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A NICE Approach to Temporary Anchorage Devices (TADs)

Abstract: This paper will give a background to NICE: including its origins, dental subjects in which it it has taken some interest and specific interest in temporary anchorage devices (TADs). Finally, the paper will discuss recommendation for clinicians involved in treating cases using TADs.

Clinical Relevance: Clinicians who are using or thinking about using TADs will know exactly what information to record to allow them to contribute to the knowledge base about this technique.

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History of NICE

NICE is the acronym used for the National Institute for Health and Clinical Excellence. Their statements and pronouncements are rarely far from the public gaze.[1] On the issue of alcohol and pregnancy, NICE was recently quoted in the papers as stating that women can drink up to 1.5 units of alcohol a day without harming their unborn baby. This guidance, reportedly from NICE, came only a few months after the Government advised pregnant women to remain teetotal. Certainly, the Royal College of Obstetricians and Gynaecologists still recommend that women should drink no more than two units of alcohol twice a week.

The development of NICE's role and responsibilities have been well documented.[2] This paper describes a number of significant concerns about the 'quality of care' delivered by healthcare professionals. One very high profile case, 'Case B', involved a child who suffered a relapse in leukaemia. Clinical opinion was divided and there was a media frenzy accusing NHS managers of refusing patients life-saving treatment. As a consequence of these and other concerns, significant NHS reforms started to be carried out in 1997.

- Customized titanium implants for orofacial reconstruction
- Cyanoacrylate instillation for occlusion of parotid sinuses
- Division of ankyloglossia (tongue-tie) for breast feeding
- Radiofrequency ablation of the soft palate for snoring
- Stereotactic radiosurgery for trigeminal neuralgia using the gamma knife
- Therapeutic sialendoscopy

Table 1. Completed interventional procedures.

NICE was officially launched in 1999, the original acronym referring to the National Institute of Clinical Excellence. On the 1 April 2005 'health' was included in the middle of this acronym, although there was obviously a silent 'H' involved. NI(H)CE declared that they had a strong commitment to improving the quality of healthcare and offered to give healthcare providers 'a lead on clinical and cost effectiveness' of treatment, as well as having a role in drawing up new guidelines for the provision of healthcare. To date, they have published guidance[1] on a number of very important subjects.

Access to NICE guidance by topic can be accessed on the internet and guidance is given on most of the systems within the body. Of particular interest to readers will be the section under 'Mouth and Dental' which demonstrates that NICE have taken interest in a number of diverse subjects, sadly none of these is what could be considered at the forefront of dental clinical work or research, at the present time (see Table 1).

NICE have drawn conclusions on a number of dental issues, including titanium implants for oro-facial reconstruction, division of ankyloglossia (tongue-tie) and sleep apnoea. They stated that there was 'limited evidence' on each of the above three procedures.. The other dental subjects that have interested NICE are the frequency

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Appendix A: Additional papers on mini / micro screw implantation for orthodontic anchorage not included in summary Table 2

The following table outlines studies considered potentially relevant to the overview not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up (FU)	Direction of conclusions	Reasons for non-inclusion in Table 2
Bae SM, Kyung HM. (2006) Mandibular molar intrusion with miniscrew anchorage. *Journal of Clinical Orthodontics* 40 (2): 107–108.	Case report n = 1 FU = 6 months	Two screws provided successful anchorage for orthodontic treatment.	Larger series are included in table 2.
Bohm B, Fuhrmann R. (2006) Clinical application and histological examination of the FAMI screw for skeletal anchorage – A pilot study. *Journal of Orofacial Orthopedics* 67 (3): 175–185.	Case report n = 1 FU = 432 days	A case report demonstrating good osseointegration and a clinically successful outcome	Larger series are included in table 2.
Freudenthaler JW, Haas R and Bantleon HP. (2001) Bicortical titanium screws for critical orthodontic anchorage in the mandible: a preliminary report on clinical applications. *Clinical Oral Implants Research* 12 (4): 358–363.	Case series n = 8 (12 screws) FU = N/S	One screw worked loose and was removed. Other complications included screw-head impingement and slight inflammation.	Larger series are included in table 2.
Fritz U, Ehmer A and Diedrich P. (2004) Clinical suitability of titanium microscrews for orthodontic anchorage-preliminary experiences. *Journal of Orofacial Orthopedics* 65 (5): 410–418.	Case series n = 17 FU = 5 months	The overall screw failure rate was 30%.	Larger series are included in table 2.
Giancotti A, Greco M, Mampieri G et al. (2004) The use of titanium miniscrews for molar protraction in extraction treatment. *Progress in Orthodontics* 5 (2): 236–247.	Case report n = 1 FU = 12 months	Successful anchorage for the 12-month orthodontic treatment.	Larger series are included in table 2.
Herman RJ, Currier GF and Miyake A. (2006) Mini-implant anchorage for maxillary canine retraction: a pilot study. *American Journal of Orthodontics & Dentofacial Orthopedics* 130 (2): 228–235.	Case series n = 16 FU not stated	Success rate depended on treatment protocol and was 100% with the second protocol. Pain comfort was excellent in all but 1 patient.	Larger series are included in table 2.
Kawakami M, Miyawaki S, Noguchi H et al. (2004) Screw-type implants used as anchorage for lingual orthodontic mechanics: a case of bimaxillary protrusion with second premolar extraction. *Angle Orthodontist* 74 (5): 715–719.	Case report n = 1 FU = 29 months	Successful anchorage with 1.5 × 15 mm screws in both upper and lower jaw.	Larger series are included in table 2.
Ko DI, Lim SH and Kim KW. (2006) Treatment of occlusal plane canting using miniscrew anchorage. *World Journal of Orthodontics* 7 (3): 269–278.	Case report n = 2 FU = to 23 months	Successful anchorage and screw removal in both patients.	Larger series are included in table 2.
Maino BG, Bednar J, Pagin P et al. (2003) The spider screw for skeletal anchorage. *Journal of Clinical Orthodontics* 37 (2): 90–97.	Case report n = 3 FU = to 10 months	Successful anchorage in all 3 patients; removal reported in 1.	Larger series are included in table 2.
Ohnishi H, Yagi T, Yasuda Y et al. (2005) A mini-implant for orthodontic anchorage in a deep overbite case. *Angle Orthodontist* 75 (3): 444–452.	Case report n = 1 FU = 21 months	Successful anchorage and screw removal at 21 months.	Larger series are included in table 2.
Paik CH, Woo YJ, Kim J et al. (2002) Use of miniscrews for intermaxillary fixation of lingual-orthodontic surgical patients. *Journal of Clinical Orthodontics* 36 (3): 132–136	Case report n = 1 FU not stated	Successful anchorage	Larger series are included in table 2.
Paik CH, Woo YJ and Boyd RL. (2003) Treatment of an adult patient with vertical maxillary excess using miniscrew fixation. *Journal of Clinical Orthodontics* 37 (8): 423–428	Case report n = 1 FU = 27 months	Successful anchorage with 150– 200 g force per screw	Larger series are included in table 2.
Roth A, Yildirim M and Diedrich P. (2004) Forced eruption with microscrew anchorage for preprosthetic leveling of the gingival margin. Case report. *Journal of Orofacial Orthopedics* 65 (6): 513–519.	Case report n = 1 FU = 3 months	Successful anchorage, and removal after 3 months without anaesthesia	Larger series are included in table 2.
Tseng YC, Hsieh CH, Chen CH et al. (2006) The application of mini-implants for orthodontic anchorage. *International Journal of Oral & Maxillofacial Surgery* 35 (8): 704–707.	Case series n = 25 FU = 16 months		Larger series are included in table 2.
Yao CC, Wu CB, Wu HY et al. (2004) Intrusion of the overerrupted upper left first and second molars by mini-implants with partial-fixed orthodontic appliances: a case report. *Angle Orthodontist* 74 (4): 550–557.	Case report n = 1 FU = 12 months	Successful anchorage with 150–200 g force. Screw removed successfully.	Larger series are included in table 2.
Youn SH. (2006) Midline correction with mini-screw anchorage and lingual appliances. *Journal of Clinical Orthodontics* 40 (5): 314–322.	Case report n = 2 FU = to 16 months	Successful anchorage in both patients. No reports of adverse events.	Larger series are included in table 2.

Figure 1. Appendix A lists case reports and small series excluded from assessment.

of the dental recall interval, heal OZONE therapy and the wisdom of removing third molars.

The very first therapeutic advice that was provided by NICE involved wisdom teeth removal. This was issued in March 2000, reference technology appraisal TA1, and the recommendations were:

- Impacted teeth that were free from disease should not be operated upon.
- There is no reliable research to suggest that the removal of wisdom teeth benefits patients.
- Patients who have healthy wisdom teeth are exposed to the risks of surgery which can include nerve damage, damage to other teeth, infection, bleeding and, rarely, death.
- After surgery to remove wisdom teeth, patients may have swelling, pain and be unable to open their mouth fully.
- Patients who have impacted wisdom teeth that are not causing problems should visit their dentist for their usual check-ups.

These NICE guideline drove a coach and horses through the very lucrative private practice in the removal of wisdom teeth, which was thought to be one of the most costly out-patient procedures covered by BUPA and PPP in the 1990s.

Some clinicians feel that leaving all these impacted teeth *in situ*, is equivalent to leaving a time-bomb ticking away, and that many problems might 'come home to roost' as the patients get into their 30s and 40s. Not only the wisdom teeth, but also the adjacent second molars may start developing significant amounts of dental decay, which could ultimately lead to significant periapical and periodontal infection. Whilst there is certainly a lack of incontrovertible scientific evidence to answer the risk-benefit question, controversy still remains as to whether 'watch and wait' is better than prophylactic removal. Certainly, as the patients get older there is going to be an increase in the difficulty of the removal of wisdom teeth should this be found to be necessary.

The most recent paper[3] to look at this issue confirms the above suspicions, as it concludes that distal caries in lower second molars adjacent to erupted mesioangular lower wisdom teeth is a common finding, occurring in the majority of cases.

NICE's orthodontic interests

In June 2007 the Chairman of the British Orthodontic Society circulated an email stating that the British Orthodontic Society had been asked for expert advice on the safety and efficacy on mini/micro-screw implantation for orthodontic anchorage. Three names were put forward from the British Orthodontic Society and these were David Bearn, Karen Drage and Jonathan Sandler, all of whom had already been involved in a number of cases using temporary anchorage devices.

As well as seeking 'expert' advice, NICE undertook a review of the literature and identified several good quality clinical studies[4-10] from which some tentative conclusions could be drawn.

Following this initial

investigation, NICE decided to set up an 'Interventional procedures consultation'. This meant that they were opening up the subject to public consultation for a four week period from the 26 June 2007 until the 24 July 2007. During this period they would be inviting comments from anybody who had an interest in the subject, prior to them making some provisional recommendations. They directed all potential contributors to their website to allow them to make comment. There was introductory material outlining some of the indications for the use of temporary anchorage devices, stating that these were used in cases where there was an increased anchorage requirement. Several methods of providing increased anchorage were described, including tying blocks of teeth together, the use of headgear and temporary anchorage devices themselves. The specific surgical procedure involved in providing temporary anchorage devices was also detailed, along with specific descriptions of the type of temporary anchorage devices to be used. There was also a note that these can be placed under local anaesthesia but no anaesthetic was required to remove them. It was specifically noted that the screws are quite small, typically 1–2 mm in diameter and from 8–15 mm in length.

The efficacy of the use of temporary anchorage devices was described looking at the case series involving 218 patients in which 600 screws were used. A good success rate was noted of between 80–95%. A further case series was detailed involving 85 patients, in which the average loss of anchorage was at worst 23% and at best 5%. There were specific comments made about the safety of the use of temporary anchorage devices, noting that screw failure was low at 3–4% and that no patients had ever reported incidence of infection or tooth injury following the placement of 239 screws. In a further study, involving 87 patients in whom 175 screws were placed, there was once again no incidence of contact with tooth roots.

The problems that may be encountered with the use of micro-screws were considered to be discomfort on the screw placement, screw failure or loosening and theoretical complications of pain, infection, nerve damage and damage to adjacent teeth, all of which were considered to be very rare outcomes.

NICE recommendations

At the end of the information provided were suggestions that special arrangements be made for audit of all patients in whom temporary anchorage devices were being considered. Two important appendices were also added to the document. Appendix A (Figure 1) listed additional papers which involved micro-screw implantation for orthodontic anchorage but were not included when considering information on which recommendations can be made. The reason none of these papers was included was that the case numbers were very small, ranging from one to very small single figures in the case series. Appendix C included all the key words, which were used in the database search for studies involving micro-screw anchorage. This information will be useful for people who are considering repeating this particular literature search.

Author's involvement with the NICE process

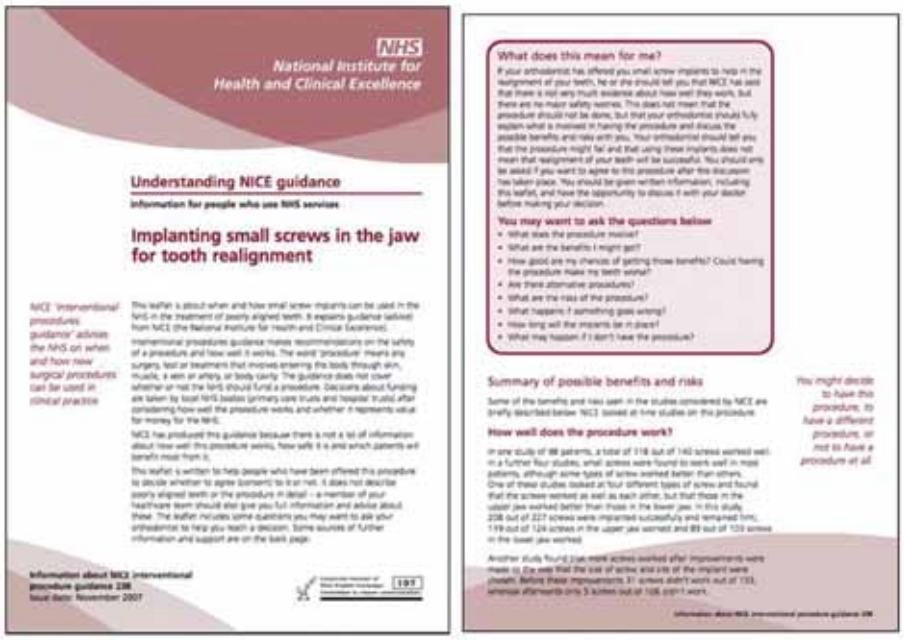
Because of my (JS) involvement with temporary anchorage devices, I was approached by NICE to see if I would be a specialist adviser to their study. My involvement to that point had been that I had completed treatment of 34 cases involving TADS, at Chesterfield Royal Hospital, and the first case I started was in February 2004. Micro-screws have been used in a variety of procedures including mesialization of posterior teeth, intrusion of posterior teeth, distalization of anterior teeth and the intrusion of anterior teeth, so I felt reasonably well qualified to act as an adviser. They initially wanted to contact a number of the patients from Chesterfield Royal Hospital who had had implant therapy. On the 12 February 2007, they sent a letter to these patients saying that NICE was seeking patients' impressions of the TAD technique and they enclosed a sheet explaining why they were looking at patient views, a consent form to allow them to use the information obtained, and a copy of the questionnaire on implant therapy.

Interestingly, one thing that was explained in the covering letter was that they did not have to complete the questionnaire if they did not wish to. In the information sheet to the patients there was an explanation of why they have been sent the letter, a small amount of detail about the background to NICE and why they needed help on this particular issue. Once again it stated explicitly that they did not have to take part and that nobody would know whether or not they had taken part. There was an explanation as to what would happen with the information provided and what would happen to NICE guidance.

NICE questionnaire

The first group of questions collected purely demographic data and then the eighth question was 'Whether they had been offered temporary anchorage devices and whether they accepted this proposal'. The tenth question was somewhat confusing in that it said 'Before having the procedure what aspects of your condition did you expect the procedure to help with' and the eleventh question was 'How well do you believe the procedure has worked'. Whilst these two questions could

Figure 2. Concise information on TADS for clinicians, downloadable in PDF format.


NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

information for people who use NHS services

Implanting small screws in the jaw for tooth realignment

What does this mean for me?

You may want to ask the questions below

Summary of possible benefits and risks

How well does the procedure work?

Figure 3. Concise information on TADS for patients, downloadable in PDF format.


Mini/micro screw implantation for orthodontic anchorage: IPG238

Table 1. Dataset: this defines the dataset items required within the audit criteria given in table 2

Dataset item ref.	Dataset required per implant	Data source	Data variable type
	Baseline data		
A	Written information on specific procedure given to patient	Data collection form or patient health record	Y/N
B	Documented discussion with patient regarding the written information on the procedure and the attendant risks	Data collection form or patient health record	Y/N
C	Written consent given by patient (or Consent Form 4 completed)	Data collection form or patient health record	Y/N
D	Type of screw implant	Data collection form or patient health record	Name
E	Length and width of screw	Data collection form or patient health record	Length in mm; width in mm
F	Point of insertion of screw	Data collection form or patient health record	Maxilla or mandible; anteriorly or posteriorly; palatally or buccally (for maxillary implants)
G	Mucoperiosteal flap required for screw insertion	Data collection form or patient health record	Y/N
H	Pre-drilling performed – for example, self-tapping or self-drilling screw used	Data collection form or patient health record	Y/N; self-tapping or self-drilling or other
	Follow-up data (immediate postoperative period and long-term outcomes)		
I	Screw lost or removed before completion of required anchorage period or within 1 year (whichever is sooner)	Data collection form or patient health record	Y/N; lost or removed?
J	Screw replaced (following loss or removal) before completion of required anchorage or within 1 year (whichever is sooner)	Data collection form or patient health record	Y/N
K	Anchorage provided by screw until completion of orthodontic treatment or for 1 year without inflammation or infection, or damage to tooth root	Data collection form or patient health record	Y/N
	Adverse events (safety outcomes)		
L	Screw removal because of infection around insertion site	Data collection form or patient health record	Y/N
M	Damage to neighbouring teeth during treatment period	Data collection form or patient health record	Y/N; if yes, description of damage
	Aggregated data		
a	The number of patients receiving a mini/micro screw insertion for orthodontic anchorage in a given period	Patient administration system	Number
b	The number of mini/micro screws inserted for orthodontic anchorage in a given period	Data collection form or patient health records	Number

Figure 4. NICE Audit requirements listed in detail, downloadable in word format.

reasonably be posed to a third year registrar in orthodontics, immediately before taking the MOrth exam, I am not sure that a 12 or 13-year-old child is able to give a meaningful answer to these particular queries. Question 12 was even more challenging in that it asked about the experiences of having the temporary anchorage devices placed and 'What improvements or negative effects they experienced in the following categories':

- Physical symptoms;
- Pain;
- Level of disability;
- Mental health/well being;
- Quality of life issues;
- Impact on others; and
- Other areas not listed above, please list.

Questions 14 and 15 were, respectively, 'Do you have any concerns about the safety of the procedure before having it?' and 'Now that you have had the procedure do you have any concerns about the safety?' If the patient started off not having any safety concerns, some might have had a serious rethink, having now received and completed the questionnaire!

Question 19 was particularly entertaining asking 'Would you recommend this procedure to a friend'? In my experience, teenage children recommend video games, iPhone applications and DVDs to each other, not to come to hospital for a temporary anchorage device!

When I was asked to be expert for NICE I was also particularly interested in why they had chosen the topic of temporary anchorage devices. To my knowledge there were no financial implications for the Government with the use of micro-screws. The answer I received informed me that any member of the public is able to notify NICE about new interventional procedures and a notifiable procedure must merely:

- Involve an incision or entry into a body cavity or the use of ionizing electromagnetic or acoustic energy;
- Be available within the NHS or about to be used for the first time in the NHS outside formal research;
- Not yet be considered standard clinical practice;
- Be a standard clinical procedure, the safety or efficacy of which has been called into question by new information.

It was pointed out that the interventional procedures programme does not consider cost when it assesses procedures, it is only interested in safety and efficacy. As a result of the public consultation on TADs, the IP project manager informed me that they received four comments in total.

Implications of national consultation

On the back of the evidence that could be deduced from the seven cited clinical case series, the opinions of the 'experts' and the comments received from the public consultation IP Guidance No. IPG 238 was duly issued on the 28 November 2007. A number of documents were placed on the NICE website, both in PDF format and word format, involving mini/micro-screw implantation for orthodontic anchorage; guidance mini/micro-screw implantation for orthodontic anchorage; understanding NICE guidance; mini/micro-screw implantation for orthodontic anchorage audit criteria and mini/micro-screw implantation for orthodontic anchorage (interventional procedures overview). By highlighting any of these particular documents they could be downloaded and then printed out as necessary.

The guidance provided excellent information both for clinicians (Figure 2) and for patients (Figure 3), which could be handed out at the appointment prior to them giving consent for placement of temporary anchorage devices. The

guidance succinctly covered all the pertinent issues and was written in very patient accessible format.

Audit criteria for patients appropriate for TADs

A number of documents were produced giving the audit criteria which make very sensible suggestions, recommending that baseline data was recorded for every patient having a micro-screw placed including:

- Written information on specific procedure;
- Documented discussion about the written information;
- The written consent by the patient;
- The type of screw implanted;
- The length and width of screw;
- The point of insertion of screw;
- The mucoperiosteal flap required for insertion.

The following data were then recommended to be collected:

- Whether the screw was lost or removed before completion of required anchorage period, or within one year;
- Whether the screw was replaced before completion of required anchorage or within one year;
- Anchorage provided by the screw until completion of orthodontic treatment or for one year without inflammation or infection or damage to the tooth root.

Adverse events should also be recorded:

- Infection of the insertion site within 1) three months, 2) six months or 3) one year;
- Damage to neighbouring teeth during the treatment period.

The aggregated data then recommended is the number of patients receiving a mini or micro-screw insertion during the period. It is then recommended that an audit report sheet is filled in summarizing the aggregated data, detailing compliance and collecting all the relevant information (Figure 4).

The British Orthodontic Society involvement

The British Orthodontic Society are now conducting a national audit which follows the NICE audit guidelines for cases that require temporary anchorage devices. With the BOS Newsletter circulated in the Spring 2008 a flyer was included suggesting that anybody involved in the use of temporary anchorage devices signs up for the national audit so that a couple of years from now each individual will be able to compare themselves with national figures on TAD usage.

Summary

A brief history of NICE is given describing their involvement with dental procedures. Their interest in TADs is described along with their recommendations for audit of all patients whose treatment involves placement of TADs.

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Abstract

THE EFFECTS OF ORTHODONTIC THERAPY ON PERIODONTAL HEALTH: A SYSTEMATIC REVIEW OF CONTROLLED EVIDENCE. Bollen AM, Cunha-Cruz J, Bakko DW, Huang GJ, Hujoel PP. *J Am Dent Assoc* 2008; **139**: 413–422.

One of the perceived (and implied) benefits of orthodontic treatment is that it improves overall periodontal health: indeed, such a claim is made in the educational literature for the public published by the American Association of Orthodontists. Epidemiological studies of untreated subjects have produced conflicting and/or weak and inconsistent data. The best evidence in establishing a relationship between orthodontic treatment and periodontal conditions would be where a study is made of both treated and untreated subjects, preferably at a point some years out of treatment. This paper aimed to perform a systematic review to assess the best evidence of the effect of orthodontic therapy on periodontal health.

The search strategy included randomized controlled trials (RCTs), cohort studies, case-control and cross-sectional studies of humans who had orthodontic treatment with fixed appliances published between 1980 and 2006. Orthodontic treatment was compared with no treatment, and studies that examined periodontal status at debond were excluded.

The electronic search of several online databases (PubMed, Web of Science, ISI, etc) and hand-searching produced a total of 24,845 articles of which only 12 were found to fulfil the criteria for inclusion in this study. Of particular interest were pocket depths, gingivitis, alveolar bone loss, periodontal pocket depth and gingival recession. Only 1 RCT was found; 3 were cohort studies and the remaining 8 were cross-sectional studies.

From these, three criteria could be evaluated and summarize:

- Alveolar bone loss was 0.13 mm (95% CI 0.07–0.20) greater in treated subjects compared with controls;
- Pocket depths were 0.23 mm (95% CI 0.15–0.30) greater;
- Gingival recession was 0.03 mm (95% CI 0.01–0.04) greater.

The effects of orthodontic therapy on gingivitis and attachment loss were inconsistent across studies. The evidence suggests that there is a small mean worsening of periodontal status of orthodontic patients compared with controls. Claims of improvement in periodontal health cannot be supported.

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