# National Institute for Health and Clinical Excellence

## 389 – Mini/ micro screw implantation for orthodontic anchorage

## Consultation Comments table

## IPAC date: September 13, 2007

| Comment no. | Consultee name and organisation | Section no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| 1 | Individual clinician | **1** | Agree | Thank you for your comment. |
| 2 | Individual clinician | **1** | Further scientific data is still required to back up the clinical experiences reported in the literature. | The recommendation in section 1.3 suggests that further audit and research are required. |
| 3 | Individual clinician | **1** | Safety can be an issue if people using the technique are inadequately trained,e.g. lack of Specialist qualification in Orthodntics or Oral Surgery, then problems could arise leading to damage to the patients. There is increasingly information being brought forward on screw size and screw site correction | Specialist advisers suggested that minimal training is required for what is a technically simple procedure. |
| 4 | Individual clinician | **2** | I could see no mention in the clinical procedure introduction that micro-implants are often placed without the need to lift a muco-periostial flap or any incisional access. In fact a pilot drill sometimes is not needed and a simple self drilling (without the need to prepare an implant site with a drill) is often used in the maxilla. | Section 2.2.2 states that a muco-periostial flap is needed for some patients. The sentence was amended to read: 'A pilot hole is drilled into the maxilla or mandible *where necessary*'. |

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| 5 | Individual clinician | **2.1** | 2.1.2 The problem with external headgear as an alternative is not only its "aesthetical non - acceptance" but also: 1. it is uncomfortable 2. Compliance is often poor 3. it is not always and alternative to micro - implants as not all anchorage requirements which are met by using micro - implants can be met by the use of headgear. only in a few situations can dental implants be used as an alternative to micro - implants: due to the increased - space requirements of the dental implants; also there is a cost differential making dental implants less efficient | This section of the guidance intends to list alternative treatments available. We do not produce clinical guidelines on the relative effectiveness of treatment options. |
| 6 | Individual clinician | **2.1** | Not only is this technique an alternative to conventional anchorage methods, but numerous case reports (accepting the limitations of such evidence) have demonstrated that mini-implant anchorage has broadened the range of malocclusions treatable by orthodontics eg anterior open bites where previously orthognathic (jaw) surgery may have been required. An additional indication is during orthognathic surgery in patients (with any type of malocclusion) where the dentition provides inadequate stability for inter-maxillary (intra-operative) fixation and post-operative traction (|Gibbons & Cousley Br J Oral Maxfac Surgery 2007). | This section of the guidance intends to list alternative treatments available. We do not produce clinical guidelines on the relative effectiveness of treatment options. |
| 7 | Individual clinician | **2.1** | While the use of conventional dental implants can be a source of anchorage in orthodontics, their use is very limited. Mini Screw Implants, have a much wider clinical application for orthodontic anchorage. | This section of the guidance intends to list alternative treatments available. We do not produce clinical guidelines on the relative effectiveness of treatment options. |
| 8 | Individual clinician | **2.1** | Headgear has the advantage of being non-invasive | This section of the guidance intends to list alternative treatments available. We do not compare the relative effectiveness of treatment options. |

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| 9 | Individual clinician | **2.2** | 2.2.1: the screws can also be self - drilling rather than self - tapping only, also they can be made from stainless steel rather than titanium 2.2.2: in the case of self drilling micro - implants: pilot hole drilling is not always necessary 2.2.3: after completion of treatment the screws are not extracted; they are removed using the driver turning it in anti - clockwise direction | Section 2.2.1 has been amended to refer to the different types of screws. In section 2.2.3, 'extracted' was replace by 'removed'. |
| 10 | Individual clinician | **2.2** | Commercially available mini-implants sizes are in the range of 1.2-2.3mm diameter and 6-15mm length (Prabhu & Cousley J Orthod 2006). The latest designs are self-drilling (as well as self-tapping), and made of titanium alloy (not pure titanium). Self-drilling versions only require a pilot hole to be drilled through dense cortical bone (mandible and hard palate), and this doesn't penetrate to the full body length (which is required for non-self-drilling / self-tapping screws). | The dimensions stated are an indication of the sizes used in the studies, and are broadly similar. Section 2.2.1 has been amended to refer to the different types of screws. |
| 11 | Individual clinician | **2.2** | Clarity is needed on the nomenclature. ""Self tapping"" screws are screwed into a pre drilled pilot hole. ""Self drilling"" screws are screwed directly into the bone without the use of a pre drilled pilot hole | Section 2.2.1 has been amended to refer to the different types of screws. The sentence in section 2.2.2 was amended to read: 'A pilot hole is drilled into the maxilla or mandible *where necessary*'. |
| 12 | Individual clinician | **2.2** | You do not need anaesthetic for a self-tapping screw and, indeed, it is safer if you don't use anaesthetic | Section 2.2.2 now reads 'The procedure *may be* performed under local anaesthesia.'. |
| 13 | Individual clinician | **2.3** | How about contacting the medical and dental protection societies and enquiring how many litigation cases involving micro - implants are known to them? as with all medical and dental interventions: "uncertain safety" sounds vague and depends on situational circumstances: i.e. appropriate uses and good indications | Thank you for your comment. The consultee's suggestion is outside the usual IP programme methods and processes. |

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| 14 | Individual clinician | **2.3** | New self-drilling designs may have higher success rates than the currently published figures because of the avoidance of drilling-associated side-effects (especially thermal necrosis of bone). Essentially this is a rapidly evolving field and unfortunately initial RCTs (whilst being highly desirable) may be based on older rather than the latest technique and design details. | IPAC normally only considers published studies in peer reviewed journals. Further audit and research are recommended in section 1.3 to produce further evidence. As with much of NICE's guidance, future review may be considered if there is a change to the evidence base |
| 15 | Individual clinician | **2.3** | All my patients requiring mini screw implants are referred to a Prosthodontist for placement. He has placed 130 implants and reports a success rate of 84% which is in line with other studies. | Thank you for your comment |
| 16 | Individual clinician | **2.3** | The technique is still developmental | 1.3 suggests that further audit and research is required. |
| 17 | Individual clinician | **2.4** | There are multiple theoretical safety concerns, but such problems are infrequent and rarely give rise to clinically detectable and irreversible damage. For example, there have been no reports that close proximity, and hence damage, to adjacent teeth has caused loss of tooth vitality or loss of the tooth itself. The major risk, as mentioned in this document, is loss of the mini-implant due to inadequate primary or secondary stability. It''s worth highlighting that failed mini-implants are frequently replaced with no irreversible consequences (based on personal experience of over 110 mini-implants of varying designs, and the literature). | A sentence has been added to the end of section 2.2.3 which reads: 'The screws can be replaced if necessary'. |
| 18 | Individual clinician | **2.4** | I my cases the only complication has been failure due to loosening of the screws. None of the other theoretical complications. Having been involved with courses, training over 120 Orthodontists and reviewing their feed back I would recommend that clinicians should attend some form of training course before placing mini screw implants. | Specialist advisers suggested that minimal training is required for what is a technically simple procedure |

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| 19 | Individual clinician | **2.4** | Damage to tooth roots and the ligament is a real potential hazard | In section 2.4.5, 'damage to adjacent teeth' was replaced with 'damage to the roots of adjacent teeth'. |
| 20 | Individual clinician | **General** | This department has presented 2 practical courses per year on Mini Screw Implants in Orthodontics. At least 120 participants. As far as I am aware this is one of the few departments that has presented a course that involves lectures, practical exercise on pigs jaws, plastic typodonts, exposure to clinicians placing implants in patients, exposure to patients in treatment with implants in place and excercise in bending up auxiliaries necessary for certain tooth movements related to the miniscrew implants. I am involved in the lecturing and practical excerises. I have lectured widely on this subject and have recently had a comprehensive article published in the Journal Of Orthodontics 34:80-94. June 2007. As frequently stated most articles are essentially clinical reports, there is a lack of scientific evaluation of histology of the bone-screw interface, soft tissue-screw interface, maximum and minimum force values, age related influence on the success or failure of the screws and may other aspects. In spite of the lack of scientific research data, the screws are being used clinically in the Far East, Australia, Europe and the USA and the clinical reports are so far aqll very encouraging. To date I have not experienced any unfavourable reactions, I have used the screws successfully for both conventional and lingual orthodontic cases. An historic review of new techniques for example the advent of Direct Bonding in the 1970/1980 also shows that the clinical practise and acceptance tends to preceed the scientific evaluations. From the data that follows the scientific studies, evolves refinements in the materials and techniques. In summary, my experience has been favourable, the technique will continue to become more widely used, and the scientific data we require will be forthcoming in due course. | Thank you for your comment<br><br>The paper referred to is a review paper with no clinical data.<br><br>Section 1.3 suggests that further audit and research are required. |