

Total prosthetic replacement of the temporomandibular joint

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg500

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 IPG329.

1 Recommendations

- 1.1 Current evidence on the efficacy and safety of total prosthetic replacement of the temporomandibular joint is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 Patient selection should be carried out in specialist units by a team with regular practice and specific expertise in the conservative and surgical management of temporomandibular joint problems, and should include consideration of all relevant medical and surgical options. The British Association of Oral and Maxillofacial Surgeons (BAOMS) has produced guidelines on patient selection.
- 1.3 The procedure should be carried out only by clinicians with specific training and experience in total prosthetic replacement of the temporomandibular joint.
- 1.4 Clinicians should submit details on all patients treated by total prosthetic replacement of the temporomandibular joint to the British Association of TMJ Surgeons UK register. Further information about the long-term safety and efficacy of the various prostheses used would be useful.

2 Indications and current treatments

- 2.1 Causes of disorders of the temporomandibular joint include inflammatory

and degenerative arthritis, trauma, infection and complications of surgery. Symptoms include pain and difficulty opening and closing the mouth, and an inability to eat a normal diet.

- 2.2 Conservative treatments for disorders of the temporomandibular joint include rest, non-steroidal anti-inflammatory drugs, bite splints and physiotherapy. Surgical options include arthroscopic surgery, remodelling of the joint surface, removal of the intra-articular disc and replacement of components of the joint such as the disc, the fossa (socket) or the mandibular condyle.

3 The procedure

- 3.1 Total prosthetic replacement of the temporomandibular joint is considered when alternative treatments have failed. It involves replacing both the skull base component (the fossa or socket) and the condyle with prostheses. The aims of the procedure are to re-establish function of the temporomandibular joint and to relieve pain.
- 3.2 With the patient under general anaesthesia, an incision is made anterior to the ear for insertion of the fossa component, with a second incision behind or below the mandible for insertion of the mandibular condyle component. The coronoid process of the mandible is sometimes removed to allow more mobility after surgery.
- 3.3 A number of different prostheses are available for this procedure.

4 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 [interventional procedure overview](#).

- 4.1 A case series of 300 patients reported significant improvements in mean pain score (measured by visual analogue scale ranging from 0 to 5 with higher scores indicating more severe pain) from 1.18 at baseline to 0.03 at 1-month follow-up and 0 at 6-month follow-up ($p < 0.001$ and $p < 0.0001$).

respectively). A case series of 288 patients reported significant improvements in mean pain scores (measured by visual analogue scale ranging from 0 to 10 with higher scores indicating worse pain) from 8.0 at baseline to 2.6 at 3-year follow-up ($p < 0.0001$). A case series of 74 patients, using similar methods, reported a change from 7.2 at baseline to 0.8 at 1-year follow-up ($p < 0.0001$).

4.2 The case series of 300 patients reported that mean diet score (measured by visual analogue scale ranging from 0 to 5 with lower scores representing a more restricted diet) improved from 2.16 at baseline to 4.96 at 1-year follow-up ($n=300$, $p < 0.0001$). After 6 months, 80% (240/300) of patients reported a general diet with no limitations. At 5- and 7-year follow-up, the scores were 4.95 ($n=166$) and 4.93 ($n=77$) respectively. The case series of 288 patients reported improvements in mean diet score (measured by visual analogue scale ranging from 0 to 10 with 0 representing a normal diet and 10 representing liquids only) from 8.2 at baseline to 2.5 at 3-year follow-up ($p < 0.0001$). The case series of 74 patients reported improvements in mean diet score (measured by visual analogue scale ranging from 0 to 10 with 0 representing liquids only and 10 representing a normal diet) from 3.8 at baseline to 9.3 at 1-year follow-up ($p < 0.0001$).

4.3 A non-randomised comparative study of 36 patients treated by total joint replacement or interpositional arthroplasty reported that the mean maximum inter-incisal opening improved from 15.6 mm and 10.3 mm at baseline to 24.9 mm and 28 mm, respectively ($p=0.02$ between the groups for the change from baseline), after the procedure (median follow-up of 12 months). The change in maximum inter-incisal opening was not significantly different between the 2 groups after adjusting for institution, the number of previous operations, laterality, age and aetiology ($p=0.056$). The case series of 300 patients reported that the mean maximum inter-incisal opening improved from 11.3 mm at baseline to 38.9 mm at 1-year follow-up ($n=300$, $p < 0.0001$). The maximum inter-incisal opening increased significantly at all follow-up intervals during the 3-year period after surgery, with no significant changes from the fourth year onwards. The 2 case series of 288 and 74 patients reported significant improvements in mean maximum inter-incisal opening from 20.4 mm and 22.4 mm respectively at baseline to 29.5 mm

(at 3-year follow-up) and 33.7 mm (at 1-year follow-up) respectively ($p < 0.0001$).

- 4.4 The case series of 300 patients reported that mean function and speech scores (measured by visual analogue scale ranging from 0 to 5 where 0 represents no function and 5 represents optimal condition) improved significantly from 2.84 at baseline to 4.8 at 1-year follow-up ($n=300$, $p < 0.0001$). At 5- and 7-year follow-up, the scores were 4.97 ($n=166$) and 4.92 ($n=77$) respectively. After 1 year, 85% of patients had an optimal score with regard to their speech and jaw movement capacity.
- 4.5 The case series of 288 patients reported that 46% of patients were enthusiastic about the procedure, 32% were very satisfied, 20% were satisfied and 2% were dissatisfied; 99.5% of patients reported that they would have the surgery again. The case series of 74 patients reported that 96% (71/74) of patients were very pleased with the procedure, 3% (2/74) were ambivalent and 1% (1/74) were dissatisfied.
- 4.6 The specialist advisers listed key efficacy outcomes as improvement in pain, improved eating ability scores and improvement in mouth opening.

5 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 [interventional procedure overview](#).

- 5.1 Blood transfusion was needed in 3% (2/74) of patients in the case series of 74 patients: in 1 patient, the neck had to be opened to control bleeding by ligating the terminal branches of the external carotid artery.
- 5.2 Temporary weakness of the temporal branch of the facial nerve was reported in 31% (23/74) of patients in the case series of 74 patients (this resolved within 6 months in all but 1 patient, who needed a brow lift because of long-term weakness). Temporary marginal mandibular palsy was reported in 11% (8/74) of patients (resolved within 6 months), and total facial palsy was reported in 3% (2/74) of patients (resolved within 6 weeks). Sensory changes to the lip and tongue were reported in 4% (3/

74) of patients (resolved within 6 weeks). Long-term sensory loss to the distribution of the auriculotemporal nerve was reported in 14% (10/74) of patients.

- 5.3 Infection was reported in 2% (44/2106) and 3% (numbers not reported) of patients treated using different prostheses in a review of 2620 patients. Three per cent (14/442) of implants had 1 or 2 components removed because of heterotopic bone formation or infection in the case series of 288 patients. Infection was reported in 3% (2/74) of patients in the case series of 74 patients: the device was removed in both patients (with successful subsequent revision using a new prosthesis).
- 5.4 Dislocation of the prosthesis was reported in 1% (14/2106) of patients in the review of 2620 patients (no further details were reported). Dislocation of the prosthesis within a few hours of the operation was reported in 1 patient in the case series of 74 patients. This was treated by light elastic intermaxillary fixation for 1 week; the dislocation did not recur and the patient had a successful outcome at 1 year.
- 5.5 Malocclusion, malposition or displacement of the prosthesis was reported in 1% (19/2106) of patients in the review of 2620 patients (management not described).
- 5.6 Reoperation, sensitivity to material, fractured component, fractured bone screw, dehiscence or perforation, heterotopic bone or scarred tissue formation, and loosening of a component were each reported in less than 1% of patients in the review of 2620 patients.
- 5.7 The specialist advisers listed anecdotal adverse effects as changes in hearing, damage to the middle cranial fossa structures, early prosthetic failure and Frey's syndrome (gustatory sweating).

6 Committee comments

- 6.1 The Committee noted that the technique and materials used for total prosthetic replacement of the temporomandibular joint have been developing over a long time and that they may continue to evolve. In

particular it noted that there is a range of prostheses available that may differ in long-term safety and efficacy.

6.2 The Committee was advised that patients with allergies to metals may react to certain types of prostheses and that patch testing is commonly done to guide the choice of prosthesis.

6.3 The Committee received a number of commentaries from patients describing beneficial effects that the procedure has had on various aspects of their lives, including improved ability to communicate at work and improved psychological wellbeing.

7 Further information

7.1 For related NICE guidance see the [NICE website](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). 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](#).