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Headgear therapy in children with Class II malocclusion and the role of compliance on treatment outcome: A nine-month randomized controlled trial

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Abstract

Objectives: To evaluate three-dimensional movements of maxillary teeth during headgear treatment in Class II growing children, using digital analytical tools, and to determine the effects of compliance on these movements.

Materials and Methods: A 9-month parallel-group randomized controlled trial was carried out on 40 children with Class II malocclusion, aged 8-12 years, half assigned to receive a cervical headgear and half to a no-treatment group, using block randomization. Subjects in the treatment group were instructed to wear the headgear for 12 hours daily and monitored using an electronic module. After 9 months, the following dental outcomes were measured: first maxillary molar distalisation, rotation, tip and torque, arch depth, and interpremolar and intermolar distances. Caregivers and participants were not blinded to group assignments, but those assessing outcomes were. Linear regression models were used to detect differences between groups and correlation coefficients to find correlations between compliance and dental outcomes.

Results: All 40 included patients were analysed. A significant difference in molar distalisation was observed between the treatment (1.2 mm) and control groups (−0.2 mm). Arch depth change was also increased to a larger extent in the treatment groups (1.3 mm vs 0.1 mm), as was the interpremolar distance (1.9 mm vs 0.4 mm). In contrast, no significant differences in molar rotation or torque change were observed. With regard to compliance, average compliance was 55%. A significant correlation was found between molar distalisation and compliance in the treatment group.

Conclusions: Headgear therapy has significant effects on molar distalisation, arch depth, and arch width. Compliance has a significant positive effect on molar distalisation.

KEYWORDS
Class II malocclusion, compliance, extraoral traction, headgear, randomized controlled trial

1 | INTRODUCTION

Since its introduction in the field of orthodontics, headgear or extraoral traction therapy has remained a popular option among orthodontists[1,2] as a non-invasive extra-oral source of traction aiming either to distalise maxillary molars in the treatment of Class II malocclusion, to reinforce anchorage, or to achieve an orthopaedic effect in Class II malocclusion treatment. In fact, despite the introduction of other non-compliance-based methods, headgear appliances are still considered a popular choice for treating Class II malocclusions in children, being used by 62% of North American orthodontists according to a survey from a few years ago.[3]

Meta-analysis data indicate that headgear can be effective in restricting sagittal maxillary growth, distalising maxillary molars, and reducing overjet.[4–7] When worn by patients as instructed, favourable results can be achieved, although as with any other removable appliances compliance is an important requirement for effective headgear therapy with optimal outcomes.[8–10]

The belief that compliance influences the success of treatment has pushed clinicians to find ways to objectify this variable.[11] Indirect clinical methods of deducing patient compliance, such as the appraisal of tooth mobility, appliance fitting, evaluation of space created between teeth or the progress of treatment, and direct questioning of the patient or parent/guardian remain questionable.[12] For this reason, modern microelectronic modules are now being used, such as those embedded into removable appliances[13] or attached to the headgear.[8] One important advantage of devices that are sensitive to force is that not only can compliance be quantified, but the force exerted on the molars can also be quantified dynamically over the period of wear.

Results from studies using objective evaluations of compliance, or adherence to instructions, have provided invaluable results. It has been seen that when applying light force (approximately 300cN) as opposed to heavy force (approximately 500cN), patients adhere better to instructions for headgear wear.[9] Interestingly, however, despite the better compliance in the light-force group, treatment outcomes were similar.[14,15] The dental movements in the heavy-force group, however, were also accompanied by more distal tipping of the maxillary molars.[16]

The fact that compliance can now be assessed objectively and quantified enables one to evaluate the dose-effect relationship between headgear use and treatment outcome when correcting Class II malocclusion, such as molar distalisation, in helping identify a potential threshold for treatment effect. Is there a certain threshold above which headgear therapy is effective? Answers to this question still remain unclear, although the aforementioned studies suggest that applying a higher force requires patients to wear it less than what would be required with lower forces to achieve similar outcomes.[14] In addition, a further important unanswered question is whether a dose-effect relationship exists between headgear wear and treatment outcome, and if so, if this relationship is linear or follows another more complex trajectory.

To delve deeper into the question of compliance and treatment outcome, the aim of the present study was (i) to use three-dimensional analytical tools to deepen our understanding of what happens to the maxillary teeth during headgear treatment and (ii) to evaluate the effect of compliance, evaluated objectively with a temperature- and force-sensitive module, on treatment outcomes on the maxillary dentition following headgear therapy in growing children with Class II malocclusion over a nine-month period.

2 | MATERIALS AND METHODS

2.1 | Trial design

The consolidated standards of reporting trials (CONSORT) guidelines were adhered to as best as possible in the reporting of the current clinical trial. The design of the trial was a parallel-group prospective randomized controlled trial with a 1:1 allocation ratio. Ethical approval was obtained from the regional ethics committee (CER 12-250), and no changes to the design of the trial were made after commencing the trial.

2.2 | Participants

Recruitment of all trial participants took place in the division of orthodontics of the University Clinics of Dental Medicine, University of Geneva, Switzerland, from March to December 2016. Eligibility was based on the following inclusion criteria: subjects 8-12 years of age; healthy periodontium; late mixed dentition; Class II malocclusion with molars in at least a half-cusp Class II relationship on both sides; an overjet of ≥6 mm; a positive overbite of ≥1 mm; an ANB angle of ≥4 degrees; Wits appraisal of ≥2 mm; and a mandibular plane angle of ≤32 degrees. Exclusion criteria were as follows: previous orthodontic treatment; tooth agenesis; eruption of second permanent molars; a unilateral or bilateral posterior crossbite; medically compromised patients or craniofacial anomalies, including cleft lip and/or palate; the use of regular systemic medication; antibiotic therapy within the last 6 months; use of anti-inflammatory medication in the month preceding the study; and a compromised periodontium or radiographic evidence of bone loss.

A total of 40 patients were selected and then randomly assigned to either the experimental or control group, using block randomization (two blocks of 6 and 2 blocks of 4, with a random sequence). Randomization was carried out using freely available online software (randomization.com) by someone not directly involved in patient care. An opaque sealed envelope with the assigned group allocation was given to the treating orthodontist following recruitment of each eligible patient. Blinding during treatment for the caregivers and participants was not possible;

however, all evaluations and statistical analyses were performed fully blinded. Informed consent was obtained from both the subjects and their parent or legal guardian prior to commencing the trial.

2.3 | Interventions

Interventions involved two parallel groups: a cervical headgear treatment group and a no treatment (control) group, respectively. Subjects in the headgear group had bands placed on the maxillary first permanent molars along with the cervical headgear, and force levels were consistently adjusted to 250-300 cN. Subjects were instructed to wear the headgear for 12 hours per day, for a period of 9 months, and patients and parents received the same set of instructions regarding use. The headgear was equipped with an electronic temperature- and force-sensitive module (Smartgear, Swissorthodontics AG, Cham, Switzerland) set to record data every 15 minutes. The triggering range of the force measured by the sensor was 100-500 cN. All subjects were informed that their collaboration was being recorded, as previous research has suggested that this improves compliance. During the nine-month study period, subjects in the treatment group were seen monthly, during which time headgear adjustments were carried out along with a recalibration of the applied force where necessary, and written reminders on oral hygiene and the use of headgear were provided. One orthodontist carried out all treatments and follow-up visits.

The control group received no treatment during the study period, and commenced treatment subsequent to the 9-month study period. This was ethically feasible since according to previous randomized clinical trials, the time point at which Class II treatment is started does not influence the efficiency of the treatment.[17,18]

At the end of the nine-month treatment period, recorded values were exported from the electronic module into an Excel spreadsheet. Headgear usage was defined when a force reading of more than zero and a temperature close to the human body temperature range of 35°C-37°C was registered. Two investigators independently examined the software outcomes with regard to compliance, in order to identify possible erroneous values, and full agreement was reached.

2.4 | Outcomes

No changes to trial outcomes were necessary after trial commencement. Compliance in the treatment group was calculated as a percentage of the recommended 12 hours per day, with 100% representing full compliance (12 hours of wear per day).

Tooth movement was measured on digital .stl scans (Trios 3, 3Shape, Copenaghen, Denmark) of plaster casts of the maxillary jaw, both in the treatment and control groups, taken at T0 (before treatment or follow-up) and at T1 (after 9 months of treatment or follow-up). The digital images were superimposed with a dedicated software (Viewbox, dHAL Software, Kifissia, Greece) on a stable area including the palatal rugae area and the middle posterior part of the palatal raphe[19] (Figure 2).

Based on the method of Huanca Ghislanzoni et al.,[20] the following measurements were recorded on the T0 and T1 scanned plaster casts:

- first molar distalisation (mm): pure sagittal distal displacement along the occlusal plane;
- first molar rotation (°): positive numbers representing distal rotation;
- first molar tip (°): positive values representing mesial inclination of the crown;
- first molar torque (°): positive values representing vestibular molar crown movement;
- arch depth (mm): the perpendicular distance between a line connecting the upper first molars and the contact point between the two central incisors;
- interpremolar distance (mm): the distance between the maxillary second premolars (or the first premolar if the second premolars nor already present) from the vestibular cusp of one premolar to the contralateral premolar;
- intermolar distance (mm): the distance between the first permanent maxillary molars from the mesiovestibular cusp of one molar to the contralateral molar.

2.5 | Statistical methods

Sample size was calculated to detect a clinically significant amount of molar distalisation of 1 mm, with a standard deviation of 1 mm, an alpha level of .05 and a power of 90%, based on a one-sided test since it was assumed that the control group would have no molar movement. One millimiter of distal molar movement with the use of headgear has been found in a Cochrane meta-analysis.[7] This resulted in a required sample of 18 patients per group, and thus 20 patients per group were included to account for any potential dropouts. Statistical analyses were performed using Statplus (AnalystSoft Inc., Walnut, California, USA). Mixed-effect linear regression models with a random effect on the subject of the treatment group and a nested random effect within the treatment group were used to determine differences in dental outcomes between the treatment and control groups. Associations between compliance and dental movements in the treatment group were assessed using correlation coefficients. Dental casts for 25 subjects were digitized twice and measurements on the digital dental casts were performed a second time within a one-month interval, and systematic error was assessed using paired-sample *t* tests, while random method error was calculated using the method of moments estimator.[21]

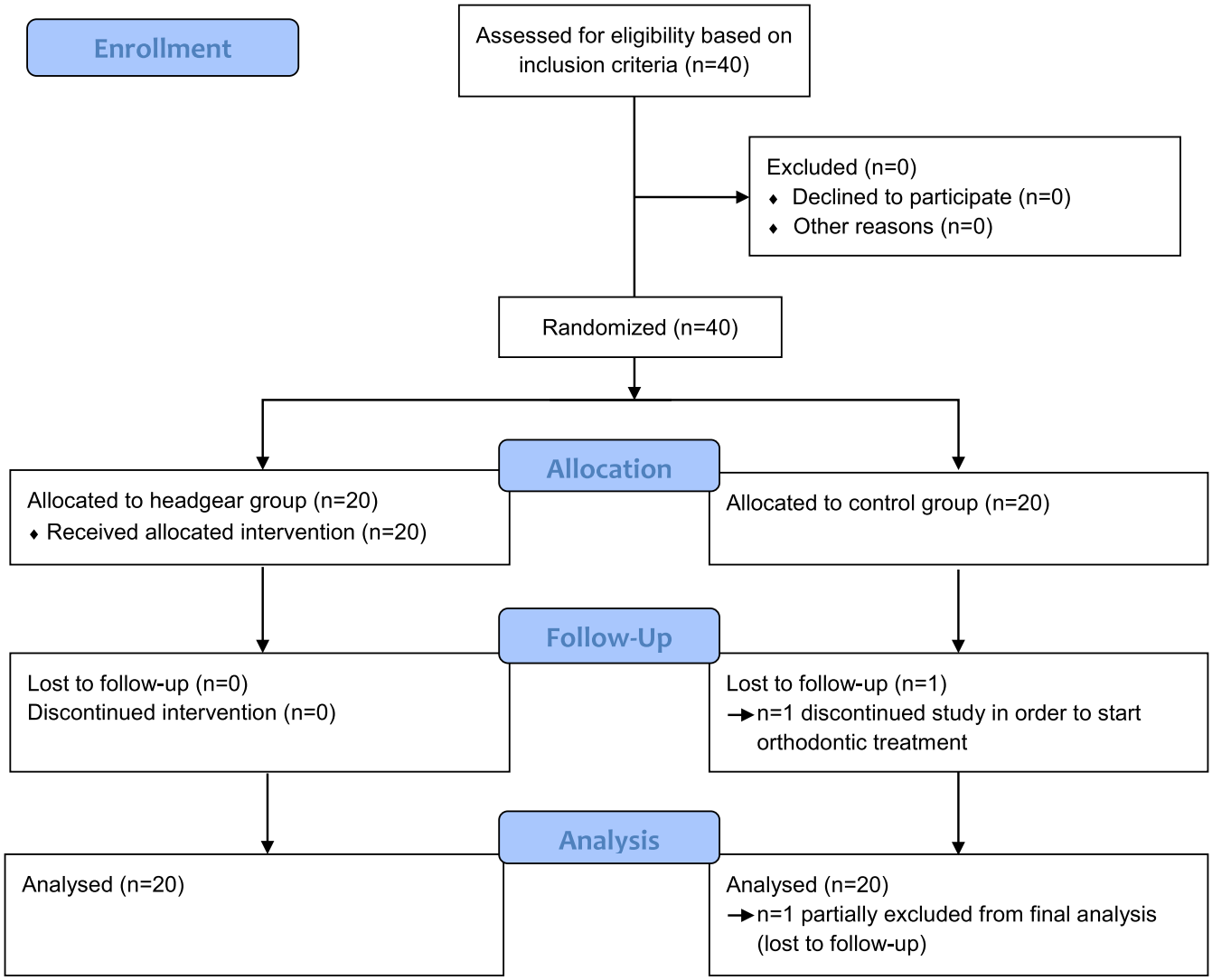

FIGURE 1 Flow diagram representing participant recruitment and flow.

3 | RESULTS

3.1 | Participant flow and recruitment

Forty patients were randomly assigned to the experimental (treatment) or control group (Figure 1). The experimental group consisted of 11 girls and 9 boys, with a mean age of 10.2+/−1.3 years. The control group was comprised of 13 girls and 7 boys, with a mean age of 9.4+/−1.2 years. Using a Chi-squared test and an independent sample *t* test, respectively, differences in sex distribution or age between the groups were not statistically significant. Baseline dental and cephalometric characteristics of the two groups were not statistically significant between the two groups. No adverse events were reported. There were no dropouts in the experimental group, but one participant in the control group dropped out before the nine-month study period had ended, as they wished to start orthodontic treatment earlier.

3.2 | Compliance

Overall, the average rate of compliance was 55% across the 9-month study period, suggesting usage for only an approximate 6.6 hours of the recommended 12 hours per day.

3.3 | Dental outcomes

The error of the method assessment revealed the absence of any significant systematic error, and random error was found to not exceed 0.5 mm for linear measurements and 2.8° for angular measurements.

The maxillary first permanent molars of the subjects in the headgear treatment group showed an average distalisation of 1.2 mm (95% CI: −0.8 mm; 1.5 mm), while control subjects showed minor mesialisation of 0.2 mm (95% CI: −0.2 mm; 0.6 mm), with a statistically significant difference of 1.4 mm (95% CI: −1.9 mm; 0.8 mm;

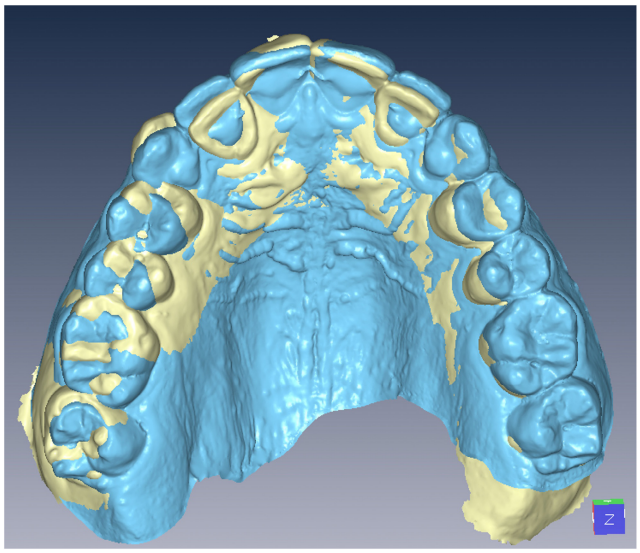

FIGURE 2 Superimposition of digital dental casts on the palatal rugae area showing before (yellow) and after (blue) moderate distalisation.

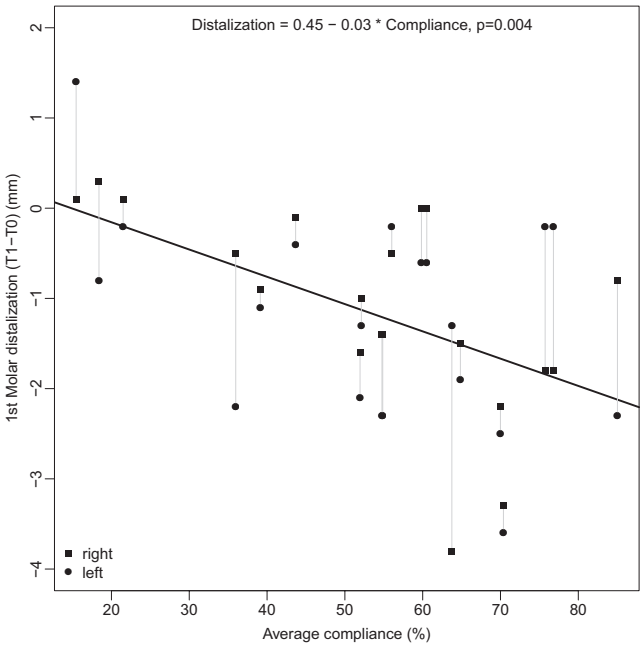

FIGURE 3 Correlation between compliance and first molar distalisation in the treatment group. Black squares represent the right side, while black circles represent the left side.

$P < .001$) (Table 1). A similar statistically significant difference in arch depth was also found, with an increase in depth of 1.3 mm (95% CI: 0.8 mm; 1.9 mm) in the treatment group and only 0.1 mm (95% CI: −0.4 mm; 0.7 mm) in the control group ($P = .005$) (Table 1).

In contrast, there were no significant differences in the rotation or torque of the maxillary first permanent molars between the treatment and control groups (Table 1). Distal tipping of the maxillary first permanent molar of 3.4° (95% CI: 4.6° dissal tipping; 2.2° mesial tipping) was observed in the treatment group, while in the control group 0.6° (95% CI: −0.7° distal tipping; 1.8° mesial tipping) of mesial tipping were observed; a statistically significant difference in crown inclination of 4.0° was thus found ($P < .001$) (Table 1). Interpremolar distance was also significantly different between groups, with first and second premolars showing widening of +1.9 mm (95% CI: 1.4 mm; 2.5 mm) and + 1.4 mm (95% CI: 1.0 mm; 1.8 mm) respectively in the treatment group versus +0.4 (95% CI: −0.2 mm; 1.0 mm) and + 0.3 mm (95% CI: −0.1 mm; 0.7 mm) respectively in the control group ($P < .001$ and $P = .001$ respectively) (Table 1). Meanwhile, no significant differences in intermolar distance were observed between the treatment and control groups (Table 1).

3.4 | Correlations

Analysis of the effect of compliance on the measured dental outcomes revealed that only distalisation of the maxillary first permanent molars was significantly correlated with compliance (Figure 3), suggesting that more intensive use resulted in more effective distalisation of these molars. Compliance was not significantly correlated with any other dental variables measured.

4 | DISCUSSION

The dental and skeletal effects of headgear therapy have been previously investigated, and meta-analysis results provided results with regard to linear changes.[4–6] One of the purposes of the present study was to use three-dimensional analytical tools[20,22] to deepen our understanding of what happens to the maxillary teeth during headgear treatment. An average molar distalisation of 1.2 mm (95% CI: −0.8 mm; 1.5 mm), coupled with an average arch depth increase of 1.3 mm (95% CI: 0.8 mm; 1.9 mm) following headgear treatment was observed. Even though the clinical significance of maxillary molar distal movements of only 1 mm or so remains questionable, similar results have been found in a recent meta-analysis.[7]

Interestingly, another important effect of headgear therapy found in the present study was what is sometimes referred to as the "lip bumper" effect,[23] which was reflected by a significant increase in the maxillary interpremolar distance (+1.9 mm and + 1.4 mm for the first and second premolars, respectively). These results are similar to those reported for the interpremolar distances in the mandibular arch (range: 2-4 mm) when a lip bumper is used.[23] Numerous studies have found similar results with both a wider and longer maxillary dental arch being measured following headgear use.[15,24–27] While the headgear applies a distally-directed force to the maxillary molars, the lateral arms of the bow keep the cheeks from resting on the posterior teeth and thus disrupt the soft tissue equilibrium of forces, making the effects of the intraoral design of the headgear inner bow very similar to that of the lip bumper. This increase in the transverse dimension along with distalisation helps create space in the upper arch, which can also result in an improvement of moderate crowding in the maxillary arch.[15]

TABLE 1 Differences in clinical variables between the treatment group and control group.

Variable	Treatment group (n = 20); mean (+/− SD)	Controls (n = 19); mean (+/− SD)	Mean difference (95% CI)	*P* value
First molar distalisation (mm)	−1.2 (+/− 1.0)	0.2 (+/− 0.5)	−1.4 (−1.9 to −0.8)	<.001[a]
First molar rotation (°)	1.3 (+/− 2.3)	0.5 (+/− 2.0)	0.8 (−0.4 to 2.1)	.176[a]
First molar tip (°)	−3.4 (+/− 3.6)	0.6 (+/− 2.3)	−4.0 (−5.7 to −2.2)	<.001[a]
First molar torque (°)	1.4 (+/− 2.7)	2.0 (+/− 3.2)	−0.6 (−2.1 to 1.0)	.464[a]
Arch depth (mm)	1.3 (+/− 1.5)	0.1 (+/− 0.8)	1.2 (0.4 to 2.0)	.005[b]
Interpremolar distance (4-4)[c]	1.9 (+/− 1.4)	0.4 (+/− 0.7)	1.5 (0.7 to 2.3)	<.001[b]
Interpremolar distance (5-5)[d]	1.4 (+/− 1.1)	0.3 (+/− 0.5)	1.1 (0.6 to 1.7)	.001[b]
Intermolar distance (6-6)	0.7 (+/− 1.7)	0.2 (+/− 0.5)	0.5 (−0.3 to 1.3)	.244[b]

Note: Values represent the mean difference and standard deviations (SD) for each group individually between T1 (9 months after the start of treatment) and T0 (start of treatment), and the mean and 95% confidence intervals (CI) for the differences between the two groups.

[a]Based on a mixed-effect linear regression model with a random effect on the subject of the treatment group and a side nested random effect within the treatment group.

[b]Based on a mixed-effect linear regression model with a random effect on the treatment group.

[c]Data missing for two subjects in the treatment group and four in the control group.

[d]Data missing for four subjects in the treatment group.

Distal movement of the molars in the treatment group in this study was not correlated with any significant distal rotation or torque changes. This might be due to the compensation bends that were progressively applied to the inner bow of the headgear inserted into the tubes on the molar band, where a distal rotation and palatal tip counteracted with compensating bends. Meanwhile, mesio-distal inclination of the molars changed significantly (distal tipping) by 4.0° compared to the control group. It is important to note that linear distalisation is likely also due in part to distal tipping of the crown, rather than a pure bodily movement, possibly causing unreliable results in the long term, as shown by Melsen et al.[28] The distal tipping of the crown is also related to the nature of the force that is applied below the centre of resistance.

Focusing more on the second aim of the present study, which was the effects of compliance on these clinical treatment outcomes, allows one to better understand an area where little is yet known. Focusing firstly on the extreme values in the present sample, allows a trend to emerge. In the least compliance subject (rate of compliance: 15%), a molar mesialisation of 1.3 mm was observed on the left molar, while the subject with the greatest amount of molar distsalisation, namely 3.9 mm seen on the right molar, showed very good relative compliance (65% compliance). After verifying the absence of significant differences between the right and left molars in the whole sample, both molars were combined, resulting in average values per patient. The greatest average molar distalisation (of 3.5 mm) was observed following 70% compliance. Having said that however, there were exceptions to this trend, with one subject with a compliance rate of 60% achieving close to zero molar distalisation. This brings to light the understanding that treatment outcome is dependent on many factors and not solely on compliance.

In a previous study, patient collaboration was quantitatively examined,[8] highlighting the current problems with collaboration. Overall, in the present study, compliance had a significantly positive effect on first permanent maxillary molars distalisation, which is often the primary objective of headgear therapy. An increase in headgear usage results in greater distalisation, the more the wear approaches the recommended 12 hours of daily use. A correlation between compliance and clinical outcome therefore exists, supporting the notion that the more the headgear appliance is used, the better the outcome, at least in terms of distalisation. However, as can be seen in the present sample, the prescribed 12 hours of daily use is not necessarily required to achieve molar maxillary distalisation and improvement of the Class II malocclusion. Whether a minimum threshold exists is not known, but this is probably very patient dependent.

Generalisability of the present results may be considered good given the design of the trial. Certain limitations were however present. The trial was not registered in a publicly available database which may give rise to bias, however when the trial was carried out, this was done much less commonly than if the trial had been carried out today. What may preclude from a very broad generalisability of the present results is potential cultural differences with regard to compliance where children in some cultures may have the tendency to be more compliance with instructions given by the orthodontist. In addition, inherent characteristics of patients that may potentially influence tooth movement, such as bone density[29,30] and masticatory muscle characteristics[31–33] are not considered in the analysis. Furthermore, even though age was not significantly different between the treatment and control groups, the treatment group was on average 8 months older which could have potentially had some influence on the results when considering the growth

spurt. It is also important to note that the present study focused on the effect of extraoral traction on the maxillary arch only, which may result in an underestimation of the overall effect of the sagittal molar correction that also depends on the contribution of mandibular growth. Lastly, the present trial was a short-term study, and it would be interesting to evaluate long-term results, and consider the burden of care relative to the final orthodontic outcome. Due to the loss of patients following the 9-month study period, however, this did not permit longer-term follow-up of patients until the end of their comprehensive orthodontic treatment.

The systematic use of headgear in children with Class II malocclusion in present-day adolescents is perhaps overly ambitious, and this highlights the need for alternative treatment options in patients where collaboration may be questionable. Alternative tools, whether requiring compliance with elastics (e.g. Carriere motion appliance)[34,35] or those that require no compliance (e.g. skeletally-anchored distaliser),[36–38] may therefore be more appropriate for first molar distalisation in some patients. One must keep in mind, however, that systems that rely on intramaxillary or intermaxillary tooth anchorage in order to distalise maxillary molars also have inherent side effects such as loss of intermaxillary anchorage or mesialization of the lower dentition and lower incisor proclination. At present, headgear can be said to remain the gold standard, presenting no intermaxillary or intramaxillary side-effects, requiring no invasive surgical procedure such as the placement of skeletal anchorage, and remaining widely used.[1–3]

5 | CONCLUSIONS

Headgear therapy had significant positive effects on molar distalisation and arch depth when compared to untreated control subjects. A significant transverse dental arch development effect in the middle of the dental arch was also observed as measured by the interpremolar distance (first and second premolars). Meanwhile, the average rate of compliance was only 55% of the recommended 12 hours of daily use, with compliance having a significant positive effect on molar distalisation. Patients with better compliance who used their headgear for a greater number of hours per day observed the greatest amount of molar distalisation. These findings confirm the importance of compliance during headgear use, and raise questions over the widespread suitability of this appliance in Class II correction in patients with suboptimal motivation.

AUTHOR CONTRIBUTIONS

LH: Conception and design of the study, Data collection and analysis, Interpretation of the results, Writing the manuscript. SK: Review and editing of the manuscript, critical input in study design, analysis, and manuscript preparation. GA: Data collection and analysis, Review and editing of the manuscript, Overall responsibility for the research.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared upon reasonable request to the corresponding author.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Informed consent was obtained from both the subjects and their parent or legal guardian prior to commencing the trial.

CONSENT FOR PUBLICATION

Not applicable.

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