

Total prosthetic replacement of the temporomandibular joint

1 Guidance

- 1.1 Current evidence on the efficacy of total prosthetic replacement of the temporomandibular joint (TMJ) in the short and medium term is adequate, but the quantity of evidence on long-term efficacy and on safety is inadequate. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake total prosthetic replacement of the TMJ should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients and/or their carers 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 patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG329publicinfo).
 - Audit and review clinical outcomes of all patients having total prosthetic replacement of the TMJ (see section 3.1).
- 1.3 Patient selection should be carried out in specialist units by a team with regular practice and specialist expertise in the conservative and surgical management of TMJ problems, and should include consideration of all relevant surgical and medical options. The British Association of Oral and Maxillofacial Surgeons has produced guidelines on patient selection (www.baoms.org.uk).
- 1.4 The procedure should be carried out only by surgeons with specific training and experience in total prosthetic replacement of the TMJ.

- 1.5 NICE encourages clinicians to collect data on all patients with the aim of providing further evidence on safety and longer-term efficacy. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Causes of TMJ disease include inflammatory and degenerative arthritis, trauma and complications of surgery. Symptoms include pain and difficulty opening the mouth, and an inability to eat a normal diet.
- 2.1.2 Conservative treatments for TMJ disease include non-steroidal anti-inflammatory drugs and physiotherapy. Surgical options include arthroscopic surgery or discectomy and replacement of components of the joint such as the disc, the fossa/socket or the mandibular condyle.

2.2 Outline of the procedure

- 2.2.1 Total prosthetic replacement of the TMJ is considered for patients in whom alternative treatments have failed. It involves replacing both the skull base component (the fossa or socket) and the condyle with a prosthesis. 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 following surgery.
- 2.2.2 A number of different prostheses are available for this procedure.

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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, available at www.nice.org.uk/IP419overview

2.3 Efficacy

- 2.3.1 Cross-sectional data from 425 patients reported to a register showed a reduction in pain using a 10-point visual analogue scale (higher scores indicating greater pain) from 7.8 preoperatively to 3.0 at 6-month follow-up.
- 2.3.2 A case series of 56 patients treated by total TMJ replacement reported a 'good' result (minimum 30 mm interincisal opening, reduced pain and stable functional occlusion) in 63% (35/56), a 'fair' result (minimum 25 mm interincisal opening and stable functional occlusion) in 23% (13/56) and little or no improvement in function or pain in 14% (8/56) of patients (mean follow-up 2.5 years).
- 2.3.3 A case series of 62 patients reported preoperative ability to eat solid food in 23% (14/62) of patients, soft foods only in 51% (32/62), and liquids only in 26% (16/62) of patients: these figures improved postoperatively to 77% (n = 48), 23% (n = 14), and 0% (n = 0) respectively (follow-up not stated).
- 2.3.4 The Specialist Advisers listed key efficacy outcomes as pain relief, correction in bite, improved mouth opening and ability to eat a more normal diet.

2.4 Safety

- 2.4.1 Persisting paresis of the frontal branch of the facial nerve was reported in 3 patients in the case series of 62 patients. Cold neuralgia and permanent neurological deficit were reported in 3/50 and 2/50 patients respectively in a comparative case series of 99 patients.
- 2.4.2 Device failure was reported in 19 patients in a case series of 215 patients – 13 from loosening, dislodgement, infection and/or immunological response and 1 from breakage of prosthetic materials; 5 patients requested removal of the prosthesis without biological indication (timing of events not stated).

- 2.4.3 In case series of 56 patients (100 joint replacements) and 62 patients (86 joint replacements), revision or removal of the prosthesis was required in 5% (5/100) and 5% (4/86) of TMJs (mean follow-up 2.5 and 14.5 years respectively). In the comparative case series of 99 patients, prosthesis removal because of pain and swelling was reported in 6% (3/50) of patients (follow-up not stated). Prosthesis revision or removal because of heterotopic bone was reported in 17 and 5 patients respectively from case series of 56 and 42 patients (time to revision or removal not stated).

- 2.4.4 The Specialist Advisers listed anecdotal adverse events as facial nerve weakness, bite disturbance, dislocation, breakage, allergic reaction, ankylosis and ongoing pain and dysfunction. They considered theoretical adverse events to include damage to structures such as maxillary vessels and failure secondary to recurrence of underlying condition.

2.5 Other comments

- 2.5.1 The Committee noted that patients with TMJ disease may suffer severe disability and this procedure has the potential to improve their quality of life significantly.
- 2.5.2 Patient commentators reported improvements in many diverse activities, including speaking, singing and kissing.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing audit support (which is for use at local discretion), which will be available when the guidance is published.
- 3.2 A register of patients undergoing this procedure is planned. Further details will be available on NICE's website when this information becomes available.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG329publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2066 for this guidance or N2067 for the 'Understanding NICE guidance'.

This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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