.

NICE Clinical Guideline 59 on the care and management of osteoarthritis in adults says that referral for joint replacement surgery should be considered for people with osteoarthritis who experience pain, stiffness and reduced function that have a substantial impact on their quality of life and are refractory to non-surgical management such as exercise and manual therapy, and pain management.

People with arthritic damage to their hip may receive total replacement of the damaged hip (total hip replacement, total prosthetic replacement). The prosthesis may be fixed in position using cement, not using cement or be hybrid where one component of the prosthesis requires cement but the other does not. Alternatively, patients may receive hip resurfacing arthroplasty which involves removing damaged surfaces of the bones inside the hip joint

and replacement with a metal surface. Hip resurfacing arthroplasty conserves more femoral bone than total hip replacement and can result in a greater range of movement after surgery, but requires the patient to have relatively strong bones, therefore tends to be used in younger, more active patients. In 2010 out of the 68,907 primary hip procedures, 36% were cemented total hip replacements (THRs), 43% were cementless THRs and 16% were hybrid procedures, 3% were large head metal on metal THRs and 3% were resurfacing arthroplasty.

Currently, artificial hip joints last on average for 10 to 15 years, some considerably longer. Some hip replacements require revision surgery because of loosening of the joint, wear and tear, pain and dislocation. Current NICE guidance says that the best prostheses should demonstrate a 'benchmark' revision rate of 10% or less at 10 years or, as a minimum, a three year revision rate consistent with this benchmark.

In June 2012, the Medicines and Healthcare Regulatory Agency (MHRA) released an updated alert that Metal on Metal (MoM) implants (total hip replacements or resurfacing) may wear at an accelerated rate in some people. The MHRA said that people with either MoM implants or resurfacing require monitoring for soft tissue damage resulting from reactions of the soft tissue to debris from these implants. For symptomatic patients with any type of MoM hip replacement or resurfacing, a whole blood ion metal measurement and imaging of the joint is recommended. In Technology Appraisals 2 and 44, further research recommendations were that long term outcomes following total hip or MoM resurfacing should be determined by compiling data in a registry. The National Joint Registry was set up by the Department of Health and Welsh Assembly Government for the mandatory collection of information on all hip, knee, ankle, elbow and shoulder replacement operations from NHS organisations and to monitor the performance of joint replacement implants. Since 2009, all NHS patients who are having hip replacement surgery are invited to fill in Patient Reported Outcome Measures (PROMs) questionnaires about their health and quality of life before and after their surgery. The Orthopaedic Data Evaluation Panel (ODEP) hosted and facilitated by the NHS Supply Chain, coordinates, receives and analyses submissions of long term performance data from manufacturers. ODEP provides the NHS with an approved list of prostheses which meet the benchmarks set out in NICE guidance and which are suitable for use in primary hip replacement.

The technology

Total hip replacement is carried out to relieve pain and disability caused by arthritis of the hip, which cannot be managed by pain medication and physiotherapy. In total hip replacement a damaged hip joint is replaced with an artificial hip prosthesis. The acetabulum (hip socket of the pelvis) is replaced with either a cup made from a single material or a two piece (modular) cup made of an outer metal shell into which a polyethylene, ceramic or metal bearing liner is placed. A monoblock (single piece) metal stem and

head or a two piece (modular) femoral component consisting of a metal stem with a metal, ceramic or ceramicised metal head is inserted into the proximal femur (top of the thigh bone) in order for the prosthesis head to articulate with the cup.

Hip resurfacing arthroplasty involves removal and replacement of the surface of the femoral head with a metal hollow hemisphere, which fits into a metal cup which locates in the acetabulum.

Primary total hip replacement manufacturers include: Amplitude, Biomet, B Braun/ Aesculap, Corin, DePuy, Exactech, JRI (Joint Replacement Instrumentation), Implantcast , Implants International, Lima WG Healthcare, Mathys Orthopaedics , Medacta UK, Othodynamics, Peter Brehm, SERF dedienne santé, Smith & Nephew, Stanmore Implants Worldwide, Stryker, Symbios SA, Waldemar Link, Wright Medical UK, Zimmer

Primary resurfacing head and cup manufacturers include: Biomet, Corin, Implantcast, Smith & Nephew, Wright Medical UK, Zimmer

Intervention(s)	1. Primary total hip replacement 2. Primary hip resurfacing arthroplasty
Population(s)	People with pain or disability resulting from end stage arthritis of the hip (for which non-surgical management has failed).
Comparators	Primary total hip replacement and hip resurfacing arthroplasty will be compared with each other for people in whom both procedures are suitable. Primary total hip replacement will be compared to non-surgical management for people in whom hip resurfacing arthroplasty is not suitable.

Outcomes	The outcome measures to be considered include: • Functional result • Pain • Bone conservation • Revision rates • Radiosteriometric analysis to asses prosthesis movement • Dislocation rates • Adverse effects of treatment (peri- and post-procedural), including degradation products were appropriate • Health-related quality of life • Mortality
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	If the evidence allows subgroups based on activity levels will be compared. If the evidence allows different types of hip prostheses will be considered separately such as: • Hip replacements with components made from different materials (metal, ceramic, polyethylene, ceramicised metal). • Cemented, cementless or hybrid prostheses. • Prostheses with differing femoral head size. • Prostheses with differing revision rates, for example ODEP ratings Guidance will only be issued in accordance with CE marking If the recommendations remain based on long term performance (revision rates, for example ODEP ratings), the collection and monitoring of performance data and arrangements for the effective implementation of such recommendations should be considered.
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 2, Apr 2000, 'Hip disease-replacement prostheses' Technology Appraisal No. 44, Jun 2002, 'Hip disease-metal on metal hip resurfacing' Related Guidelines: Clinical Guideline No. 79, Nov 2004, 'Rheumatoid arthritis: the management of rheumatoid arthritis in adults' Clinical Guideline No. 59, Feb 2008, 'Osteoarthritis: The care and management of osteoarthritis in adults CG 59. Review in progress, earliest anticipated date of publication Nov 2013. Related Interventional Procedures: Intervention Procedure Guidance No. 112, Feb 2005 'Minimally invasive two-incision surgery for total hip replacement' Intervention Procedure Guidance No. 408, Sept 2011 'Arthroscopic femoro-acetabular surgery for hip impingement syndrome'

Appendix B