



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 Eklund¹ 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 on-plants 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.

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

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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 × 0.025-in nickel-titanium aligning archwires followed by 0.019 × 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

Statistical analysis

We carried out a sample size calculation using data derived from a study that used the pitchfork analysis (Luecke and Johnston⁹). Their results suggested that the molars moved forward 3.2 mm (SD 1.5 mm). Altman¹⁰ described a sample size calculation for 3 independent groups with continuous data.

Standard deviation of variable (s) = 1.5 mm

Clinically relevant difference (δ) = 2.0 mm

Standard difference = δ/s , or $2.0/1.5 = 1.33$

With Altman's nomogram¹⁰ with a standardized difference of 1.33, a sample size of 20 in each group would give a power of 0.85 with a significance level of 0.05. Assuming a 20% dropout rate means that 25 patients needed to be recruited into each group.

RESULTS

A total of 51 patients were included, 25 randomly allocated to the headgear group and 26 to the implant group. Thirty-eight subjects were female: 20 in the headgear group and 18 received implants. Of the 13 male subjects, 6 had headgear, and 7 were in the implant group. Their average age was 15.2 years (headgear average, 14.8; implant average, 15.7; range, 12-39 years).

Two patients, randomly assigned to the implant group, dropped out before treatment started (1 moved out of the area, and 1 family was splitting up). There were 2 other patients assigned to the implant group whose implants failed to osseointegrate on 2 consecutive occasions. For them, an alternative approach to treatment was chosen: 1 patient ended up with a compromise extraction pattern involving a second premolar on 1 side and a canine on the other side of the maxillary arch, and the other converted to headgear as the method of supplementing anchorage.

In the headgear group, 1 patient dropped out of the study before headgear treatment started (her family was moving). There were 3 failures; 1 patient had a different method of providing anchorage, and there were 2 compromise extraction patterns after it became evident that headgear would not provide sufficient anchorage. One patient had both maxillary lateral incisors extracted and the other had both maxillary canines extracted (Fig 1).

The average numbers of visits per course of treatment were 19 in the headgear group and 26 in the implant group (Table I). Despite this, the total active treatment times (excluding the 3-month period for osseointegration) were almost identical: 2.23

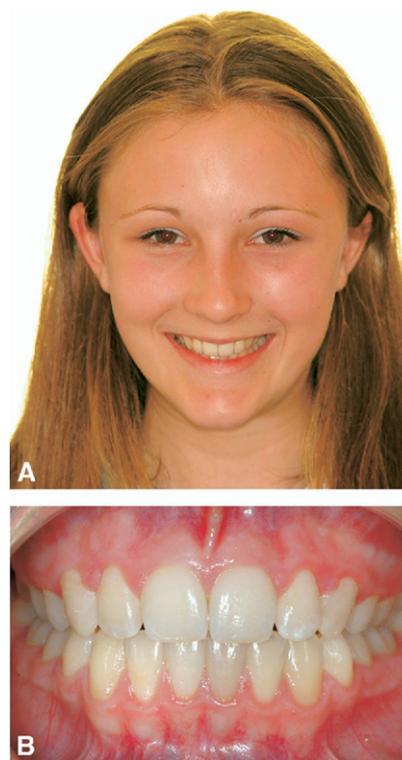


Fig 1. Patient with failed headgear treatment: A, extraoral view; B, intraoral view.

years for the headgear group and 2.15 years for the implant group. The mean numbers of unscheduled visits were 1.54 in the headgear group and 1.26 in the implant group.

The results of the cephalometric analysis were detailed in another article.¹¹ To summarize, a modified Pancherz cephalometric analysis (Fig 2) was used to assess dental and skeletal changes in the 2 groups.⁸ Maxillary position was assessed by measuring the distance from A-point to a constructed vertical line through sella; the implant group had an average of -0.7 mm (range, $-0.4-0.0$) and the headgear group had $+0.3$ mm (range, $-0.8-1.3$).

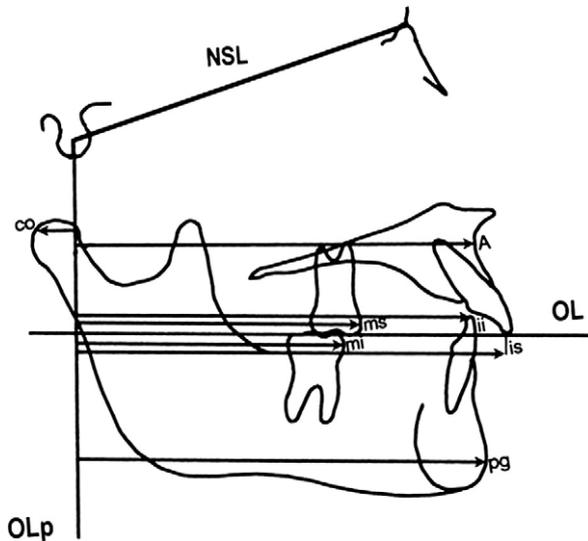
The mandibular base was assessed by measuring pogonion to the constructed vertical. The implant group changed on average 0.2 mm (range, 2.8-4.23), and the headgear group changed 1.7 mm (range, 0.1-3.3).

The maxillary molars moved forward 1.5 mm (range, 0.4-2.7) in the implant group and 3 mm (range, 1.6-4.5) in the headgear group. The mandibular molars moved forward 2.9 mm (range, 1.8-4.0) in the implant group and 3.4 mm (range, 2.0-4.8) in the headgear group. No treatment change between the 2 groups was statistically significantly different.

The PAR score was used as an accepted method of

Table I. Descriptive data for treatment in the groups, including the results of the unpaired *t* test to assess the differences

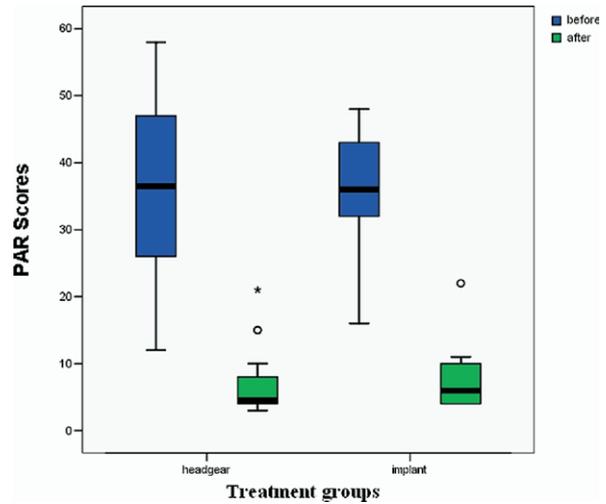
	Implant group		Headgear group		95% CI		P value
	Mean	SD	Mean	SD	Lower bound	Upper bound	
Duration of treatment (y)	2.15	0.59	2.23	0.62	-0.28	4.34	.667
Casualties (n)	1.26	1.25	1.54	1.92	-0.70	1.26	.561
Failed appointments (n)	1.55	2.83	1.00	1.64	-2.01	.92	.450
Visits (n)	26.21	7.41	19.20	4.58	-10.70	-3.31	<.001

**Fig 2.** Modified Pancherz analysis.⁸ NSL, Nasion to sella line; OL, occlusal line; OLP, perpendicular to occlusal line; ms, mesial of upper molar; ii, lower incisor tip; mi, mesial of upper molar; is, upper incisor tip; pg, pogonion. Reprinted from Am J Orthod Dentofacial Orthop¹¹.

assessing the occlusion at the start and the end of treatment, thereby assessing the quality of treatment outcome. The mean PAR scores at the start of treatment were 35.9 for the headgear group and 35.7 for the implant group. The ranges of the scores are shown in the Figure 3, which clearly demonstrates pretreatment equivalence.

At the end of treatment, the mean PAR scores were 6.7 for the headgear group and 7.4 for the implant group. Both groups were within the greatly improved category, with a 78.1% reduction in the headgear group and a 78.3% reduction in the implant group. The differences between the groups at the start and end of treatment were assessed by using an independent sample *t* test; the differences were not statistically significant (Table II).

The data were analyzed with multiple regression analysis. The dependent variable was the PAR score, and independent variables were age, sex, PAR baseline

**Fig 3.** Box plot to check pretreatment equivalence.

score, and treatment group (Table III). This analysis showed that no independent variable had a predictive effect in the model. Furthermore, R^2 was only 0.053, suggesting that the model fit was not good, and that other factors such as individual variation and treatment mechanics had an influence.

Twenty-five patients were originally randomized to the implant group, and 23 actually started treatment. The mean age of this group was 15.7 years (range, 12-39).

There were 6 surgical failures before orthodontic loading; therefore, the surgical success rate was considered to be 74%. All 6 patients whose first implant failed opted to have a second implant placed, and 4 of the replacements osseointegrated successfully. The orthodontic success rate of implants could therefore be argued to be greater than 90% because only 2 implant patients of 23 did not end up with implant-assisted supplementation of anchorage.

On the 6-point scale from 1 (uncomfortable) to 6 (comfortable), 75% of the respondents scored between 4 and 6—ie, at the comfortable end of the scale for implant placement—and no patient scored 1, indicating that the placement of implants was generally acceptable.

Table II. Descriptive data for PAR scores in 2 groups, including an unpaired *t* test to assess the differences

	Implant group		Headgear group		95% CI		P value
	Mean PAR score	SD	Mean PAR score	SD	Lower bound	Upper bound	
PAR score before treatment	35.67	8.78	35.91	14.05	-6.97	7.46	.946
PAR score after treatment	7.38	4.23	6.73	4.71	-3.41	2.10	.634
PAR score difference	28.29	8.07	29.09	14.49	-6.43	8.04	.822

Table III. Regression analysis on PAR

Significant variables	Coefficient	95% CI		P value
		Lower bound	Upper bound	
Treatment group	.034	-2.706	3.315	.839
Age	.059	-.257	.362	.734
Sex	.068	-2.608	3.932	.684
PAR baseline	.221	-.049	.226	.199

For regression analysis, $n = 51$, $F = 0.495$, $P < .05$, and adjusted $R^2 = -0.053$.

According to the statistical analysis, there was no significant correlation between any variables with treatment outcome.

These ratings were repeated when the patients were asked to assess their comfort over the first 3 days, and 75% scored 4 to 6 at the comfortable end of the spectrum; none scored 1.

On implant removal, the questionnaire was again distributed; 40% scored 5, 40% scored 3, and 20% scored 1, indicating that implant removal was slightly less comfortable than implant placement.

DISCUSSION

It was with some trepidation that 2 authors (P.J.S. and D.T.) approached the Chesterfield Local Research and Ethics Committee asking for approval to place implants in the jaws of children. Surprisingly, the assembled group of experts had no problem with intraoral titanium implants placed under local anesthesia. They expressed reservations, however, about the use of headgear after they heard about past problems with this technique. They wondered whether headgear, with its rare but potentially damaging side effects, will continue to receive ethical committee approval after there is scientific evidence of an acceptable alternative.

The headgear patients in the study surprised the clinicians with the speed and efficiency of this method of anchorage supplementation. In some cases, the headgear was discontinued after only 5 months; on average, headgear wear was continued for 9 months. We believed that we had witnessed the Hawthorne effect. This phenomenon was named by French¹² when describing the unexpected outcomes of a series of

studies conducted at Western Electric Company's Hawthorne works in Cicero, Illinois, that involved the manipulation of working conditions during the 1920s and 1930s. The investigators in the original studies noticed that the workers' behavior was altered when they knew that they were in an experiment. We think that, because so much time had been spent with all patients both before the randomization explaining the study and the randomization, obtaining written consent, and afterwards collecting detailed documentation of their responses to treatment, they were motivated to cooperate beyond the level that we would normally have expected. Maybe the answer with all headgear patients is to spend significantly more time with them to try to achieve a similar level of enthusiasm and motivation as we witnessed in our study.

The ease with which the patients accepted the relatively new technique involving midpalatal implants also came as a surprise. Perhaps, the patients just saw it as an extension of the trend toward lip, nose, and tongue studs as well as eyebrow and other body part piercing. Certainly, this theory is strengthened by the 6 implant patients who, at the end of treatment, refused to have the implant removed and preferred to keep it in place. The technique of placing the implant was readily accepted by children as young as 12 years of age. Most patients said that there was no real pain but, rather, a feeling of discomfort for 2 or 3 days after the surgery; a few patients commented that the implant felt "bulky" and temporarily interfered with speech.

Most of the failed first implants were the earlier ones placed, and there could well be a learning curve for surgeons with this relatively new technique. All implant clinicians stressed the need for slow drill speeds. This is thought to significantly lower the temperature in the surrounding bone and increase the chance of true osseointegration. Ground sections were carried out for 6 implants; each implant sectioned showed intimate approximation of the cancellous bone with the screw threads, suggesting successful osseointegration (Fig 4).

The 6-mm implants with a 2.5-mm neck length were used in most patients, but, on 4 occasions, an emergency implant was required. The indication for an emergency implant is when primary stability with the

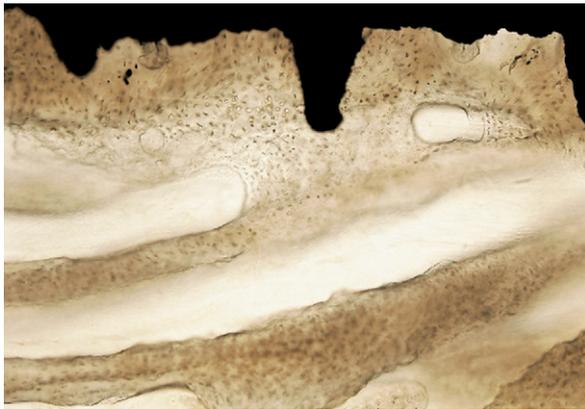


Fig 4. Ground section: tight proximity between implant threads and cancellous bone indicates effective osseointegration.

usual 3.3-mm diameter implant is unobtainable, due to slight overdrilling of the implant site. The emergency implant was 4.0 mm in diameter, and primary stability was achieved in all 4 patients.

The implant patients were all reviewed at 3 days, 1 week, and 3, 6, and 12 weeks. Five of the 6 failed implants were slightly loose at 3 weeks; in 1 subject, the implant was loose at 12 weeks. All failed implants were simply unscrewed from the soft tissues. On no occasion was local anesthetic required for removal: no patient experienced discomfort during the procedure, and the tissues healed uneventfully. At this stage, the patients were given a choice of either having another implant placed or an alternative approach to management of the anchorage (headgear or choice of extractions), and every patient requested that the implant be replaced. This indicates the universal acceptability of the technique. No implants, identified as firm at 12 weeks, failed later under orthodontic forces.

Patients reported slightly more discomfort on implant removal than on implant placement, and 6 patients wanted to keep their implants in place. The usual disclaimers were issued, warning the patients about the possibility of infection around the fixture, but their wishes were respected. They were all told to return immediately if they experienced any problems around the implant.

In any intention-to-treat analysis, it is important to report on every patient and ensure that each is analyzed in the original group; this was done in our study. Several patients were listed as failed headgear or failed implant cases. This does not mean failed orthodontic treatment, as shown in Figure 1. A more than satisfactory esthetic and functional result was still obtained for these patients by altering the extraction pattern to



Fig 5. Bonded palatal arch with loss of anchorage on right where premolar bond failed.

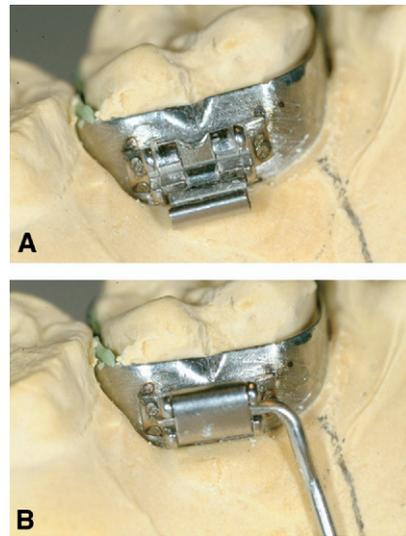


Fig 6. Lingual hinge cap assembly: **A**, open position; **B**, closed position.

reduce reliance on the randomly chosen method of anchorage supplementation—eg, extraction of canines or lateral incisors.

The 1 main difference between the 2 groups was the number of treatment appointments, with a significantly higher number in the implant group (Table I). This was to be expected, because, with this new technique, the patients were required to see the surgeons for a preoperative check before the surgery appointment. We were keen to identify whether and when the implants became loose; therefore, all implant patients were all seen at 3 days, 1 week, and 3, 6, and 12 weeks after implant placement. They also had an additional visit for implant removal. Despite more visits, the total time in fixed appliances was almost identical between the 2 groups.

The palatal arches used to attach the implants to the teeth varied throughout the study. We began by using palatal arches bonded to the premolars. These were easy for the technician to construct, but they tended to



Fig 7. Distal jet to distalize first molars, attached via lingual hinge caps.

debond, thus allowing the posterior teeth to come forward (Fig 5). Bands soldered to molars were also tried, but these were difficult to place unless the paths of insertion of the 2 bands were not only similar, but also similar to the path of insertion of the internal hexagon on the implant abutment over the implant. The method of attachment we found to be most successful was the lingual hinge cap assembly (Ormco, Glendora, Calif) (Fig 6). This appliance was easy to make and versatile, and allowed easy discontinuation of anchorage supplementation when appropriate. It also allowed distal jets to be used if distalization of the molar was required (Fig 7) and allowed a simple palatal arch to control all movement of the molars.

Total active orthodontic treatment time was counted from the time the bonds were placed in the patient until they were removed. This was found to be almost identical (implant group, 2.15 years \pm 0.59; headgear group, 2.23 years \pm 0.62), and there was no statistical significance to this difference. Obviously, if the 3-month osseointegration period was added to the mean time of the implant patients, there would have been a significant difference. Most patients, however, consider their time in braces as time

from bonds on to bonds off. The 2 techniques were the same in this regard.

CONCLUSIONS

The use of palatal implants to reinforce anchorage was as effective as extraoral anchorage with headgear.

REFERENCES

1. Creekmore TD, Eklund MK. The possibility of skeletal anchorage. *J Clin Orthod* 1983;17:266-9.
2. Booth-Mason S, Birnie D. Penetrating eye injury from orthodontic headgear—a case report. *Eur J Orthod* 1988;10:111-4.
3. Samuels RHA, Jones ML. Orthodontic facebow injuries and safety equipment. *Eur J Orthod* 1994;16:385-94.
4. Wehrbein H, Merz BR, Diedrich P, Glatzmaier J. The use of palatal implants for orthodontic anchorage. Design and clinical application of the orthosystem. *Clin Oral Implants Res* 1996;7:410-6.
5. Wehrbein H, Merz BR, Diedrich P. Palatal bone support for orthodontic implant anchorage—a clinical and radiological study. *Eur J Orthod* 1999;21:65-70.
6. Skeggs RM. A systematic review of surgical reinforcement of anchorage during orthodontic treatment [thesis]. Sheffield, United Kingdom: University of Sheffield; 2005.
7. Tinsley D, O'Dwyer JJ, Benson PE, Doyle PT, Sandler J. Orthodontic palatal implants: clinical technique. *J Orthod* 2004;31:3-8.
8. Panchez H. The mechanism of Class II correction in Herbst appliance treatment. *Am J Orthod* 1982;82:104-13.
9. Luecke PE, Johnston LE. The effect of maxillary first premolar extraction and incisor retraction on mandibular position: testing the central dogma of "functional orthodontics." *Am J Orthod Dentofacial Orthop* 1992;101:4-12.
10. Altman DG. Practical statistics for medical research. London: Chapman and Hall; 1991.
11. Benson PE, Tinsley D, O'Dwyer JJ, Majumder A, Doyle P, Sandler JP. Midpalatal implants for orthodontic anchorage—a randomized clinical trial. *Am J Orthod Dentofacial Orthop* 2007;132:606-15.
12. French JRP. Field experiments: changing group productivity. In: Miller JG, editor. Experiments in social process: a symposium on social psychology. New York: McGraw Hill; 1950. p. 79-96.