

# 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](http://ClinicalTrials.gov) Identifier:

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NCT00995436. **Protocol:** The protocol was published on the above site before the trial commencement.

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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.<sup>1-7</sup> Of these, 1 study suggested that headgear and midpalatal implants were equally effective in providing anchorage,<sup>1</sup> whereas another large study found in favor of surgically assisted anchorage.<sup>2</sup> 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.<sup>3,4</sup> 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.<sup>5-7</sup> 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

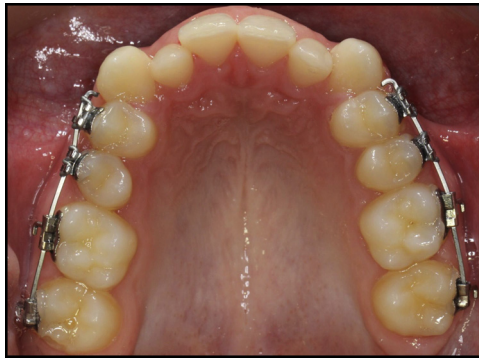
Participants were recruited at 2 hospital orthodontic departments in the United Kingdom, Chesterfield Royal Hospital and Royal Derby Hospital, and treated by 2 clinicians (J.S. and A.M.), both of whom have wide experience with the treatment methods. The clinicians were salaried hospital employees, and 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](http://ClinicalTrials.gov) Identifier: NCT00995436, and the protocol was published on that site before the trial. We followed the guidelines in the declaration of Helsinki.<sup>8</sup>

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, Trevis prescription (American Orthodontics, Sheboygan, Wis) maxillary and mandibular preadjusted



**Fig 1.** Sectional fixed appliances to fully align maxillary molars before DC1 records.

edgewise fixed appliances. During the initial phase of treatment, we derotated the molars in all 3 treatment groups. This involved bracket placement on all premolars and molars in the maxillary buccal segments and working through 3 archwires (0.016-in Sentalloy [Dentsply, GAC, Bohemia, NY], 0.018 × 0.025-in Neo-Sentalloy, and 0.019 × 0.025-in stainless steel [American Orthodontics]) until the molars were aligned (Fig 1). At this point, the first data collection (DC1) records were taken.

We observed the following treatment protocols.

For the headgear patients, this was a pragmatic trial, and all operators determined the design of the headgear according to their current treatment protocols. They placed 250 g of force per side on the headgear bow and requested at least 100 hours of headgear wear per week from the patients. We asked them to fill in a diary of headgear wear throughout treatment. The clinician checked both the headgear force and the compliance with headgear charts at each visit. Extractions were performed once the headgear was fitted.

For the Nance button patients, molar bands were fitted, and an alginate impression was taken over the bands; a Nance button on a 1.0-mm stainless steel palatal arch was made by an orthodontic technician. A large Nance button was used to cover the entire vertical part of the hard palate. This was fitted 1 week later, and any required extractions were arranged.

For the TADs patients, the maxillary and mandibular fixed appliances were placed, and arrangements were made for the necessary extractions before the TADs were placed. On the sides requiring anchorage supplementation, 8 × 1.6-mm TADs (American Orthodontics) were placed under local anesthesia, usually at the junction of the attached gingivae with the reflected mucosa and mesially to the maxillary molars. The TADs were placed before any retraction force was placed on the canines. Retraction was carried out with nickel-titanium

springs ligated directly from the canine to the TAD to produce 90 to 100 g of force.

All patients were treated similarly, with a standard archwire sequence (0.016-in Sentalloy, 0.018 × 0.025-in Neo-Sentalloy, and 0.019 × 0.025-in stainless steel), and the canines were retracted to achieve a Class I canine relationship before complete overjet reduction and space closure. Anchorage supplementation was discontinued once the canines were Class I and there was sufficient space in the maxillary arch to complete the correction of the malocclusion. At this point, the operator judged that no further anchorage supplementation was needed; therefore, the headgear was stopped, and the TADs or the acrylic Nance button was removed.

### Outcomes, primary and secondary

The primary outcome measure in this study was movement of the molars. The following secondary outcome measures were collected from the patients' treatment records.

1. The process of treatment (number of attendances, duration of treatment, number of missed and canceled appointments, and any emergency appointments).
2. The dento-occlusal outcome of treatment using the PAR index with the United Kingdom weightings.<sup>9</sup> Calibrated dental technicians, blinded to treatment allocation, performed this.

In addition, the patients were given questionnaires about the comfort and discomfort levels of placement and removal of both TADs and Nance palatal arches during the week after the procedure. The headgear patients only completed a questionnaire about their clinical experiences.

There were no outcome changes after commencement of the trial.

The data were collected at the following time points: at the start of full arch treatment when anchorage supplementation was provided (DC1), when anchorage supplementation was no longer required (DC2), and when active orthodontic treatment was complete (DC3). The following were collected: (1) maxillary and mandibular silicone impressions (DC1, DC2, DC3); (2) photographs, 4 extraoral and 5 intraoral (DC1, DC3), and intraoral (DC2); (3) orthopantomogram images (DC1, DC3); (4) TADs questionnaire (2 weeks after placement and 2 weeks after removal); (5) Nance questionnaire (2 weeks after placement and 2 weeks after removal); (6) headgear questionnaire (2 weeks after headgear was stopped); and (7) PAR scores (DC1, DC3).

Data collected from patient notes included (1) number of attendances; (2) number of visits from DC1 to DC2 and from DC2 to DC3; (3) duration of overall treatment;

(4) number of missed or canceled appointments; and (5) frequency and reason for additional appointments for appliance breakage.

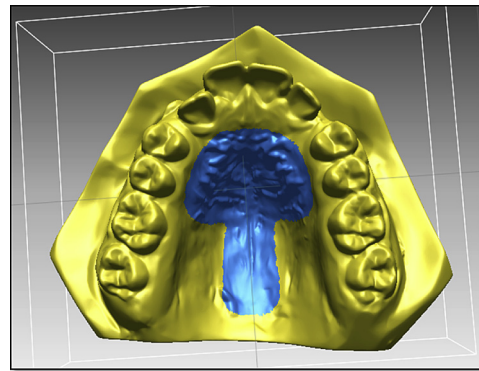
To make sure that the study models taken at DC2 did not provide information on the treatment allocation, we did the following. In the Nance group, the palatal arch was cut away from the bands, and the acrylic Nance button removed 2 weeks before the DC2 records were taken. This allowed any inflammation of the palatal tissues to subside and normal anatomy to reestablish. In the TADs group, the TADs were also removed before the impressions were taken.

To allow 3-dimensional (3D) digital scans of the models to be produced, the study models were sent to Bioprecision Diagnostics (Yeovil, Somerset, United Kingdom), where they were scanned by a 3Shape scanner ([www.3shape.com](http://www.3shape.com)) using 3Shape Scanserver and 3Shape ScanItOrthodontics software packages (3Shape, Copenhagen, Denmark). Surface shape measurements of the models were recorded through triangulation, and the computer then converted this information into a 3D polygon mesh. The detailed scans were trimmed using another software (RhinoCAD; McNeel Europe, Barcelona, Spain; [www.rhino3d.com](http://www.rhino3d.com)).

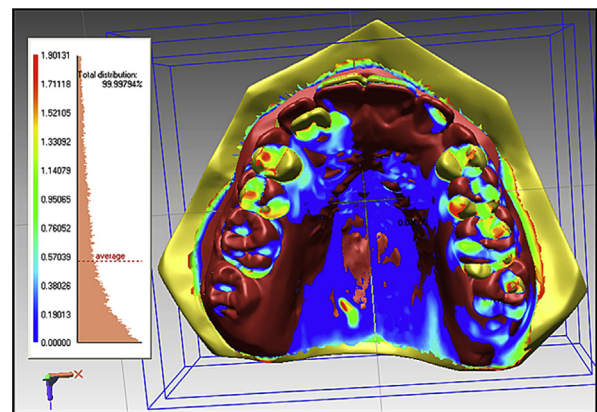
We measured tooth movement using Rapidform 2006 (Geomagic, Rock Hill, SC) software that allowed superimposition of the DC1 and DC2 maxillary 3D digital models, using the iterative closest point algorithm. This is a minimization routine, whereby many iterations of the superimposition process are performed within 6 degrees of freedom. On the pitch, yaw, and roll axes, the models can either translate or rotate, until the computer successfully minimizes the sum of the squares of the Euclidean distances between corresponding points on the 3D digital models at DC1 and DC2. The computer is directed to base the superimposition on an area of known stability common to both the DC1 and DC2 models; we selected this as the blue mushroom-shaped area based on the palatal rugae and a stable area of the hard palate shown in [Figure 2](#). The precision of the superimposition was assessed by the color of the models; the blue part of the spectrum indicates almost perfect superimposition of the 2 areas that are common to both digital models ([Fig 3](#)).

The DC1 maxillary molar outlines were then selected ([Fig 4](#)). The software constructed a DC1 molar shell, and this molar shell was superimposed on the DC2 molar occlusal surface, using best-fit algorithms. Tooth movement was calculated by measuring the difference in position of the DC1 and DC2 centers of mass ([Fig 5](#)).

A research assistant (R.G.) who was blinded to treatment allocation made the superimpositions and measurements of tooth movement.



**Fig 2.** Blue “mushroom” covering points of known stability for regional superimpositions.



**Fig 3.** Color of the model represents the accuracy of the superimposition.

### Sample size calculation

Calculation of the sample size was based on the ability to detect a clinically relevant difference in anchorage loss of 1.5 mm between 2 of the treatment groups. The expected standard deviation of mesial molar movement was taken from the study of Luecke and Johnstone,<sup>10</sup> who investigated molar movement in premolar extraction patients when anchorage was supplemented with headgear. The calculation indicated that for a study with a power of 80% and an alpha of 0.05, we required 21 participants per group. We assumed a dropout rate of 20%, based on a previous study suggesting that a minimum of 75 patients was required.<sup>5</sup> nQuery Advisor statistical software (Statistical Solutions, Boston, Mass) was used for the actual calculation.

### Interim analyses and stopping guidelines

No interim analyses were planned, and the data-monitoring committee was happy with our progress throughout the study.



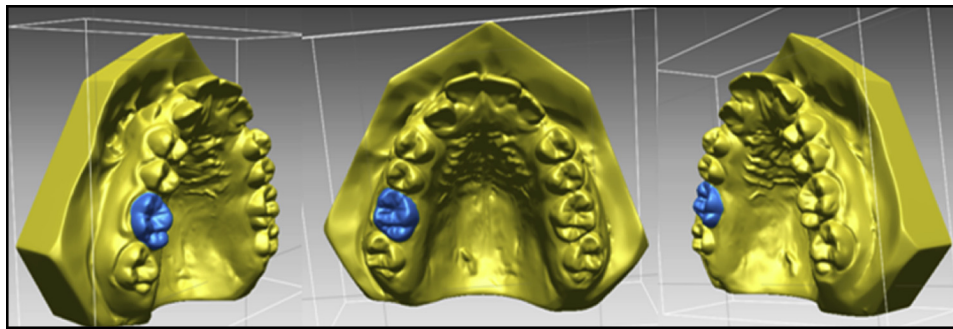


Fig 4. Models rotated to allow the entire occlusal, buccal, and palatal surfaces to be highlighted.

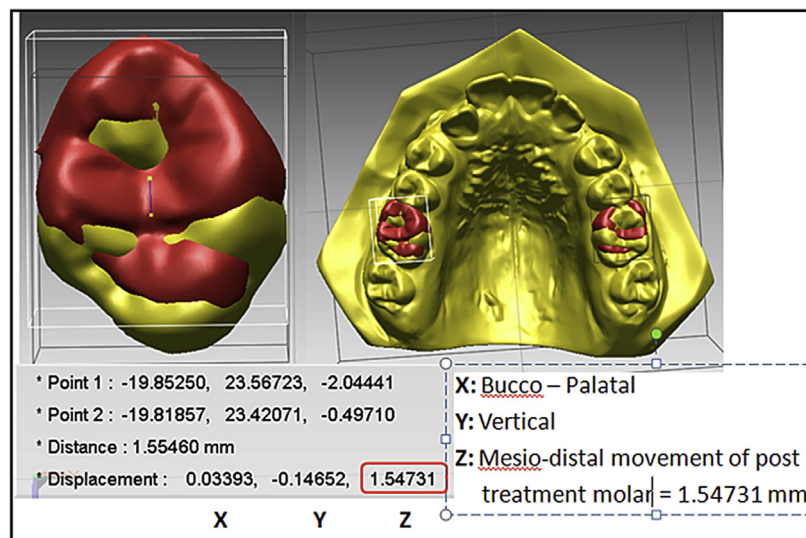


Fig 5. Movement of maxillary right molar shell and measurements in all 3 planes.

#### Randomization (random number generation, allocation concealment, implementation)

Randomization (random number generation, allocation concealment, implementation) was done as follows. When we identified patients who satisfied the inclusion criteria, we asked them to take part in the trial. Once informed consent was obtained from either competent patients or their parents, the orthodontist accessed the University of Nottingham Clinical Trials Unit randomization service (<http://www.ctsu.nottingham.ac.uk/0822/login.asp>) to obtain a treatment allocation. This ensured separation of the recruitment and randomization processes.

The randomization was based on a computer-generated pseudorandom code with random permuted blocks of randomly varying sizes. The sequence was held on a secure server according to standard operating

procedures. When the patient and the parent had consented to be in the study, the randomization center at the University of Nottingham Clinical Trials Unit was contacted. Demographic data were entered; after confirmation of the veracity of the data, the group allocation was indicated. Twenty-seven patients were randomized to the TADs group, 26 to the Nance group, and 25 to the headgear group. At DC2, we analyzed 22 TADs patients, 26 Nance patients, and 23 headgear patients (Fig 6).

#### Blinding

The clinicians and the patients were blinded to the allocation sequence; however, it was impossible to blind them to the treatment method. Assessment was blind because it was impossible to distinguish between the groups, since the Nance and the TADs had been removed before the DC2 records were taken.

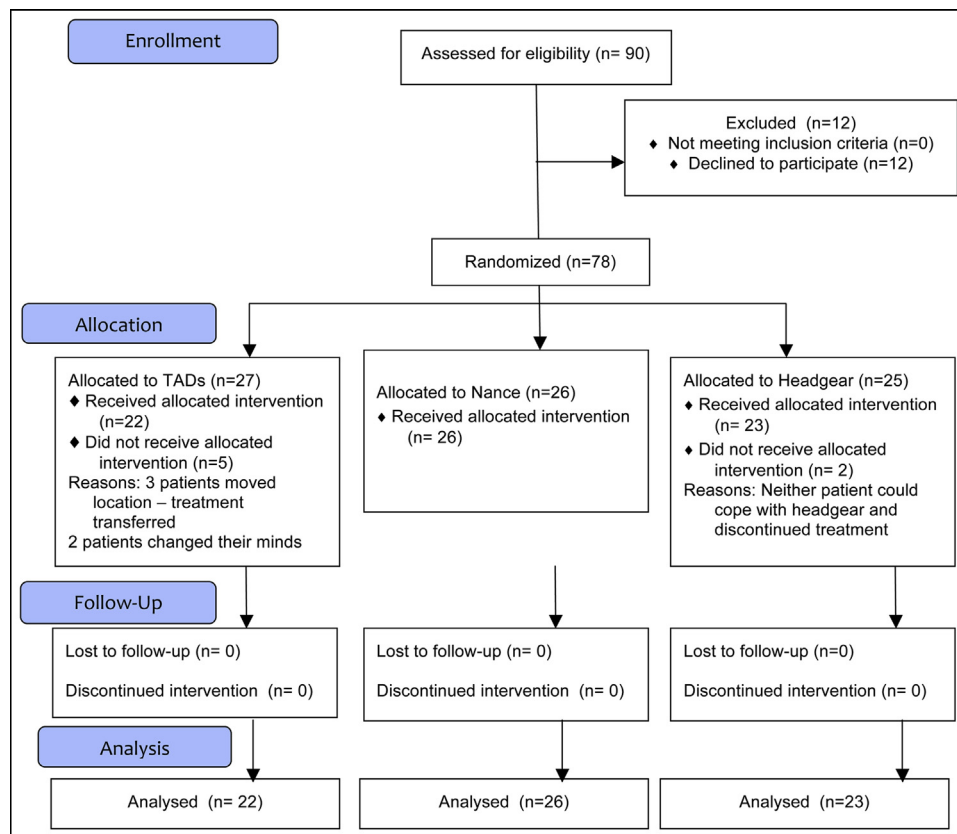


Fig 6. CONSORT 2010 flow diagram.

### Statistical analysis

A double determination was performed on 20 pairs of superimposed digital models. The study models were randomly picked and analyzed at 2 time points 4 weeks apart.

Bland-Altman plots,<sup>11</sup> intraclass correlation coefficients, and paired *t* tests were used to assess reliability.

Summary statistics were calculated for the data at the start and finish points of the study. We checked the variances of the molar movements for normality; when they were found to be normally distributed, parametric tests were appropriate.

A per-protocol analysis was performed. All patients in the study either were included in the data analysis or, if they had dropped out, were reported on individually.

The data were analyzed with analysis of covariance (ANCOVA), with headgear as the reference group and molar movement at DC2 as the dependent variable. The independent variables were the treatment groups (Nance, headgear, and TADs). Because the groups were unbalanced in their sex distributions after randomization, we also fitted sex as a covariate to adjust for the baseline scores.

A similar analysis was carried out for the secondary outcome measures; the dependent variables were total treatment time, total number of visits, number of missed and canceled appointments, and dento-occlusal changes as measured by PAR scores. When it was relevant, the pre-treatment PAR score was fitted as a covariate.

The SPSS software package was used (version 21; SPSS, Chicago, Ill), and statistical significance was set at the 5% level.

## RESULTS

### Participant flow

Ninety patients were initially informed about the study, and 12 declined to enter. Three did not want to wear headgear, 3 did not want the Nance button, but only 1 patient did not want to take part because he or she was unhappy at “the thought of TADs.” The other 5 patients had personal reasons for not wanting to take part in a research study. All patients who declined were offered alternative treatments.

Of the 78 patients enrolled, 27 were allocated to TADs (16 girls, 11 boys; average age, 14.15 years; SD,

**Table I.** Sample summary statistics at start of treatment, by treatment group, and for total sample

Patient details	Headgear	Nance	TADs	Total
Age (y)	14.38 (1.67) n = 25	14.14 (1.48) n = 26	14.15 (1.25) n = 27	14.22 (1.46) n = 78
PAR score	33.13 (13.40) n = 23	36.92 (12.52) n = 26	34.86 (13.39) n = 22	35.06 (12.99) n = 71
SNA (°)	80.99 (3.43) n = 23	81.40 (5.13) n = 26	82.12 (3.31) n = 24	81.51 (4.06) n = 73
Girls (n, %)	14/25 (56%)	7/26 (27%)	16/27 (59%)	37/78 (47%)

Values are mean (SD).

**Table II.** Molar tooth movements

Outcome	Headgear (n = 23)	Nance (n = 26)	TADs (n = 22)
Maxillary right molar (z) (mm)	1.36 (1.83)	1.84 (1.32)	0.80 (1.60)
Maxillary left molar (z) (mm)	1.99 (2.09)	2.09 (1.32)	0.99 (1.15)

Values are mean (SD).  
z, Mesiodistal movement of the molar teeth.

1.25 years), 26 to Nance (7 girls, 19 boys; average age, 14.14 years; SD, 1.48 years), and 25 to headgear (14 girls, 11 boys; average age, 14.38 years; SD, 1.67 years). The first patient was enrolled on August 5, 2008, and the final patient was enrolled 28 months later on December 22, 2010. All treatments were completed by February 2013. Two headgear patients and 5 TADs patients dropped out during the treatment period. The headgear patients were unable to cooperate with their treatment. The patients allocated to the TADs group stopped treatment for various social and domestic reasons. No patient who dropped out had reached the stage of having the TADs placed.

The flow of patients through the study is shown in Figure 6. No dropout patient reached a stage where the DC2 records could be taken.

### Baseline data

At baseline, information regarding age, sex, starting PAR score, and maxillary prominence was collected. Summary statistics for the patients are included in Table I. The baseline characteristics were similar in the 3 groups at the start of treatment. There was a lower proportion of girls in the Nance group compared with the other 2 groups.

### Molar tooth movement

The amounts of molar movement are shown in Table II, and the results of the data analysis are included in Table III. This showed that the differences between the treatments were small, with wide confidence intervals

that included zero. The  $R^2$  values were also small, signifying that the model explained a small amount of the variation. As a result, we concluded that no method of anchorage supplementation was more effective than another.

Table IV includes information on the total treatment time and the number of visits. Table V contains the linear regression on these variables, showing that there were no significant differences between the 3 groups. The numbers of canceled and missed appointments were almost identical between the groups.

Dento-occlusal changes, measured by the PAR index, are shown in Table VI. The linear regression models for the effects of treatment on the posttreatment PAR scores are shown in Table VII. The analysis shows a significant effect ( $P = 0.05$ ): the TADs group was 4 PAR points lower than the headgear group.

### Reproducibility of the method

An error analysis was performed on 20 pairs of superimposed digital models. The models were selected using a computer-based random-number generator. The intraclass correlation coefficients ranged from 0.94 to 0.97, and systematic errors assessed with the Bland-Altman plots<sup>11</sup> included no clinically important discrepancies. This demonstrated that the method of recording data had a high level of reliability, and any method errors were acceptable.

### Patient perceptions

Table VIII contains data from the 6-point Likert scale that measured the patients' perceptions of discomfort, with 1 representing "uncomfortable" and 6 "comfortable." The scores between the Nance button palatal arches and the TADs both on placement and on removal were almost identical. Free text comments were almost always positive with TADs; 17 of the 22 patients reported no problems, and 20 would recommend this method to their peers. The Nance free text session listed a number of minor problems, and 20 of the 26 patients in the

**Table III.** ANCOVA models for the effects of treatment on molar tooth movement measured on digital models

Outcome	Effect of treatment (95% CI)*	Overall effect of treatment	R <sup>2</sup>	Covariate
Maxillary right molar (z) mm	Nance, 0.62 (−0.32 to 1.55) TADs, −0.58 (−1.53 to 0.36)	F (2, 67) = 3.10; P = 0.05	0.07	Sex
Maxillary left molar (z) mm	Nance, −0.09 (−1.00 to 0.83) TADs, −0.96 (−1.89 to −0.04)	F (2, 67) = 2.58; P = 0.08	0.09	Sex

z, Mesiodistal movement of the molar teeth; F, level of significance P = 0.05.

\*Reference category is headgear.

**Table IV.** Total treatment time and number of visits from the initial placement of appliances to debond of all attachments

Process of treatment	Headgear (n = 23)	Nance (n = 26)	TADs (n = 22)	Total (n = 71)
Total treatment time (mo)	28.01 (17.46-38.51)	27.43 (15.03-39.83)	26.83 (8.5-45.16)	27.42 (13.5-41.34)
Total visits (n)	19.24 (6.66-31.8)	21.77 (13.13-30.41)	18.38 (5.8-30.04)	19.84 (8.57-31.11)

Values are mean (95% confidence interval).

**Table V.** ANCOVA models for total treatment time and number of visits during treatment

Outcome	Effect of treatment (95% CI)*	Overall effect of treatment	R <sup>2</sup>	Covariate
Total treatment time (mo)	Nance, −0.58 (−4.68 to 3.52) TADs, −1.18 (−5.41 to 3.04)	F (2, 69) = 0.16; P = 0.87	0.01	None
Total visits (n)	Nance, 2.53 (−0.62 to 5.68) TADs, −0.87 (−4.08 to 2.35)	F (2, 72) = 2.47; P = 0.09	0.06	None

F, Level of significance P = 0.05.

\*Reference category is headgear.

**Table VI.** Start and finish PAR scores for the 3 groups and reduction of PAR scores

PAR scores	Headgear (n = 23)	Nance (n = 26)	TADs (n = 22)	Total (n = 71)
Start	33.13 (13.40)	36.92 (12.52)	34.86 (13.39)	35.06 (12.99)
Finish	11.91 (7.39)	11.38 (5.73)	8.27 (4.13)	10.59 (6.04)
Reduction	21.26 (10.61)	25.69 (11.47)	26.59 (13.82)	24.54 (12.04)

Values are mean (SD).

group reported no problems; 24 would recommend this anchorage method to their peers.

### Questionnaires

The headgear questionnaire data are shown in [Table IX](#). On average, the headgear was worn for 3 hours less than requested and for just less than 10 months. Headgear was scored on the negative end of the scale for comfort and convenience, and 13 of the 23 patients would recommend this method of anchorage supplementation.

When asked specifically whether they had problems with headgear, only 3 patients mentioned that headgear interfered with sleep, and another 3 mentioned some pain, discomfort, or rubbing experienced while wearing the headgear; 3 comments suggested that the headgear made them self-conscious or embarrassed.

During the first 3 days of Nance appliance wear, the score was at the comfortable end of the scale, and the discomfort lasted just over 2.5 days. On removing the Nance, similarly positive scores were recorded for comfort.

Twenty of the Nance patients indicated that they had no problems with the appliance, whereas the remaining 6 mentioned gum irritation or inflammation, problems with cleaning, or food getting under the arch. Despite this, 24 of 26 said that they would recommend this method to a friend.

The TADs group scored the level of comfort on placement and over the first 3 days as similar to the group with the Nance button palatal arch. On removal of the TADs, comfort was also scored similarly to removal of the Nance. Most patients (20 of 22) would recommend this method of anchorage supplementation to their friends.

The free text responses were also valuable in giving insight into the patients' perceptions. Seventeen patients recorded no problems. When asked whether they experienced any problems after placement of the TADs, 1 respondent noted that 1 TAD became loose, and another reported occasional discomfort.

### Extractions

All patients in the study needed maximum anchorage, implying that no mesial movement of the



**Table VII.** ANCOVA model for the effects of treatment on the PAR score at finish

Outcome	Effect of treatment (95% CI)*	Overall effect of treatment	R <sup>2</sup>	Covariate
PAR finish	Nance, -1.24 (-4.36 to 1.89) TADs, -3.97 (-7.20 to -0.73)	F (2, 67) = 3.13; P = 0.05	0.23	PAR start

F, Level of significance P = 0.05.

\*Reference category is headgear.

**Table VIII.** Questionnaire results about comfort on placement and removal

Anchorage method	Placement comfort	Comfort during first 3 days	Discomfort days (n)	Removal comfort	Discomfort after 3 days	Discomfort duration (days)
TADs	4.41 (1.1)	3.73 (1.55)	2.82 (2.11)	4.25 (1.41)	4.81 (1.54)	1.00 (1.4)
Nance	4.62 (1.3)	3.46 (1.48)	2.65 (2.04)	4.31 (1.44)	4.92 (1.06)	1.12 (1.73)

These data were derived from the 6-point Likert scale measuring the patients' perceptions of discomfort, with 1 representing uncomfortable and 6 representing comfortable. Values are mean (SD).

**Table IX.** Questionnaire results about headgear wear, comfort, and convenience

Headgear	Hours requested	Hours actually worn	Months	Comfort	Convenience	Social interference	Did it bother you?
Mean	13.87	10.87	9.89	2.87	2.91	3.78	2.76
SD	3.31	4.01	4.73	1.39	1.41	1.51	1.55

These data were derived from the 6-point Likert scale, with 1 representing a large negative effect and 6 representing little effect or comfort. Values are mean (SD).

**Table X.** Extraction patterns

Maxillary first premolars	38
Maxillary first and mandibular second premolars	9
4 first premolars	7
1 first and 3 second premolars	5
1 first premolar and 1 other tooth	3
1 first premolar and 3 other teeth	3
4 first molars	3
Other extraction pattern	9
No extractions	1

molars would be acceptable. Clearly, there was a space requirement in all patients, and several extraction patterns were adopted (Table X).

### Harms

We found no serious harms from the treatments. The only adverse effect was that 1 TAD fractured on placement; the fractured fragment, after consultation with the patient, the parent, and the oral surgeon, was left in place. Healing was uneventful.

## DISCUSSION

### Main findings in the context of the existing evidence, interpretation

The results of this study showed no clinically or statistically significant differences in the effectiveness of the 3 methods of anchorage supplementation.

Importantly, no method prevented the mesial movement of the maxillary molars.

Our results do not agree with those reported in previous studies that demonstrated less loss of anchorage with surgically assisted methods.<sup>2,12</sup> However, in these studies, the authors used osseointegrated midpalatal implants or onplants, which might be more effective than the methods we evaluated. Another study reported similar anchorage losses to ours; however, the study was underpowered, and the difference between the 2 groups was not statistically significant.<sup>1</sup>

Distal molar movement when using TADs in patients needing maximum anchorage has also been reported in a number of studies.<sup>3,4,13</sup> It is relevant to consider that these studies all used cephalometric measurements, with inherent errors of projection, patient positioning, magnification, and imprecise landmarks involving averaging of superimposed structures. Our method for measuring tooth movement might have been more accurate.

We considered the potential biases in previous research. In 1 study, the assessor was not blinded to the treatment method.<sup>3</sup> In none of 6 studies was an attempt made to differentiate between the left and right molars; this could have led to errors in interpretation and measurement.<sup>2-5,12,13</sup>

The sex imbalance was taken into account in the statistical analysis, and this made no difference in the results.

There were no dropouts from the Nance group and only 2 from the headgear group. In the TADs group, however, there were 5 dropouts; all occurred before the TADs had been fitted. Although the number in this group was still above the sample size, it could be suggested that this introduced a moderate risk of attrition bias.

Secondary outcome measures in this study included treatment time and number of visits. We found that the overall treatment times were similar to other studies.<sup>1,5</sup>

It is also clear, from reviewing other studies in this area, that few investigators have reported the final outcomes of treatment.<sup>2-4,6,10,12,13</sup> Therefore, we evaluated the final occlusal result of the treatment with the PAR index. This analysis showed a clinically and statistically significant difference between the TADs and the headgear groups. The only other study that previously investigated this outcome reported no difference in the PAR scores for midpalatal implant and headgear treatments; this is different from our results.<sup>5</sup> It is difficult to identify the reasons for this finding; it might reflect the natural variability between studies.

We found some important and interesting results from the patient perception questionnaires. First, there were no marked differences in the perceptions of the patients who had been treated with the TADs or the Nance palatal arches. This suggests that the 2 interventions were equally acceptable to patients.

When we considered the perceptions of the headgear patients, it was interesting that the average hours of reported wear were 3 hours less than the minimum of 14 hours that we requested. Five patients reported that they thought that the headgear only needed to be worn for half of a day. This demonstrates that even with careful planning and explanations of treatment, mixed messages can still arise, and full cooperation is not always forthcoming. Although this level of cooperation could be considered disappointing, this was a pragmatic study, and we are reporting on treatment of real-world patients whose behavior is relevant to practice.

Whereas there were few real differences in the scores from the Likert scales, the free text sections showed important clinically relevant findings, and it was clear that patients preferred not to wear headgear.

This study adds to the body of evidence that TADs are an efficient and effective method of supplementing anchorage. Although there were no differences between the 3 interventions in terms of reinforcing anchorage, it was clear that our patients preferred TADS and Nance palatal arches to headgear. If we also consider patient safety concerns with headgear, it could be suggested that the TADS or the Nance palatal arch should be used in preference to headgear.

Although there were no difference between the effectiveness of TADS and Nance treatments, this information should be given to patients along with the description of the treatment process so that they can make an informed choice of their preferred treatment. This study provides clinically relevant information that will aid orthodontists and patients in determining the optimum form of anchorage reinforcement.

The failure rate of TADs in this study was 2.8%, which is significantly lower than the 12% failure rate reported elsewhere.<sup>14</sup>

### Limitations

In this study, it was not possible to blind the operators and patients to the treatment allocations. Nevertheless, the assessment of the outcomes was blinded, and we considered that the risks of observation and detection bias were low. We think that attrition bias might be an issue, however, because more patients dropped out of the study in the TADs group. This could be interpreted as the patients' possible reluctance to accept the surgical placement of TADs.

### Generalizability

The external validity or generalizability of this study is good. It was carried out at 2 district general hospitals by experienced clinicians. The patients were selected from the normal caseloads of the departments, and all received routine care.

### CONCLUSIONS

We can conclude the following: (1) there was no difference in the effectiveness of TADS, Nance button palatal arches, and headgear for reinforcing anchorage during orthodontic treatment; and (2) the information from this study can be used to help orthodontists and patients determine their preferences for the method of anchorage reinforcement.

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