NICE guidance

Insertion of customised titanium implants, with soft tissue cover, for orofacial reconstruction

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg449

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 Guidance

1.1 Current evidence on the efficacy and safety of customised titanium implant insertion for orofacial reconstruction, including reconstruction of the orbital floor, where implants are covered or expected to become substantially covered with soft tissue, is adequate for this procedure to be used with normal arrangements for clinical governance, consent and audit or research. This guidance does not cover complex orofacial reconstruction involving multiple bony and cartilaginous structures, with little or no soft tissue cover.

2 The procedure

2.1 Indications and current treatments

2.1.1 Orofacial reconstruction 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). In some sites in the orofacial skeleton (such as the orbital floor), such implants are initially exposed, but there is good radiological and clinical evidence that a protective soft tissue covering forms over them.

2.1.2 The traditional method of forming titanium implants for facial reconstruction is to bend and cut titanium mesh during the operation. 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 first step in making a customised titanium implant for orofacial reconstruction is to create a precise anatomical model of the patient's skull or a 3-dimensional simulated computer image, using computed tomography or cone-beam computed tomography scans and CAD-CAM techniques. The implant is then shaped using the contours of this model.

2.2.2 The implantation procedure is performed 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 extent of surrounding damage. In most cases the implant is covered, either using existing soft tissue from the area or by transplant of a tissue flap from a donor site. However, implants abutting the paranasal sinuses are left partially exposed in the expectation of soft tissue cover developing as a result of fibrosis and epithelialisation.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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.

2.3.1 A non-randomised comparative study of 64 patients with facial asymmetry who had orbitozygomatic reconstruction for enophthalmos (posterior displacement of the eyeball) reported good globe projection in 76% (19 out of 25) of patients treated by customised implants compared with 59% (23 out of 39) of patients treated by traditional implants at 1-month follow-up; 8% (2 out of 25) of patients treated by customised implants needed an ocular prosthesis compared with 21% (8 out of 39) of patients treated by traditional implants (p values not reported). A case series of 29 patients reported that enophthalmos was fully corrected in 69% (20 out of 29) of patients and improved in 31% (9 out of 29) of patients, at a mean follow-up of 14 months. However, it was noted that overcorrection of enophthalmos occurred in 10% (3 out of 29) of patients.

2.3.2 A non-randomised comparative study of 24 patients reported significantly better reduction of binocular single vision loss area (p=0.015), correction of primary globe position in vertical visual disparity (p=0.012) and improvement in upgaze disparity (p=0.003) for patients treated by customised implants compared with patients treated by traditional implants at 12-month follow-up. The case series of 29 patients reported that diplopia had resolved in 21% (5 out of 24) of patients, improved in 37% (9 out of 24) of patients and not changed in 42% (10 out of 24) of patients, at a mean follow-up of 14 months.

2.3.3 The case series of 29 patients reported that restricted ocular motility resolved in 15% (4 out of 26) of patients, improved in 35% (9 out of 26) of patients and did not change in 50% (13 out of 26) of patients, at a mean follow-up of 14 months.

2.3.4 The non-randomised comparative study of 64 patients with facial asymmetry who had orbitozygomatic reconstruction reported perfect reduction of the zygoma in 92% (23 out of 25) of patients treated by customised implants (including 11 procedures that used computer-assisted navigation) compared with 74% (29 out of 39) of patients treated by traditional implants (p value not reported).

2.3.5 In a case series of 22 patients with orbital defects, 1 out of 17 patients with preoperative diplopia needed ocular motor surgery after the initial procedure (follow-up 24 months).

2.3.6 The Specialist Advisers listed key efficacy outcomes as long-term function and

durability of the implant, and return to normal daily activities.

2.4 Safety

2.4.1 Titanium mesh became unintentionally exposed in 2 patients in a case series of 20 patients who had undergone reconstruction of high maxillary defects. In 1 patient, the mesh became exposed in the oral cavity at 36 months; in the other patient, the mesh became exposed through the infraorbital skin at 4 months. Both patients had further surgery. A palpable plate rim was reported in 1 patient in the case series of 22 orbital reconstructions. The patient developed pain and irritation at the inferior orbital margin, where she was able to feel the plate flange and screw (timing not reported). The flange was trimmed and the screw removed in a further operation.

2.4.2 Infection in the region of the implant was reported in 1 patient in the case series of 29 patients who had undergone extensive orbital reconstruction. Maxillary sinusitis was reported in 1 patient in the non-randomised comparative study of 64 patients (treatment group not reported). This resolved after debridement and drainage.

2.4.3 Oronasal fistulae were reported in 2 patients in the case series of 20 patients who had undergone maxillary reconstruction. The fistulae were detected at the edge of palatal skin paddles 1 year after surgery and were sealed with removable partial dentures.

2.4.4 Visual deterioration occurred in 1 patient in the case series of 22 patients. The patient developed a sudden-onset subjective decrease in visual acuity, with no perception of light after 8 hours. This resolved within a week of the implant being removed. Transient loss of visual acuity occurred in 1 patient in a case series of 15 patients who had undergone orbital reconstruction, which was attributed to the mesh plate encroaching on the optic nerve. Reoperation led to complete recovery.

2.4.5 Intraconal soft tissue scarring, limited ocular motility and persistent diplopia were reported in 1 patient from the case series of 15 patients with orbital defects. Diplopia improved after revisional surgery.

2.4.6 Oculomotor nerve palsy occurred in 1 patient in the non-randomised comparative study of 64 patients with a follow-up period of 1 month (treatment group not reported); surgery was carried out to correct the resulting strabismus.

2.4.7 The Specialist Advisers listed additional theoretical adverse events as bone resorption, loosening of the implant, and loss of the integrated elements 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.