

AIRWAY AND HARD TISSUE DIMENSIONS IN CHILDREN TREATED WITH EARLY AND LATER TIMED CERVICAL HEADGEAR – A RANDOMIZED CONTROLLED TRIAL

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Short title: TIMING AND HEADGEAR TREATMENT

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SUMMARY

Background: A Kloehn-type cervical headgear (CH) aims to correct skeletal jaw discrepancy in Class II children. A few studies have reported CH treatment effects on airway dimensions, but none of them have been randomized according to timing.

Objectives: To evaluate related craniofacial structures and pharyngeal airway dimensions in children with a Class II occlusion treated with CH and randomized into early and late treatment groups.

Trial design: Randomized, parallel-group, prospective controlled trial.

Methods: The material comprised 67 seven-year-old children with a Class II occlusion. Sealed-envelope randomization in 1:1 ratio was used to divide the children into two equal groups. In the early group ($n = 33$), CH treatment was started immediately or after eruption of the first maxillary molars. In the second, late group ($n = 34$), the active CH treatment was started about one and half year later. The active CH treatment was continued in both groups until normal Class I occlusion on first molars was achieved. Cephalometric radiographs were taken from both groups at the beginning of follow-up (T0), at the beginning of CH treatment of the second group (T1), and at the end of CH treatment of the second group (T2). Changes in cephalometric measurements were used as primary outcomes. Blinding was applicable for outcome assessment.

Results: Fifty-six children completed the study. The posterior change in the position of the maxilla was significant for early treatment males at T0-T1 (SNA; $P < 0.001$, ANB; $P = 0.009$) and T0-T2 (SNA; $P = 0.012$). The palato-mandibular angle (PL-ML) decreased during T0-T1 in early treatment females ($P = 0.018$) and early treatment males ($P = 0.037$). The retroglossal airway increased ($P = 0.010$) in early treatment males at T0-T1. Highly significant positive correlations ($P < 0.001$) between skeletal and upper airway dimensions during early CH treatment were found in males. No harms were encountered.

Conclusions: Despite the effective CH treatment, no harmful upper airway changes were found.

Trial registration: Clinical Trials NCT02010346.

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INTRODUCTION

Reduced lower facial skeletal dimensions and anteroposterior discrepancy are typical features of Class II patients. The influence of these facial characteristics to pharyngeal structures has attracted a high level of interest. Several cephalometric studies in adolescents have shown the association between craniofacial morphologic features and airway dimensions in Class II malocclusion. Class II patients with retrognathic mandible tend to have smaller or diminished upper airway dimensions (1, 2). Three-dimensional studies of the upper airway have also shown the association between decreased airway volume and Class II malocclusion (3-5).

A Kloehn-type cervical headgear (CH) is a widely used extra-oral orthodontic device for children with a Class II occlusion. The most common finding concerning its effects on the nasomaxillary complex is the reduction of SNA value, either as a result of restricting the forward growth of the maxilla (6-11) or by the distal placement of the maxilla (12-14). Regardless of whether the reduction of SNA value is a result of restricting the maxillary growth or the distal placement of the maxilla, recovery of the maxilla by anterior movement has been reported in long-term follow-up studies (6, 10, 13).

There are only few studies concerning the effects of CH on upper airway dimensions, and the reports are controversial. The use of CH has been stated to increase the retropalatal airway space in children, but not to cause any effect on other parts of the upper airway (15). However, no control group was used in the study. On the other hand, the use of CH has been reported to reduce the anteroposterior dimensions at all pharyngeal airway levels (16). Reduced anteroposterior upper airway dimensions during sleep have also been found in adults wearing CH (17).

There has been wide discussion concerning the effectiveness and proper timing of orthodontic treatment of Class II malocclusion. It has been reported that CH treatment can be more favourable in the early mixed dentition (18). Later studies have suggested that functional orthodontic treatment is more efficient in the permanent dentition or during the pubertal growth spurt (19, 20). Early treatment has been shown to have a favourable effect on Class II skeletal problems (21, 22) but to prolong total treatment time (23). The effectiveness of CH therapy has been indicated in corrections of Class II malocclusion during early treatment (24). There are no previous studies concerning the effect of CH treatment timing on airway dimensions.

The purpose of the present study was to evaluate craniofacial structures and pharyngeal airway dimensions in children with a Class II occlusion treated with a Kloehn-type CH when treatment timing was set as a variable. The hypothesis was that the timing of CH treatment would have no effect on pharyngeal airway dimensions.

SUBJECTS AND METHODS

Trial design, ethical issues and registration

The research was designed as a prospective, parallel-group, controlled trial randomized in 1:1 ratio according to the CONSORT guidelines. The study protocol was approved by the Ethics Committee of the Oulu University Hospital, Finland (EETTMK: 46/2003) and by the health service authorities in the municipalities involved in the study. The trial is registered at ClinicalTrials.gov, number NCT02010346.

Participants and randomization

The study sample was selected from birth cohorts in three municipalities in northern Finland. Seven-year-old healthy schoolchildren were screened for the study by the clinicians in the municipality health centres. The eligibility criteria were Class II occlusion and overjet 6 mm or more and deep bite. The exclusion criteria were PL-ML angle (the angle between the palatal line and the mandibular line) over 35° and previous orthodontic treatment. Children with inborn facial syndrome and severe facial asymmetry were not included in study. Also children with symptoms of sleep-disordered breathing, known chronic or recurrent upper airway infections or history of adenoidectomy and/or tonsillectomy were excluded.

All the children fulfilling the eligibility criteria accepted to participate in the research. The children and their parents were informed about the study and they signed an informed consent before entering the study. After screening, 67 children were included in the study, 28 female and 39 male (mean age 7.2 years, standard deviation (SD) 0.55). The children were randomly divided into two groups. Numbered, sealed, opaque envelopes were used to randomize the children in 1:1 ratio into either the early or the late treatment groups. One investigator (J.J.) had the responsibility of preparing the envelopes. Every child eligible for the study was allowed to pick and open one of the envelopes. The note was handed to the clinician to inform which treatment was to be carried out for the child.

Interventions

In the first group ($n = 33$; 13 female and 20 male), CH therapy was started immediately or after eruption of the first maxillary molars (mean age 7.8 years, SD 0.53). The active CH therapy was continued until normal Class I occlusion on first molars was achieved. When necessary, reduced use of CH was applied following the active treatment.

In the second group ($n = 34$; 15 female and 19 male), no active treatment was performed during the active treatment of the first group T0-T1. In the second group, the active CH therapy started about one and half years later (mean age 9.5 years, SD 0.59), and analogously, lasted until normal Class I occlusion on first molars was achieved. The treatment protocol was identical to the first group.

For the use of CH, maxillary first molars were banded with gingival HG tubes. A Kloehn-type CH with a long outer bow was used. The long outer bows were bent 10° upwards and the inner bow was held 5 mm wider than the distance between the CH tubes. A force of 500 g was used to provide orthodontic force to the maxilla and upper dental arch. The patients were instructed to wear the CH for 8 to 10 hours during the night.

Outcomes

Three lateral cephalograms were taken of each patient regardless of the group they belonged to. The lateral cephalometric radiographs were taken at the beginning of treatment of the first group (T0, mean age 7.3 years, SD 0.53), at the time of the beginning of treatment of the second group (T1, mean age 9.6 years, SD 0.51), and at the time of the end of treatment of the second group (T2, mean age 11.5 years, SD 0.57).

Cephalograms were taken in a standard cephalostat in standing position, the head fixed in the cephalostat with bilateral ear rods and nasal positioner in natural head position. The teeth were bitten in maximal intercuspal position and the lips were in a relaxed position.

Since the children were treated in three different municipalities and the radiographs were taken in different health centres, all the lateral cephalograms taken were calibrated before landmark definition to correct the magnification. There was a radiopaque millimetre ruler in the cephalograms for verifying the calibration. WinCeph 8.0 (Rise Corporation, Japan) was used for digitizing landmarks and for calculating linear measurements and angles. Landmarks were digitized by one of the authors (K.P-P.).

The cephalometric landmarks, linear and angular measurements are presented in Figure 1. For the methodological error, twenty lateral cephalograms selected at random were traced and measured twice with an interval of two weeks to assess measurement repeatability.

Blinding

Blinding of patients and their parents or orthodontic treatment providers was not possible. Before the study, a code was given (J.J.) to all patient material to be collected so that the patients and the groups could not be identified by the data collectors, outcome adjudicators (K.P-P.) and data analysts when the documents were evaluated.

Sample size calculation

The sample size calculation was based on previous research with a similar study protocol (9). GPower 3.1 software was used to calculate the adequate sample size in each group with independent samples *t*-test, a power of 80% and a significance level of 0.05. To determine the effect size, the means and standard deviations of ANB angle at the end of study were used. According to the sample size calculation, eleven subjects in each group would be appropriate to obtain sufficient power.

Current study is a longitudinal follow-up study where the children are followed from age 7 to age 18. This article follows years 7 to 11.5. Since long follow-up studies are prone to patient migration, refusal and disappearance, to secure the success and completion of the study the sample sizes and intake were increased.

Statistical methods

Intra-rater reliability was measured by intraclass correlation coefficients (ICC) for linear and angular measurements to compare the repeated measurements in cephalometric analyses.

The cephalometric values were compared between the early treatment group and the late treatment group. Gender was included in the study. The differences between time points were calculated and means of differences were compared between treatment groups with independent samples *t*-test. For differences that were not normally distributed, the Mann-Whitney *U*-test was used. Pearson correlation coefficients were calculated between skeletal measurements and airway measurements.

A Benjamini-Hochberg procedure was used to correct for multiple comparisons across all independent samples *t*-tests (25). The statistical package IBM SPSS Statistics, version 20, was used for the statistical analyses.

RESULTS

Participant flow

The flow of the subjects through the study is shown in Figure 2. Total of 270 subjects were screened for eligibility. 203 children were excluded for not meeting the inclusion criteria. Sixty-seven children were randomized in a 1:1 ratio to either early or late treatment groups. The primary analysis (T0) was intended for all randomly assigned patients. During the first follow-up, one child in the early group moved out of the region before receiving CH treatment and one child moved out during the CH treatment. One patient refused to continue the study before receiving CH treatment. Two patients from the late group moved out of the region during the first follow-up. For the analysis at T1, sixty-two children were analysed. During the second follow-up, four children from the early group moved out of the region, and two patients from the late group refused to take part in the study before receiving CH treatment. At T2, fifty-six children were analysed. In EG group 19 patients out of 30 were having reduced used of CH at T1 and consequently in LG group 10 patients out of 32 were having reduced used of CH at T2. The mean time for reduced use of CH for EG was 11 months and for LG was 14 months.

The characteristics of the patients including age and gender distributions in early and late treatment groups are shown in Table 1. Table 2 shows the cephalometric values in both groups at the beginning of the study. There were two significant differences out of 19 parameters at T0. The airway size at the levels r11-r12 and va1-va2 were significantly smaller at early group compared to late group ($P = 0.013$, $P = 0.041$).

Patient recruitment in three municipalities in northern Finland commenced in February 2004 and ended in June 2008. No harms were encountered during the follow-up of the two groups. The follow-up study of the patients is still in progress.

Outcomes

ICC value varied from 0.636 to 0.987 for angular measurements and from 0.914 to 0.993 for linear measurements, indicating a satisfactory level of intra-investigator reliability. The lowest ICC value was found in PL-ML measurement and the highest value was in SNA measurement for angular

measurements. For linear measurements the lowest value was in PNS-S and the highest value in H-ML measurement.

Cephalometric measurements between early and late treatment groups

The skeletal cephalometric comparison of the early and late treatment groups is shown in Table 3. A more posterior movement of the maxilla expressed as a significant decrease in SNA angle was found in the early group males when compared with the late group males at T0-T1 ($P < 0.001$) (significant also after Benjamini-Hochberg correction) and T0-T2 ($P = 0.012$). The same effect was found when genders were pooled. SNA angle was significantly decreased in the early group when compared with the late group at T0-T1 ($P < 0.001$) (significant also after Benjamini-Hochberg correction) and T0-T2 ($P = 0.002$). Change in SNB angle was significantly larger for the late group compared with the early group at T0-T2 ($P = 0.039$) when genders were pooled. The change in ANB angle was significantly larger for the early group males compared with the late group males at T0-T1 ($P = 0.009$) and this was also seen for the early group compared with the late group at T0-T1 ($P = 0.004$) when genders were pooled together. The palato-mandibular angle (PL-ML) decreased significantly at T0-T1 in the early group females compared with the late group females ($P = 0.018$) and correspondingly, in the early group males compared with the late group males ($P = 0.037$). Similar effect was found when genders were pooled for the early group compared with the late group ($P = 0.002$) at T0-T1. Angle between Sella-Nasion line and palatal plane (NSL-PL) was significantly larger for the early group compared with the late group at T0-T1 ($P = 0.016$) when genders were pooled.

Changes in the pharyngeal airway measurements in the early and late treatment groups are shown in Table 4. The anteroposterior airway diameter at the level of the base of the tongue (r11-r12) was significantly increased in males in the early group between time points T0-T1 compared with the late group males ($P = 0.010$). The same effect was found when genders were pooled. The r11-r12 value was significantly increased in the early group compared with the late group at T0-T1 ($P = 0.034$). The distance from vallecula epiglottis to posterior pharyngeal wall (va1-va2) was significantly increased in the early group compared with the late group at T0-T1 ($P = 0.030$).

Correlations between skeletal and airway measurement changes

Table 5 shows correlations between skeletal and upper airway measurements in the early treatment group during early CH treatment (T0-T1). All skeletal measurements with a highly significant correlation ($P < 0.001$) with upper airway soft tissue measurements were positive and seen in male

patients. Nasopharyngeal variables (PNS-ad1, PNS-ad2) and the oropharyngeal retropalatal variable (PNS-u1) correlated highly significantly with skeletal variables, indicating sagittal position of maxillary posterior point (PNS) to posterior cranial base (PNS-S, PNS-U1, PNS-Ba). Correlation coefficient parameters (r) ranged from 0.811 to 0.887. The same correlation was seen when genders were pooled. Nasopharyngeal variables (PNS-ad1, PNS-ad2) and oropharyngeal retropalatal variables (PNS-u1, u1-u2) correlated highly significantly with skeletal variables (PNS-S, PNS-U1, PNS-Ba). Correlation coefficient parameters (r) ranged from 0.633 to 0.807.

Table 6 shows correlations between skeletal and upper airway measurements in the late treatment group during CH treatment (T1-T2). There were only few highly significant positive correlations ($P < 0.001$). The MPT measurement, indicating the maximal thickness of the soft palate, correlated positively with SNB value in females ($r = 0.890$). When genders were pooled, nasopharyngeal variables PNS-ad1 and PNS-ad2 showed highly significant correlations with skeletal variables PNS-S and PNS-Ba. Correlation coefficient parameter (r) ranged from 0.705 to 0.782.

DISCUSSION

Interpretation

The results of the present study showed differences in treatment effects between early and late CH therapy in children. In males, early CH treatment proved to be more effective in placing the maxilla distally compared to later treatment. After treatment of both groups, the sagittal position of the maxilla was significantly more posterior in early treatment group males compared to late treatment group males. Our results showing the distal placement of the maxilla and improvement in the maxillomandibular relation are in accordance with the findings of previous studies (6, 11-14).

The palato-mandibular angle (PL-ML) decreased significantly after early CH treatment in both females and males. This is probably explained by rotation of the maxilla during CH therapy. A similar change in palatal plane orientation has been reported before, suggesting that the maxillary plane rotates anteriorly downward during the CH treatment (8, 10).

We found that upper airway measurements were not significantly affected by CH treatment. However, in early treatment males, the retroglossal airway (r11-r12) was significantly increased by early CH treatment. Otherwise, upper airway measurements were not significantly affected in any group. It has previously been suggested that wearing CH increases tongue pressure on the lingual surface of lower incisors and therefore results in patency of the lower airway (26). This would

explain the increase in the airway at the base of the tongue. Vertical position of the tongue expressed as H-ML measurement was not affected by the treatment. The repeatable evaluation of tongue posture, however, is vulnerable to several sources of error such as the state of relaxation at the point of x-ray exposure.

There are no previous randomized studies evaluating upper airway changes during CH treatment. There are previous conflicting reports on the effects of CH therapy on pharyngeal dimensions (15, 16). However, a proper control group is lacking in these studies. Thus the effect of normal upper airway growth or regression of the lymphoid tissue could not have been taken into account in previous studies. In the present study, the later treated group served as a control group for the early treated group. Growth-related changes were excluded by examining both groups at the same age.

The optimal timing of CH treatment has been extensively discussed in the literature (19-22). The treatment response is influenced by several factors, such as skeletal maturity, growth velocity, biologic response and co-operation. It is generally known that favourable skeletal changes are achieved when children are treated before or during the pubertal growth spurt. The greatest amount of favourable growth is gained during the growth peak (19). CH treatment philosophy, however, is based on restriction of maxillary growth anteriorly. On the basis of our results, the most effective restriction is achieved in early treated males, in other words, before they reach the growth velocity period. In previous CH studies, gender has not been taken into account. Females reach their increased growth velocity a couple of years earlier than males (27). The approaching growth spurt may diminish the restrictive growth effect of CH, which is highly dependent on the sutural growth of the maxilla. Thus, we suggest that the maxillary sutural effect caused by CH is the most effective well before reaching the growth spurt.

An increased awareness of the deleterious effects of childhood obstructive sleep-disordered breathing (SDB) has raised our interest in pharyngeal airway structures. Class II malocclusion is associated with decreased pharyngeal airway dimensions (2, 3). On the other hand, mandibular retrognathia and smaller upper airway size are common findings in children with SDB (28-30). Orthodontic treatment by skeletal growth modification may have a favourable effect on pharyngeal airway size. This has been indicated with activator (31), face mask (32), and rapid palatal expansion (33) therapies. Since CH restricts the forward growth of the maxilla, its possible effect on the posterior airway needs to be clarified. According to our results, no harmful effects were found in either study group. Although CH treatment effectively restricted maxillary growth especially in

early treated males, the found decrease in airway dimensions after CH therapy was not significant. When correlations between skeletal and soft tissue variables were analysed, a strong positive correlation was observed between the skeletal position of maxilla and the upper airway dimensions in the early treatment group. This clearly shows how closely soft tissues follow changes in skeletal structures during functional therapy. This is an important finding, since CH therapy in children with SDB may contribute to apnoea symptoms (34). We have to emphasize that current results can be applied to healthy children with no symptoms of upper airway problems.

Limitations

For ethical reasons, it was not possible to use untreated controls, and the two treatment groups acted as controls for each other. As the timing of the treatment method was one of the outcomes, this protocol fulfilled the aim of this study. The normal growth in the late group during early group treatment was also an outcome.

In spite of the found differences in two out of 19 parameters at T0, these differences are not likely to affect the end results, since only the changes, not the absolute values, between time points were analysed.

Each patient was instructed to wear the CH for the requested time. The use of CH was not recorded. The outcome was based on measured results. The study sample was relatively small for a clinical study, but according to sample size calculation it was sufficient.

For ethical reasons CH treatment had to be continued in both EG and LG groups in part of the patients to maintain the good occlusion. Therefore some overlapping of CH treatment at time points T1 and T2 was inevitable.

Lateral radiograph has several limitations when evaluating three-dimensional airway dimensions. Despite its inability to provide volumetric data, it has been previously demonstrated that cephalometric analysis is a reliable screening tool when evaluating airway structures (35). Cone beam computed tomography (CBCT) gives a three-dimensional view of the airways, but unfortunately it was not ethical to use CBCT imaging to examine growing children under normal orthodontic treatment without breathing problems in a longitudinal sense due to unnecessary radiation.

Generalization

These screened and treated children meeting the inclusion criteria and the treatment results of the present study can be generalized to children aged from 7 to 11.5 years old. Several clinicians in three municipalities were involved in the clinical treatment of the patients, but they all worked according to a standardized study protocol which reflects a common CH treatment protocol used for children with Class II malocclusion. The outcome from several operators makes the study results more generalizable than if the patients had only come from one dental clinic or been treated by one or two clinicians.

CONCLUSION

Cervical headgear proved to be an effective orthodontic device in correcting Class II malocclusion and skeletal discrepancy. The most significant skeletal effect with CH was obtained in the early treatment group in males. Neither early CH nor late CH had any adverse effects on upper airway dimensions.

PROTOCOL

The protocol was not published prior to trial commencement.

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CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest regarding this study.

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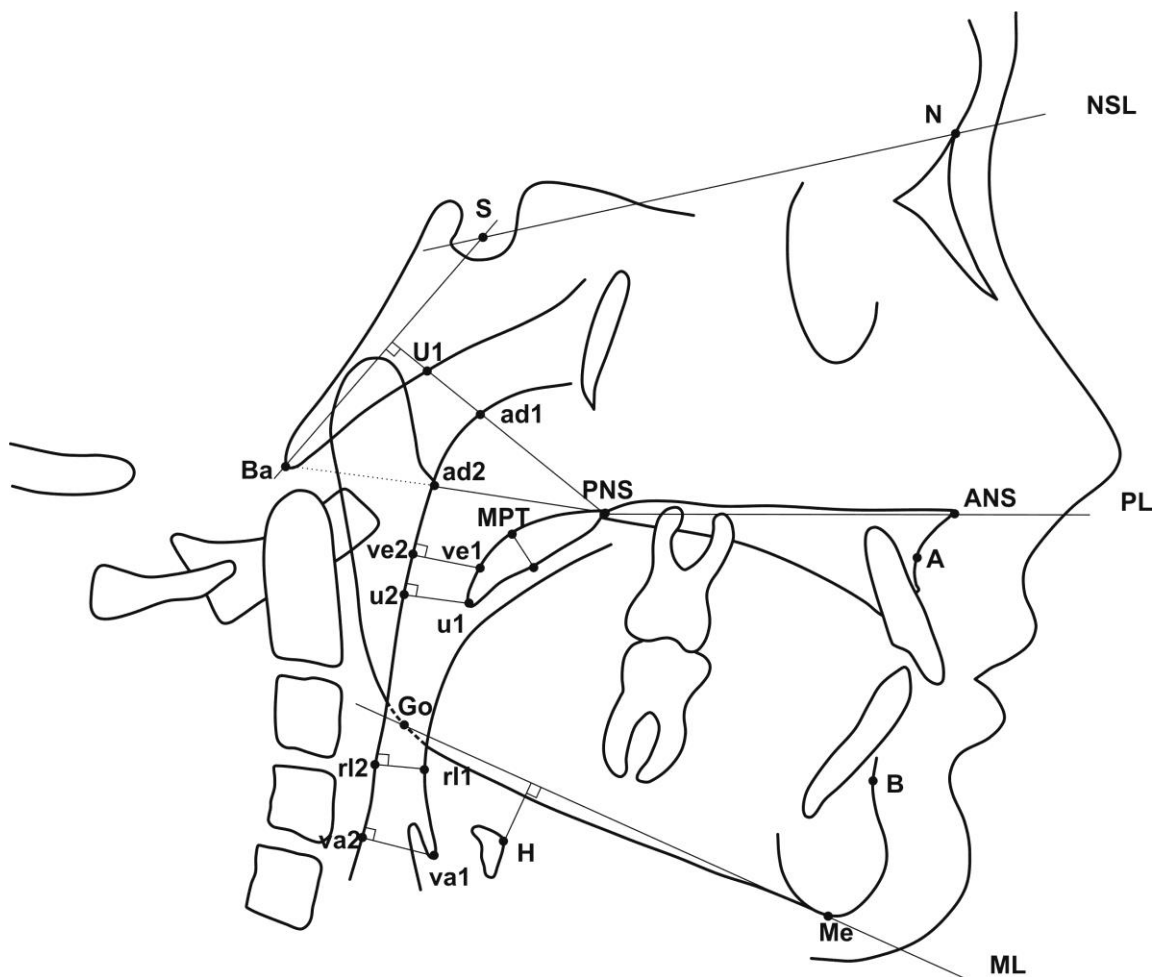


Figure 1 Cephalometric landmarks, planes and measurements used in the cephalometric analysis.

Skeletal landmarks—N: nasion, the most anterior point on the frontonasal suture. S: sella, the centre of the sella turcica. Ba: basion, the lowest point on the anterior rim of the foramen magnum. ANS: anterior nasal spine, the anterior point of the bony nasal floor. PNS: posterior nasal spine, the posterior point of the bony hard palate. A: subspinale, the deepest point on the outer contour of the maxillary alveolar process. B: subramentale, the deepest point on the outer contour of the mandibular alveolar process. Me: menton, the inferior point on the outline of the symphysis. Go: gonion, a point at the gonial angle located by bisecting the posterior and inferior borderlines of the mandible. H: hyoid bone, the most anterior and superior point on the body of the hyoid bone.

Reference lines—NSL: nasion-sella line, the line through N and S. PL: palatal line, the line through ANS and PNS. ML: mandibular line, the line through Me and Go. Craniofacial measurements—

SNA: the angle between the lines N-S and N-A. SNB: the angle between the lines N-S and N-B.

ANB: the angle between the lines N-A and N-B. PL-ML: the angle between the palatal line and mandibular line. NSL-PL: the angle between the nasion-sella line and palatal line. NSL-ML: the angle between the nasion-sella line and mandibular line. ANS-PNS: palatal length, the distance between ANS and PNS. PNS-S: the distance between PNS and S. PNS-U1: the distance between PNS and U1 (the point on the contour of the external cranial base on the perpendicular line from PNS to sella-basion line). PNS-Ba: the distance between PNS and Ba. H-ML: the distance from H perpendicularly to the mandibular line. Pharyngeal measurements—PNS-ad1: the distance from PNS to ad1 (adenoid tissue point on the perpendicular line from PNS to sella-basion line). PNS-ad2: the distance from PNS to ad2 (adenoid tissue point on the line from PNS to basion). MPT: the maximal thickness of the soft palate. PNS-u1: the distance between PNS and the tip of the soft palate (uvula). ve1-ve2: the minimal distance from the soft palate (velum palatine) perpendicularly to the posterior pharyngeal wall. u1-u2: the distance from the tip of the soft palate (uvula) perpendicularly to the posterior pharyngeal wall. r11-r12: the minimal distance from the base of the tongue (radix linguae) perpendicularly to the pharyngeal wall. va1-va2: the distance from the vallecula epiglottis perpendicularly to the posterior pharyngeal wall.

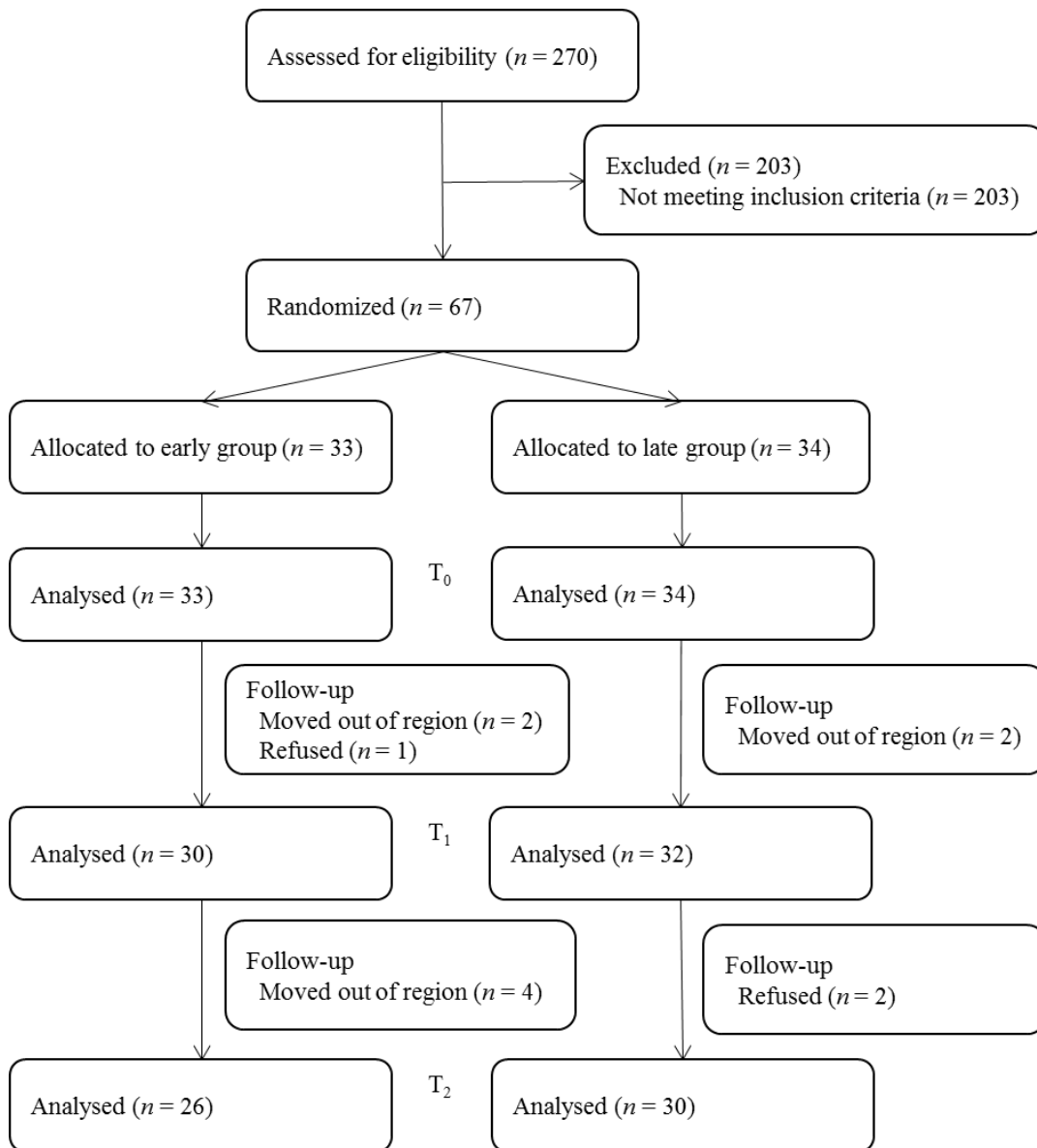


Figure 2 The flow of the subjects through each stage of the study.

Table 1 Background information of gender distribution and mean age and standard deviation (SD) at the beginning of the follow-up and at the initiation of headgear (HG) treatment in early group (EG) and late group (LG) subjects.

	Total			Female			Male		
	<i>n</i>	Beginning of the follow-up, mean age (SD)	Initiation of HG treatment, mean age (SD)	<i>n</i>	Beginning of the follow-up, mean age (SD)	Initiation of HG treatment, mean age (SD)	<i>n</i>	Beginning of the follow-up, mean age (SD)	Initiation of HG treatment, mean age (SD)
EG	33	7.2 (0.54)	7.8 (0.53)	13	7.3 (0.35)	7.9 (0.58)	20	7.1 (0.62)	7.7 (0.48)
LG	34	7.2 (0.56)	9.5 (0.59)	15	7.1 (0.48)	9.4 (0.53)	19	7.2 (0.63)	9.6 (0.63)

Table 2 Cephalometric values in the groups at T0.

Measurement	EG			LG			<i>P</i>		
	Mean	SD	95% CI for mean	Mean	SD	95% CI for mean			
Skeletal									
SNA (°)	82.3	3.30	81.1	83.5	82.2	2.34	81.3	83.0	0.855
SNB (°)	77.1	3.17	76.0	78.3	76.8	1.99	76.1	77.5	0.642
ANB (°)	5.2	1.92	4.5	5.9	5.4	1.83	4.7	6.0	0.720
PL-ML (°)	28.4	4.47	26.8	30.0	27.6	5.13	25.9	29.4	0.516
NSL-PL (°)	4.8	2.40	3.9	5.7	6.0	3.68	4.7	7.3	0.128
NSL-ML (°)	33.2	4.72	31.5	34.9	33.6	4.64	31.9	35.3	0.722
ANS-PNS (mm)	44.9	3.19	43.7	46.0	44.6	2.93	43.5	45.6	0.687
PNS-S (mm)	41.6	2.10	40.9	42.4	42.1	3.50	40.8	43.3	0.562
PNS-U1 (mm)	27.0	2.77	26.0	28.0	26.9	2.72	26.0	27.9	0.885
PNS-Ba (mm)	41.4	2.62	40.5	42.4	41.7	4.15	40.3	43.2	0.716
H-ML (mm)	10.3	3.12	9.1	11.6	10.3	4.26	8.7	11.9	0.987
Airway									
PNS-ad1 (mm)	16.0	2.94	14.9	17.0	14.6	4.24	13.1	16.1	0.123
PNS-ad2 (mm)	20.7	3.65	19.4	22.0	18.9	5.82	16.8	20.9	0.121
MPT (mm)	6.9	1.23	6.4	7.3	6.9	1.00	6.6	7.3	0.903
PNS-u1 (mm)	25.5	3.01	24.4	26.5	26.0	3.12	24.9	27.1	0.501
ve1-ve2 (mm)	7.7	1.57	7.1	8.2	6.9	2.45	6.0	7.8	0.125
u1-u2 (mm)	8.9	1.55	8.4	9.5	8.6	2.51	7.8	9.5	0.582
rl1-rl2 (mm)	8.0	2.52	7.1	8.9	9.7	3.08	8.7	10.8	0.013*
va1-va2 (mm)	7.4	2.59	6.5	8.4	8.9	3.08	7.8	10.0	0.041*

**P* < 0.05

Table 3 Mean values, standard deviations (SD), 95% confidence intervals (CI) for mean values and significances of the difference for skeletal measurements between the time points (T0-T1, T0-T2) for the early group (EG) and the late group (LG).

			Female				Male				Total			
			Mean	SD	95% CI for mean		Mean	SD	95% CI for mean		Mean	SD	95% CI for mean	
SNA	EG	T0-T1	-0.7	2.08	-2.0	0.6	-1.7	1.18	-2.3	-1.1	-1.3	1.66	-1.9	-0.6
		LG	0.2	1.01	-0.4	0.8	0.1	0.98	-0.5	0.6	0.1	0.98	-0.3	0.5
	<i>P</i>	0.183				<0.001***#				<0.001***#				
	EG	T0-T2	-1.3	1.46	-2.3	-0.2	-1.3	1.57	-2.2	-0.4	-1.3	1.50	-1.9	-0.7
		LG	0.1	1.60	-0.9	1.1	0.2	1.53	-0.7	1.1	0.1	1.53	-0.5	0.7
	<i>P</i>	0.057†				0.012†*				0.002**				
SNB	EG	T0-T1	0.6	0.96	-0.1	1.2	0.5	0.97	0.0	1.0	0.5	0.95	0.2	0.9
		LG	0.6	1.15	-0.2	1.3	0.9	1.37	0.1	1.6	0.7	1.26	0.2	1.2
	<i>P</i>	0.970				0.453				0.529				
	EG	T0-T2	1.0	0.93	0.3	1.6	0.2	1.12	-0.5	0.8	0.5	1.10	0.0	1.0
		LG	1.6	1.70	0.5	2.6	1.2	1.58	0.2	2.1	1.3	1.62	0.7	2.0
	<i>P</i>	0.354				0.065				0.039*				
ANB	EG	T0-T1	-1.3	2.06	-2.6	0.0	-2.2	1.27	-2.9	-1.5	-1.8	1.69	-2.5	-1.2
		LG	-0.4	0.61	-0.7	0.0	-0.8	1.62	-1.6	0.1	-0.6	1.28	-1.1	-0.1
	<i>P</i>	0.161				0.009**				0.004**				
	EG	T0-T2	-2.0	1.37	-3.0	-1.1	-1.5	1.71	-2.5	-0.5	-1.7	1.57	-2.4	-1.1
		LG	-1.5	0.68	-1.9	-1.1	-1.0	1.93	-2.1	0.2	-1.2	1.49	-1.8	-0.6
	<i>P</i>	0.228				0.445				0.235				
PL-ML	EG	T0-T1	-1.9	2.38	-3.4	-0.4	-1.6	2.30	-2.8	-0.4	-1.7	2.30	-2.6	-0.9
		LG	1.0	3.18	-1.0	3.0	0.3	3.00	-1.1	1.8	0.59	3.04	-0.5	1.7
	<i>P</i>	0.018†*				0.037†*				0.002**				
	EG	T0-T2	-2.2	1.92	-3.4	-0.8	-2.0	2.76	-3.6	-0.4	-2.1	2.40	-3.1	-1.1
		LG	-1.7	2.61	-3.4	-0.0	-0.9	4.17	-3.1	1.3	-1.2	3.55	-2.6	0.1
	<i>P</i>	0.593†				0.492†				0.338				
NSL-PL	EG	T0-T1	1.4	2.03	0.1	2.7	1.0	1.84	0.0	2.0	1.2	1.90	0.4	1.9
		LG	-0.6	2.75	-2.4	1.1	-0.9	4.40	-3.3	1.4	-0.8	3.72	-2.2	0.7
	<i>P</i>	0.075†				0.199†				0.016*				
	EG	T0-T2	0.9	1.74	-0.4	2.1	1.0	1.72	0.0	2.0	1.0	1.69	0.2	1.7
		LG	0.5	2.90	-1.4	2.3	-0.1	4.86	-2.9	2.7	0.2	4.01	-1.5	1.8
	<i>P</i>	0.734†				0.973†				0.371				
NSL-ML	EG	T0-T1	-0.5	1.78	-1.6	0.6	-0.7	2.69	-2.1	0.7	-0.6	2.31	-1.5	0.3
		LG	0.4	3.70	-1.9	2.6	-0.5	1.75	-1.4	0.4	-0.1	2.73	-1.2	1.0
	<i>P</i>	0.504†				0.977†				0.459				
	EG	T0-T2	-1.2	2.23	-2.7	0.4	-0.9	3.31	-2.9	1.0	-1.0	2.86	-2.2	0.2
		LG	-1.2	3.90	-3.7	1.2	-0.8	2.59	-2.3	0.7	-1.0	3.20	-2.3	0.3
	<i>P</i>	0.953				0.900				0.973				
ANS-PNS	EG	T0-T1	1.5	1.62	0.5	2.6	2.5	4.77	-0.1	5.0	2.1	3.73	0.6	3.5
		LG	1.7	2.20	0.3	3.0	2.4	1.86	1.5	3.4	2.1	2.00	1.4	2.9
	<i>P</i>	0.892				0.966				0.961				
	EG	T0-T2	1.6	2.89	-0.4	3.7	4.6	4.31	2.1	7.1	3.4	4.00	1.7	5.1
		LG	3.8	3.67	1.5	6.1	4.2	2.23	3.0	5.4	4.0	2.88	2.9	5.1
	<i>P</i>	0.145				0.720				0.515				

PNS-S	EG	T0-T1	0.9	1.99	-0.3	2.2	2.3	7.70	-1.8	6.4	1.7	5.92	-0.6	4.0
	LG	T0-T1	2.2	3.59	-0.1	4.6	1.7	3.48	-0.0	3.3	1.9	3.47	0.3	3.1
		<i>P</i>	0.451†				0.313†				0.898			
PNS-U1	EG	T0-T2	1.1	3.89	-1.7	3.9	3.9	5.00	1.0	6.8	2.7	4.70	0.7	4.7
	LG	T0-T2	3.5	3.99	1.0	6.0	1.6	3.33	-0.2	3.4	2.4	3.69	1.0	3.8
		<i>P</i>	0.209†				0.976†				0.796			
PNS-U1	EG	T0-T1	-0.0	2.32	-1.5	1.5	1.9	7.76	-2.3	6.0	1.1	6.04	-1.3	3.4
	LG	T0-T1	1.2	4.02	-1.4	3.7	0.8	2.88	-0.6	2.2	0.9	3.30	-0.3	2.1
		<i>P</i>	0.386				0.574				0.917			
PNS-U1	EG	T0-T2	0.5	3.53	-2.1	3.0	2.7	4.31	0.2	5.2	1.8	4.09	-0.1	3.5
	LG	T0-T2	2.4	4.37	-0.4	5.1	1.1	2.90	-0.5	2.6	1.6	3.59	0.2	3.0
		<i>P</i>	0.283				0.228				0.890			
PNS-Ba	EG	T0-T1	-0.6	2.75	-2.3	1.2	-0.5	6.72	-4.1	3.1	-0.5	5.31	-2.6	1.5
	LG	T0-T1	1.4	2.66	-0.3	3.1	0.9	4.86	-1.5	3.2	1.1	4.11	-0.4	2.6
		<i>P</i>	0.101†				0.062†				0.195			
PNS-Ba	EG	T0-T2	-1.1	4.82	-4.5	2.4	1.3	4.86	-1.5	4.1	0.3	4.89	-1.7	2.4
	LG	T0-T2	1.1	4.20	-1.6	3.8	-0.9	3.79	-3.0	1.1	0.1	4.03	-1.6	1.5
		<i>P</i>	0.154†				0.910†				0.754			
H-ML	EG	T0-T1	1.0	4.38	-2.1	4.1	-0.2	2.76	-2.1	1.6	0.4	3.58	-1.3	2.0
	LG	T0-T1	-2.8	6.35	-8.1	2.5	1.0	7.24	-3.1	5.0	-0.4	7.05	-3.4	2.7
		<i>P</i>	0.150				0.612				0.679			
H-ML	EG	T0-T2	2.9	7.24	-3.2	9.0	1.0	3.41	-1.5	3.4	1.8	5.36	-0.8	4.5
	LG	T0-T2	0.6	6.61	-4.1	5.3	0.9	3.69	-1.2	3.0	0.8	4.98	2.9	0.8
		<i>P</i>	0.492				0.954				0.512			

†Mann-Whitney, * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$, #significant after Benjamini-Hochberg correction

Table 4 Mean values, standard deviations (SD), 95% confidence intervals (CI) for mean values and significances of the difference for airway measurements between the time points (T0-T1, T0-T2) for the early group (EG) and the late group (LG).

			Female				Male				Total				
			Mean	SD	95% CI for mean		Mean	SD	95% CI for mean		Mean	SD	95% CI for mean		
PNS-ad1	EG	T0-T1	1.0	3.33	-1.1	3.1	0.7	4.12	-1.5	2.9	0.8	3.74	-0.6	2.3	
		LG	0.7	2.89	-1.2	2.5	1.5	3.26	-0.0	3.1	1.2	3.10	0.1	2.3	
				<i>P</i>	0.771				0.489				0.676		
	EG	T0-T2	1.9	3.68	-0.8	4.5	2.5	3.50	0.5	4.5	2.2	3.51	0.8	3.7	
		LG	2.8	5.44	-0.6	6.3	1.2	4.03	-1.0	3.3	1.9	4.67	0.1	3.8	
				<i>P</i>	0.639				0.344				0.759		
PNS-ad2	EG	T0-T1	0.6	4.52	-2.3	3.4	0.5	6.54	-3.0	4.0	0.5	5.66	-1.7	2.7	
		LG	2.2	3.83	-0.3	4.6	1.6	4.37	-0.5	3.7	1.8	4.12	0.3	3.3	
				<i>P</i>	0.401†				0.072†				0.305		
	EG	T0-T2	-0.4	5.98	-4.6	3.9	0.6	4.48	-2.0	3.2	0.2	5.06	-1.9	2.3	
		LG	4.4	6.69	0.1	8.6	-0.0	4.58	-2.5	2.4	1.9	5.89	-0.4	4.1	
				<i>P</i>	0.101				0.715				0.287		
MPT	EG	T0-T1	-0.8	0.92	-1.3	0.2	0.9	1.22	0.3	1.6	0.2	1.39	-0.3	0.8	
		LG	-0.0	1.67	-1.1	1.1	0.4	1.05	-0.1	0.9	0.2	1.31	-0.3	0.7	
				<i>P</i>	0.181				0.143				0.980		
	EG	T0-T2	-0.7	1.34	-1.6	0.3	1.1	1.79	0.1	2.2	0.4	1.83	-0.4	1.2	
		LG	0.3	1.38	-0.6	1.1	0.5	1.12	-0.1	1.1	0.4	1.22	-0.1	0.8	
				<i>P</i>	0.135				0.219				0.969		
PNS-u1	EG	T0-T1	0.7	3.16	-1.3	2.7	1.7	5.91	-1.5	4.8	1.3	4.88	-0.6	3.1	
		LG	1.5	4.62	-1.4	4.5	0.8	3.43	-0.9	2.4	1.1	3.88	-0.4	2.5	
				<i>P</i>	0.619†				0.701†				0.874		
	EG	T0-T2	0.7	3.45	-1.8	3.1	1.8	4.74	-0.9	4.6	1.3	4.21	-0.4	3.1	
		LG	2.8	4.82	-0.2	5.9	1.0	3.26	-0.8	2.7	1.8	4.03	0.2	3.3	
				<i>P</i>	0.247				0.564				0.710		
ve1-ve2	EG	T0-T1	1.2	2.33	-0.3	2.7	1.1	3.08	-0.5	2.7	1.1	2.74	0.1	2.2	
		LG	0.1	2.66	-1.5	1.8	0.5	2.74	-0.8	1.8	0.4	2.67	-0.6	1.3	
				<i>P</i>	0.307				0.532				0.263		
	EG	T0-T2	0.8	3.61	-1.8	3.3	0.2	1.40	-0.6	1.0	0.5	2.51	-0.6	1.5	
		LG	0.7	1.88	-0.5	1.9	0.4	2.69	-1.0	1.8	0.5	2.34	-0.4	1.5	
				<i>P</i>	0.978				0.827				0.891		
u1-u2	EG	T0-T1	0.1	2.32	-1.4	1.5	0.3	2.82	-1.1	1.8	0.2	2.59	-0.8	1.2	
		LG	0.1	3.04	-1.9	2.0	-0.0	2.26	-1.1	1.1	0.0	2.54	-0.9	0.9	
				<i>P</i>	0.994				0.658				0.732		
	EG	T0-T2	-0.5	3.26	-2.9	1.8	-0.4	1.91	-1.5	0.7	-0.4	2.49	-1.5	0.6	
		LG	-0.8	1.62	-1.8	0.3	-0.2	2.18	-1.3	1.0	-0.4	1.95	-1.2	0.3	
				<i>P</i>	0.826				0.771				0.971		
rl1-rl2	EG	T0-T1	-0.2	3.25	-2.2	1.9	0.84	3.55	-1.0	2.7	0.4	3.41	-0.9	1.7	
		LG	-0.5	4.25	-3.2	2.2	-2.2	3.03	-3.6	-0.7	-1.5	3.58	-2.8	-0.2	
				<i>P</i>	0.814				0.010*				0.034*		
	EG	T0-T2	-0.9	2.59	-2.7	1.0	-0.7	2.12	-1.9	0.5	-0.8	2.27	-1.7	0.2	
		LG	-1.0	2.71	-2.7	0.8	-1.7	3.47	-3.5	0.2	-1.4	3.13	-2.6	0.1	

va1-va2	EG	T0-T1	0.8	3.07	-1.2	2.7	1.1	3.05	-0.5	2.8	1.0	3.00	-0.2	2.2
	LG	T0-T1	-0.6	3.25	-2.6	1.5	-0.9	2.71	-2.2	0.4	-0.7	2.88	-1.8	0.3
		<i>P</i>	0.933				0.389				0.457			
		<i>P</i>	0.312				0.052				0.030*			
	EG	T0-T2	0.2	2.16	-1.4	1.7	0.1	2.58	-1.5	1.6	0.1	2.35	-0.9	1.1
	LG	T0-T2	-0.6	4.37	-3.4	2.2	-0.5	2.96	-2.1	1.1	-0.6	3.56	-1.9	0.8
		<i>P</i>	0.605				0.581				0.439			

†Mann-Whitney, * $P < 0.05$

Table 5 The correlations (*r*) between skeletal and airway measurements changes after early headgear treatment (T0-T1).

		PNS-ad1	PNS-ad2	MPT	PNS-u1	ve1-ve2	u1-u2	rI1-rI2	va1-va2
SNA	Female	0.519	0.563	-0.019	0.565	0.287	-0.145	0.342	0.118
	Male	0.474	0.370	0.299	-0.099	-0.154	0.219	0.202	0.536*
	Total	0.519**	0.482*	-0.080	0.279	0.077	0.017	0.239	0.261
SNB	Female	0.407	0.309	-0.342	-0.359	0.543	-0.020	-0.153	-0.137
	Male	0.123	0.255	0.105	0.014	0.447	0.483	0.226	0.242
	Total	0.260	0.281	-0.054	-0.153	0.478*	0.296	0.058	0.073
ANB	Female	0.343	0.438	0.125	0.751**	0.072	-0.119	0.437	0.194
	Male	0.360	0.162	0.198	-0.099	-0.489	-0.170	0.015	0.342
	Total	0.377	0.332	-0.053	0.367	-0.180	-0.144	-0.214	-0.225
PL-ML	Female	0.544	0.497	-0.181	0.338	0.435	-0.018	0.085	0.374
	Male	-0.191	0.039	0.068	0.118	0.205	-0.297	-0.411	-0.550*
	Total	-0.078	0.189	0.025	0.179	0.281	-0.189	-0.204	-0.145
NSL-PL	Female	-0.400	-0.335	0.390	0.121	-0.650*	-0.030	-0.003	-0.286
	Male	-0.054	-0.240	-0.166	0.322	-0.404	-0.329	-0.055	0.226
	Total	-0.206	-0.266	-0.027	0.232	-0.480*	-0.212	-0.039	-0.023
NSL-ML	Female	0.252	0.261	0.205	0.582*	-0.172	-0.073	0.090	0.156
	Male	-0.513	-0.311	-0.121	0.120	-0.131	-0.504*	-0.615*	-0.403
	Total	-0.205	-0.111	-0.054	0.272	-0.138	-0.384*	-0.365	-0.207
ANS-PNS	Female	-0.172	-0.052	-0.080	0.388	0.169	0.093	0.018	0.203
	Male	0.775***	0.737**	0.564*	0.756**	0.263	0.454	0.623*	0.422
	Total	-0.573**	0.596**	-0.430*	0.707***	0.221	0.356	0.467*	0.343
PNS-S	Female	0.478	0.617*	0.001	0.412	0.649*	0.461	0.322	0.366
	Male	0.828***	0.887***	0.420	0.821***	0.424	0.602*	0.733**	0.359
	Total	0.713***	0.807***	0.344	0.767***	0.406*	0.521**	0.596**	0.319
PNS-U1	Female	0.528	0.576	-0.342	0.296	0.615*	0.124	0.143	0.399
	Male	0.835***	0.751**	0.529*	0.839***	0.328	0.309	0.747**	0.264
	Total	0.722***	0.689***	0.401*	0.769***	0.330	0.251	0.581**	0.263
PNS-Ba	Female	0.606*	0.778**	0.058	0.508	0.604*	0.350	0.367	0.194
	Male	0.692**	0.811***	0.301	0.624*	0.407	0.754**	0.575*	0.389
	Total	0.650***	0.790***	0.204	0.605**	0.427*	0.633***	0.491**	0.318
H-ML	Female	-0.555	-0.374	0.313	-0.119	0.121	0.412	0.447	-0.171
	Male	-0.150	0.072	0.114	0.345	-0.054	0.395	0.696*	0.330
	Total	-0.406	-0.242	0.049	0.026	0.030	0.396	0.510*	0.011

P* < 0.05, *P* < 0.01, ****P* < 0.001**Table 6** The correlations (*r*) between skeletal and airway measurements changes after late headgear treatment (T1-T2).

		PNS-ad1	PNS-ad2	MPT	PNS-u1	ve1-ve2	u1-u2	rI1-rI2	va1-va2
SNA	Female	0.627*	0.627*	0.733*	0.373	-0.090	-0.417	-0.280	0.360
	Male	0.175	0.115	0.107	-0.184	0.326	0.684**	0.229	0.099
	Total	0.461*	0.375	0.471*	0.185	0.059	-0.072	-0.087	0.292
SNB	Female	0.399	0.465	0.890***	0.264	-0.184	-0.502	-0.373	0.204
	Male	-0.026	-0.027	0.044	-0.247	0.129	0.399	0.301	-0.101
	Total	0.271	0.280	0.430*	0.077	0.034	-0.136	-0.088	0.027
ANB	Female	0.756**	0.641*	0.175	0.426	0.069	-0.063	0.000	0.470
	Male	0.192	0.128	0.067	0.127	0.105	0.115	-0.142	0.245
	Total	0.239	0.111	0.069	0.141	0.000	0.087	0.014	0.349
PL-ML	Female	-0.496	-0.375	0.002	-0.466	0.399	-0.125	-0.151	-0.467
	Male	-0.186	-0.295	0.168	0.033	0.085	0.240	-0.110	0.039
	Total	-0.403*	-0.411*	0.080	-0.264	0.142	0.079	-0.077	-0.169
NSL-PL	Female	0.277	0.316	0.008	0.389	-0.139	0.209	0.264	0.767**
	Male	0.228	0.408	-0.068	0.008	-0.164	-0.435	-0.380	-0.131
	Total	0.259	0.380	-0.026	0.215	-0.121	-0.105	-0.093	0.302
NSL-ML	Female	-0.366	-0.205	0.000	-0.247	0.356	0.003	0.017	0.008
	Male	0.068	0.077	0.085	0.018	0.000	0.093	-0.263	0.038
	Total	-0.230	-0.137	0.031	-0.156	0.105	0.075	-0.068	0.058
ANS-PNS	Female	0.471	0.535	0.779**	0.318	-0.262	-0.186	-0.125	0.444
	Male	-0.219	0.062	-0.260	0.204	0.184	-0.028	0.056	-0.063
	Total	0.309	0.373	0.458*	0.297	-0.079	-0.156	-0.073	0.278
PNS-S	Female	0.817**	0.740**	0.429	0.507	0.165	0.052	-0.086	0.385
	Male	0.588*	0.696**	0.289	0.226	0.487	0.623*	0.344	0.231
	Total	0.723***	0.736***	0.354	0.407*	0.363	0.251	0.085	0.267
PNS-U1	Female	0.676*	0.629*	0.470	0.327	0.089	-0.004	-0.059	0.328
	Male	0.462	0.330	-0.047	0.304	0.301	0.012	-0.227	-0.387
	Total	0.612**	0.517**	0.229	0.338	0.219	-0.019	-0.156	0.041
PNS-Ba	Female	0.790**	0.835**	0.670*	0.588	-0.054	-0.231	-0.096	0.623*
	Male	0.658**	0.736**	0.136	0.165	0.419	0.590*	0.415	0.339
	Total	0.705***	0.782***	0.370	0.402*	0.242	0.116	0.137	0.425*
H-ML	Female	0.633	0.413	-0.355	-0.106	-0.298	0.486	0.590	0.589
	Male	0.008	0.094	-0.279	0.685**	0.479	-0.206	-0.262	-0.148
	Total	0.218	0.261	-0.297	0.582**	0.288	0.038	-0.044	0.093

P* < 0.05, *P* < 0.01, ****P* < 0.001