NICE National Institute for Health and Care Excellence

NICE guidance

Insertion of customised exposed titanium implants, without soft tissue cover, for complex orofacial reconstruction

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG28.

1 Recommendations

This guidance only covers the use of titanium implants for complex orofacial reconstruction, often involving multiple surfaces, including bony and cartilaginous structures, without soft tissue cover or the expectation of substantial soft tissue cover. It does not cover the use of titanium implants for orofacial reconstruction where the implants are covered or expected to become substantially covered with soft tissue.

1.1 Current evidence on the efficacy of inserting customised exposed titanium implants, without soft tissue cover, for complex orofacial reconstruction is based on very small numbers of patients. With regard to safety there is concern about the risk of recurrent infection and other complications resulting from long-term exposure of the implants. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake insertion of customised exposed titanium implants, without soft tissue cover, for complex orofacial reconstruction should take the following actions.

- Inform the clinical governance leads in their trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the

use of NICE's information for the public is recommended.

- Audit and review clinical outcomes of all patients having insertion of customised exposed titanium implants, without soft tissue cover, for complex orofacial reconstruction.

1.3 Patient selection is of fundamental importance. The procedure should only be offered to patients for whom there are no other options for reconstruction after consideration by head and neck surgeons and plastic surgeons.

2 The procedure

2.1 Indications and current treatments

2.1.1 Complex orofacial reconstruction involving multiple surfaces, including bony and cartilaginous structures, without the expectation of substantial soft tissue cover is most frequently needed after severe orofacial trauma or removal of orofacial tumours, but may also be used to treat congenital facial abnormalities. Various materials are used including autologous grafts; tissue-engineered bone; alloplastic materials such as silicone, titanium or hydroxyapatite; and composites (for example, titanium mesh embedded in porous polyethylene).

2.1.2 The traditional method of forming titanium implants for complex orofacial reconstruction is to bend and cut titanium mesh during the operation. Positioning the implant in the appropriate site requires an accurate assessment of shape and fit, and a number of insertion attempts may be necessary before correct implant shape is achieved. In this procedure, computer-aided design and computer-aided manufacturing (CAD-CAM) techniques are used to create a customised implant before the operation to insert the implant. The aim is to improve both functional and cosmetic outcomes.

2.2 Outline of the procedure

2.2.1 The design and construction of custom-made implants can be achieved by a number of different techniques. In most cases, customised implants are designed and manufactured using CT scan data by CAD-CAM and 3-dimensional printing techniques. In some cases, a model is constructed on which the implant is shaped and made, either directly or indirectly.

2.2.2 With the patient under general anaesthesia the sterilised titanium implant is fixed to adjacent bone using titanium screws. Precise details of the operation will depend on where the implant is to be used and the integrity of surrounding structures.

2.3 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A case series of 14 patients who had undergone reconstruction procedures following removal of head and neck tumours reported that the maxilla, hemimandible and nose were successfully reconstructed without needing to raise flaps for coverage. Attempts to reconstruct the subtotal mandible in 2 patients failed because of lack of soft tissue adherence. Both patients underwent further conventional procedures after the implants were removed.

2.3.2 In the case series of 14 patients, appearance was described as excellent in 3 patients (details of appearance were not described for the remaining patients). After 2 years of follow-up, all patients remained disease-free and had an acceptable quality of life.

2.3.3 The specialist advisers listed key efficacy outcomes as reduced operating time, reduced morbidity, long-term implant retention rates, fixation (screw) removal rates and survival rates (for patients with cancer).

2.4 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.4.1 Ulceration through the skin of titanium-coated hollow screw reconstruction plate (THORP) implants was reported in all patients with buccal placement of plates in the case series of 14 patients. Eight patients had been treated using THORP but it was not reported how many of them had buccal placement of the implant. It was noted that 1 patient was treated by fitting an acrylic cover plate over the exposed section of the THORP implant. Case reports described unintentional implant exposure in 2 patients that occurred after insertion of large titanium implants for nasal reconstruction. Both patients needed a number of additional procedures.

2.4.2 Infection due to methicillin-resistant Staphylococcus aureus (MRSA) resulting in removal of the implant was reported in 1 patient in the case series of 14 patients.

2.4.3 Fistulae were reported in 4 patients in the case series of 14 patients. Two of the fistulae were closed with relatively simple flap procedures, and a third was closed using adjuvant hyperbaric oxygen therapy. The fourth fistula was found after 2 years at the site of one of the rivet heads on the THORP implant. This orocervical fistula failed to close after 4 flap procedures and hyperbaric oxygen therapy; eventually titanium chain mail with a solid titanium diaphragm was used to close it.

2.4.4 The specialist advisers listed theoretical adverse events as recurrent infection, bone infection, possible septicaemia, externalisation, bone resorption, loosening of the implant, poor aesthetics and failure of the prosthesis.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.