Midpalatal implants vs headgear for orthodontic anchorage—a randomized clinical trial: Cephalometric results

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Introduction: The purpose of this study was to compare the clinical effectiveness of the midpalatal implant as a method of reinforcing anchorage during orthodontic treatment with that of conventional extraoral anchorage. This was a prospective, randomized, clinical trial at Chesterfield and North Derbyshire Royal Hospital NHS Trust and the Charles Clifford Dental Hospital, Sheffield, in the United Kingdom. Methods: Fifty-one orthodontic patients between the ages of 12 and 39, with Class II Division 1 malocclusion and absolute anchorage requirements, were randomly allocated to receive either a midpalatal implant or headgear to reinforce orthodontic anchorage. The main outcome was to compare the mesial movement of the molars and the incisors of the 2 treatment groups between the start and the end of anchorage reinforcement as measured from cephalometric radiographs. Results: The reproducibility of the measuring technique was acceptable. There were significant differences between T1 and T2 in the implant group for the positions of the maxillary central incisor (P < .001), the maxillary molar (P = .009), and the mandibular molar (P < .001). There were significant differences between T1 and T2 in the headgear group for the positions of the mandibular central incisor (P < .045), the maxillary molar (P < .001), and the mandibular molar (P < .001). All skeletal and dental points moved mesially more in the headgear group during treatment than in the implant group. These ranged from an average of 0.5 mm more mesially for the mandibular permanent molar to 1.5 mm more mesially for the maxillary molar and the mandibular base. No treatment changes between the groups were statistically significant. Conclusions: Midpalatal implants are an acceptable technique for reinforcing anchorage in orthodontic patients. (Am J Orthod Dentofacial Orthop 2007;132:606-15)

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nchorage is of fundamental importance in orthodontic treatment. A common method of reinforcing anchorage in the maxillary arch is to use an extraoral attachment to the first molars, but this headgear is not popular with patients and is frequently not worn as prescribed, leading to poor treatment results.1 The dangers of headgear wear are well documented; the most severe is damage to the eyes.3 Endosseous dental implants have proved to be an effective method of restoring edentulous spaces and are now being used to support orthodontic anchorage.4 Various different types of implant are used for orthodontic anchorage, including bone screws,5 bone plates,6 and palatal implants.7 They are relatively simple to place, but complications include soft- or hard-tissue infection and failure of the implant. Implants placed on the buccal aspect, such as the miniscrews, risk damage to adjacent tooth roots.

To date, there has been no published randomized clinical trial comparing an orthodontic implant system with a conventional form of anchorage control. Our aim in this study was to compare the clinical effectiveness of the midpalatal implant as a method of reinforcing anchorage during orthodontic treatment with extraoral anchorage reinforcement; we present the cephalometric results.

MATERIAL AND METHODS

Ethical approval for this study was obtained from North Derbyshire Health and South Sheffield Local Research Ethics committees. The subjects were recruited from the orthodontic departments of Chester-
The patients in the study all needed absolute anchorage, and no forward movement of upper molars could be allowed for successful treatment.

The following exclusion criteria were applied: poor oral hygiene, unwilling to wear fixed appliances, unwilling to wear headgear or have the implant placed, and medical history precluding fixed appliance treatment.

When a patient was judged suitable, he or she was given information about the study. Initial (T1) records were obtained: study models, intraoral and extraoral photographs, and appropriate radiographs, including a lateral cephalometric radiograph. The treatment options of headgear or a palatal implant were explained in detail, and written information was given to patients and parents. The patients had a review appointment at least 2 weeks later to discuss the study further. If they agreed to enter it, they were randomly allocated to 1 of the 2 treatment groups.

In group 1 (implant), a midpalatal implant (6-mm Ortho implant; Straumann, Waldenburg, Switzerland) was surgically placed according to the manufacturer’s guidelines by 1 of 2 oral and maxillofacial surgeons (A.M. and P.D.). A standard technique was used, including a stent to ensure safe and accurate implant positioning. After a 3-month integration period, the implants were connected with a transpalatal arch made in the laboratory to bands on the maxillary molars (Fig 1).

In group 2 (headgear), extraoral anchorage in the form of a Nitom Locking Facebow (Ortho-Care, Bradford, United Kingdom) was fitted to bands on the maxillary molars. Variable-pull headgear was used with a force of 450 g on each side (Fig 2). Patients received detailed instructions on the use of headgear and were requested to wear it 100 to 120 hours per week. A chart was given to each patient to record the hours of headgear wear. Each patient was reviewed 2 weeks after fitting the headgear to assess cooperation.

The randomization was carried out by using computer-generated random numbers in a block design by a researcher unconnected with the recruitment of most patients (P.E.B.). Allocation was concealed in consecutively numbered, sealed opaque envelopes, which were opened after the patient and parent agreed to enter the trial and signed the consent form. Extractions were undertaken in both arches if a space analysis suggested that this was required to achieve the treatment objectives. Most extractions were of premolars.

Most patients (42) were recruited, assigned, and treated at Chesterfield and North Derbyshire Royal Hospital NHS Trust by 3 orthodontists (D.T., J.J.O’D., P.J.S.). The remaining 9 patients were recruited and treated at the Charles Clifford Dental Hospital by 3 orthodontists (D.T., J.J.O’D., P.E.B.). The 2 groups were treated identically, except for the method of anchorage reinforcement.

Once the clinician was satisfied that the anchorage reinforcement was secure, the extractions were carried...
Stainless steel preadjusted edgewise brackets with a 0.022-in slot size (MBT, American Orthodontics, Marlow, United Kingdom) were bonded to all teeth mesial to the first molars in both arches, and an initial 0.016-in nickel-titanium aligning wire was placed. The subsequent archwire sequence was 0.018-in nickel-titanium archwire, followed by posted 0.019 × 0.025-in stainless steel wire, with curves where appropriate to manage the overbite. Spaces were closed, and the maxillary anterior labial segments were retracted with nickel-titanium closing springs (12 mm, medium force) by using sliding mechanics. Intermaxillary elastics were used when considered necessary by the treating clinician.

Anchorage reinforcement was continued until the mandibular arch was aligned and the maxillary canines were in a Class I relationship with the mandibular canines. At this stage, the patient was instructed to stop wearing the headgear, or the implant was disconnected from the molar bands. At the same appointment, a lateral cephalogram and study models were taken (T2).

The main outcome of this study was to compare the mesial movement of the molars and the incisors of the 2 treatment groups between T1 and T2. This was carried out with the lateral cephalograms by using the Pancherz analysis. Other measures such as treatment outcome, patient acceptability, compliance, discomfort, and implant stability will be reported elsewhere.

Blinding of the operator and the patient to treatment allocation was not possible during this study, but all radiographs were made anonymous by obscuring patient details. The implants were concealed by using an opaque marker on both sides of the radiograph (Fig 3). An opaque marker was also placed in the approximate position of an implant on the radiographs of the headgear group, so that the assessor was unaware to which treatment group the radiograph belonged.

The T1 radiographs were numbered consecutively in random order by a researcher (P.E.B.) and traced on a light box in a darkened room by a second researcher (J.J.O’D.). A grid was constructed from the T1 radiograph by using 2 reference planes, the occlusal line (OL) and the occlusal line perpendicular (OLp) (Fig 4). The grid was transferred to the second radiograph by superimposition on the nasion-sella line with sella as the registering point. Linear measurements from OLp to 1 of 6 landmarks were obtained with a digital caliper by a third researcher (D.T.). The landmarks as defined by Pancherz were used:

A, the deepest point on the anterior contour of the maxilla.
Pg, the most anterior point on the bony chin.
IsSu, the incisal tip of the most prominent maxillary central incisor.
Li, the incisal tip of the most prominent central mandibular incisor.
Sm, the mesial contact point of the maxillary first permanent molar.
Lm, the mesial contact point of the mandibular first permanent molar.

After 2 weeks, the measurements were repeated on the radiographs of 10 implant patients and 10 headgear patients, all randomly selected. Both T1 and T2 radiographs were assessed in random order; thus, 20 radiographs from each group were remeasured.

**Statistical analysis**

Statistical advice was obtained, suggesting that a sample size of 40 patients would be sufficient to detect a 2-mm (± 1.5 mm) difference in mesial molar movement between the treatment groups at a significance level of 0.05 and a power of 0.85. A 20% dropout rate was expected; therefore, a final sample size of 50 patients was recommended.

The repeated readings from the 40 radiographs measured twice were assessed with a paired t test for systematic error. The intraclass correlation coefficient was calculated for these readings to monitor random error.

The distribution of the data was found to be normal; therefore, parametric statistics were applied. The measurements of the T1 radiographs from the 2 treatment groups were assessed with an independent t test to check for pretreatment equivalence. The difference in each treatment group in skeletal and dental positions from the T1 and T2 radiographs was examined with a paired t test, and the changes in the skeletal and dental positions between the groups were compared with an independent t test. The statistical significance level was set at $P < .05$.

**RESULTS**

Recruitment to this study began in January 2001 and continued until December 2002. A total of 51 patients were enrolled, 25 in the implant group and 26 in the headgear group. There were 38 female and 13 male subjects (headgear, 20 female and 6 male; im-
Fig 5 shows the flow of participants through the trial. Two patients from the implant group and 1 from the headgear group withdrew before receiving treatment. Two patients had failed implants; 1 received headgear, and the other had a compromise extraction treatment. Four patients were unable to wear the headgear; 3 received compromise extraction treatment, and 1 received an implant. One patient was excluded because a radiograph at T2 was not obtained. All patients were analyzed on an intention-to-treat basis. Therefore, the data from 23 of the 25 patients in the implant group and 24 of the 26 patients in the headgear group were included in the analysis.

Table I shows the results of the repeated readings of the 40 radiographs. The mean differences between the readings were small, and no systematic differences were detected. The intraclass correlation coefficients for the repeated readings are shown in Table II. There was substantial or excellent agreement between all measurements.

The descriptive statistics of the readings from the T1 and T2 radiographs for both groups are shown in Table III. An independent t test for pretreatment equivalence showed no significant differences between the implant and headgear groups at T1.

The skeletal and dental changes between the T1 and T2 radiographs in the 2 groups are shown in Table IV. There were significant differences between the T1 and T2 measurements in the implant group for the positions of the maxillary base \( (P = .048) \), the maxillary central incisor \( (P < .001) \), the maxillary molar \( (P = .009) \), and the mandibular molar \( (P < .001) \).

There were significant differences between the T1 and T2 measurements in the headgear group for the positions of the mandibular base \( (P = .040) \), the mandibular central incisor \( (P < .001) \), the maxillary molar \( (P < .001) \), and the mandibular molar \( (P < .001) \).

Table V shows the T1 and T2 differences in the skeletal and dental changes between the groups. This demonstrates that all skeletal and dental points moved mesially more in the headgear group during treatment than in the implant group. These ranged from an average of 0.5 mm more mesial movement for the mandibular

### Table I. Differences between first and second readings of the 20 implant and 20 headgear radiographs and a paired t test for systematic error

<table>
<thead>
<tr>
<th>Position</th>
<th>Mean difference (mm)</th>
<th>SD</th>
<th>95% CI</th>
<th>Min</th>
<th>Max</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary base (A-OLp)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>IM reading 1 vs reading 2</td>
<td>0.4</td>
<td>1.5</td>
<td>−0.3 to 1.1</td>
<td>−2.9</td>
<td>3.7</td>
<td>.239</td>
</tr>
<tr>
<td>HG reading 1 vs reading 2</td>
<td>0.4</td>
<td>1.4</td>
<td>−0.2 to 1.1</td>
<td>−2.5</td>
<td>2.2</td>
<td>.173</td>
</tr>
<tr>
<td>Mandibular base (Pg-OLp)</td>
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<td></td>
</tr>
<tr>
<td>IM reading 1 vs reading 2</td>
<td>0.4</td>
<td>2.7</td>
<td>−0.9 to 1.6</td>
<td>−5.5</td>
<td>4.7</td>
<td>.563</td>
</tr>
<tr>
<td>HG reading 1 vs reading 2</td>
<td>0.2</td>
<td>2.1</td>
<td>−0.7 to 1.2</td>
<td>−3.8</td>
<td>3.6</td>
<td>.634</td>
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<tr>
<td>Maxillary central incisor (IsSu-OLp)</td>
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<tr>
<td>IM reading 1 vs reading 2</td>
<td>0.1</td>
<td>1.8</td>
<td>−0.8 to 0.9</td>
<td>−4.1</td>
<td>3.0</td>
<td>.884</td>
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<tr>
<td>HG reading 1 vs reading 2</td>
<td>0.0</td>
<td>1.4</td>
<td>−0.7 to 0.6</td>
<td>−2.7</td>
<td>2.2</td>
<td>.987</td>
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<tr>
<td>Mandibular central incisor (Li-OLp)</td>
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<td></td>
</tr>
<tr>
<td>IM reading 1 vs reading 2</td>
<td>0.1</td>
<td>1.7</td>
<td>−0.7 to 0.6</td>
<td>−4.0</td>
<td>2.6</td>
<td>.722</td>
</tr>
<tr>
<td>HG reading 1 vs reading 2</td>
<td>−0.1</td>
<td>1.4</td>
<td>−0.7 to 0.6</td>
<td>−2.5</td>
<td>2.5</td>
<td>.828</td>
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<tr>
<td>Maxillary permanent molar (Sm-OLp)</td>
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<tr>
<td>IM reading 1 vs reading 2</td>
<td>−0.2</td>
<td>1.5</td>
<td>−0.9 to 0.5</td>
<td>−3.5</td>
<td>2.3</td>
<td>.589</td>
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<tr>
<td>HG reading 1 vs reading 2</td>
<td>−0.3</td>
<td>1.4</td>
<td>−1.0 to 0.4</td>
<td>−2.6</td>
<td>2.2</td>
<td>.363</td>
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<td>Mandibular permanent molar (Lm-OLp)</td>
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</tr>
<tr>
<td>IM reading 1 vs reading 2</td>
<td>−0.1</td>
<td>2.2</td>
<td>−1.2 to 0.9</td>
<td>−6.7</td>
<td>2.8</td>
<td>.814</td>
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<tr>
<td>HG reading 1 vs reading 2</td>
<td>0.2</td>
<td>1.4</td>
<td>−0.4 to 0.9</td>
<td>−2.6</td>
<td>3.0</td>
<td>.455</td>
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</tbody>
</table>

CI, Confidence interval; IM, implant; HG, headgear; Min, minimum; Max, maximum.

### Table II. Intraclass correlation coefficients for the repeat readings of the 20 implant and 20 headgear radiographs

<table>
<thead>
<tr>
<th>Position</th>
<th>Implant</th>
<th>Headgear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary base (A-OLp)</td>
<td>0.88</td>
<td>0.93</td>
</tr>
<tr>
<td>Mandibular base (Pg-OLp)</td>
<td>0.86</td>
<td>0.84</td>
</tr>
<tr>
<td>Maxillary central incisor (IsSu-OLp)</td>
<td>0.87</td>
<td>0.96</td>
</tr>
<tr>
<td>Mandibular central incisor (Li-OLp)</td>
<td>0.89</td>
<td>0.95</td>
</tr>
<tr>
<td>Maxillary permanent molar (Sm-OLp)</td>
<td>0.89</td>
<td>0.93</td>
</tr>
<tr>
<td>Mandibular permanent molar (Lm-OLp)</td>
<td>0.89</td>
<td>0.93</td>
</tr>
</tbody>
</table>
permanent molar to an average of 1.5 mm more mesial movement for the maxillary molar and the mandibular base, but no treatment changes between the groups were statistically significant.

The ratio of incisor retraction to mesial molar movement was calculated for each patient (IsSU-OLpT2–IsSU-OLpT1)/(Sm-OLpT2–Sm-OLpT1). This showed that, for every millimeter of mesial movement of the molar, there was an average 2.3 mm of incisor retraction in the implant group compared with an average forward movement of the incisor of 1.2 mm in the headgear group.

DISCUSSION

This is the first report of a randomized clinical trial comparing the use of a palatal implant with a conventional extraoral method for anchorage reinforcement. It showed that, although there were some significant differences in the movement of skeletal and dental points in each group, the differences between the groups were not statistically significant.

There are several problems in conducting randomized clinical trials in orthodontics, but this approach is generally accepted to produce a high level of evidence, when comparing 2 alternative treatment methods. The fundamental question with this study was whether midpalatal implants are as good as conventional methods of reinforcing anchorage in orthodontic patients. The answer is clearly “yes.” There were no statistically significant differences between the tooth movements in patients with implants or headgear.

To go a step further and ask whether implants are more efficient than headgear in reinforcing anchorage is not as clear. The differences in the movement of the dental points are interesting. The reduction of overjet in the implant group was principally by retracting the maxillary incisors (average, 2.1 mm); this was highly significant. Retraction of the maxillary incisors in the headgear group was much less (average, 0.7 mm) and not statistically significant. Overjet reduction in the headgear group was helped by considerable proclination of the mandibular incisors (mean, 1.7 mm),

Table III. Descriptive statistics of the readings from T1 (pretreatment) and T2 (end of anchorage) radiographs for the implant and headgear groups (23 implant and 24 headgear patients)

<table>
<thead>
<tr>
<th>Position</th>
<th>IM T1</th>
<th>IM T2</th>
<th>HG T1</th>
<th>HG T2</th>
<th>IM T1</th>
<th>IM T2</th>
<th>HG T1</th>
<th>HG T2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary base (A-OLp)</td>
<td>71.8</td>
<td>71.1</td>
<td>71.5</td>
<td>71.7</td>
<td>72.3</td>
<td>72.5</td>
<td>72.2</td>
<td>73.8</td>
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<tr>
<td>Mandibular base (Pg-OLp)</td>
<td>72.3</td>
<td>72.5</td>
<td>72.2</td>
<td>73.8</td>
<td>77.1</td>
<td>74.9</td>
<td>76.6</td>
<td>76.1</td>
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<tr>
<td>Maxillary central incisor (IsSU-OLp)</td>
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<td>74.9</td>
<td>76.6</td>
<td>76.1</td>
<td>72.1</td>
<td>72.8</td>
<td>71.8</td>
<td>73.4</td>
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<td>49.9</td>
<td>51.4</td>
<td>49.9</td>
<td>52.9</td>
<td>50.2</td>
<td>53.1</td>
<td>50.1</td>
<td>53.3</td>
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<tr>
<td>Maxillary permanent molar (Sm-OLp)</td>
<td>50.2</td>
<td>53.1</td>
<td>50.1</td>
<td>53.3</td>
<td>50.2</td>
<td>53.1</td>
<td>50.1</td>
<td>53.3</td>
</tr>
<tr>
<td>Mandibular permanent molar (Lm-OLp)</td>
<td>50.2</td>
<td>53.1</td>
<td>50.1</td>
<td>53.3</td>
<td>50.2</td>
<td>53.1</td>
<td>50.1</td>
<td>53.3</td>
</tr>
</tbody>
</table>

CI, Confidence interval; IM, implant; HG, headgear; Min, minimum; Max, maximum.
whereas the change in the position of the mandibular incisors in the implant group was less marked (mean, 0.7 mm).

The average retraction of the maxillary incisors might appear small, considering the nature of the malocclusions treated. Wehrbein et al found a mean reduction in overjet of 6.2 mm, measured from study casts in 9 patients with Class II malocclusions treated with midpalatal implants to support anchorage. The method of measuring maxillary incisor movement used in this study is related to, but is not a direct measurement of, overjet reduction. The change in the position of the maxillary incisor in the implant group (2.1 mm) is comparable with changes in similar groups of patients in a randomized clinical trial comparing treatment with Twin-block (−3.1 mm) and Herbst (−2.4 mm) appliances by using the same cephalometric technique. The mesial movement of the maxillary molars could be said to represent the mean anchorage loss in this study, because the subjects all had Class II malocclusions. By this measure, the mean anchorage loss was twice as much in the headgear group (mean, 3.0 ± 3.4 mm) compared with the implant group (mean, 1.5 ± 2.6 mm). Wehrbein et al found a lower mean anchorage loss of 0.9 mm (± 0.3 mm) measured from cephalograms with a technique of superimposing on anterior nasal spine and posterior nasal spine, and measuring the mesial movement of the cusp tip point. They suggested that part of the anchorage loss was due to

<table>
<thead>
<tr>
<th>Position</th>
<th>Mean change (mm)</th>
<th>SD</th>
<th>Lower</th>
<th>Upper</th>
<th>Min</th>
<th>Max</th>
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<tr>
<td>Maxillary base (A-OLp)</td>
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<tr>
<td>IM T2-T1</td>
<td>−0.7</td>
<td>1.6</td>
<td>−1.4</td>
<td>0.0</td>
<td>−3.5</td>
<td>3.2</td>
<td>.048</td>
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<td>HG T2-T1</td>
<td>0.3</td>
<td>2.5</td>
<td>−0.8</td>
<td>1.3</td>
<td>−8.3</td>
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<td>.611</td>
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<td>Mandibular base (Pg-OLp)</td>
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<tr>
<td>IM T2-T1</td>
<td>0.2</td>
<td>2.5</td>
<td>−0.9</td>
<td>1.3</td>
<td>−4.1</td>
<td>5.7</td>
<td>.684</td>
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<tr>
<td>HG T2-T1</td>
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<td>0.1</td>
<td>3.3</td>
<td>−4.6</td>
<td>13.6</td>
<td>.040</td>
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<tr>
<td>Maxillary central incisor (IsSu-OLp)</td>
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</tr>
<tr>
<td>IM T2-T1</td>
<td>−2.1</td>
<td>2.0</td>
<td>−3.0</td>
<td>1.3</td>
<td>−5.8</td>
<td>3.2</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>HG T2-T1</td>
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<td>4.9</td>
<td>−2.8</td>
<td>1.4</td>
<td>−7.1</td>
<td>12.7</td>
<td>.493</td>
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<tr>
<td>Mandibular central incisor (Li-OLp)</td>
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<tr>
<td>IM T2-T1</td>
<td>0.7</td>
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<td>−6.4</td>
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<tr>
<td>HG T2-T1</td>
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<td>3.3</td>
<td>−4.1</td>
<td>12.9</td>
<td>.045</td>
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<td>Maxillary permanent molar (Sm-OLp)</td>
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<tr>
<td>IM T2-T1</td>
<td>1.5</td>
<td>2.6</td>
<td>0.4</td>
<td>2.7</td>
<td>−4.2</td>
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<td>4.5</td>
<td>−2.0</td>
<td>11.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mandibular permanent molar (Lm-OLp)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IM T2-T1</td>
<td>2.9</td>
<td>2.5</td>
<td>1.8</td>
<td>4.0</td>
<td>−1.6</td>
<td>8.2</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>HG T2-T1</td>
<td>3.4</td>
<td>3.3</td>
<td>2.0</td>
<td>4.8</td>
<td>−2.0</td>
<td>9.7</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

CI, Confidence interval; IM, implant; HG, headgear; Min, minimum; Max, maximum.

<table>
<thead>
<tr>
<th>Position</th>
<th>Mean difference (mm)</th>
<th>95% CI of the difference</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary base (A-OLp)</td>
<td>1.0</td>
<td>−0.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Mandibular base (Pg-OLp)</td>
<td>1.5</td>
<td>−0.4</td>
<td>3.4</td>
</tr>
<tr>
<td>Maxillary central incisor (IsSu-OLp)</td>
<td>1.4</td>
<td>−0.8</td>
<td>3.7</td>
</tr>
<tr>
<td>Mandibular central incisor (Li-OLp)</td>
<td>1.0</td>
<td>−0.9</td>
<td>2.9</td>
</tr>
<tr>
<td>Maxillary permanent molar (Sm-OLp)</td>
<td>1.5</td>
<td>−0.3</td>
<td>3.2</td>
</tr>
<tr>
<td>Mandibular permanent molar (Lm-OLp)</td>
<td>0.5</td>
<td>−1.2</td>
<td>2.2</td>
</tr>
</tbody>
</table>

CI, Confidence interval.
*Equal variances not assumed.

The average retraction of the maxillary incisors might appear small, considering the nature of the malocclusions treated. Wehrbein et al found a mean reduction in overjet of 6.2 mm, measured from study casts in 9 patients with Class II malocclusions treated with midpalatal implants to support anchorage. The method of measuring maxillary incisor movement used in this study is related to, but is not a direct measurement of, overjet reduction. The change in the position of the maxillary incisor in the implant group (−2.1 mm) is comparable with changes in similar groups of patients in a randomized clinical trial comparing treatment with Twin-block (−3.1 mm) and Herbst (−2.4 mm) appliances by using the same cephalometric technique.

The mesial movement of the maxillary molars could be said to represent the mean anchorage loss in this study, because the subjects all had Class II malocclusions. By this measure, the mean anchorage loss was twice as much in the headgear group (mean, 3.0 ± 3.4 mm) compared with the implant group (mean, 1.5 ± 2.6 mm). Wehrbein et al found a lower mean anchorage loss of 0.9 mm (± 0.3 mm) measured from cephalograms with a technique of superimposing on anterior nasal spine and posterior nasal spine, and measuring the mesial movement of the cusp tip point. They suggested that part of the anchorage loss was due to
to bending of the transpalatal bar used to connect the anchor teeth to the implant. They advised increasing the size of the archwire from a square 0.8 × 0.8-mm wire to 1.2 × 1.2 mm. We used an 0.8-mm wire, and some anchorage loss in the implant group might be attributed to this. Other loss might be due to early failures of the transpalatal arch. It was the clinical impression that the implants did not move under normal orthodontic forces, but this is the subject of a further investigation.

There was great individual variation in response to treatment in the 2 groups. This was also noted in other clinical investigations and reduced the power of those studies. Although there were no statistically significant differences in the tooth movements between the groups, the upper confidence limits ranged from 2.2 to 3.7 mm, whereas the lower limits ranged from −0.3 to −1.2 mm. This nonsymmetrical arrangement of the confidence intervals around the differences suggests that there might be a significant difference, but this study lacked the power to detect it. The main reason for the discrepancy between the predicted outcomes and what was observed is that the sample size was calculated on the basis of data from 2 studies. Both found much smaller variations in the treatment changes than in this study. The results of these previous studies were from samples selected on the basis of available records and consecutively treated patients that might have been subjected to bias. As a result of this, we based our sample size on a smaller standard deviation than was actually found. Using the actual standard deviation (3.0), we extrapolated that a sample size of 80 (40 in each group) would be required to find a significant difference of 2 mm between the 2 groups (α = 0.05; 1-β = 0.85). This sample size should be used as the starting point of any study of the same outcome in the future.

All patients in this trial were analyzed on an intention-to-treat basis. This means that even those whose implant failed or who did not comply with the instructions for wearing the headgear were analyzed in their original groups. This might have altered the outcome of the trial, but we considered it the best way of avoiding bias and possibly overestimating the effect of a new form of treatment.

The effects on the skeletal landmarks were interesting. There was no restraining effect on the forward growth of the maxilla in patients who wore headgear. There appeared to have been more mandibular growth in this group. This is contrary to findings in other studies. Tulloch et al found an average reduction in the SNA angle of 0.92° per year in a group allocated to early correction of Class II malocclusion with headgear. This compared with an increase of 0.26° per year in a control group, but these differences were lost by the end of a second phase of treatment. The reason for this lack of skeletal effect from the headgear is unclear. Compliance with headgear wear was assessed by experienced clinicians treating these patients and reinforced with charts completed at home. However, clinical indicators of compliance with headgear wear can be misleading.

The mandibular base (Pg-OLp) moved forward on average between 1 and 2 mm more than the maxillary
base (A-OLp) in both groups of patients. This proved sufficient to counteract the mesial movement of the maxillary molar that occurred in most patients and helped to achieve the desired Class I canine relationship.

The effect of intermaxillary elastic wear on the outcome is difficult to determine. On the whole, these were prescribed sparingly in both groups. The decision to advise patients to wear Class II elastics was made by the treating clinician on a visit-by-visit basis. This depended on overjet, overbite, canine and molar relationships, and the amount of space required to be closed in both arches. Adjustments of the final canine position, the relative positions of the maxillary and mandibular centerlines, and the final occlusal interdigitation were, as in normal clinical practice, perfected by using interocclusal elastics of varying strengths and positions. There was no evidence that they were used more frequently in 1 group than in the other.

The dropout rate in this study was similar between the groups; 19% (5 of 26) of the patients in the headgear group failed to complete treatment compared with 16% (4 of 25) in the implant group, although 2 failures in the implant group were due to surgical failure of the implant, rather than patient compliance. All patients who had failed implants requested further implant placement. This failure rate is similar to the rates in other studies, including early treatment with a Twin-block functional appliance, and prospective cohort studies of the Twin-block appliance and the Herbst appliance, but much less than later treatment with the Twin-block.

There is extensive reporting in the literature of high levels of success (>95%) with osseointegrated implants used to restore the dentition. Wehrbein et al reported a 100% success rate in a prospective trial involving the Straumann palatal implant placed in 9 patients. Bernhart et al reported the results of a prospective study of orthodontic treatment with palatal-implant support in 21 mainly adult patients. All their implants achieved primary stability; however, 2 became mobile shortly after the start of orthodontic treatment and 1 after 8 months of treatment.

The surgical failure rate of the implants in this study was high, with implants in 6 of the 24 implant patients (25%) failing to achieve primary stability at the first attempt. Four patients received a second implant, which achieved osseointegration, but, in 2 patients, the second implant failed, and they had compromise treatment. The failed implants were among the first placed by the surgeon, and there was improvement in the failure rate as the trial progressed. In addition, no implant was lost after it successfully achieved primary stability.

The palatal implant is only 1 type of implant used for orthodontic anchorage; it relies on osseointegration for stability. Other implants do not rely on osseointegration but are mechanically retained. These can potentially be loaded with orthodontic forces immediately, but there are few published failure rates for these implants. The use of implants for aiding orthodontic tooth movement is an exciting and fast-moving field. Future research must document all failures and investigate the acceptability of this form of treatment to patients as well as the efficiency of achieving planned movements.

There are several reasons for suggesting that implants are an acceptable alternative to other forms of anchorage reinforcement. One reason would be the lower complication rate of implants compared with headgear. A survey of 1117 practitioners in the United Kingdom and Ireland reported 33 injuries from Kloehn facebows. The most serious injury is damage to the eye, with subsequent loss of sight. There are few reported complications from midpalatal implants. Wehrbein et al also found few complications, with 5 of their 9 patients reporting no postoperative pain after implant placement. Patient acceptability in our study was also good, with only 1 patient experiencing minor postoperative pain requiring a single dose of analgesic on the evening of implant placement.

CONCLUSIONS

Midpalatal implants are an acceptable technique for reinforcing anchorage in orthodontic patients.

In this randomized clinical trial, we found no statistically significant differences in the tooth movements achieved between patients with orthodontic anchorage supported with a midpalatal implant compared with conventional headgear, but there were important differences in the movement of teeth in the groups.

Further studies should examine patient-based measures of acceptability for implant treatment and clinical efficiency.

We thank Institut Straumann AG for providing the implants and other financial and technical assistance during this study.

REFERENCES