Metal on metal hip implants

Summary

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Table of Contents

Project Management Team ................................................................. 4
Abbreviations .................................................................................. 5
Summary ............................................................................................ 6
Participants ....................................................................................... 10
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## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AFIDEO</td>
<td>Association of European manufacturers, importers and distributors of orthopaedic and traumatology implants</td>
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<td>ANSM</td>
<td>National Medicines and Health Products Safety Agency (formerly Afssaps)</td>
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<td>AFSSAPS</td>
<td>French Healthcare Products Safety Agency</td>
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<tr>
<td>ACV</td>
<td>Added clinical value</td>
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<td>CCAM</td>
<td>Classification of medical procedures</td>
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<tr>
<td>CEPP</td>
<td>Committee for the Assessment of Products and Services</td>
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<td>CEPS</td>
<td>Committee for the Pricing of Healthcare Products</td>
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<td>CNAMTS</td>
<td>National Salaried Workers’ Health Insurance Fund</td>
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<td>CNEDiMTS</td>
<td>National Committee for the Evaluation of Medical Devices and Health Technologies (former Committee for the Assessment of Products and Services)</td>
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<tr>
<td>DGOS</td>
<td>Directorate General for the Provision of Healthcare</td>
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<td>DGS</td>
<td>Directorate-General for Health</td>
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<td>DSS</td>
<td>Social Security Directorate</td>
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<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>HAS</td>
<td>Haute Autorité de Santé</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>LPPR</td>
<td>List of products and services qualifying for reimbursement</td>
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<td>PMSI</td>
<td>Programme for clinical information systems</td>
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<td>RR</td>
<td>Relative risk</td>
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<tr>
<td>RSI</td>
<td>Health and retirement scheme for independent workers</td>
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<td>EAB</td>
<td>Expected actual benefit</td>
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<td>SNITEM</td>
<td>National union of the medical technology industry</td>
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<tr>
<td>SOFCOT</td>
<td>French Society of Orthopaedic and Trauma Surgery</td>
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<tr>
<td>AB</td>
<td>Actual benefit</td>
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<td>UNCAM</td>
<td>National Association of health insurance funds</td>
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Summary

• Background

The aim of total hip replacement is to enable patients with functionally severe osteoarthritis of the hip or a true femoral neck fracture to recover a painless mobile hip. In the absence of specific complications, the efficacy of hip implants is currently based primarily on implant survival as functional results are always achieved.

There are four main types of bearing surfaces (femoral head component - acetabular component) in hip implants:

- metal on polyethylene (with conventional polyethylene): the 'reference' bearing surface, for which greatest experience is available. These are generally accepted to have a 15- to 20-year survivorship;
- ceramic on polyethylene;
- ceramic on ceramic;
- metal on metal.

These different bearing surfaces have been reimbursed in France for many years. The first three categories of hip implants are listed under generic descriptions as their benefit has been demonstrated in clinical studies. Metal on metal hip implants are listed under their brand name on the list of products and services qualifying for reimbursement (LPPR) following an opinion from the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS). The findings published in 2012, which came particularly from three national registries (England & Wales, Australian and New Zealand National Registries), led CNEDiMTS to make an internal referral on 20 March 2012 to reassess hip implants with metal on metal bearing surface in order to establish whether these should be reimbursed.

The conclusions of this report do not incorporate the results of the work by the French National Medicines and Health Products Safety Agency (ANSM) and the ongoing European work on the assessment of the risks of metal on metal hip implants.

• Objectives – Working method

The working method adopted to assess metal on metal hip implants included:

- a critical analysis of the scientific literature;
- an analysis of data provided by the manufacturers;
- obtaining the opinions of health professionals during individual hearings by HAS’ Medical Devices Assessment Department: the opinions of the experts heard were recorded in a standardised questionnaire containing 25 proposals to be scored and discussed. This method enabled each opinion to be taken into account without seeking consensus between the experts;
- the CNEDiMTS conclusions.

These findings are described in the assessment report.

In addition, when required by the CNEDiMTS conclusions, the Commission’s opinions currently available on each metal on metal hip implants listed on the LPPR were updated.
Assessment – Data analysis

Fifteen references were selected from the systematic literature review: three national hip arthroplasty registries (Australian, New Zealand and England & Wales National Registries), four publications from registries, four meta-analyses or systematic reviews and four randomised controlled trials.

The assessment was based on the following endpoints: functional results, findings on revision surgery and survival implant and complications and causes of revision surgery.

The comparative studies included in the meta-analyses and systematic reviews and the randomised controlled trials selected were designed to demonstrate the superiority of hip implants with a metal on metal bearing surface, compared with metal on conventional polyethylene hip implants, or compared with another type of metal on metal hip implants.

The thematic analysis identified three categories of metal on metal total hip implants:

- conventional total hip implants with a femoral head diameter of 32 mm or less;
- conventional total hip implants with a femoral head diameter of 36 mm or more;
- total hip resurfacing implants.

The literature and national registries provide the following information about conventional total hip implants with metal on metal for small diameter femoral heads (32 mm or less):

- similar functional results to those achieved with the reference bearing surface (metal on conventional polyethylene);
- a longer survival with this type of devices than for the reference bearing surface in patients under 50 years old and equivalent results for those over 50 years old;
- no specific disadvantages: low incidence of osteolysis, metallosis and inguinal pain.

The literature does not provide evidence that conventional total hip implants with a "large diameter" (36 mm or more) metal on metal bearing surface are functionally superior to metal on polyethylene bearing surface. The benefit of large diameter femoral heads (reduced risk of dislocation) is counterbalanced by specific disadvantages (regional pain, osteolysis, pseudotumours) which may lead to revision surgery.

The national registries report lower survival rates for large diameter conventional total hip implants compared with the reference bearing surface.

In terms of the functional results for total hip resurfacing implants, the literature does not provide evidence that hip resurfacing implants are superior to total hip implants with a metal on polyethylene bearing surface, but does report similar functional results.

In terms of implant survival, the literature and national arthroplasty registries do not provide evidence that hip resurfacing implants are superior to total hip implants with a metal on polyethylene bearing surface in an unselected patient population. However, the implant survival reported by the England & Wales’ Registry was similar for populations selected by age (55 years old) and diameter of femoral head (large femoral heads).

In terms of complications, the literature does not provide evidence that total hip resurfacing implants are superior to total hip implants with a metal on polyethylene bearing surface. The complications reported are similar in type and incidence. A low dislocation rate is reported for hip resurfacing implants.
• **Summary of hearings**

The views of the experts heard are summarised as follows:

- that conventional total hip implants with a metal on metal bearing surface and a small diameter femoral head (≤ 32 mm) are of use in the indications currently listed on the LPPR following the opinion from CNEDiMTS;

- that conventional total hip implants with a metal on metal bearing surface and large diameter femoral head (≥ 36 mm) are no longer indicated.

They were divided, however, regarding the benefit of total hip resurfacing implants.

They also believed that patients implanted with a total hip implant with a large diameter metal on metal bearing surface (whether conventional or resurfacing) should have specific clinical and radiological follow up.

• **Conclusions of the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS)**

- **Conventional total hip implants with a metal on metal bearing surface and small diameter femoral head of 32 mm or less**

In light of the literature and hearings from experts, the Committee recommends that total hip implants with a metal on metal bearing surface and with femoral heads which are 32 mm or less in diameter continue to be reimbursed by the community in their current indications, i.e.

- severe functional hip disease causing daily disability, not sufficiently improved by correct medical care, after an observation period of a few weeks to months in patients under 50 years old and in patients between 50 and 70 years old who have a high level of activity and life expectancy;

- true femoral neck fractures in people under 70 years old, with a Parker activity score of 6 or above.

The Committee recommends that the conditions for use and prescription adopted by the Committee in 2007 be continued, and reinforced:

- Monitoring of renal function in patients who have received implants

- Contraindications: renal impairment and chromium, cobalt or nickel allergy. Allergy to these metals should be screened for from the patient's clinical history and possibly a skin test.

- The use of prostheses with a metal on metal bearing surface is not recommended in women of childbearing age.

In addition, the Committee is awaiting data to provide information about the long-term survival rate of the implants.

- **Conventional total hip implants with a metal on metal bearing surface and with large diameter femoral heads of 36 mm or over**

In light of the literature, hearings of experts, the existence of available alternatives and the need for specific follow up (both clinical and radiological) of patients receiving implants with these alternatives, the Committee recommends that conventional total hip implants with a metal on metal bearing surface and femoral heads with a diameter of 36 mm or over should no longer be reimbursed by the community.
- **Total hip resurfacing implants**

In light of the literature, hearings of experts and the functional benefit of hip resurfacing implants enabling young, active patients to return to their physically demanding occupational and/or sporting activities and despite the existence of available alternatives and the need for specific follow up (both clinical and radiological) of patients receiving implants, the Committee recommends that resurfacing implants continue to be reimbursed by the community in a selected population of young, active patients with osteoarthritis of the hip whose native femoral head is 48 mm in diameter or over. The Committee recommends that hip resurfacing arthroplasty be regulated in terms of the competence and experience of the implanting surgeon and in terms of the level of specialisation of the centre in which the procedure is performed. In addition, further clinical data need to be obtained.

For both the conventional hip implants with a metal on metal bearing surface and a femoral head of diameter 32 mm or under, and the total hip resurfacing implants, the Committee emphasises that their utility depends on their design (design and composition) and that it continues to be necessary for the Committee to examine specific clinical data for each implant.
Participants

► The national professional council for the following medical speciality was consulted for this assessment:
French Society of Orthopaedic and Trauma Surgery (SOFCOT)

► Project team
Prof Richard-Alexandre ROCHWERGER, orthopaedic surgeon, La Conception Hospital, Marseille (13)
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In addition to their participation in the project team whose task was to develop the proposals to be put to the experts in the individual hearings, Mr Rochwerger and Mr Charrois contributed to this work through their careful reviewing of this report.

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