HAUTE AUTORITÉ DE SANTÉ

REVIEW OF HOMOGENEOUS CATEGORIES OF MEDICAL DEVICES

Elbow joint implants

Short text

September 2012

The complete report can be downloaded from
www.has-sante.fr

Haute Autorité de Santé
Communication and Publications Department
2 avenue du Stade de France - F 93218 Saint-Denis La Plaine CEDEX
Tel.: +33 (0)1 55 93 70 00 - Fax: +33 (0)1 55 93 74 00

This document was validated by CNEDiMTS in September 2012.

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Project management team

This dossier was prepared by Caroline Guerin (project manager, Medical Devices Assessment Department, tel.: 01 55 93 71 47, e-mail: c.guerin@has-sante.fr).

The research and the management of the documents were carried out by Aurélien Dancoisne (Information scientist, documentation department, tel.: 01 55 93 73 39, e-mail: a.dancoisne@has-sante.fr) and Laurence Frigere (assistant Information scientist, documentation department, tel.: 01 53 93 73 32, e-mail: l.frigere@has-sante.fr).

Yakaré Tounkara was responsible for organising the meetings and the secretarial work (tel.: 01 55 93 37 45, e-mail: y.tounkara@has-sante.fr and Stéphanie Luzio (e-mail: s.luzio@has-sante.fr).

The estimate of the target population was made by Emmanuelle Schapiro (project manager, Medical Devices Assessment Department, tel.: 01 55 93 37 76, e-mail: e.schapiro@has-sante.fr).

Officials in charge:

Head of Medical Devices Assessment Department: Dr. Catherine Denis (tel.: 01 55 93 37 40, e-mail: c.denis@has-sante.fr).

Assistant to the head of Medical Devices Assessment Department: Corinne Collignon (tel.: 01 55 93 37 44, e-mail: c.collignon@has-sante.fr).

Head of Communication and Public Information Department: Frédérique Pagès (tel.: 01 55 93 73 23, e-mail: f.pages@has-sante.fr).

The working group

The working group consisted of the following experts:

Prof. Thierry Begue, orthopaedic surgeon, Antoine-Béclère Hospital, Clamart (92)

Dr Pascal Clappaz, orthopaedic surgeon, Convert Clinic, Bourg-en-Bresse (01)

Dr Pascal Cottias, orthopaedic surgeon, Ermitage Clinic, Dammarie-lès-Lys (77) and Cochin Hospital, Paris (75)

Dr Bertrand Coulet, orthopaedic surgeon, Montpellier University Hospital, Montpellier (34)

Dr Philippe Didailler, orthopaedic surgeon, Dracy Medico-surgical orthopaedic centre, Dracy-le-Fort (71)

Prof. Christian Dumontier, orthopaedic surgeon, Jouvenet Clinic and Saint-Antoine Hospital, Paris (75)

Prof. Fabrice Duparc, orthopaedic surgeon, Rouen University Hospital, Rouen (76)

Dr Nicolas Jay, public health physician, Faculty of Medicine of Nancy, Nancy (54)

Dr Cécile Nerot, orthopaedic surgeon, Reims University Hospital, Reims (51)

Dr Patricia Ribinik, physical medicine and rehabilitation physician, Gonesse Hospital, Gonesse (95)

Prof. Richard-Alexandre Rochwerger, orthopaedic surgeon, Hospital of the Conception, Marseilles (13)

Prof. Thierry Thomas, rheumatologist, Saint Etienne University Hospital, Saint-Etienne (42)

Prof. Christian Vallée, radiologist, Raymond Poincaré Hospital, Garches (92)

The members of the working group were appointed by the CNEDiMTS board from among the experts proposed by the relevant associations or learned societies, experts who replied to the call for candidates, and experts known to HAS.

In accordance with Decree 2004-1139 of 26 October 2004 (Articles R.161-84 to R.161-86 of the Social Security Code), all the experts completed a declaration of interests, mentioning direct or indirect links with any company or body involved in the field of the tasks of HAS. These declarations of interest have been published on the HAS website.

The analysis of the declarations of interest was carried out in accordance with the "*Guide des déclarations d'intérêts et de gestion des conflits d'intérêts de la HAS" [HAS Guide to declarations of interests and management of conflicts of interest]* (adopted by the HAS board on 3 March 2010). A summary table of the interests declared was examined by the CNEDiMTS board, which decided on the final composition of the working group. The interests declared by the experts chosen were also considered "not major" by the CNEDiMTS board.

The summary table of the interests declared was made public and, where appropriate, updated on the basis of the updated declarations of interests of the experts at the beginning of each meeting of the working group and on presentation of the working group's opinion at CNEDIMTS.

Short text

Context

Since 2004, the committee has undertaken a review of all the products and services registered under generic descriptions in the list of reimbursable products and services (LPPR). This review has concerned standard fabricated elbow joint implants including two main categories of prosthesis:

- Total elbow (humero-ulnar) prostheses
- Radial head prostheses

and custom-made elbow implants.

The rarity of the indications for implantation of an elbow prosthesis compared with other prostheses such as hip, knee or shoulder prostheses should be emphasised. In France, operations for arthroplasty of the elbow remain confined to a few clinical conditions such as traumatology and its sequelae, arthritis, rheumatoid arthritis and other even more exceptional or even marginal conditions for implantation (haemophilic arthropathy and tumours).

Objective – Working method

The objectives of this study were to assess the interest of the products, that is to say:

- The indications for the different types of prosthesis;
- The therapeutic effect/complications ratio;
- The place of the product in treatment strategy.

Whenever this was possible or necessary, the new modalities of use and prescribing, as well as the technical specifications needed for inclusion of the product in the LPPR, were defined.

The working method is based on a systematic review of the literature, the analysis of the dossiers submitted by the manufacturers, and opinion of healthcare professionals meeting in a multidisciplinary working group focussed on the subject.

Assessment - Analysis of the data

Systematic analysis of the literature revealed few studies with a high level of evidence. No guidelines and no assessment reports could be identified.

The assessment covered the following assessment criteria: functional assessment, measurement of mobility, rates of survival or revision of the implant, radiological assessment, complications.

Overall, the assessment of the interest of the different types of prosthesis was difficult because of:

- a small estimated target population for elbow joint (about 1000 patients a year);
- the lack of comparative and prospective studies;
- the heterogeneity of the clinical data available which generally did not give any information about the specific interest of the device by pathology (the population included was heterogeneous and often with associated multiple pathology).

- **Working group opinion**

In the absence of literature with high levels of evidence and guidelines from learned societies or a professional consensus, the proposals of the working group are based essentially on expert opinions.

The main proposals of the working group concerned:

- The medicalisation of the generic descriptions, defining the indications by types of prosthesis;
- The need to differentiate between the different standard fabricated joint implants by category for the purposes of better follow-up. The indications adopted for each of these categories and the minimal technical specifications were set out in the classification;
- For radial head prostheses, the working group proposed that the “mixed” nature of the material should be defined as a metal-polyethylene combination. All other combinations of materials coud be covered according to the brand name procedure inscription. The objective is to allow to follow up these devices and to collect the clinical data considered necessary;
- The retaining of the generic description of “non-metal monoblock radial head prostheses” (prostheses made of materials which are neither metal nor mixed) with a restriction to silicone, however, as the sole non-metal constituent material possible;
- A change in the wording in the indications for custom-made joint implants.

- **General conclusion of the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS)**

CNEDiMTS adopted the main points of the working group‘s proposals, adding some supplementary details about the wording of the indications for the radial head and humero-ulnar standard fabricated prostheses, and on that of the made-to-measure elbow joint implants. Clarification was also added by the Committee concerning the materials which made up certain prostheses defined below (humero-ulnar, humero-radial and distal humeral prostheses).

A distinction was drawn between four main categories of standard fabricated joint implants:

1. The radial head prosthesis
2. The humero-ulnar prosthesis
3. The humero-radial prosthesis
4. The distal humeral prosthesis.

For the “radial head prosthesis” category, the Committee recommends the creation of three generic descriptions depending on the monoblock or modular nature of the radial head and the materials which comprise it.

For the “humero-ulnar prosthesis” category, the Committee recommends the creation of two generic descriptions and one entry for each brand name depending on the mechanism linking of the prostheses (the physical linking of the humeral and ulnar components).

For the “humero-radial prosthesis” category, the Committee recommends a general description.

Finally, for the last category, “distal humeral prosthesis”, the Committee recommends one entry for each brand name.

The arguments and the proposed classification are described in the complete report.

List of abbreviations

CNEDiMTS	National committee for the evaluation of medical devices and health technologies
HAS	Haute Autorité de Santé [National authority for health]
LPPR	List of products and services qualifying for reimbursement
SED	Medical Devices Assessment Department
SR	Systematic review
TEA	Total Elbow Arthroplasty
TEP	Total Elbow Prosthesis
TR	Radial head