ORIGINAL ARTICLE

Palatal implants are a good alternative to headgear: A randomized trial

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Introduction: The objective of this study was to compare the effectiveness of midpalatal implants with that of headgear as methods of supplementing anchorage during orthodontic treatment. This was a randomized, clinical trial at the Chesterfield and North Derbyshire Royal Hospital NHS Trust and the Charles Clifford Dental Hospital, Sheffield, United Kingdom. **Methods:** Fifty-one orthodontic patients between the ages of 12 and 39 with absolute anchorage requirements were randomly allocated to receive either a midpalatal implant or headgear to reinforce orthodontic anchorage. The outcome measures of the trial were the surgical and orthodontic success rates of the implants, the number of visits, and the length of treatment time, and the success of treatment as judged by the peer assessment rating (PAR) score reductions and the patients' attitudes to implant placement. **Results:** The surgical success rate of the implants was 75%, and the orthodontic success rate was more than 90%. Both implants and headgear proved to be effective methods of reinforcing anchorage. The total number of visits was greater in the implant group, but the overall treatment times were almost identical. There were no statistically significant differences between the 2 groups in PAR scores either at the start or the end of treatment, and the percentages of PAR score reductions were almost identical. The patients had no problems accepting midpalatal implants as a method of reinforcing anchorage. **Conclusions:** Midpalatal implants are an acceptable technique for reinforcing anchorage in orthodontic patients and a good alternative for patients who do not wish to wear headgear. (Am J Orthod Dentofacial Orthop 2008;133:51-7)

Since the article by Creekmore and Eklund[1] in 1983, there has been increasing interest in the use of metal implants in orthodontics. Many studies have been done with midpalatal implants or microscrews to assist various tooth movements. Metal onplants and bone plates have also been used successfully to provide a rigid site from which force can be delivered to the teeth while avoiding unwanted movement of the anchorage unit.

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Headgear has also been shown to be an effective method of supplementing anchorage in orthodontic patients, but the technique is not without its disadvantages. Eye damage has been documented,[2] and many efforts have been made to increase the safety of this technique.[3]

The use of midpalatal implants as a source of anchorage was first described in the mid-1990s,[4] and additional skull studies were carried out to determine the appropriateness of the midpalatal area for the placement of these fixtures.[5]

Much has been written on the application of metal implants as a method of supplementing anchorage. As clinicians in the 21st century, we must practice, as much as possible, evidence-based medicine. Before embarking on the wholesale prescription of a new technique, it is important to evaluate the quality of evidence supporting its use. An excellent systematic review using Cochrane methodology to evaluate the evidence for the use of implants in orthodontics was published in 2005.[6] An electronic search was carried out by using both the MEDLINE and the EMBASE databases to identify all studies involving the surgically assisted orthodontic-anchorage technique in English-language journals to 2004. In addition, all journals in English on orthodontics, dentistry, and implantology

were hand searched for relevant articles. References of all research trials were checked and letters sent to all authors on implant-related articles asking for unpublished data. Unpublished studies were sought through journals and conference proceedings. Implant manufacturers were also asked for details of all research being carried out about implant anchorage.

In all, 157 articles on implants were identified; 90 were excluded as nonrelevant after examination of the title and the abstract. The remaining 67 were evaluated in detail, and 57 were excluded as inappropriate according to a predetermined checklist. Of the final 10 articles, none was considered of a high enough scientific standard to include in the review. It was against this background of a serious lack of scientific evidence for the use of implants in orthodontics that we set up our implant study.

MATERIAL AND METHODS

Our aim was to compare the effectiveness of the midpalatal implant with that of headgear as methods of supplementing anchorage during orthodontic treatment. The null hypothesis was that there was no difference in effectiveness of midpalatal implants for supplementing anchorage compared with extraoral anchorage with headgear.

Ethical approval was granted by the Chesterfield Local Ethical Committee, and permission was given for this randomized controlled trial at both Chesterfield Royal Hospital and Sheffield Dental Hospital in the United Kingdom. Patients who had an absolute anchorage requirement were invited to take part in this study, and written informed consent was obtained. Patients with various Class I, Class II Division 1, and Class II Division 2 malocclusions were included. The dental requirement for inclusion was a malocclusion in which any forward movement of the molars would prevent achievement of an ideal Class I canine relationship.

Patients with clefts or craniofacial syndromes, patients requiring orthognathic surgery, patients with unsatisfactory oral hygiene or an unwillingness to accept the treatment modality to which they were assigned, and patients with a medical history precluding fixed appliance therapy were excluded from the study.

Initial records were obtained for all patients, and, if the patients were suitable for inclusion, the study was described in detail to the patients and written information was given to them outlining what would be involved. The patients were interviewed several weeks later to see whether they wished to participate. If so, written consent was obtained, and they were then randomly allocated to either the headgear or the implant group. Randomization was carried out by using a block design and computer-generated random numbers. The allocations were concealed in consecutively numbered, sealed envelopes.

Forty-two patients were recruited at Chesterfield and 9 at Sheffield, and the 2 groups were treated with similar techniques at both hospitals; the only difference was the method of anchorage reinforcement used.

In the headgear group, a Nitom (OrthoCare, Bradford, England)[3] safety headgear bow connected to a snap-away headcap to deliver the extraoral forces to the maxillary molars was used. The headgear direction chosen was that thought appropriate for each patient's clinical situation, and 450 g of force was applied on fitting. The patients were given detailed instructions in the use of headgear and were asked to wear it for 100 to 120 hours per week. Headgear charts were provided for all patients, and they were reviewed regularly to check for cooperation and comfort with headgear wear. Extractions were prescribed only after the level of cooperation with the headgear had been ascertained.

In the implant group, a Straumann midpalatal implant (Orthosystem Straumann, Basel, Switzerland) was placed by 1 of 2 maxillofacial surgeons using a standardized technique involving radiographic and surgical stents.[7] The implant was left for 3 months to integrate; then the fixed appliances were placed, and the implant was connected with various palatal arches to supplement the anchorage.

A questionnaire was given to the patients both immediately after implant placement and on removal of the implant. They were asked to indicate the grade they would assign to the surgery from 1 (totally comfortable) to 6 (very uncomfortable). They were also asked to grade discomfort during the first few days after the surgery and were invited to comment about their impressions of the procedure.

The standard approach to fixed appliance treatment involved 0.016-in and 0.018 $\times$ 0.025-in nickel-titanium aligning archwires followed by 0.019 $\times$ 0.025-in stainless steel working archwires. Most patients were finished with 0.016-in regular stainless steel.

We recorded the following main outcomes: (1) whether the patients completed the treatment; (2) dento-occlusal alignment and changes according to the peer assessment rating (PAR); (3) the treatment process, including duration of treatment and the number of extra visits; (4) the patients' perceptions of the treatment (particularly how they coped with placement and removal of the palatal implants); and (5) the cephalometric changes as assessed by the modified Pancherz analysis.[8]