Comparison of effects of cervical headgear treatment on skeletal facial changes when the treatment time is altered: a randomized controlled trial

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Short title: Dentoskeletal changes, timing and cervical headgear

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Summary

Background: There is a lack of evidence based on longitudinal information in the field of Class II malocclusion management with cervical headgear (CH), especially in a randomized setting.

Objectives: The main objective of this study was to evaluate skeletal facial changes, particularly in vertical dimensions, after Kloehn-type CH treatment in children when the timing of treatment is altered.

Trial design: Prospective, parallel-group, randomized controlled trial.

Methods: Screened children with Class II malocclusion were randomized in 1:1 ratio to two groups of equal size by sealed-envelope randomization: the early group (EG), where active CH treatment was started at the age of 7.8 years, and the late group (LG), where CH treatment was started at the age of 9.5 years. The active treatment was continued until normal Class I occlusion on first molars was achieved. Cephalograms were taken at three different time points. Changes in cephalometric measurements were compared between groups and genders. Blinding was applicable for outcome evaluation.

Results: Of 67 randomized children, 56 completed the study. Upper facial height increased during the CH treatment phase, as the parameter N–ANS increased significantly during the active treatments of EG ($P < 0.05$) and LG ($P < 0.05$). Also, the parameter NSL–PL increased significantly during the treatment of EG ($P < 0.01$) and during the treatment of LG ($P < 0.01$). The Gonial angle decreased significantly in the early CH treatment group compared to the later treatment group (T_0–T_2: $P < 0.01$). CH improved the anteroposterior jaw relationship. No harms were encountered.

Conclusions: Although the upper facial height increased, the mandible showed anterior rotation after CH treatment. The Gonial angle was significantly decreased in the EG compared to the LG. There were gender-specific differences in both sagittal and vertical dimensions when examining interrelations in dimensional changes. The differences found between the early and later treatment groups were not clinically important when the cephalometric results are considered.

Clinical Registration: ClinicalTrials.gov (NCT02010346).

Keywords: Class II malocclusion; Cervical headgear; Timing; Randomized controlled trial

Introduction

Since its introduction, headgear has been widely used in treatment of Class II malocclusion, and early work with headgear laid the foundation for the use of the cervical headgear (CH) known today (1, 2). Since then, the effects of CH on craniofacial structures have raised many questions, despite extensive research on the subject. The most well-known findings of these studies are the effects on the maxilla. The CH inhibits forward growth of the maxilla, the maxilla moves distally, and simultaneously, the palatal plane rotates downwards anteriorly (3-8). On the other hand, these changes have been shown to be reversible in long-term follow-up (7, 9).

Distal movement and a slight extrusion of maxillary first molars have also been reported (4-6, 10). This change in the position of the upper molars has been suggested to be responsible for a posterior rotation of the mandible (5, 6). For this reason, the use of CH is not recommended in patients with vertical growth pattern, even though there are reports where the use of CH with vertical growth pattern did not worsen the posterior growth (11). On the contrary, anterior rotation of the mandible has been reported (11, 12).

Most studies of CH treatment have concluded this rotation of the mandible to be a secondary effect, and there are only few studies of the detailed effects of CH on mandibular growth in sagittal and vertical dimensions. These studies have shown that CH treatment does not alter the mandibular plane angle and that vertical dimensions of the face are generally not affected (13-15). It has been stated that after CH treatment, the mandible grows forward, following the normal individual growth pattern, and that treatment does not have adverse effects on vertical growth (4, 7, 16, 17).

Gender distribution is usually described in study materials, but its effect on treatment outcomes has generally been disregarded. There are a few reported differences between genders after CH treatment, but these are mostly considered to be gender-specific growth changes and not caused by CH treatment (4, 13). Recent evidence has shown that when the timing of the treatment is altered, gender does have an effect on treatment outcomes (8, 18).

Although CH has been widely used and extensively studied, systematic reviews and meta-analyses have revealed that there are only a few prospective randomized clinical trials of the effects of CH treatment on Class II malocclusion. These reports commonly suffer from lack of a proper control group or have been based on retrospective material. Some studies have looked at the dentofacial effects of CH compared to other orthodontic devices (19-22). For this reason, it is important to examine these longitudinal changes in detail in a randomized setting.

Objective

The aim of this study was to evaluate skeletal facial changes, especially in vertical dimensions, after Kloehn-type CH treatment in children when timing of treatment is altered. The hypothesis was that the timing of treatment affects the growth changes in the examined structures.

Subjects and Methods

Study Design, registration and ethical issues

This study is a prospective, parallel-group, controlled trial randomized in 1:1 ratio and reported according to the CONSORT 2010 statement guidelines (23). The trial is registered at ClinicalTrials.gov (NCT02010346), and before start, 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.

Sample size calculation

The sample size was calculated with independent samples *t*-test at a significance level of 0.05 and a power of 80 per cent, resulting in a sample size of eleven in each group (7). Our study is a longitudinal follow-up study where the patients are followed from ages 7 to 18 years. Because long studies are prone to dropouts, to secure the completion of the study the intake was increased. Also, if the results would show a reason why it is necessary to do split analyses, for example, if the gender is reflected to the results, the size of the subgroups would be sufficient.

Participants and eligibility criteria

The patients were selected from birth cohorts in three municipalities in northern Finland between February 2004 and June 2008, and 7-year-old schoolchildren were screened for the study by clinicians in health centres. The inclusion criteria were Class II occlusion and overjet 6 mm or more and deep bite. The exclusion criteria were previous orthodontic treatment and PL–ML angle (the angle between the palatal line and the mandibular line) over 35 degrees. In addition, children with inborn facial syndrome and severe facial asymmetry were not included. Sixty-seven children with Class II malocclusion (mean age 7.2 years, standard deviation (SD) 0.55, 28 females, 39 males) met the inclusion criteria and were included in the study and randomized into two groups.

The sample size calculation, screening and randomization as well as blinding have been described in detail in previous articles of this study (8, 18).

Interventions

The children were randomly divided into two equal-sized groups: the early group (EG) and the late group (LG). A treatment protocol with CH treatment was carried out for all children. In the EG (n = 33; 13 female and 20 male), CH treatment was started after eruption of the first maxillary molars (mean age 7.8 years, SD: 0.53) and continued until normal Class I occlusion on molars was achieved. Reduced use of CH was applied after active treatment when necessary. In the LG (n = 34; 15 female and 19 male), equivalent CH therapy was performed proximately one and half years later (mean age 9.5 years, SD: 0.59).

A Kloehn-type CH with a long outer bow and maxillary first molar bands with gingival tubes was used. The outer bows were bent 10 degrees upwards and the inner bow was held 5 mm wider than the distance between the gingival tubes. An orthodontic force of 500 g was provided. The duration of CH use was 8–10 hours during the night. The CH therapy was carried out by clinicians in community health centres. A more detailed description of the interventions is available in the previous articles (8, 18).

Participant flow

Patient flow through the study is illustrated in Figure 1. A total of 270 children were assessed for eligibility. 67 subjects were enrolled in the study and randomized to either early or later treatment groups. The primary analysis (T_0) was intended for all randomly assigned patients. During the first follow-up, 3 patients in the EG and 2 in the LG dropped out from the study. 62 children participated in the second analysis (T_1). During the second follow-up, 4 patients in the EG and 2 in the LG dropped out. A total of 56 children completed the second follow-up (T_2). A more detailed description of the participants is available in the previous articles (8, 18). Of the 67 subjects at the baseline, 6 subjects did not attend in either analysis T_1 or T_2, but they did not differ from those who did, in terms of group or gender, or any of the linear or angular measurements at T_0.

Outcomes

Lateral cephalograms were taken from all the subjects at three different time points during the follow-up. The cephalograms were taken at baseline (T_0, mean age 7.3 years, SD: 0.53), at the beginning of treatment in the LG (T_1, mean age 9.6 years, SD: 0.51), and at the end of treatment in the LG (T_2, mean age 11.5 years, SD: 0.57).

Cephalometric software (WinCeph 8.0, Rise Corporation, Japan) was used for cephalometric evaluation. Lateral cephalograms were calibrated in regard to magnification before the landmark definition. The evaluation and landmark digitalization was carried out by one of the authors (JJ). Cephalograms with poor quality for measuring were excluded. The cephalometric points, reference lines, and explanation of the less used cephalometric measurements used in the analysis are shown in Figures 2 and 3.

Statistical analysis

Statistical significances for difference between the groups at each time point were evaluated using Mann-Whitney *U*-test, and for difference between the groups in change during study periods using general linear model for repeated measures. In the mean values of each time point, all participants at that time point were included. In mean change scores, only those who had cephalograms for both time points were included. To evaluate whether the changes in SNA and facial axis (T_0–T_2) were associated with changes in other measures, Pearson's correlation coefficients between change scores were calculated. To evaluate whether the baseline measure of facial axis was associated with changes in other measures during the study, correlation coefficients between facial axis T_0 and change scores T_0–T_2 were used.

Examiner reliability

To determine the error of the method, 20 randomly selected lateral cephalograms were traced and measured twice with a 2-week interval. The intra-rater reliability was measured by intraclass correlation coefficient (ICC) to compare the repeated measurements. ICCs for linear measures were good/excellent (range: 0.807–0.992) for other measures but moderate for U6(d)–PtV (0.561). In angular measures, ICCs were good/excellent (0.828–0.969) for other measures but moderate for NSL–PL (0.692).

Results

Outcomes

Cephalometric measurements between the groups (genders combined)

Table 1 shows the linear measurements at different time points and changes during the study periods. N–ANS changed differently among the groups; the increase was significantly higher in EG during T_0–T_1, and in LG during T_1–T_2. At T_2, the value of N–ANS was at the same level in both groups. Convexity (mm) decreased in both groups, but at different time periods: during T_0–T_1 in EG and during T_1–T_2 in LG. A decrease in U6(d)–PtV value was seen in EG during T_0–T_1 compared to LG.

Changes in angular measurements at different time points and study periods are shown in Table 2. Differences in changes in the angles SNA, ANB and angle of convexity were seen between the groups at both time periods. In the EG, decreases occurred during the first time period and in the LG, during the second time period. An increase in NSL–PL angle was also seen in EG at T_0–T_1 and in LG at T_1–T_2. During the study, Gonial angle decreased significantly more among EG than among LG at T_0–T_2. There was a significant difference in OL–ML angle at T_1–T_2 between the groups. During T_1–T_2, OL–ML angle decreased among EG but increased among LG. The linear and angular measurements during the follow-ups and at the end of the follow-up did not reveal any gender differences between the results.

Correlations between changes in SNA angle and cephalometric measurements (genders separated)

Table 3 shows the correlation of change in SNA angle at T_0–T_2 to changes in linear measurements at T_0–T_2. The change in SNA correlated differently to linear changes between genders. Significant correlations were seen in EG males and LG females, but they were opposite. Negative correlations were seen in parameters N–ANS, N–Me, Cd–A, Cd–Gn and Cd–Go among EG males. In LG females, the correlation was opposite and positive correlations were seen in parameters ANS–Me, Cd–A, Cd–Gn, S–tGo and convexity (mm). The change in SNA angle was negatively correlated with the change in N–ANS and positively correlated with the change in U6(d)–PtV among EG females.

Table 4 shows the correlation of change in SNA angle at T_0–T2 to changes in angular measurements at T_0–T_2. The change in SNA was positively correlated with the changes in sagittal angles SNB and facial plane angle among both groups and genders. No other correlations were observed among EG males. Positive correlations were observed in the change of SNA with the changes in sagittal parameters ANB and angle of convexity among LG females and in the change of vertical parameter facial axis among EG females and LG males. Negative correlations in the change of SNA were observed with the changes of vertical parameters NSL–PL among EG females and LG males, and NSL–ML among LG females and males. Negative correlations were seen between the change in SNA and angles NSL–RL and NSL–OL among both genders of LG.

Correlations between changes in facial axis and cephalometric measurements (genders separated)

Table 5 shows the correlation of change in facial axis at T_0–T_2 to changes in angular measurements at T_0–T_2. The change in facial axis was positively correlated with the change in facial plane angle among both groups and genders. Positive correlations were observed between the change of facial axis and change of sagittal parameters SNA among EG females and LG males and SNB among EG females and males and LG males. In vertical parameters, a positive correlation was observed between the change of facial axis and change of Gonial angle among LG females. The change in facial axis was negatively correlated with the change in NSL–RL among both groups and genders. The change in facial axis correlated negatively with vertical parameters NSL–PL among EG females, with NSL–ML among EG females and LG males and with NSL–OL among EG males and LG males.

The correlations between facial axis at T_0 and angular measurement changes in T_0–T_2 were seen only in LG males. Sagittal parameters SNA, SNB, and facial plane angle correlated negatively with the facial axis at T_0; on the contrary, vertical parameters NSL–ML, NSL–RL, and NSL–OL correlated positively with facial axis. The facial axis at T_0 correlated negatively with the change of facial axis in T_0–T_2 among LG males.

Harms

No harms were encountered during the follow-up between T_0–T_2.

Discussion

Interpretation

Although Class II malocclusion and its treatments have been widely studied, there is a lack of clinical trials providing high-quality evidence-based information on the management of Class II malocclusion and the true effects of CH treatment on the craniofacial complex (21, 24). The complexity of the Class II malocclusion, the variations in headgear design and the use of retrospective material in numerous studies have given significant amount of information, but this information has also been shown to be inconsistent.

This randomized controlled trial was aimed to evaluate skeletal facial changes in children after early or later timed CH treatment. We have earlier shown the effects of treatment timing and gender on the upper airway and related skeletal structures in CH treatment (8). Here, the genders were first pooled together to study further the effect of timing especially on the skeletal vertical parameters. The genders were, however, examined separately to examine the longitudinal interrelations of facial structures.

The idea was to study especially timing of the early treatment (EG) during the early mixed dentition compared to the later treatment (LG) starting around the onset of late mixed dentition. The outcome of this study could be different if the groups were treated in different growth stages. However, it is noteworthy that in many studies on CH treatment, the initiation of treatment has been done between 8.5 and 10.5 years, before or during the initiation of the second mixed dentition (4, 5, 11, 12).

The results of this study show that the CH treatment improves the antero-posterior relationship of the maxilla and the mandible. The decrease in the convexity of the middle face and in the SNA angle shows the restriction of maxillary forward growth, especially during early treatment, which is in accordance with the previously reported findings (8, 25-27). However, due to normal growth, the midfacial length increased despite the restricting force of CH on the maxilla. Our results also showed normal growth of the mandible. This is in concordance with previous studies in children with normal occlusion (28, 29). It has also been shown that dentofacial growth of untreated Class II children does not notably differ from growth of children with normal occlusion (30). The results indicated that the most noticeable increase in mandibular length occurred during early treatment phase (T_0–T_1) in both groups regardless of the treatment of the EG. This partly explains the decrease in the angle of convexity and improvement of the antero-posterior jaw relationship, which were more prominent in the early-treated children.

Our results showed slight distalization of the upper first molars after early CH treatment. At the end of the second follow-up, the anterior growth of the maxilla overcomes the distal movement of upper molars. Our previous study of dental arch effects after CH showed that the movement of upper molars is seen in significant lengthening of the dental arch, pointing out that the movement is mostly dental in nature (18).

Downward rotation of the palatal plane anteriorly and increase in the upper anterior face height was seen in both EG and LG immediately after active CH treatment. This supports the previous reports on CH treatment (4, 6, 8, 31). The force vector created by CH works below the centre of resistance of the maxilla, changing the growth direction and causing the palatal plane to rotate downward anteriorly. It is interesting that the timing of treatment did not affect the magnitude of change.

The decrease in the mandibular plane angle showed anterior rotation of the mandible in both treatment groups. Our finding of the anterior rotation of the mandible is in concordance with previous studies (4, 11, 12). Several studies have reported an opposite result, a posterior rotation of the mandible after CH treatment (5, 6, 32). This has led to the assumption that CH has a tendency to open the bite, especially in patients with vertical growth pattern. This has in turn resulted in avoiding the use of CH to prevent undesirable side-effects, such as posterior rotation of the mandible and an increase in lower anterior face height. Studies looking the effect of CH treatment on patients with different mandibular plane angles and growth patterns have shown that mandibular rotation responses differ with low and high angle groups (33, 34). It has been stated that there is less anterior mandibular rotation seen after CH treatment with the high angle group (34). On the other hand, it has also been found that patients with pronounced horizontal growth show bite opening after CH treatment (11, 33). These might be the possible causes to different outcomes of the CH. It has to take into account that in our study children with PL–ML angle over 35 degrees were excluded. Thus the most severe high angle and low angle patients were not present at the groups and this might reflect to the results.

A longitudinal growth study with untreated Class II subjects has shown that the Gonial angle decreases during normal growth (35). According to this study, the annual change in Gonial angle was less than 1 degree. A previous study of the effects CH treatment on growth patterns has shown that CH reduces the mandibular angle (ArGoMe) (11). This study shows a similar effect and a decrease in the Gonial angle in both treatment groups during T_0–T_2 after active treatment. Most of the changes occurred during the first follow-up (T_0–T_1) and the decrease in the Gonial angle after early CH treatment was significant compared to later treatment. This is probably a consequence of the prepubertal growth spurt. A study with Class II patients has shown that children with a Gonial angle less than 125.5 degrees are favourable candidates for future functional jaw orthopaedics (FJO) (36). This study showed that CH treatment significantly decreases the Gonial angle, and it could be speculated that especially early CH treatment improves the Class II patients' response to possible forthcoming FJO by decreasing the Gonial angle.

There was difference between the genders in how the decrease in the SNA angle (T_0–T_2) correlated to other cephalometric changes. Significant correlations in linear measurements were seen in EG males and LG females, but they were opposite in direction. In those EG males whom SNA decreased the most, both the vertical and sagittal parameters showed the largest increase. In contrast, in LG females the correlation was opposite, with measurements decreasing alongside with SNA. In angular measurements, correlations with the change in the SNA angle were seen among both groups and genders, but there were differences between the sagittal and the vertical changes. The change in SNA correlated positively with the sagittal measurement changes and negatively with the vertical changes, indicating a decrease in sagittal and an increase in vertical parameters.

Between the correlations of the change in facial axis and the angular measurement changes at T_0–T_2, an outcome analogous to the change in SNA angle correlations was seen. Correlations were observed among both groups and genders, positive correlations were seen in the change in sagittal parameters, whereas negative correlations were seen in the vertical parameters. Correlations between facial axis at T_0 and angular measurement changes in T_0–T_2 were seen only in LG males. Sagittal parameters decreased the most among those with the largest facial axis at T_0, whereas on the contrary, vertical parameters increased the most. In those LG males who had the largest facial axis at T_0, the facial axis showed the largest decrease.

These findings suggest that the more the CH restricts the forward growth of the maxilla, the more the vertical portions of the face increase, pointing to opening rotation in angular parameters. An increase in linear measurements, especially in EG males, suggests that normal growth overcomes the opening rotation and normal growth rotation occurs. At the end of the follow-up, the vertical and horizontal changes in facial dimension linear measurements did not show significant differences between the groups. It is important that children with remarkable skeletal bite opening were excluded from the study. They might respond differently to CH treatment than children with normal growth pattern in the change of facial axis. Most of the changes in dimensions occurred during the first follow-up (T_0–T_1). The linear and angular measurements during the follow-ups and at the end of the follow-up did not reveal any gender differences in results.

Limitations

Lack of a proper control group could be seen as weakness of this study. However, it is not ethical to use untreated Class II malocclusion patients for long-term controls, and the use of historical control groups has been shown to weaken the treatment effects (37). As the timing of the treatment was the subject to be investigated, the two treatment groups served as controls for one another. The differences between normal growth and treatment effect were shown during the treatment of the EG and the follow-up of the LG at T_0–T_1.

The ICC for one linear measurement and one angular measurement was considered moderate, but these two results were still reported. The effect of these measurements should be interpreted with discretion.

Because the aim was to study long-term effects of CH treatment and there were no data from dropouts in later time points, per-protocol analyses were used, and in every step, data were used from all subjects that it was available. Intention-to-treat analysis is recommended in the CONSORT 2010 statement guidelines, but our data were not suitable for it (23). As a result, there might be a post-randomization bias and false-positive results (38). However, there were only six participants who attended only at baseline, and based on the dropout analysis, they did not differ from those who attended also later.

Generalization

The result of this study can be generalized to children with Class II malocclusion. On the basis of these results, CH is a competent treatment option in both early and later treatment phases.

Conclusion

Although the upper facial height increased during active CH treatment in both groups, an anterior rotation of the mandible was seen in both treatment groups after CH treatment. This is likely due to remodelling in the gonial area. At the end of the follow-up, there were no major differences in linear and angular measurements caused by the effects of the timing of treatment or gender. There was a gender difference in the response to treatment with CH in inter-correlations of the cephalometric values. The differences between the early and later treatment groups were not clinically important when the cephalometric results are considered.

Protocol

The protocol was not published prior to trial commencement.

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Conflict of interest

None to declare.

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FIGURE LEGENDS

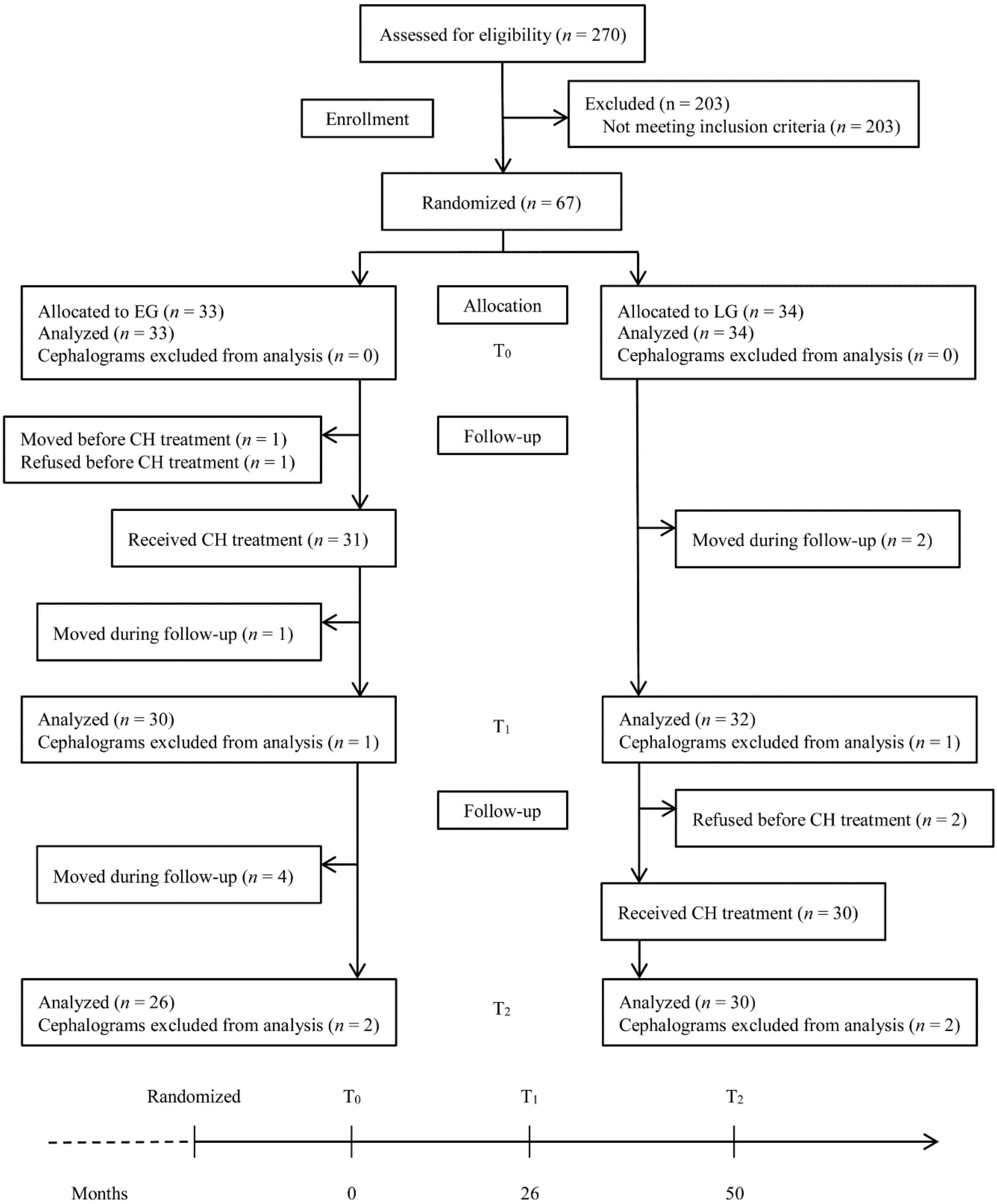

Figure 1. The flow diagram and the timeline of the study.

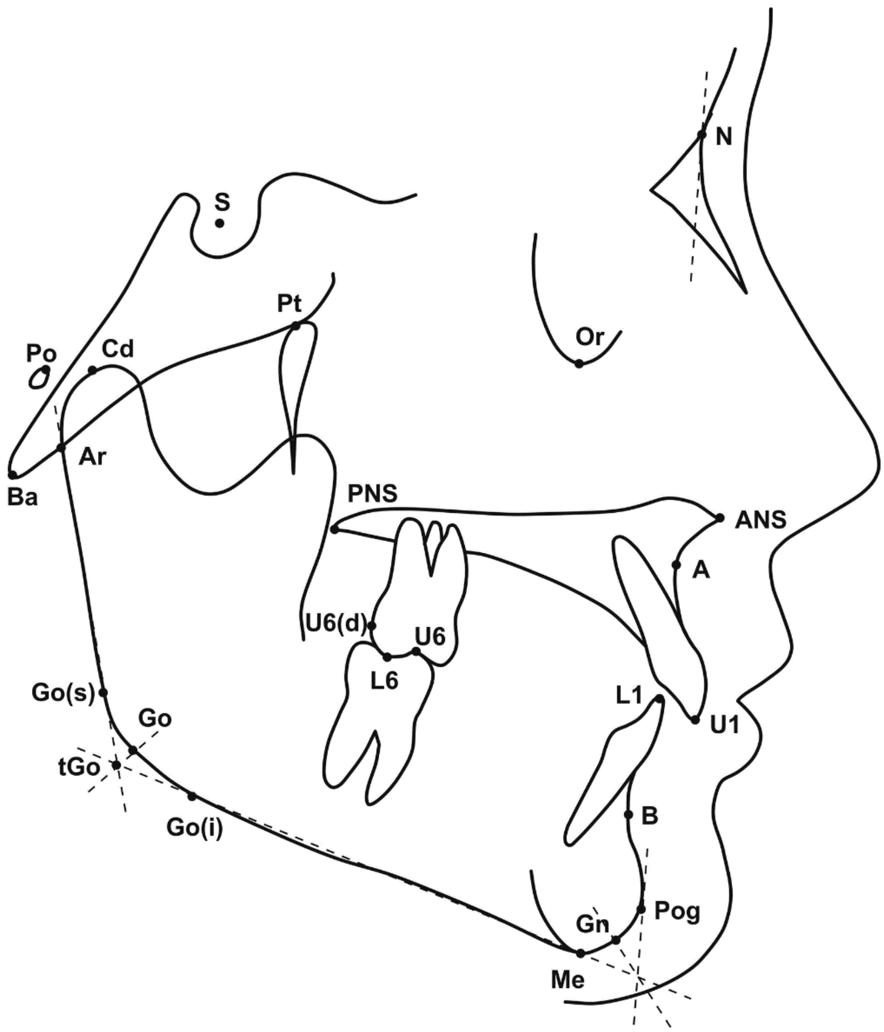

Figure 2. Cephalometric points – S: sella; N: nasion; Pt: the most superior and posterior point of pterygomaxillary fissure; Po: porion; Or; orbitale; Cd: condylion; Ar: articulare; Ba: basion; ANS: anterior nasal spine; PNS: posterior nasal spine; A: subspinale; B: supramentale; Pog: pogonion; Gn: gnathion: a point located on the symphysis constructed by bisecting the angle formed by lines N–Pog and Me–Go(i); Me: menton; Go(s): superior gonion; Go(i): inferior gonion; Go: gonion: a point on the angle of mandible constructed by bisecting the angle formed by lines Ar–Go(s) and Me–Go(i); tGo: tangent gonion: the intersection point of lines Ar–Go(s) and Me–Go(i); U1: the tip of maxillary central incisor; L1: the tip of mandibular central incisor; U6: the occlusal point of maxillary first molar; L6: the occlusal point of mandibular first molar; U6(d): the most distal point of maxillary first molar.

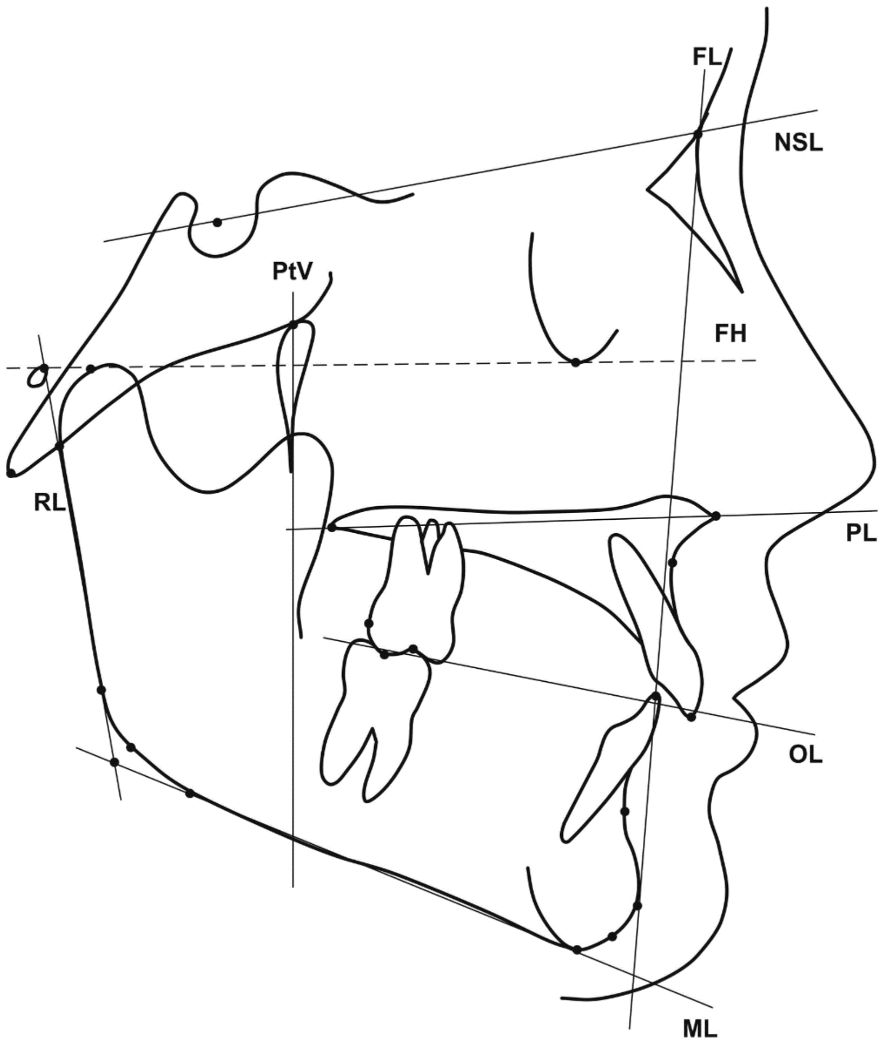

Figure 3. Reference lines – NSL: N–S line; FH: Frankfort horizontal plane: Or–Po line; PL: palatal plane: ANS–PNS line; OL: occlusal plane: the line from the midpoint of U1 and L1 to the midpoint of U6 and L6; ML: mandibular plane: Me–Go(i) line; RL: ramus plane: Ar–Go(s) line; FL: facial plane: N–Pog line; PtV: pterygoid vertical: a line perpendicular to FH from Pt.
Less used cephalometric measurements – U1–FL: the distance of perpendicular line from U1 to facial plane; L1–FL: the distance of perpendicular line from L1 to facial plane; U6(d) –PtV: the distance of perpendicular line from U6(d) to pterygoid vertical; convexity (mm): the distance of perpendicular line from A to facial plane; angle of convexity: the angle formed by intersection of lines N–A and A–Pog; Facial plane angle: the angle of N–S line and facial plane; Gonial angle: the angle formed by ramus plane and mandibular plane; Facial axis: the angle of lines Ba–N and Pt–Gn.

Table 1. Mean values with 95% CIs for linear measurements at different time points and change scores during study periods. *P*-value for the group difference.

	Group	T_0		T_1		T_2		T_0–T_1		T_1–T_2		T_0–T_2	
	EG *n*	33		29		24		29		24		24	
	LG *n*	34		31		28		31		27		28	
		Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI
N–S	EG	63.2	62.0; 64.3	66.3	64.3; 68.4	65.9	64.4; 67.4	2.9	1.1; 4.8	–0.2	–1.9; 1.4	2.8	1.3; 4.3
	LG	63.5	61.4; 65.6	66.1	63.5; 68.6	67.6	64.9; 70.4	2.4	0.2; 4.5	0.9	–2.5; 4.2	3.6	0.3; 7.0
N–ANS	EG	40.1	38.7; 41.5	45.3	45.3; 46.5	45.8	44.2; 47.4	*5.2	3.3; 7.0	*0.8	–0.2; 1.8	5.6	4.1; 7.1
	LG	41.9	40.4; 43.5	44.3	43.3; 45.4	47.2	46.0; 48.4	*2.4	0.8; 4.0	*2.7	1.5; 3.9	5.5	3.5; 7.4
ANS–Me	EG	55.3	53.9; 56.6	56.6	54.8; 58.3	57.0	55.7; 58.3	1.1	–0.6; 2.9	0.7	–0.8; 2.3	1.5	–0.3; 3.2
	LG	55.1	52.9; 57.3	58.2	55.9; 60.6	58.1	56.2; 59.9	2.9	0.8; 5.0	–0.4	–2.7; 1.8	2.7	0.5; 4.9
N–Me	EG	93.0	91.1; 95.0	100.0	97.4; 102.6	101.1	98.6; 103.7	6.9	4.1; 9.7	1.6	–0.4; 3.7	7.8	5.4; 10.3
	LG	94.9	91.5; 98.3	100.3	97.6; 103.1	103.3	101.0; 105.5	5.1	2.8; 8.1	2.6	–0.3; 5.5	8.3	4.7; 12.0
Cd–A	EG	74.9	73.6; 76.2	78.4	76.0; 80.8	79.0	76.9; 81.1	3.0	0.8; 5.3	1.1	–0.9; 3.2	4.1	2.1; 6.1
	LG	76.0	73.3; 78.8	81.1	78.2; 84.0	81.1	79.3; 83.0	4.8	2.0; 7.6	–0.4	–3.9; 3.1	4.9	1.0; 8.7
Cd–Gn	EG	91.6	90.2; 93.0	98.0	95.2; 100.7	99.1	96.8; 101.4	6.1	3.6; 8.6	1.7	–0.8; 4.3	7.6	5.5; 10.0
	LG	92.7	89.1; 96.3	100.0	96.6; 103.4	101.1	98.9; 103.3	6.7	3.3; 10.1	0.7	–3.4; 4.9	8.3	3.9; 12.7
Cd–Go	EG	46.1	44.8; 47.4	49.1	47.4; 50.8	50.5	49.0; 52.0	3.0	1.3; 4.6	1.4	–0.2; 3.0	4.3	2.9; 5.7
	LG	46.2	44.3; 48.1	50.0	48.1; 51.9	50.3	48.7; 52.0	3.8	1.6; 6.0	0.2	–2.2; 2.7	4.4	1.7; 7.1
S–tGo	EG	61.3	59.6; 62.9	66.5	64.1; 68.9	67.6	65.8; 69.4	5.2	3.5; 6.9	1.4	–0.2; 3.0	6.4	4.7; 8.1
	LG	61.9	59.7; 64.3	66.8	64.5; 69.2	68.2	66.3; 70.2	4.7	2.4; 7.3	1.2	–1.5; 3.8	6.4	3.8; 9.0
U1–FL	EG	6.7	5.9; 7.6	7.3	6.5; 8.1	7.8	6.9; 8.6	0.7	–0.1; 1.4	*0.5	–0.2; 1.2	0.9	0.1; 1.6
	LG	8.3	7.1; 9.5	9.0	7.8; 10.2	8.4	7.2; 9.6	0.9	0.2; 1.6	*–0.7	–1.5; 0.1	0.3	–0.6; 1.1
L1–FL	EG	2.7	2.0; 3.4	2.4	1.7; 3.2	3.0	2.2; 3.8	–0.2	–0.7; 0.2	0.7	0.3; 1.1	0.1	–0.2; 0.5
	LG	3.4	2.4; 4.3	3.4	2.4; 4.4	3.7	2.6; 4.7	0.3	–0.1; 0.7	0.0	–0.6; 0.6	0.4	–0.4; 1.3
U6(d)–PtV	EG	9.9	8.9; 10.9	**9.6	8.5; 10.7	10.9	9.0; 12.5	**–0.6	–1.4; 0.2	1.5	0.2; 2.9	1.1	–0.3; 2.5
	LG	10.5	9.7; 11.4	**12.0	10.9; 13.0	12.4	11.2; 13.6	**1.4	0.6; 2.2	0.3	–1.2; 1.8	1.9	0.8; 3.1
convexity (mm)	EG	4.0	3.2; 4.7	**2.3	1.6; 3.1	2.6	1.9; 3.2	***–1.5	–2.0; –1.0	**0.2	–0.2; 0.6	–1.4	–1.9; –0.8
	LG	4.1	3.4; 4.8	**3.8	3.2; 4.4	3.1	2.2; 3.9	***–0.1	–0.6; 0.4	**–0.7	–1.2; –0.3	–1.0	–1.6; –0.4

* $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$

Table 2. Mean values with 95% CIs for angular measurements at different time points and change scores during study periods. *P*-value for the group difference.

	Group	T_0		T_1		T_2		T_0–T_1		T_1–T_2		T_0–T_2	
	EG *n*	33		29		24		29		24		24	
	LG *n*	34		31		28		31		27		28	
		Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI
SNA	EG	82.2	80.8; 83.7	**80.2	78.7; 81.6	80.8	79.0; 82.6	***–2.1	–2.8; –1.4	**0.6	–0.3; 1.5	–1.5	–2.2; –0.8
	LG	82.4	81.1; 83.6	**83.2	81.8; 84.5	81.7	80.5; 83.0	***1.0	–0.1; 2.1	**–1.4	–2.4; –0.5	–0.7	–1.6; 0.3
SNB	EG	77.2	76.0; 78.5	76.8	75.5; 78.2	77.3	75.5; 79.1	*–0.4	–1.0; 0.2	0.4	–0.3; 1.0	0.2	–0.5; 0.9
	LG	77.2	76.1; 78.3	78.3	77.1; 79.4	77.9	76.8; 78.9	*1.1	0.0; 2.2	–0.5	–1.4; 0.3	0.7	–0.2; 1.5
ANB	EG	5.0	4.2; 5.7	**3.3	2.6; 4.1	3.5	2.9; 4.2	***–1.8	–2.4; –1.1	***0.3	–0.2; 0.7	–1.6	–2.2; –1.1
	LG	5.2	4.5; 5.8	**4.9	4.3; 5.5	3.9	3.2; 4.6	***–0.1	–0.7; 0.5	***–0.9	–1.3; –0.5	–1.3	–1.9; –0.7
angle of convexity	EG	10.6	8.8; 12.4	*6.8	5.0; 8.6	7.2	5.7; 8.7	***–4.0	–5.5; –2.6	**0.5	–0.5; 1.5	–3.7	–5.3; –2.6
	LG	11.2	9.5; 13.0	*10.1	8.6; 11.6	8.1	6.3; 10.0	***–0.5	–1.7; 0.7	**–1.9	–2.9; 1.0	–3.0	–4.3; –1.8
Facial plane angle	EG	76.8	75.6; 78.0	76.8	75.6; 78.0	77.2	75.6; 78.9	0.1	–0.6; 0.7	0.4	–0.3; 1.1	0.7	–0.1; 1.5
	LG	76.6	75.4; 77.7	78.1	76.8; 79.4	77.7	76.5; 78.9	1.3	0.2; 2.4	–0.4	–1.4; 0.5	1.0	0.2; 1.8
NSL–PL	EG	3.9	2.5; 5.4	*6.4	5.4; 7.5	6.0	4.7; 7.2	**2.4	1.0; 3.8	**–0.5	–1.4; 0.5	1.9	0.4; 3.5
	LG	5.3	4.2; 6.3	*4.8	3.6; 5.9	6.6	5.7; 7.6	**–0.5	–1.9; 0.9	**1.9	0.8; 3.0	1.7	0.6; 2.8
NSL–ML	EG	31.7	29.8; 33.6	31.1	29.6; 32.6	30.6	28.7; 32.5	–0.6	–1.9; 0.7	–0.3	–1.2; 0.6	–1.5	–2.7; –0.2
	LG	32.5	30.8; 34.2	31.3	29.2; 33.3	31.9	30.0; 33.8	–1.2	–2.6; 0.2	0.6	–0.6; 1.7	–0.7	–1.7; 0.4
Gonial angle	EG	127.9	125.8; 129.9	124.6	122.8; 126.4	123.3	121.0; 125.5	*–3.4	–4.8; –2.0	–0.9	–2.0; –0.3	**–4.7	–6.2; –3.3
	LG	127.9	125.7; 130.1	127.2	124.8; 129.5	126.3	124.0; 128.6	*–1.3	–2.4; –0.1	–1.3	–2.6; –0.1	**–2.3	–3.3; –1.2
NSL–RL	EG	83.9	81.9; 85.9	86.5	84.6; 88.3	87.4	85.0; 89.8	*2.8	1.1; 4.5	0.6	–1.0; 2.1	3.2	1.8; 4.7
	LG	84.6	82.3; 87.0	84.1	81.9; 86.3	85.6	83.7; 87.6	*0.1	–1.8; 2.0	1.9	0.3; 3.5	1.6	0.0; 3.2
NSL–OL	EG	17.9	16.1; 19.6	17.1	15.6; 18.6	17.2	15.4; 18.9	–0.8	–2.1; 0.5	0.3	–0.9; 1.5	–1.0	–2.7; 0.7
	LG	18.6	17.2; 20.0	17.0	15.3; 18.6	16.5	15.1; 17.8	–1.3	–2.8; 0.1	–0.7	–2.0; 0.6	–1.8	–2.9; –0.8
OL–ML	EG	13.8	12.4; 15.3	14.0	12.9; 15.0	13.5	12.2; 14.7	0.2	–0.9; 1.3	***–0.6	–1.4; 0.2	–0.4	–2.3; 1.4
	LG	13.9	12.4; 15.4	14.2	12.7; 15.8	15.5	13.9; 17.0	0.1	–0.9; 1.2	***1.2	0.6; 1.9	1.2	0.4; 2.0
Facial axis	EG	89.2	87.7; 90.8	88.8	87.2; 90.3	88.3	86.6; 90.0	–0.7	–2.1; 0.7	–0.6	–1.8; 0.6	–0.8	–2.0; 0.4
	LG	88.7	87.5; 89.9	89.2	87.8; 90.6	88.5	87.4; 89.7	0.1	–1.0; 1.3	–0.7	–1.8; 0.4	–0.5	–1.5; 0.5

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

Table 3. Pearson's correlation coefficients of linear measurements changes in T_0–T_2 to change of SNA in T_0–T_2.

	Change in SNA T_0–T_2			
	EG		LG	
	Females	Males	Females	Males
Change in T_0–T_2	*n* = 10	*n* = 14	*n* = 12	*n* = 16
N–S	-0.391	-0.372	0.562	0.380
N–ANS	*-0.665	*-0.641	0.391	-0.388
ANS–Me	0.580	-0.244	*0.617	0.306
N–Me	-0.472	*-0.547	0.521	-0.056
Cd–A	-0.124	*-0.597	*0.643	0.265
Cd–Gn	0.226	*-0.570	*0.617	0.261
Cd–Go	0.494	*-0.581	0.464	0.231
S–tGo	0.172	-0.464	*0.580	0.106
U1–FL	-0.016	0.027	0.372	0.162
L1–FL	-0.079	-0.168	0.252	0.181
U6(d)–PtV	*0.712	-0.032	-0.449	-0.204
convexity (mm)	0.089	0.216	*0.679	0.364

* $P < 0.05$

Table 4. Pearson's correlation coefficients of angular measurements changes in T_0–T_2 to change of SNA in T_0–T_2.

	Change in SNA T_0–T_2			
	EG		LG	
	Females	Males	Females	Males
Change in T_0–T_2	*n* = 10	*n* = 14	*n* = 12	*n* = 16
SNA				
SNB	*0.636	**0.741	***0.863	**0.742
ANB	0.379	0.325	*0.623	0.448
angle of convexity	0.091	0.316	*0.667	0.333
Facial plane angle	0.575	**0.681	**0.724	***0.773
NSL–PL	*-0.656	-0.278	-0.421	*-0.618
NSL–ML	-0.612	-0.112	*-0.577	**-0.640
Gonial angle	-0.148	0.276	0.312	0.239
NSL–RL	-0.236	-0.474	*-0.636	*-0.540
NSL–OL	-0.093	-0.468	**-0.804	*-0.545
OL–ML	-0.362	0.326	0.311	-0.083
Facial axis	*0.757	0.398	0.200	*0.621

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

Table 5. Pearson's correlation coefficients of angular measurements changes in T_0–T_2 to change of Facial axis in T_0–T_2.

	Change in Facial axis T_0–T_2			
	EG		LG	
	Females	Males	Females	Males
Change in T_0–T_2	*n* = 10	*n* = 14	*n* = 12	*n* = 16
SNA	*0.757	0.398	0.200	*0.621
SNB	*0.663	*0.639	0.505	***0.880
ANB	0.065	-0.340	-0.395	-0.279
angle of convexity	-0.268	-0.424	-0.301	-0.365
Facial plane angle	*0.702	**0.738	*0.609	***0.857
NSL–PL	*-0.668	-0.430	-0.415	-0.483
NSL–ML	*-0.700	-0.480	-0.411	***-0.818
Gonial angle	0.112	0.033	*0.611	0.391
NSL–RL	-0.473	*-0.576	**-0.741	**-0.741
NSL–OL	-0.612	**-0.692	-0.178	***-0.781
OL–ML	0.228	0.286	-0.249	0.022
Facial axis				

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