Effectiveness of 3 methods of anchorage reinforcement for maximum anchorage in adolescents: A 3-arm multicenter randomized clinical trial

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Introduction: The objective of this 3-arm parallel randomized clinical trial was to compare the effectiveness of temporary anchorage devices (TADs), Nance button palatal arches, and headgear for anchorage supplementation in the treatment of patients with malocclusions that required maximum anchorage. This trial was conducted between August 2008 and February 2013 in 2 orthodontic departments in the United Kingdom. **Methods:** The study included 78 patients (ages, 12-18 years; mean age, 14.2 years) who needed maximum anchorage. Eligibility criteria included no active caries, exemplary oral hygiene, and maximum anchorage required. **Outcome:** The primary outcome was mesial molar movement during the period in which anchorage supplementation was required. The secondary outcomes were duration of anchorage reinforcement, number of treatment visits, number of casual and failed appointments, total treatment time, dento-occlusal change, and patients' perceptions of the method of anchorage supplementation. **Randomization:** Treatment allocation was implemented by contacting via the Internet the randomization center at the University of Nottingham, Clinical Trials Unit. The randomization was based on a computer-generated pseudo-random code with random permuted blocks of randomly varying size. **Blinding:** A research assistant who was blinded to the group allocation recorded all data. **Intervention:** The patients were randomly allocated to receive anchorage supplementation with TADs, a Nance button on a palatal arch, or headgear. They were all treated with maxillary and mandibular preadjusted edgewise fixed appliances with 0.022-in slot prescription brackets. They were followed until orthodontic treatment was complete. **Results:** Seventy-eight patients were randomized in a 1:1:1 ratio among the 3 groups. The baseline characteristics were similar in the groups, and they were treated for an average of 27.4 months (SD, 7.1 months); 71 completed orthodontic treatment. The data were analyzed on a per-protocol basis and showed no differences in the effectiveness of anchorage supplementation between TADs, Nance button palatal arches, and headgear. Compared with headgear, the average mesial movements of the maxillary right molar were 0.62 mm (−0.32 to 1.55 mm) with the Nance and −0.58 mm (−1.53 to 0.36 mm) with TADs; the maxillary left molar was moved −0.09 mm (−1.00 to 0.83 mm) with the Nance and −0.96 mm (−1.89 to −0.04 mm) with the TADs. Peer assessment rating scores were significantly better with the TADs than in the headgear and Nance groups. The patient questionnaires showed that comfort levels on placement of the TADs and the Nance were similar. Headgear was more troublesome and less popular with the patients. **Conclusions:** There was no difference in the effectiveness between the 3 groups in terms of anchorage support. There were more problems with the headgear and Nance buttons than with the TADs. The quality of treatment was better with TADs. As a result, TADS might be the preferred method for reinforcing orthodontic anchorage in patients who need maximum anchorage. **Trial registration:** ClinicalTrials.gov Identifier:

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In this article, we present the results of a randomized controlled trial investigating the effectiveness of methods of anchorage reinforcement for orthodontic treatments requiring maximum anchorage. When the evidence base underpinning this type of treatment is critically examined, the level of evidence is not high. For example, when we reviewed recently published trials as part of a Cochrane Review we found 7 publications.[1-7] Of these, 1 study suggested that headgear and midpalatal implants were equally effective in providing anchorage,[1] whereas another large study found in favor of surgically assisted anchorage.[2] Interestingly, both studies used palatally placed osseointegrated surgical anchorage devices. Two further studies evaluated temporary anchorage devices (TADs), comparing them with conventional anchorage, such as headgear, palatal arches, and banding of second molars.[3,4] These studies concluded that TADs were more effective than other methods of anchorage supplementation.

When we consider any form of orthodontic treatment, it is essential to study the patients' perceptions, since their values can differ between treatment methods. Unfortunately, this has only been considered in a few studies evaluating anchorage supplementation.[5-7] This information has been confined to the patients' perception of pain or discomfort associated with implant placement or removal. They reported that the placing and removal of midpalatal implants and onplants are uncomfortable, requiring extensive local anesthesia and often postsurgery analgesia, compared with the relatively simple procedures of placement and removal of TADs.

We therefore decided to investigate the effectiveness of 3 methods of anchorage supplementation, with a group of patients defined as needing maximum anchorage, and report on both orthodontists' and patients' values.

We tested the hypothesis that there is no difference in the effects of TADs, headgear, and Nance button palatal arches when used to reinforce orthodontic anchorage with respect to (1) the amount of molar tooth movement, (2) the duration of treatment, (3) the number of treatment visits, (4) the total treatment time, (5) dento-occlusal changes (peer assessment rating [PAR] index), and (6) the patients' perceptions of the treatment.

MATERIAL AND METHODS

Trial design

This 3-arm parallel group randomized clinical trial had a 1:1:1 allocation ratio.

Participants, eligibility criteria, and settings

Participants were recruited at 2 hospital orthodontic departments in the United Kingdom, Chesterfield Royal Hospital and Royal Derby Hospital, and treated by 2 clinicians (J.S. and A.M.), both of whom have wide experience with the treatment methods. The clinicians were salaried hospital employees, and all treatments were provided within the United Kingdom's National Health Service at no direct cost to the patient or family. The study was approved by the Central Research Ethics Committee and the research and development departments at Chesterfield Royal Hospital and Royal Derby Hospital National Health Service trusts. A data-monitoring committee was established, and annual reports were submitted to this committee throughout the study to reassure them that progress was being made and that any untoward effects were reported. The trial was registered at ClinicalTrials.gov Identifier: NCT00995436, and the protocol was published on that site before the trial. We followed the guidelines in the declaration of Helsinki.[8]

The study was carried out with 78 patients. To be included, patients had to be between 12 and 18 years old. The operators had assessed them as needing maximum anchorage. This was defined as "no mesial movement of the molars during the period of anchorage supplementation." No attempt was made to achieve distal molar movement because clinically this was not required.

The exclusion criteria for the study were patients who (1) required functional appliance therapy or orthognathic surgery, (2) had previous orthodontic treatment or extractions, (3) had hypodontia of more than 1 tooth per quadrant, (4) had craniofacial syndromes or clefts, and (5) had poor dental health precluding orthodontic treatment.

Interventions

All patients were fitted with McLaughlin, Bennett, Trevisi prescription (American Orthodontics, Sheboygan, Wis) maxillary and mandibular preadjusted