HAUTE AUTORITÉ DE SANTÉ

SUMMARY REPORT

Assessment of shoulder joint implants

CNEDiMTS / March 2014

OBJECTIVE

This summary reports the main conclusions of the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) on the assessment of shoulder joint implants.

The objective of this assessment is to propose a new nomenclature for implants refundable by National Health Insurance. It specifies, when an arthroplasty has been decided upon, the indications for which each type of implant can be considered and the relevant minimum technical specifications.

The opinion of the CNEDiMTS including the recommended nomenclature and the full assessment report can be downloaded from the HAS website: http://www.has-sante.fr

BACKGROUND

The CNEDiMTS is in charge of the periodic review of all products and services included under generic descriptions in the list of products and services qualifying for reimbursement (LPPR). The assessment made was of standard fabricated shoulder joint implants including three main categories of implants:

- humeral implants, modular or monoblock;
- heads or caps;
- glenoid implants, modular or monoblock;

and custom-made implants, whether humeral or glenoid.

It should be emphasised that indications for shoulder joint implants are less common than for other prostheses such as those of the hip or the knee.

OBJECTIVES – WORKING METHOD

The objectives of the re-assessment were:

- to determine the indications for shoulder joint implants in the diseases concerned;
- to assess their actual benefit (AB) in each indication;
- to characterise the technical specifications influencing the AB of these devices;
- to define the role of these implants in the therapeutic strategy;
- to propose an updated nomenclature.

The working method used comprised a systematic review of the literature, analysis of the files submitted by manufacturers, and consultation of expert healthcare professionals who met in a multidisciplinary working group dedicated to the topic. The experts consulted were doctors specialising in orthopaedic surgery, radiodiagnostics and medical imaging, physical medicine and rehabilitation, and rheumatology, a pharmacist, and a university professor of digital modelling and simulation.

ASSESSMENT – ANALYSIS OF THE DATA

A systematic analysis of the literature found few studies with a high level of evidence. Six registries were identified but the data available did not always allow the results to be broken down by type of implant. The guidelines identified provided the group with little useful information.

The assessment covered the following endpoints:

- clinical endpoints: assessment of mobility, pain or quality of life;
- imaging endpoints: assessment of the preoperative lesions and of lesions occurring during follow-up;
- complications or revision surgery.

Ultimately, assessing the value of the different types of prosthesis proved difficult because of:

- the lack of comparative and prospective studies;
- the short follow-up period available for certain products, particularly the most recent;
- the large variety of products available;
- the limited estimated target population for shoulder joint implants based on the population actually treated, of the order of 12,500 patients a year.

THE WORKING GROUP'S OPINION

Development of the nomenclature

In view of the lack of literature with a high level of evidence and the lack of guidelines issued by learned societies, the working group's proposals are based mainly on expert opinions.

The working group's main proposals covered:

- A description of the implants, preferably according to their anatomical location but also their anchorage;
- The medicalisation of generic descriptions, defining the indications according to the type of arthroplasty performed;
- The need to differentiate the different standard fabricated joint implants by category for better follow-up. The indications recorded for each of these categories and the minimum technical specifications have been stipulated in the nomenclature;
- The distinction between the main characteristics differentiating implants of the same type, i.e.:
  - the need to use a cement,
  - the design of the reconstruction,
  - the length,
  - the material;
- The need to distinguish between implants made of ceramic and aluminium, in order to follow their survival, and those made of pyrocarbon or tantalum;
- The exclusion of generic descriptions of the implants:
  - dual mobility or intermediate mobility implants,
  - inverted humeral implants with metaphyseal-epiphyseal anchorage,
  - interposition implants,
  - partial resurfacing implants,
  - glenoid implants with a metal base secured by expansion screws;
- The continued reimbursement of custom-made joint implants.

Therapeutic use

Once the need for surgery has been diagnosed, the following decision trees show the main types of implants that can be used, according to the clinical situation.

Diagram 1. Decision tree for the choice of implant - Arthropathy with functioning rotator cuff

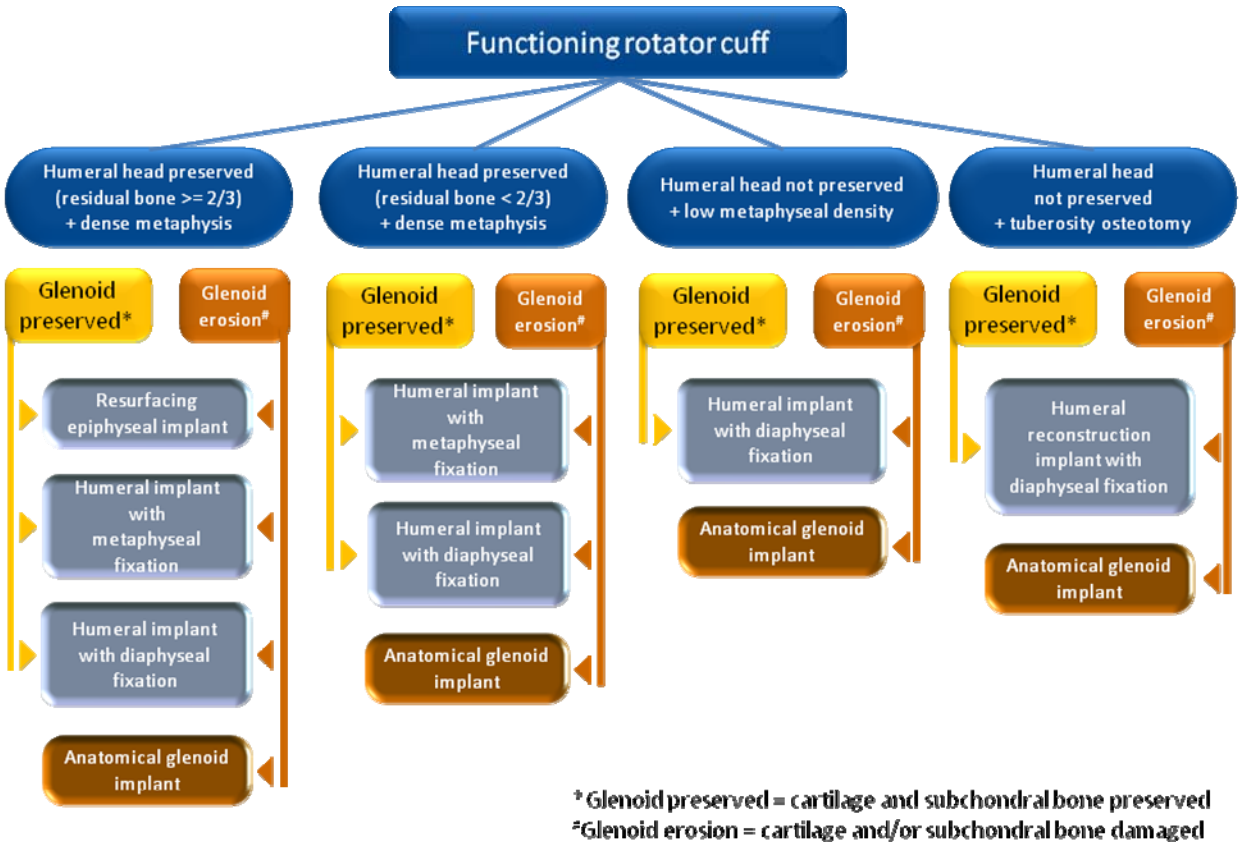


Diagram 2. Decision tree for the choice of implant - Arthropathy with non-functioning rotator cuff

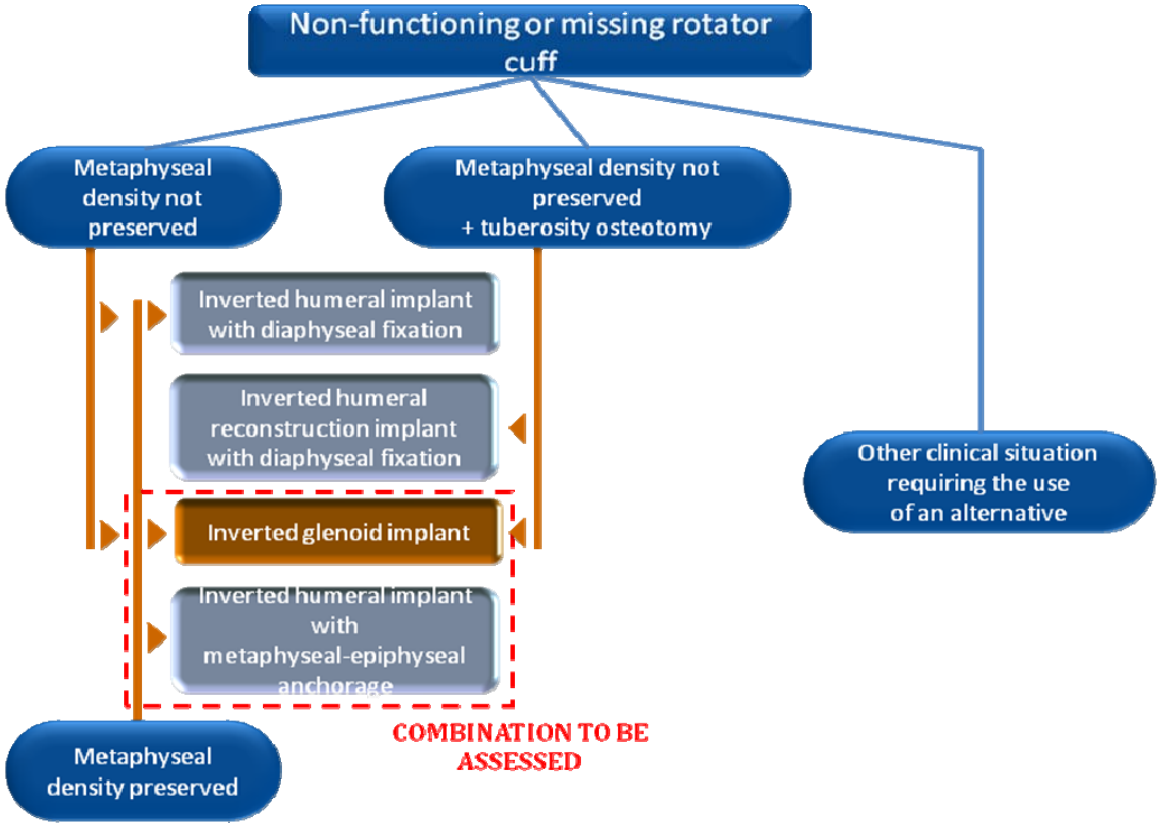
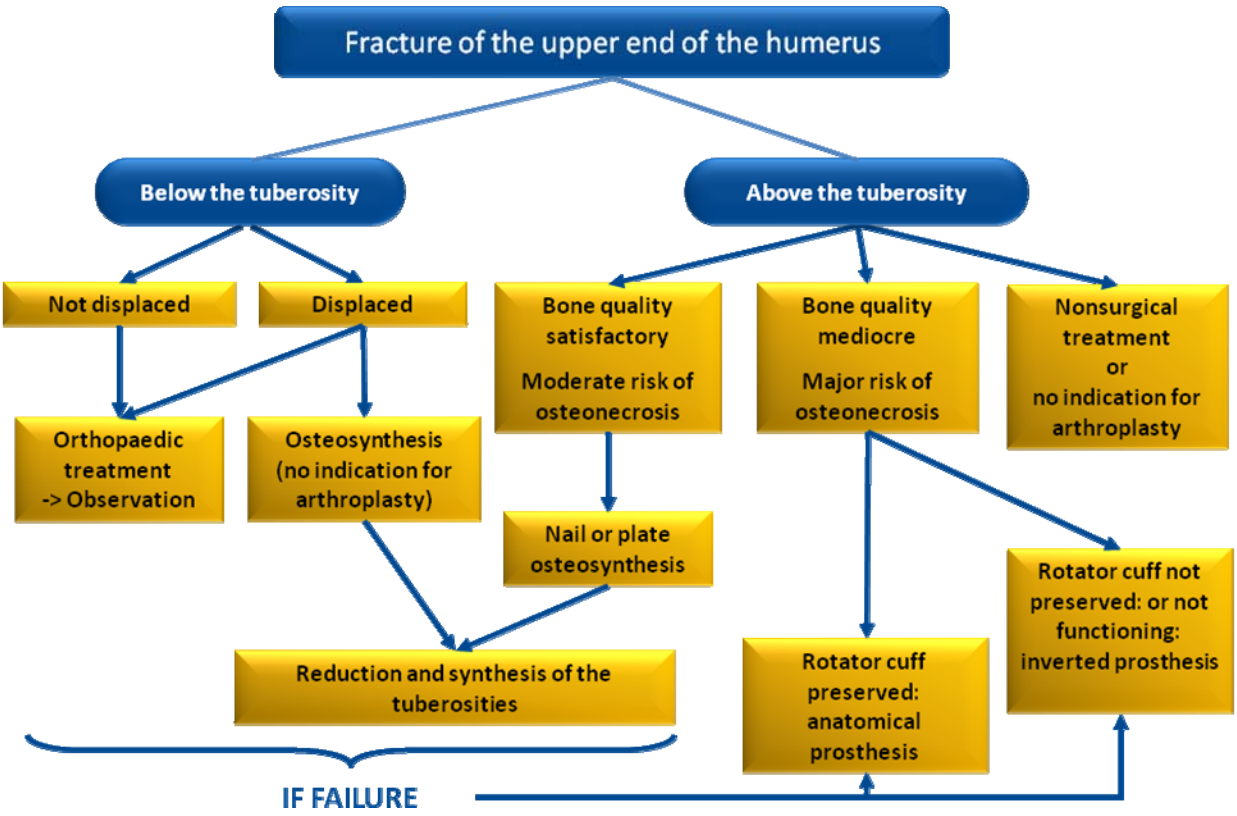


Diagram 3. Decision tree for the choice of implant - Fracture of the upper end of the humerus



GENERAL CONCLUSION OF THE CNEDIMTS

The CNEDiMTS Opinion can be downloaded from www.has-sante.fr.

The CNEDiMTS has adopted all the working group's proposals regarding the classification of implants: the indications, the methods of prescription and use and the specific technical features of each type of implant.

The recommended nomenclature was made deliberately modular, since it covers, as appropriate, the circumstances in which implants can be combined, for each main group of indications. Conversion options have been preferred.

The CNEDiMTS recommends, for implants that do not meet the minimal technical specifications described in the nomenclature, particularly because of their design or constituent materials, inclusion under the brand name, which entails submitting an application for a specific assessment; thus, the following were specifically designated by the Committee as being eligible for inclusion under the brand name of the implants:

- implants containing tantalum;
- implants containing pyrocarbon;
- dual mobility or intermediate mobility implants;
- inverted humeral implants with metaphyseal-epiphyseal anchorage;
- interposition implants;
- partial resurfacing implants;
- glenoid implants with a metal base secured by expansion screws.

It has validated the working group's proposals on the information needed for the clinical assessment of shoulder joint implants.

A new nomenclature, based on that assessment, is recommended in the opinion.