



HAUTE AUTORITÉ DE SANTÉ

**TREATMENT WITH IMPLANT-SUPPORTED
DENTURES IN ADULTS WITH MULTIPLE TOOTH
AGENESIS RELATED TO A RARE DISEASE -
ASSESSMENT OF PROCEDURES ASSOCIATED WITH
PRE-IMPLANT SURGERY, IMPLANT AND IMPLANT-
SUPPORTED DENTURE PLACEMENT**

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Department of Medical and Surgical Procedures Assessment

This document can be downloaded from
www.has-sante.fr

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INTRODUCTION

One of the missions of the *Haute Autorité de Santé* (HAS) is to evaluate the expected clinical benefit (ECB) of professional procedures, then gives its opinion with regard to their inclusion on, modification of the conditions for their inclusion on, or removal from the list described in article L. 162-1-7 of the French Social Security Code (CSS), i.e. the list of procedures reimbursed by National Insurance. In particular, HAS' opinion is sent to the French Association of National Health Insurance Funds (UNCAM) which takes a decision on whether to include procedures, modify the conditions for their inclusion or remove them.

Evaluation of ECB takes account of diagnostic or therapeutic benefit and benefits to public health. The assessment of diagnostic or therapeutic benefit takes into account the efficacy, safety and role of the procedure in the diagnostic or therapeutic strategy. Public health benefit is assessed in terms of impact on the health of the population (mortality, morbidity, quality-of-life, clinical need not covered with regard to the severity of the disorder), impact on the health care system, and impact on public health programmes and policies. The different criteria for assessment of ECB are described in article R. 162-52-1 of the CSS.

In addition, the article specifies that any improvement in ECB (IECB) should also be assessed, i.e. any additional benefit provided by the procedure being evaluated compared with existing alternative techniques.

This document contains the opinions of HAS relating to the ECB and IECB of 23 procedures involved in successive phases of the treatment and to their inclusion on the list of procedures described in article L. 162-1-7 of the CSS.

These opinions are based on the justifications and conclusions of the HAS health technology assessment "*Traitement implantoprothétique de l'adulte atteint d'agénésies dentaires multiples liées à une maladie rare. Evaluation des actes associés à la chirurgie préimplantaire, à la pose d'implants et à la pose d'une prothèse amovible supra-implantaire*" [Treatment with implant-supported dentures in adults with multiple tooth agenesis related to a rare disease - assessment of procedures associated with pre-implant surgery, implant and implant-supported denture placement](July 2010), the short text of which appears below. The report can be downloaded from the HAS website.

SHORT TEXT OF THE EVALUATION REPORT: "TREATMENT WITH IMPLANT-SUPPORTED DENTURES IN ADULTS WITH MULTIPLE TOOTH AGENESIS RELATED TO A RARE DISEASE"

I. INTRODUCTION AND BACKGROUND

The request for assessment of procedures with a view to reimbursement of the cost of treating multiple tooth agenesis related to rare diseases, in adults, follows the first HAS report published in 2006 concerning reimbursement for children with the same disorders.

In the earlier report, it was decided that the expected clinical benefit of certain procedures relating to the placement of two or even four implants in the anterior mandible to provide a stable foundation for a removable denture was adequate in children from the age of six years up to the end of growth. Following this report, the procedures concerned were included on the list of procedures reimbursed by French National Insurance and included in its fee structure.

The Minister and UNCAM requested a further assessment to ensure equity in access to diagnosis, treatment and reimbursement for adult patients, in accordance with the French national rare diseases plan.

Conventional removable dentures are often unstable and are poorly tolerated because of poor function, poor aesthetic appearance and for psychological reasons. An implant-supported denture may be tried, to improve denture stability.

This report describes the assessment of 23 procedures involved in successive phases of treatment, namely :

- pre-implant assessment,
- surgical preparation of the implant site,
- implant placement, including placement of the implants themselves and their attachment system,
- denture placement ; only removable implant-supported dentures were considered in this assessment. Implant-supported fixed dentures are another prosthetic option for adults; they are not included in this dossier as they were not included in the assessment request from UNCAM.

Diagnosis of a rare disease requires services from reference centres approved under a French national scheme. These centres are linked with centres of competence to offer a structured care network and provide clinical management. Tooth agenesis may occur in a number of rare diseases, the most common being ectodermal dysplasia.

II. METHOD

This assessment was produced using a method based on :

- a critical analysis of data in the scientific literature;
- the opinions of professionals in a working group;

As the analysis of specific studies of treatment of rare disease-related multiple tooth agenesis provided insufficient evidence on the efficacy and safety of the procedures, it was felt appropriate to search the results of assessments dealing with these same procedures in the context of implant-supported management of multiple edentulousness, irrespective of aetiology.

A further literature search identified a very large number of recent documents on the management of edentulous patients in general by means of implants, of different levels of evidence.

Systematic reviews were then selected to extrapolate their results and conclusions to the specific management of multiple tooth agenesis, and to provide evidence on the efficacy and safety of the procedures concerned.

III. ASSESSMENT RESULTS

The analysis of published data and consideration of the opinions of the working group experts led to the following conclusions :

III.1 Pre-implant assessment

A pre-implant workup should be carried out, including clinical and radiological data, analysis of study models on an articulator and the use of surgical and radiological guides, to assess the volume and quality of available bone, to select the type, number and diameter of implants and to visualise their position and the final result before work begins.

A CT scan should be done for precise determination of bone volume and type, and to check the position of adjacent anatomic structures.

The CT scan could be replaced by cone beam CT imaging of the face provided that the system, field size and settings chosen result in a lower level of radiation than a CT scan performed using optimised low-dose protocols, for a comparable and adequate image quality.

III.2 Surgical preparation of the implant site

III.2.1 Maxillary sinus augmentation :

Sinus grafting is a predictable technique with a high implant survival rate. It is difficult to recommend any one technique rather than another; bone substitutes (BIO-OSS and CERASORB) seem to be as effective as autogenous bone grafts and could be used in their place to augment an atrophied maxillary sinus.

Better evaluation is needed to determine optimum graft healing time and to establish the best time for implant placement and loading.

III.2.2 Alveolar bone augmentation techniques

Different techniques (block or particulate grafts, guided bone regeneration) and materials (autogenous bone, allogenic or xenogenic replacement materials, alloplastic synthetic materials) can be used, but there is insufficient evidence to determine which are the most effective.

Practitioners should therefore weigh up carefully the benefits and risks associated with these techniques. The degree of edentulousness, site, and degree of atrophy should be taken into account to establish the option associated with the lowest morbidity. So major bone graft procedures in an atrophied mandible are not routinely justified as short implants could be used, with fewer complications than if conventional implants were used in conjunction with iliac bone grafts.

III.2.3 Horizontal ridge expansion

There are few current data; the implant survival rate reported is similar to that for untreated bone (mostly in the maxilla, with immediate implant placement) but the

data remain insufficiently conclusive about the long-term stability of the bone volume obtained after expansion.

III.2.4 Alveolar distraction

Distraction can be an effective method of increasing vertical bone before implant placement. Analysis of the different elements of the procedure shows that the consolidation period (minimum 12 weeks) has a significant effect on implant survival. Further studies are needed for a better assessment of the different protocols in order to improve results.

III.2.5 Pre-implant Le Fort I osteotomy (total lower maxillary osteotomy) with interpositional bone graft, and Pre-implant mandibular anterior segmental osteotomy with interpositional bone graft

These techniques should only be used for maxillary atrophy combined with intermaxillary relationships which cannot be treated by other augmentation methods.

Data relating to the maxilla show that this procedure is reliable, with a relatively small failure level; the implant survival rate is slightly lower than that obtained for procedures without augmentation; and there is substantial postoperative morbidity, although in most cases this is temporary.

No data on efficacy were found for preprosthetic mandibular anterior segmental osteotomy with interpositional graft, by the intraoral route. Experts considered this technique to be reliable.

III.2.6 Inferior alveolar nerve transposition

Sensory loss (hypoesthesia) is a classical adverse event after transposition of the inferior alveolar nerve.

No data were found on efficacy. The technique is difficult to perform; the indication should be established after a rigorous workup.

III.2.7 Sub-epithelial connective tissue or connective tissue gingival graft and Muco-gingival repair with a laterally, coronally or apically positioned flap

The most recent published data show that apically-positioned flaps with vestibuloplasty are effective in increasing the width of the keratinised tissue and attached gum. Augmentation with autogenous tissue significantly increases the width of the attached gum. There are very few data on augmentation of soft tissue volume; they tend to favour connective tissue grafts over free gingival grafts.

In conclusion, certain bone augmentation techniques involve complex major procedures potentially associated with complications.

They are not always preceded by evaluation of whether or not they will improve treatment outcomes or the patient's quality of life.

It is therefore essential to weigh up the options carefully and critically to decide whether there is a real need for bone volume augmentation or periodontal surgery, i.e. by considering the actual benefit to the patient and the most effective technique in these very specific genetic situations, where bone quality and morphology affect the clinical decision.

An objective aesthetic evaluation and the patient's own views should also be taken into account.

III.3 Implant placement

III.3.1 Survival rate

The implant survival rate is good, irrespective of morphology or surface, but it is not yet possible to conclude that any one type of implant is better than any other in terms of long-term success.

The 5-10 year survival rate for implants supporting a complete mandibular overdenture is high, around 95%. Survival rates are lower in the maxilla (the trabecular maxillary bone structure provides less stability than the cortical mandibular bone).

With preprosthetic alveolar and sinus reconstruction techniques, which are often required for an atrophied maxilla, the implant survival rate was felt to be satisfactory and close or in some cases, even comparable to, that obtained in untreated bone. There are few data for techniques involving maxillary osteotomy and major reconstruction, and they tend to show that the implant survival rate is lower in treated bone than in untreated bone. However, these data need to be confirmed by further good quality studies after long-term follow-up.

III.3.2 Loading

The usual option for patients with an atrophied maxilla is a two-stage protocol, with implant loading 3-6 months after placement.

The short-term results obtained with the different treatment protocols for edentulous mandibles are similar. Longer term data are needed for a definite conclusion on whether immediate loading is beneficial.

III.3.3 Number of implants

In an edentulous mandible, implant survival rate and patient satisfaction are not affected by the number of implants.

Current data suggest that in most cases, a full removable overdenture supported by at least two implants in the mandible and a full removable overdenture supported by at least four implants in the maxilla are good alternatives to a conventional full denture.

III.3.4 Complications

Biological complications may occur after implant placement.

Estimated implant loss is 2.5% before loading and up to 5% after loading (at five years) with a full overdenture. Peri-implantitis and bone loss > 2.5 mm have also been reported, although less frequently.

III.4 Implant-supported dentures

III.4.1 Clinical performance and patient satisfaction

An implant-supported mandibular overdenture significantly improves masticatory function, denture stability (irrespective of type of attachment) and patient satisfaction. There are few studies of maxillary overdentures. However, the few data available show that patients who are satisfied with a conventional maxillary denture do not obtain any significant improvement with a full implant-supported overdenture, whether or not the palate is covered.

Patients report satisfaction with the aesthetic and functional improvement and a very favourable impact on self-esteem, professional and social life.

III.4.2 Complications

Mucogingival and mechanical complications have been reported, more frequently for the maxilla. These complications require repair, modification or reworking of different parts of the denture. Variation in levels of denture maintenance seem to be related to the types of denture and attachment used, but these data need to be developed further by studies comparing different designs of denture.

In any case, the frequency of complications and the need for relining and repair, or even changes of attachment, emphasise the fact that regular maintenance should be included in planning for rehabilitation after implant placement.

III.5 Conditions under which procedures are carried out

III.5.1 Multidisciplinary approach

Care should be provided by a multidisciplinary team which includes orthodontists, maxillofacial surgeons and denture specialists; this is essential for treatment success. Such a team improves coordination, providing the patient with appropriate care and reducing the amount of inappropriate treatment delivered by potentially inexperienced carers.

III.5.2 Technical facilities for surgical procedures

Implant surgery should be carried out in a specific intervention room or other suitable room in strict compliance with asepsis protocols throughout the procedure. For the specific ridge and sinus augmentation techniques, the technical facilities should be modified according to the type of surgery, type of anaesthesia, duration of procedure and harvesting site; they can be carried out in specific or adapted intervention rooms or in an operating theatre. Maxillofacial osteotomies or bone grafts with large volume extra-oral or intra-oral harvesting always require the use of an operating theatre.

These techniques require specific skills.