



Mini/micro screw implantation for orthodontic anchorage

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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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 There is limited evidence that mini/micro screw implantation provides adequate orthodontic anchorage and there are no major safety concerns. Therefore, clinicians wishing to use this procedure should do so with normal arrangements for clinical governance.
- 1.2 During the consent process clinicians should ensure that patients understand that there is a failure rate associated with the use of mini/micro screws and that the success of dental alignment cannot be guaranteed. They should provide patients with clear, written information. In addition, use of NICE's information for the public is recommended.
- 1.3 Evidence about optimal screw size and site of implantation (upper/lower jaw or buccal/lingual side of the bone) is limited. Therefore, further audit and research to clarify these issues would be useful (see section 3.1).

2 The procedure

2.1 Indications

Some orthodontic procedures require a fixed anchorage point to which a force can be applied in order to move teeth that are malpositioned, misaligned or impacted. The teeth requiring realignment may be located in the upper or lower jaw. Treatment may require force to be applied in any direction, and over a range of time periods.

2.1.2 There are several methods for providing anchorage points for orthodontic treatment. The choice of method depends on the required site of anchorage and the direction and degree of the force to be applied. Usually, anchorage is achieved using the support of other teeth, but the forces of orthodontic treatment may cause unintended, iatrogenic movement in these teeth. External head gear can be employed to provide anchorage, although this may not be aesthetically acceptable to some patients. Surgically inserted osseointegrated dental implants can also be used to provide anchorage points, although a healing period is required before orthodontic force can be applied.

2.2 Outline of the procedure

- 2.2.1 Orthodontic screw systems can be used when sufficient anchorage cannot be achieved from existing teeth. Screws (referred to interchangeably in the literature as mini or micro) are typically 1 mm to 2 mm in diameter and 8 mm to 15 mm in length, self-tapping or self-drilling, titanium alloy or stainless steel, and consist of a body that connects to the bone, a neck that protrudes through the gum mucosa and a head suitable for connection to orthodontic loading systems. However, various dimensions and types of screws are used and there is no universal agreement about how these are classified.
- 2.2.2 The procedure may be performed under local anaesthesia. A pilot hole is drilled into the maxilla or mandible where necessary, and the screw is inserted into the alveolar bone. For some screws a mucoperiosteal flap is created in the gum to aid insertion. More than one screw can be inserted if necessary. Orthodontic loading can be achieved immediately after insertion, although it is often undertaken at a subsequent visit.
- 2.2.3 Following completion of orthodontic treatment, the screws can be extracted (often without anaesthesia) and any incision sites are normally expected to heal spontaneously. The screws can be replaced if necessary.

2.3 Efficacy

- 2.3.1 Across four case series of 44, 29, 58 and 87 patients, screw implantation was reported to be successful (usually defined as stable anchorage for 1 year or until completion of orthodontic treatment) in 0% to 85%, 85%, 81% to 89%, and 92% (208 out of 227) of screws, respectively (absolute figures presented where available). Success rates varied with the type of screw used. The case series of 87 patients fitted with 227 screws reported no statistically significant difference in success rates for four different screw types at 15-month follow-up (p=0.154; success rates varied from 80% to 94%). This series reported that the success rate was significantly higher for screws inserted into the maxilla (96%; 119 out of 124) compared with the mandible (86%; 89 out of 103; p=0.01). Another case series of 98 patients fitted with 140 screws reported that the overall success rate (defined as anchorage stability with no morbidity) was 84% (118 out of 140).
- A further case series of 85 patients fitted with 239 screws reported that the average rate of anchorage loss decreased significantly, from 23% (31 out of 133) in one patient group to 5% (5 out of 106) in a subsequent group, once parameters for the selection of screw size and site of insertion had been refined (p<0.001). For more details, see the <u>overview</u>.
- 2.3.3 Two Specialist Advisers considered the procedure to be novel and of uncertain safety and efficacy; one considered it to be an established procedure. They noted that only data from case series are currently available to support the efficacy of the procedure, but that two randomised controlled trials are underway in the UK.

2.4 Safety

- In seven case series, the rate of screw failure (breakage) ranged from 3% (2 out of 59) to 4% (8 out of 227).
- A case series of 85 patients (239 screws inserted) reported that no patients suffered haemorrhage, abscess formation or tooth injury (follow-up period unclear).

- 2.4.3 Two case series reported that there were no instances of contact with tooth roots during the procedure in 175 screw insertions relating to 87 patients. For more details, see the overview.
- 2.4.4 The Specialist Advisers considered adverse events to be discomfort on screw placement and screw failure or loosening. Other theoretical complications were pain, infection, nerve damage and damage to the roots of adjacent teeth.

3 Further information

This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant <u>audit criteria</u> and developed an audit tool (which is for use at local discretion).

Sources of evidence

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

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.