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The effects of early headgear treatment on dental arches and craniofacial morphology: an 8 year report of a randomized study

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SUMMARY The aim of this study was to determine the long-term effects of early headgear (HG) treatment on craniofacial structures. The total study group comprised 68 children (40 males and 28 females) aged 7.6 years (standard deviation 0.3 years). The children, who had a Class II tendency in occlusion and moderate crowding, were randomly divided into two groups of equal size. In the first group, HG treatment was initiated immediately. In the second group, which served as a control group, only minor interceptive procedures were performed during the first follow-up period of 2 years. During the 8 year follow-up, orthodontic therapy, including fixed appliances and possible extractions, was carried out when necessary.

The results showed that the most evident difference between the groups was the wider and longer dental arches in the HG group, which could only partly be explained by the higher rate of extractions in the control group. For the cephalometric measurements, the most significant difference was in the maxillary plane orientation. The peer assessment rating (PAR) score, showing the general outcome of treatment, was at the same level in both groups at follow-up. The deficit of the early HG treatment was the longer mean total treatment time, resulting from the two-phase treatment.

Introduction

Controversial results have been presented concerning the effects of headgear (HG). According to most reports, however, a posterior movement of the maxilla is achieved after the use of cervical HG (Melsen and Enemark, 1969; Wieslander, 1974; Melsen, 1978; Baumrind *et al.*, 1978; Tulloch *et al.*, 1997a, b; Kirjavainen *et al.*, 2000). Another common finding has been opening of the bite, mostly due to downward movement of the anterior maxilla. In this respect, the results of different studies are highly variable and in some reports no significant craniofacial component has been achieved, in spite of the positive dental effect (Baumrind *et al.*, 1983; Hubbard *et al.*, 1993; Keeling *et al.*, 1998). It is noteworthy that among these studies, the works of Tulloch *et al.* (1997a, b) and Keeling *et al.* (1998) are based on randomized trials, representing a higher level of evidence.

There has been much debate over the appropriate treatment time as well as the most suitable methods concerning crowding diagnosed during the early mixed dentition (Gianelly, 1994; Little, 2002; McNamara, 2002; Proffit and Tulloch, 2002). Traditionally, one of the most popular treatment methods has favoured the extraction of primary canines. Later, the choice of treatment has in many cases led to the extraction of two or four premolars. The advantage of this method has been the early alignment of the anterior teeth, which is thought to reduce treatment time with fixed appliances during subsequent therapy. As the trend in camouflage treatment of crowding has been to favour non-extraction methods, at least in borderline cases, the number of premolar extractions has remained relatively low when compared with the situation decades ago (Proffit, 1994).

An evident consequence of the trend to avoid the extraction of permanent premolars has been the need to expand the dental arches. The ideal goal of expansion is to achieve a permanent result where good alignment of the dental arches is gained with all the permanent teeth in occlusion even at long-term follow-up. The key question in this treatment philosophy is, in addition to the stability of the treatment result, the appropriate timing for the expansion of the dental arches. According to earlier well-adopted follow-up studies, permanent expansion of dental arches was considered uncertain and relapse after expansion was evident, especially in the lower arch (Sinclair and Little, 1983; Little and Riedel, 1989; Little *et al.*, 1990). In spite of these results, expansion techniques have been widely used in orthodontics in order to facilitate the alignment of all permanent teeth, whenever possible. Thus, a fundamental question, when the outcome of treatment is considered, is whether it is possible to maintain the expansion in dental arches, if the expansion is well timed.

The purpose of the present longitudinal randomized investigation was to determine the long-term effects of early HG treatment on dental arches and craniofacial morphology, when treatment is started during the early mixed dentition.

The hypothesis was that with the early use of cervical HG, significant increases in dental arch dimensions can be achieved.

Subjects and methods

Two hundred and forty 7-year-old children were screened for the investigation. The inclusion criteria were a need for orthodontic treatment due to moderate crowding and a Class II tendency. The crowding was clinically diagnosed as moderate, based on the degree of space deficiency in the anterior regions of the dental arches. Seventy-one of the screened children met the inclusion criteria; three refused to be entered into the study. The total study group comprised 68 children of both sexes (40 males and 28 females) aged 7.6 years [standard deviation (SD) 0.3 years]. Twenty per cent of the children had an Angle Class II molar relationship. Eighty per cent had either a bilateral cusp to cusp molar relationship, a unilateral cusp to cusp relationship, or a Class I relationship on either side.

The children were randomly divided into two groups of equal size, matched according to gender. This was undertaken by one author (TK) using random numbers. To conceal the allocation, most of the practitioners who undertook the treatment were not given information concerning the aim or rationale of the study.

In the first group, HG treatment was initiated immediately. The mean treatment time was 16 months. In the second group, which served as the control, only minor interceptive procedures were performed during the follow-up period. The criteria for providing interceptive treatment in the control group was to achieve improved alignment of the anterior teeth during the early mixed dentition. The interceptive procedures in the control group were extraction of the upper primary canines in 38 per cent and lower primary canines in 35 per cent, to ease the eruption of the lateral incisors. In addition, in 19 per cent of the subjects in the control group, interdental stripping was carried out.

In the HG group, the maxillary first molars were banded and cervical HG was used, but no other appliances were used. The long outer bows of the HG were bent 10 degrees upwards in relation to the inner bow. The inner bow of the HG was expanded and was constantly held 10 mm wider than the dental arch. The patients were instructed to wear the HG during sleep, for 8–10 hours.

The records included in the present study were taken before (T0), and after follow-up periods of 2 (T1) and 8 years (T2). The comprehensive investigations included a clinical examination, impressions for dental casts and a radiographic examination (dental pantomogram and a lateral cephalogram).

Between T1 and T2 there was no difference between the groups in the treatment protocol. Orthodontic treatment, if needed, during this phase comprised fixed appliance treatment, including extractions of permanent premolars due to crowding.

Fifteen linear dimensions were measured on the dental casts. The measurements were carried out using a digital three-dimensional measuring device and a technique based on machine vision (Heikkilä and Silvén, 1996; Pirttiniemi *et al.*, 1998). The method has previously been found to be accurate and in the present study double determinations were undertaken on every measurement to assess the level of intra-examiner error.

The highest tips of the cusps at a tangent to the occlusal plane were marked with a sharp pencil. The cusp tips of the canines (at T0 the primary canines and later permanent canines, when erupted) were marked using the method described by Ghafari *et al.* (1998). The cusp tips were consistently marked at the same point: the intersection of the cusp occlusal contour with the buccal vertical axis of the cusp. The variables used are shown and explained in Figure 1.

The Peer Assessment Rating (PAR) scores (Richmond *et al.*, 1992) were determined from the dental casts taken at the 8 year examination.

Five angular measurements, describing skeletal changes, were chosen to represent skeletal variables: SNA, SNB, ANB, NL/ML (the angle between the line intersecting anterior and posterior nasal spine and the line from the inferior surface of the symphysis to the antegonial notch), and SN/NL (the angle between the line from nasion to sella and the line intersecting anterior and posterior nasal spine). Both gender groups were pooled for the statistical analyses.

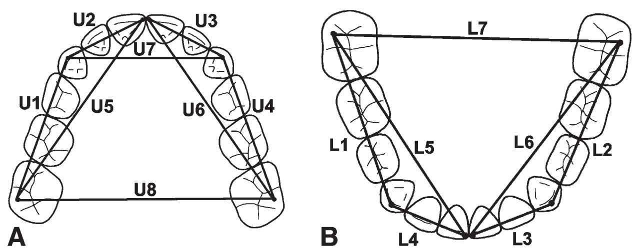

Figure 1 The dimensions of the dental arches measured at the start of the study and at the 2 and 8 year follow-ups ($n = 54$). U1, U4, the distance from the tip of the buccodistal cusp of the upper right and left first permanent molars to the highest point of the canine in the same quadrant; U2, U3, the distance between the highest points of the upper canines and the extreme mesio-incisal point of the mesial incisor in the same quadrant; U5, U6, the distance between the highest point of the distobuccal cusps of the first upper permanent molar and the extreme mesio-incisal point of the mesial incisor in the same quadrant; U7, the distance between the highest points of the upper canines; U8, the distance between the highest points of the distobuccal cusps of the first maxillary permanent molars; L1, L2, the distance from the tip of the buccodistal cusp of the lower right and left first permanent molars to the highest point of the canine in the same quadrant; L2, L4, the distance between the highest points of the lower canines and the extreme mesio-incisal point of the lower mesial incisor in the same quadrant; L5, L6, the distance between the highest point of the distobuccal cusps of the first permanent molar and the extreme mesio-incisal point of the mesial incisor in the same quadrant of the lower dentition; L7, the distance between the highest points of the distobuccal cusps of the first mandibular permanent molars.

Statistical methods

The normality of the sample was assessed before the analyses and, as there were only minor deviations, the use of parametric tests was preferred. If the measurement was taken from both the right and the left side of the dental cast, the statistical comparison of the HG and control groups was carried out using the repeated measures ANOVA model. If just one dimension on each dental cast was measured, the independent samples *t*-test procedure was used. The independent samples *t*-test procedure was also used for statistical analysis of the cephalometric data. The calculations were made with SAS (SAS Institute Inc., Cary, North Carolina, USA. Software release 8.2) procedures PROC MIXED and PROC TTEST.

The PAR scores between the control and HG groups were compared using the Mann–Whitney *U*-test for independent samples. The intra-observer error of the method in dental cast analysis was measured using intraclass correlation (ICC). The systematic error of the method has been analysed previously (Pirttiniemi *et al.,* 1998).

Results

The repeated measurements in dental cast analyses were compared using ICC. The correlation scores ranged from 0.988 to 0.998.

Eighty-three per cent of the 64 children who continued to the second phase of treatment at T1 completed the follow-up at T2 and full records were available. The trial was conducted using the intention-to-treat-principle. Figure 2 shows the flow of the subjects through each stage of the trial.

In 16 per cent of the HG group, extractions were undertaken during the late mixed dentition period. In all patients, the extractions were only in the lower arch. In 34 per cent of the control group, bilateral extraction of the first premolars was carried out. The difference in the upper dental arch was significant ($P < 0.01$). In 70 per cent of the extraction cases in the control group, all four premolars were extracted, and in 30 per cent two premolars symmetrically. In 27 per cent of the HG group, fixed appliance therapy, after the first phase of treatment, was undertaken. In 57 per cent of the control group, fixed appliance treatment was carried out. The difference between the groups was significant ($P < 0.05$).

The mean active treatment time (excluding retention) was 25 months in the HG group and 21 months in the control group. There were, on average, 17 treatment sessions in the HG group and 14 in the control group.

Maxillary dental arch changes

In upper lateral segments (U1 + U4), the space loss was –1.31 mm (SD 0.43 mm) in the HG group and

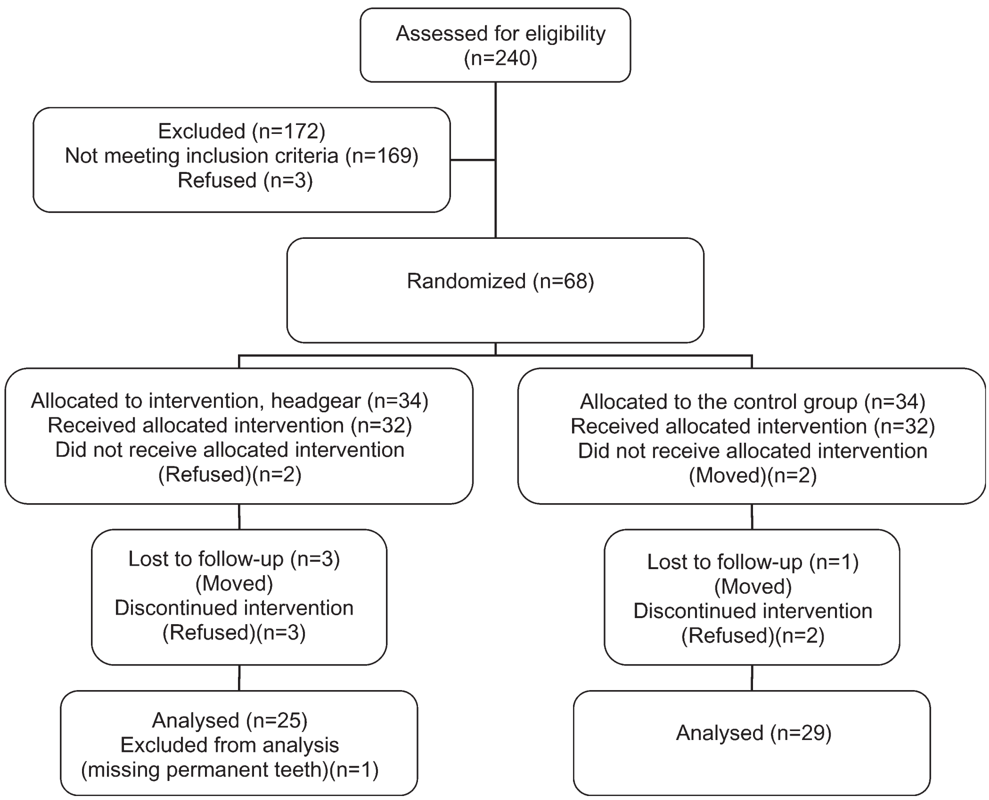

Figure 2 Chart showing the flow of subjects through each stage of the trial.

–2.91 mm (SD 0.61 mm) in the controls at the 8 year follow-up. The difference between the groups was significant (*P* = 0.0473). For total maxillary arch length (U5 + U6), the increase in the HG group was 1.22 mm (SD 0.41 mm) and –1.06 mm (SD 0.44 mm) in the controls (*P* = 0.0006; Table 1).

The change in the distance between the upper molars (U8) in the HG group was 4.08 mm (SD 0.60 mm) and in the controls 1.65 mm (SD 0.48 mm; *P* = 0.0026; Table 1).

Mandibular dental arch changes

In the lower lateral segments (L1 + L2), the space change in the HG group was –2.08 mm (SD 0.39 mm) and –3.66 mm (SD 0.59 mm) in the controls. The difference between the groups was significant (*P* = 0.0091; Table 1).

For total mandibular arch length (L5 + L6), the change in the HG group was –0.61 mm (SD 0.35 mm) and –2.13 mm (SD 0.46 mm) in the controls (*P* = 0.0211). The change in the distance between the lower molars (L7) in the HG group was 3.01 mm (SD 0.50 mm) and in the controls 0.62 mm (SD 0.38 mm; *P* = 0.0004; Table 1).

Effect of extractions

The groups were further divided into subgroups according to extraction of permanent teeth. In the subjects in the HG group without extractions, the space change in the anterior maxillary arch (U2 + U3), total maxillary arch (U5 + U6), and between the canines (U7) and first molars (U8) was significant when compared with those in the control group without extractions at the 8 year examination (Table 2, Figure 3a). For the subjects in the HG group without extractions, space loss in the total mandibular arch length (L5 + L6) and between the lower first molars (L7) was smaller than in the control subjects without extractions at the 8 year examination. When the subgroups with extractions were compared, there was no significant difference between the groups (Table 2, Figure 3b).

PAR score

The mean PAR score in the HG group at the 8 year follow-up was 5.6 (range 1–14) and 5.6 (range 1–12) in the control group. In the extraction cases in the HG and control groups, the mean PAR score was 5.25 (range 3–8) and 6.6 (range 2–12), respectively. The difference between the groups was not significant. The mean overbite in the HG and control groups at the 8 year follow-up was 2.9 mm (SD 1.36 mm) and 2.9 mm (SD 3.6 mm), respectively. The mean overjet in the HG and control groups at the 8 year follow-up was 4 mm (SD 1.23 mm) and 3.6 mm (SD 1.20 mm), respectively. The differences were not significant.

Cephalometric findings

For only one of the five analysed cephalometric parameters was the change during T0–T2 in the HG group significantly different from the controls. The angle between the sella line and the nasal line (SN/NL) was found to be decreased in the HG group (–0.1 degrees; SD 1.98 degrees), but increased in the controls (1.5 degrees; SD 1.61 degrees). The difference was significant (*P* = 0.008; Figure 4).

While SNA angle decreased at the 2 year examination in the HG group by 1.7 degrees (SD 1.39 degrees), the change

Table 1 Dental arch changes (in mm) between 2 (T0–T1) and 8 (T0–T2) year follow-ups in the headgear (HG) and control groups.

	Mean	Standard deviation	Confidence limit for mean: Lower 95%	Confidence limit for mean: Upper 95%	*P*
U1 + U4					
T0–T1 control	–1.01	0.24	–1.50	–0.53	
T0–T1 HG	–0.45	0.29	–1.05	0.15	0.1418
T0–T2 control	–2.91	0.61	–4.16	–1.66	
T0–T2 HG	–1.31	0.43	–2.20	–0.43	0.0473
U2 + U3					
T0–T1 control	1.51	0.19	1.12	1.90	
T0–T1 HG	2.73	0.29	2.14	3.32	0.0008
T0–T2 control	1.91	0.24	1.42	2.40	
T0–T2 HG	2.67	0.34	1.95	3.39	0.0680
U5 + U6					
T0–T1 control	0.50	0.27	–0.05	1.06	
T0–T1 HG	2.48	0.46	1.54	3.42	0.0004
T0–T2 control	–1.06	0.44	–1.97	–0.15	
T0–T2 HG	1.22	0.41	0.36	2.08	0.0006
U7					
T0–T1 control	1.45	0.37	0.69	2.20	
T0–T1 HG	3.34	0.46	2.41	4.28	0.0020
T0–T2 control	2.85	0.34	2.16	3.55	
T0–T2 HG	4.04	0.55	2.88	5.19	0.0628
U8					
T0–T1 control	1.20	0.31	0.56	1.84	
T0–T1 HG	3.92	0.50	2.91	4.94	0.0001
T0–T2 control	1.65	0.48	0.65	2.64	
T0–T2 HG	4.08	0.61	2.82	5.34	0.0026
L1 + L2					
T0–T1 control	0.14	0.17	–0.20	0.48	
T0–T1 HG	–0.06	0.30	–0.67	0.55	0.4392
T0–T2 control	–3.66	0.59	–4.87	–2.46	
T0–T2 HG	–2.08	0.39	–2.89	–1.26	0.0091
L3 + L4					
T0–T1 control	0.03	0.22	–0.43	0.48	
T0–T1 HG	1.24	0.23	0.76	1.72	0.0001
T0–T2 control	0.99	0.26	0.45	1.52	
T0–T2 HG	0.78	0.31	0.13	1.44	0.9747
L5 + L6					
T0–T1 control	0.01	0.21	–0.42	0.44	
T0–T1 HG	1.31	0.31	0.66	1.94	0.0007
T0–T2 control	–2.13	0.46	–3.06	–1.19	
T0–T2 HG	–0.61	0.35	–1.35	0.13	0.0211
L7					
T0–T1 control	0.43	0.25	–0.08	0.94	
T0–T1 HG	2.82	0.43	1.93	3.70	0.0001
T0–T2 control	0.62	0.38	–0.16	1.41	
T0–T2 HG	3.01	0.50	1.96	4.06	0.0004

Table 2 Dental arch changes (in mm) at the 8 year follow-up in the headgear (HG) and control groups in patients with and without extraction of permanent teeth.

	No extractions			Extractions			
	Confidence limit for mean			Confidence limit for mean			
	Mean	Lower 95%	Upper 95%	Mean	Lower 95%	Upper 95%	*P* value
U1 + U4							
T0–T2 control	–1.15	–1.64	–0.66	–7.31	–9.40	–5.22	<0.0001
T0–T2 HG	–0.98	–1.52	–0.44	–2.82	–9.50	3.86	0.0944
Difference *P* value	0.6173			0.0362			
U2 + U3							
T0–T2 control	1.48	0.93	2.03	2.99	2.38	3.60	0.0024
T0–T2 HG	2.74	2.04	3.43	2.38	–1.88	6.63	0.6967
Difference *P* value	0.0046			0.5401			
U5 + U6							
T0–T2 control	–0.10	–0.80	0.60	–3.45	–5.52	–1.39	0.0001
T0–T2 HG	1.53	0.81	2.24	–0.17	–5.52	5.19	0.1142
Difference *P* value	0.0015			0.0766			
U7							
T0–T2 control	2.54	1.70	3.37	3.64	2.28	5.00	0.1411
T0–T2 HG	4.25	3.00	5.50	3.07	–2.03	8.17	0.4263
Difference *P* value	0.0194			0.6834			
U8							
T0–T2 control	2.11	0.98	3.23	0.51	–1.78	2.79	0.1387
T0–T2 HG	4.42	3.22	5.62	2.56	–4.50	9.62	0.2463
Difference *P* value	0.0055			0.3382			
L1 + L2							
T0–T2 control	–2.33	–2.95	–1.71	–6.91	–10.24	–3.58	<0.0001
T0–T2 HG	–2.02	–2.81	–1.22	–2.42	–10.14	5.30	0.7241
Difference *P* value	0.5041			0.1274			
L3 + L4							
T0–T2 control	0.48	0.00	0.96	1.54	0.66	2.42	0.0205
T0–T2 HG	0.73	0.14	1.32	1.06	–2.96	5.07	0.6685
Difference *P* value	0.4903			0.5730			
L5 + L6							
T0–T2 control	–1.48	–2.19	–0.77	–3.70	–6.54	–0.85	0.0247
T0–T2 HG	–0.74	–1.20	–0.28	0.13	–9.87	10.13	0.3909
Difference *P* value	0.0019			0.1530			
L7							
T0–T2 control	0.65	–0.25	1.55	0.56	–1.37	2.50	0.9214
T0–T2 HG	3.06	1.84	4.28	2.75	–1.23	6.73	0.8341
Difference *P* value	0.0016			0.1940			

was reversed at the 8 year examination. The change during T0–T2 in SNA angle was 0.0 degrees (SD 2.96 degrees). The corresponding change at T0–T2 in the controls was –0.6 degrees (SD 1.89). The difference was not significant between the groups ($P = 0.140$; Figure 3).

There was an increase of 2.6 degrees (SD 2.07 degrees) in the HG group in SNB angle between T0 and T2 and the change was significant ($P = 0.005$). There was also an increase of 1.19 degrees (SD 2.07) in SNB angle in the control group during T0–T2 and, thus, the difference between the two groups was not significant ($P = 0.068$; Figure 3).

The decrease in ANB angle in the HG group at the 8 year examination during T0–T2 was 2.7 degrees (SD 1.66; $P < 0.001$) and the corresponding decrease in the control group was 1.9 degrees (SD 1.68; $P = 0.021$). The difference between the groups was not significant ($P = 0.140$; Figure 4).

At the 8 year examination in the HG group, the mean value of the NL/ML angle was 24.8 degrees (SD 4.83), and for the controls 24.7 degrees (SD 4.76; $P = 0.970$).

Discussion

The aim of this study was to determine the long-term effects of early HG treatment on crowding and craniofacial structures. When the results are examined, it is interesting to note how little the two groups differ from each other,

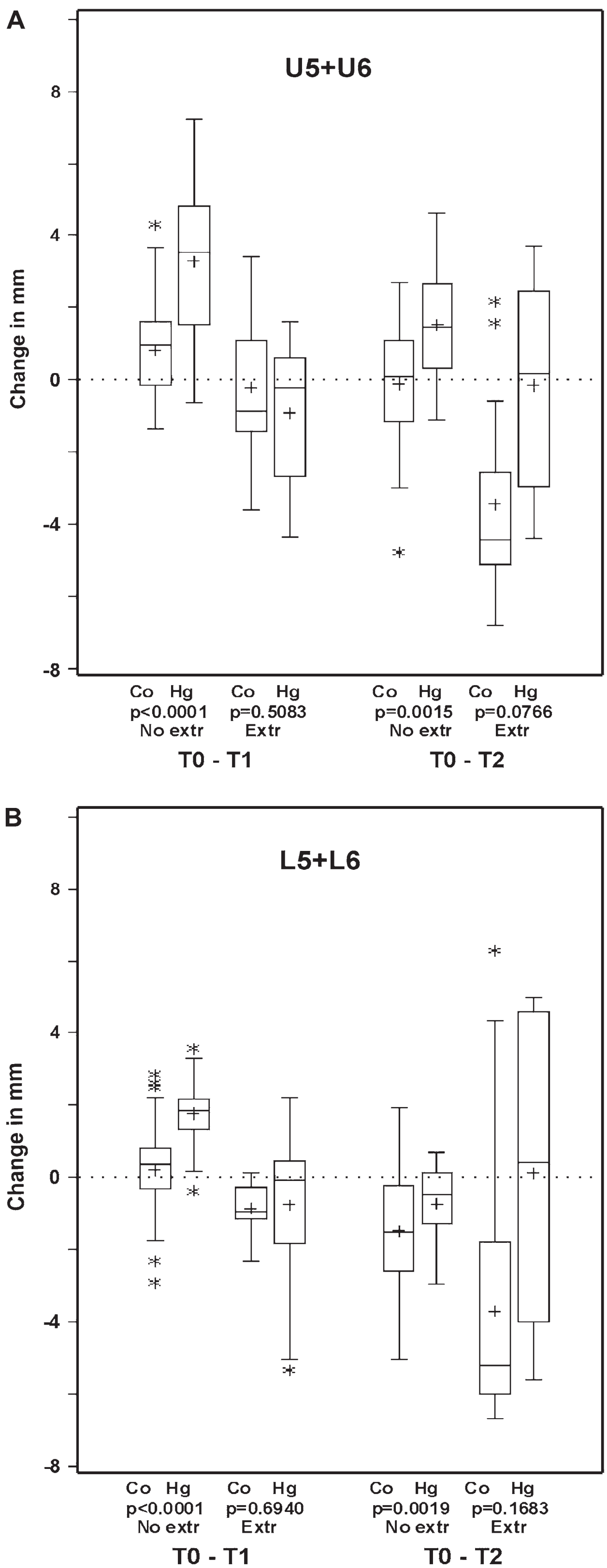

Figure 3 Box plot (medians, 75 per cent percentiles and ranges) showing the change between T0–T1 and T0–T2 in (A) maxillary (U5 + U6) and (B) mandibular (L5 + L6) space in patients with and without extractions of permanent teeth in the headgear (Hg) and control (Co) groups.

when the number of extracted teeth and transversal arch dimensions are not taken into account. The PAR score, which assesses the alignment of the teeth and also the general outcome of the treatment results, was at the same level in both groups at the final follow-up. In addition, the values for overbite and overjet did not significantly differ between the groups. Thus, neither treatment method was superior when it comes to the general outcome of treatment. It is interesting that Proffit and Tulloch (2002) similarly found no significant differences in outcome in early treatment groups and a control group treated with conventional orthodontics started at a later stage of occlusal development.

If the need for fewer extractions and a wider dental arch are considered benefits of early treatment, the deficit is the longer total treatment time in the cases of two-phase treatment. This issue is indeed most commonly raised as the clear disadvantage of two-phase treatment (Tulloch *et al.*, 1998). It is, however, interesting that in the present study, fewer children in the HG group underwent fixed appliance treatment than in the control group. This result is probably due to the fact that in some cases the alignment of teeth and improved occlusion after HG therapy were sufficient and no further treatment was needed. On the other hand, a number of children in the control group were found not to need fixed appliance treatment, in spite of moderate crowding in the early mixed dentition. The evident finding is thus, that if subjects with moderate crowding are treated in the early mixed dentition, a small number are treated without a good indication, as the crowding will, in some cases, correct spontaneously. While functionally a more favourable molar occlusion can be achieved using HG, to gain a good occlusion does not necessarily require early treatment. The key issue would be to develop diagnostic methods so that those children who would benefit most from early expansion of the dental arches could be identified.

The dental arch measurements showed expansion in the upper arch in the HG group after 2 years of treatment with an expanding HG. This expansion was still present in the molar region at the 8 year follow-up, as no decrease in the mean maxillary width change was observed in the HG group. An even more interesting finding is that the expansion found in the lower arch in the HG group at the 2 year follow-up was still present at the 8 year follow-up. Thus, it can be speculated that expansion of the upper arch in the early mixed dentition is capable, probably due to occlusal factors, of making spontaneous expansion of the lower arch possible. The increase in transverse dimensions after use of an expanding HG has been reported previously (Kirjavainen *et al.*, 2000), but this finding in a long-term controlled study has not been reported. Ghafari *et al.* (1994) found an increase in intercanine distance, but not in intermolar distance, after the use of HG. However, in their study they did not use an expanding face bow, which may explain the difference in the results. The sagittal dimensions of the

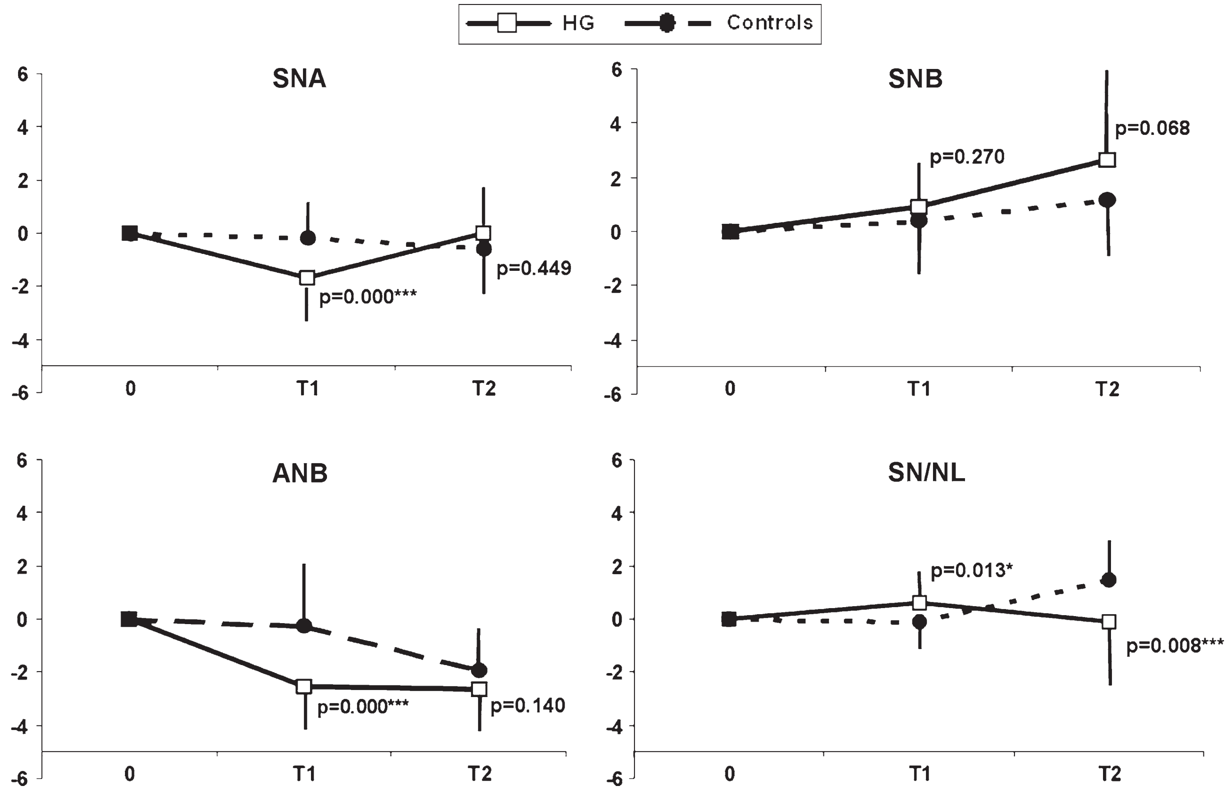

Figure 4 The change in SNA, SNB, ANB and SN/NL angles between T0 and T2 in the headgear (HG) and control groups.

upper and lower dental arches also remained larger in the HG group at the follow-up, and this difference was still present when the HG and control groups were divided into subgroups on the basis of extraction of the permanent teeth. The difference was, however, significant only when the non-extraction cases were compared. One possible factor may be the very low number of extractions in the HG group, which makes the statistical comparison limited.

An obvious consequence of arch expansion is that fewer extractions were necessary in the HG group. In this respect, it is interesting that Baccetti *et al.* (2001) found that early expansion of the maxillary arch resulted in an improved skeletal component, while expansion carried out during the later stages of skeletal maturation only led to dental changes. This fact can be explained by the fusion and ossification of the mid-palatal suture during puberty (Melsen, 1975).

The skeletal changes at the long-term follow-up were relatively small between the studied groups. At the 8 year follow-up, these obvious skeletal changes appeared partly to be reversed. It has been previously reported that after HG treatment for a period of 2 years the position of the maxilla is more posteriorly located, when compared with controls (Mantysaari *et al.*, 2004). At the 8 year follow-up, the position of the maxilla was not posterior in the HG group. There was no significant difference between the HG and control groups for SNA and ANB angles at the 8 year follow-up, although there was a tendency for SNB angle to be larger in the HG group, which could indicate a favourable anterior growth pattern in this group. These results are in agreement with Keeling *et al.* (1998).

The angle between the sella and nasal lines was found to be decreased in the HG group but increased in the controls at the 8 year follow-up. It is noteworthy that the direction of change between T0 and T1 was opposite to that between T1 and T2 in the HG group. This finding might be explained by the restraining effect of the HG and the recovery of maxillary growth after traction. An interesting finding in any case is that no bite opening was seen in the HG group, as the palato-mandibular angle remained at the same level in the HG group and the controls. One factor affecting the palatomandibular angle could be the treatment age: the extraoral force was applied well before the growth spurt and thus possible adverse growth effects remained relatively small.

Conclusion

In this randomized long-term follow-up study, small occlusal differences were found between an early HG group and a control group. The cephalometric values between the groups did not differ significantly. The most significant difference was in the maxillary plane orientation. The most evident difference between the groups was the wider and longer dental arches in the HG group, which could only partly be explained by the higher rate of extractions in the control group. The disadvantage of early HG treatment was the longer mean total treatment time resulting from the two-phase treatment.

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