

Adherence to instructions and fluctuation of force magnitude in cervical headgear therapy

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ABSTRACT

Objectives: To investigate how patients adhere to instructions and how force magnitude fluctuates and influences the use of cervical headgear (CHG) therapy.

Materials and Methods: In this controlled clinical trial, subjects (n = 40) were treated with CHG with light (L, 300 g) or heavy (H, 500 g) force. Patients were asked to wear CHG for 10 hours per day for 10 months (ie, during sleep), but the importance for treatment of wearing CHG also in the evening hours was emphasized. Adherence to instructions and force magnitude in CHG use were monitored by electronic module (Smartgear, Swissorthodontics, Switzerland).

Results: Force magnitude can be set at a certain level, L or H, even if great individual variability is seen in all subjects (0–900 g). Children in the L group used CHG longer per day than those in the H group (9.3 hours \pm 1.5 hours and 7.8 hours \pm 2.1 hours, respectively, $P = .002$). During evening hours, CHG was used more ($P = .02$) in the L group than in the H group. In both groups, CHG was used less in the evening hours during school breaks than in the evening hours during school ($P < .001$).

Conclusions: Children with lower force in CHG seem to adhere better to the instructions for CHG use. Daily rhythm also influences the time of appliance use regardless of force magnitude. The force can be set to a certain magnitude level, even though there is substantial individual variability. (*Angle Orthod.* 2019;89:268–274.)

KEY WORDS: Cervical headgear; Adherence; Force magnitude

INTRODUCTION

Headgear (HG) remains one of the most commonly used orthodontic appliances in publicly and privately funded oral health care services.^{1,2} Recent systematic reviews indicated that HG is a viable and effective appliance in patients with Class II, Division 1 malocclusion with maxillary prognathism.^{3,4} The selected and recommended (activated) force in cervical headgear (CHG) varies greatly, from 200 to 1000 g,^{5–9} but very little to no information is available on the stability of force during CHG use. Force magnitude of less than 450 g has been considered to produce orthodontic impact, while greater than 450 g results in an orthopedic effect.^{10–12} Also, the recommended use time of the HG varied considerably, from 8 to 16 hours/day+night^{5,8,9,13,14} to even to full-time use.¹⁵

As with all removable appliances, CHG is active only when in use. Therefore, patient compliance is a decisive factor and may be also the weakest link to a successful treatment outcome.^{16,17} Usually, adherence to instructions is evaluated only subjectively during follow-up visits,¹⁶ while keeping in mind that patients tend to overrate the use of a removable appliance.^{16,18–20} Lack of

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cooperation by patients was found to be one of the most important reasons why CHG is not favored by some orthodontists.² Without an objective means to ascertain CHG use, it is not possible to verify adherence to instructions in CHG therapy. The development of small microelectronic devices (Smartgear, Swissorthodontics, Switzerland) offers the possibility of objectively evaluating both force magnitude and adherence to instructions during HG therapy. No previous studies have examined the influence of force magnitude on adherence or its fluctuation during use.

The aim of this controlled clinical trial on CHG therapy was to study how patients adhere to instructions on CHG use and how force magnitude fluctuates and possibly influences compliance.

MATERIALS AND METHODS

Subjects in the present study were recruited from a pool of children eligible for treatment at the Health Care Center of Turku, in Turku, Finland. The subjects were deemed potential research subjects during screening if they met the following clinical criteria:

- Class II (or end-to-end) molar relationship
- Mixed dentition stage
- Moderate dental crowding

A complete orthodontic examination was performed, including radiologic examination (panoramic and lateral radiographs), dental and facial photography, and impressions for study models. The treatment plan was designed by an experienced orthodontist (Dr Karsila), and if the treatment method included CHG as the only initial orthodontic device, the subject was invited to participate. Patients and parents signed an informed consent. The Ethical Committee of the Hospital District Southwest Finland approved the research plan (ETMK 77/180/2011).

The CHG was made for each patient by a dental student as part of their clinical orthodontic instruction at the Institute of Dentistry, University of Turku. All patients were supervised closely during all phases by an experienced orthodontist (Dr Karsila) and a post-graduate orthodontic student (Dr Varho). The inner bow of the CHG was expanded (3–4 mm) and the long outer bow bent 10–20° upward in relation to the inner bow. The children were allocated into two groups of equal size, a (L) and heavy (H) group, and force magnitude was set to 300 g and 500 g, respectively. The force magnitude was set while the patient was sitting and looking straight ahead. Patients were advised to wear the HG for 10 hours (ie, during sleep), but the importance for treatment of wearing HG also in the early evening hours was emphasized. Patients were seen every 6–8 weeks until the end of the study

at 10 months, and the force and use of the HG were controlled and readjusted during visits. During the study, children and their parents did not know which group, L or H, they belonged to, but they knew they were participating in a trial. Initially, 44 children were recruited, but two left in the middle of the study, one moved out of the city, and one dropped out because of aplasia in the lower permanent premolars first noticed after the treatment was initiated. Thus, the present study was based on 40 children, 22 in the L group and 18 in the H group (15 boys and 25 girls). The first 6–8 weeks were an adjustment period with 300-g force in both groups and thus left out of the study. During this period, the patients were instructed gradually to learn to place the HG and sleep with it. Therefore, this period was omitted from the results. The total number of days monitored was 11,344.

Adherence to instructions in HG use was monitored via a Smartgear (Swissorthodontics) module integrated into the HG's neck strap on the right. The module measured force and temperature once a minute, calculated average temperature, and delivered force every 15 minutes. The temperature and force measurement accuracy were 1°C and 10 g, respectively. Also, the time at which CHG was inserted/removed and the date were registered. The information was read by Smartgear Compliance Control System version 2.1.2 (Swissorthodontics) and converted into table format (Excel, Windows 7, Microsoft, Redmond, Wash), and the use of CHG was analyzed. A day was set to start at 3:00 PM and end at 2:45 PM the following day (eg, Sunday was a day that started on Sunday at 3:00 PM and ended on Monday at 2:45 PM).

Wear time of the HG was studied for the entire treatment period as well as separately during school terms and school breaks (Christmas and summer). The distinction between "in use" and "not in use" was deduced using both HG force and temperature measurements. The HG was considered "in use" when the force was more than zero. In some cases/instances, it was difficult to decide whether the HG had been in use or not; for example, the temperature might have been higher than normal room temperature but with zero force. The final decision as to whether the HG was in use or not was made by the researcher (Dr Talvitie). For 10 randomly selected children, the data were reevaluated by the same researcher, and only 0.29% of the whole study period measurement points were classified differently (not in use vs in use). Therefore, the evaluation method was considered reliable.

Statistical Analysis

The average daily wear time in hours and the percentage of days the CHG was not in use during

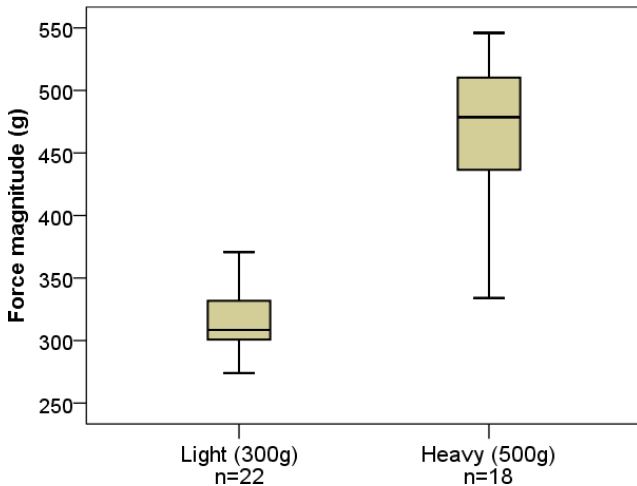


Figure 1. Acting force magnitude can be influenced by adjusting force level in CHG therapy, but even when the force is set at 300 g or 500 g, the delivered force can be much less or much more individually ($P < .001$).

the whole study period were calculated for each subject ($N = 40$). Mann-Whitney test was used for comparisons between groups (low vs high, boys vs girls) and Wilcoxon signed rank test for comparisons within groups (whole period vs school term vs school break). P values of less than .05 were interpreted as statistically significant.

RESULTS

At the initiation of treatment, the mean age of the patients was 9.7 (SD ± 0.73 years) and 9.9 years (SD ± 0.74 years) in the L and H groups, respectively.

Mean force magnitude was calculated for all subjects, and all instances of substantial variability in force magnitude were recorded (range 0–900 g) during use. Mean force in the L and H groups was 317 g (SD ± 27 g) and 462 g (SD ± 66 g), respectively, which was a statistically significant difference ($P < .001$, Mann-Whitney test; Figure 1). Some fluctuation in force magnitude was seen at all times during CHG wear (Figure 2).

Over the study period, HG was not used in 8.5% (SD $\pm 9.9\%$) and 17.0% (SD $\pm 19.5\%$) of the nights in L and

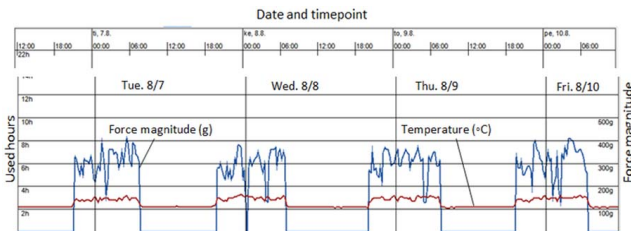


Figure 2. Fluctuation in force magnitude (blue line) and change in temperature (red line) are seen during CHG use over a 4-day period in one person in the L group.

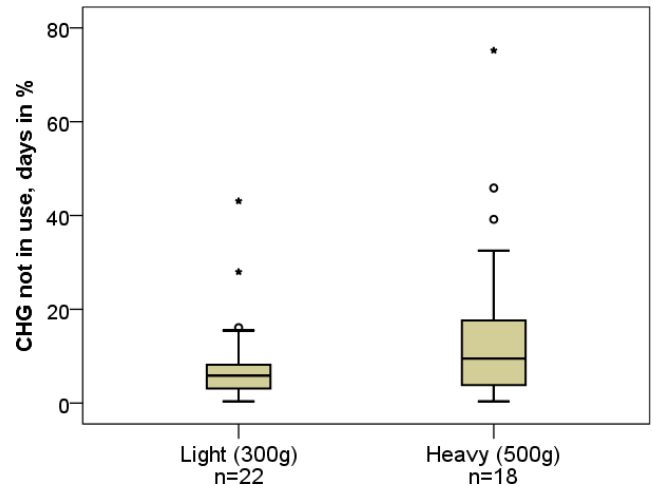


Figure 3. In most cases, CHG use in both groups was more than 80% of the nights. No difference was found between the groups ($P = .083$).

H groups, respectively, which was not a statistically significant difference ($P = .083$, Mann-Whitney test; Figure 3). No difference ($P = .192$, Mann-Whitney test) in wear time was found between boys and girls during the whole study period.

During the whole study period, HG was used on average for 9.3 hours (SD ± 1.5 hours) and 7.7 hours (SD ± 2.1 hours) per day in L and H groups, respectively ($P = .002$, Mann-Whitney test; Figure 4; Table 1). During school terms, CHG was used for 9.3 hours (SD ± 1.3 hours) and 7.8 hours (SD ± 2.0 hours) per day in the L and H groups, respectively ($P = .001$, Mann-Whitney test), and during school breaks, CHG was used for 9.3 hours (SD ± 2.1 hours) and 7.7 hours (SD ± 2.4 hours) per day, respectively ($P = 0.009$, Mann-Whitney test; Figure 5). Also, during evening

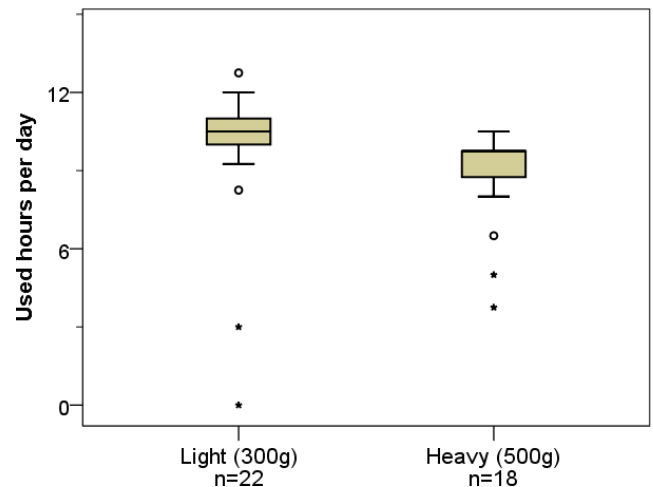


Figure 4. Median time CHG was used for 10.0 hours a day with light force (300 g) and with heavy force (500 g) for 8.3 hours a day ($P = .002$).

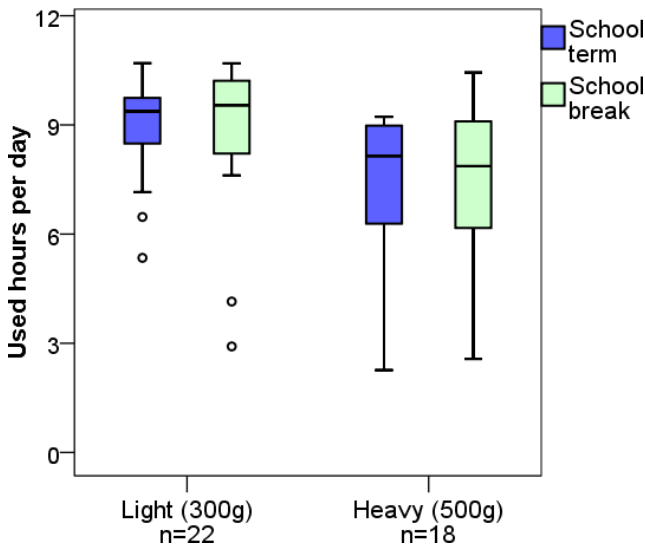


Figure 5. With light force, CHG was used for more hours during school terms and breaks; $P = .001$, $P = .009$, respectively.

hours (8:00 PM–12:00 PM), the appliance was used more in the L group both during school breaks ($P = .037$) and during school terms ($P = .011$; Figure 6). Subjects with the lower force in the L group adhered to the instructions better than those in the H group. Wear time in the L group was about 1 hour less than the advised 10 hours, while in the H group, it was more than 2 hours less.

DISCUSSION

All patients in the present study were treated at the university teaching clinic, where patients are closely supervised in HG use by an experienced orthodontist. Therefore, the findings cannot be directly extrapolated to ordinary orthodontic practice. In Finland, orthodontic care is offered to patients if their malocclusion fulfills certain predetermined criteria. Treatment is free of charge for children, which translates to equal opportunities for all children irrespective of a family's socioeconomic status.

Only a few previous studies have looked at CHG force magnitude and its stability. No previous studies have been conducted for as extended a treatment period as the one presented here. This controlled clinical trial showed that acting force magnitude can be influenced by adjusting the force level in the CHG, but even when the force is set at 300 g or 500 g, the delivered force can be much less or much more individually. Based on previous studies, force magnitudes of 300 g and 500 g were chosen to produce orthodontic and orthopedic impacts, respectively.^{10–12} In the H group, the force level was significantly higher than in the L group despite substantial variability in

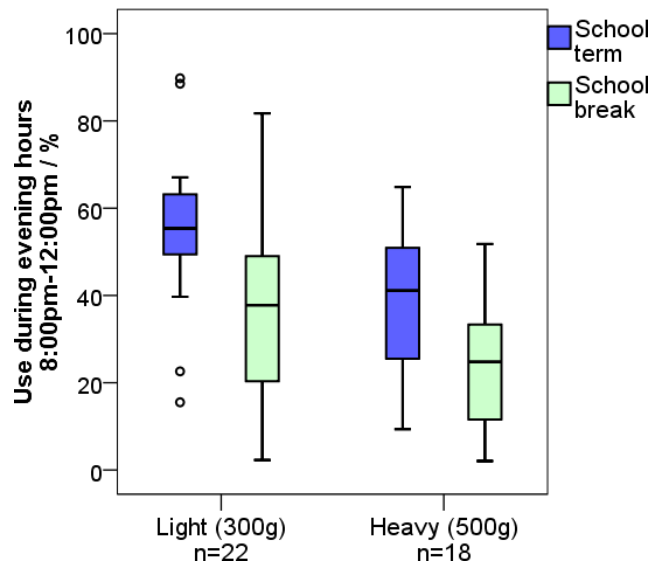


Figure 6. With light force, use during evening hours was better than with heavy force during school terms and breaks (8:00 PM–12:00 PM; $P = .000$, $P = .000$, respectively), but adherence in both groups was better during school terms ($P = .037$, $P = .011$, respectively).

force magnitude in both groups during HG use. In previous studies, fluctuation of HG force has been thought to be related to changes in head position during sleep.^{21,22} The current findings were in line with these studies, and positional changes were the probable reason for the force fluctuation. Range of force also confirms that CHG is actually used; if no fluctuation is seen and force magnitude is stable during supposed wear time, the patient is trying to cheat in CHG wear and has somehow activated only the appliance.²²

The present findings were in line with those of Witt et al.²³ in that force magnitude may influence adherence and compliance. Higher force magnitude in the appliance probably caused more pressure on the neck and was more inconvenient. Probably for this reason, children in the H group inserted the CHG just before going to sleep but earlier in the L group, which meant shorter wear time in the H group. According to Lyons and Ramsay,²² a downward tilt of the head lowered HG force magnitude. Furthermore, Pirilä-Parkkinen et al.²⁴ suggested that children in CHG therapy tended to avoid heavy pressure on the neck and alter their head posture to a more comfortable position. Based on the previous studies and the present findings, it can be assumed that with H force, it is more difficult to find a comfortable head position during sleep. This may mean that children had to seek a better head position more frequently, which would explain the greater individual variability seen in the H group compared with the L group.

Table 1. Mean Magnitude of Force in CHG in High and Light Force Groups, Mean Total Wear Time, and During School Times and Breaks^a

	Light Force (L)							
	n Valid	Mean	SD	Minimum	Maximum	Percentiles		
						25	Median	75
Mean force, if CHG was used (g), N = 40	22	317	27	274	371	300	309	335
Whole treatment period								
CHG used in a day (h)	22	9.30	1.52	4.80	11.04	8.75	9.98	10.23
Use during evening hours 8:00 PM–12:00 PM (%)	22	49.0	18.1	11.3	87.2	38.2	49.6	58.6
Not in use of monitored days (%)	22	8.5	9.9	0.4	43.1	2.9	5.9	8.4
School terms								
CHG used in a day (h)	22	9.31	1.33	5.56	11.12	8.76	9.75	10.13
Use during evening hours 8:00 PM–12:00 PM (%)	22	54.6	17.3	15.5	89.8	47.5	55.4	63.7
Not in use of monitored days (%)	22	7.3	7.9	0.0	32.8	1.9	5.0	8.2
School breaks								
CHG was used in a day (h)	22	9.30	2.06	3.03	11.11	4.95	9.92	10.64
Use during evening hours 8:00 PM–12:00 PM (%)	22	37.1	20.8	2.3	81.7	20.1	37.8	49.8
Not in use of monitored days (%)	22	11.1	15.4	0.0	65.3	4.2	6.4	10.9
School terms vs school breaks								
CHG used in a day, <i>P</i> value					NS			
CHG use during evening hours 8:00 PM–12:00 PM, <i>P</i> value					****			
CHG not in use of monitored days, <i>P</i> value					NS			

^a CHG indicates cervical headgear.

* *P* = .05; ** *P* = .01; *** *P* = .001; **** *P* = .0001.

The patients in question here were at a cooperative age, in prepuberty, for the use of an extraoral appliance,^{16,25} which probably influenced the good compliance found in this study. Patients and their parents were also aware that they were participating in a study in which use of CHG was monitored, but patients and parents did not know which force magnitude was being used. This kind of study design subjects not only the participants but also the orthodontists to the Hawthorne effect, which is defined as a behavioral change in a patient and therapist when they are aware they are participating in a trial.²⁶ Previous studies confirmed that adherence to instructions was better if patients were aware they were being monitored.^{27–29} Of particular interest is the study by Sandler et al.,³⁰ who concluded that “headgear patients surprised the clinicians with the speed and efficacy,” which the authors considered a sign of the Hawthorne effect. A recent systematic review on the Hawthorne effect in randomized controlled trials in orthodontics concluded that in only 10 of 290 studies was the effect considered and discussed despite its evident role in causing overly optimistic results or even false-positive interpretations.³¹ In the present study, the treating orthodontists and students may also have been more and highly motivated to encourage the children in their HG use than in a busy, “ordinary” orthodontic office. On the other hand, observed influences of the Hawthorne effect have been reported to be short term and to disappear in 6 months.³²

Most children used CHG on more than 80% of the nights, which can be considered to be regular during the study period. The device was left totally out somewhat more often during school breaks in both groups, with no discernible difference between the groups. Even if summer break took place 6 months after the initiation of the study period, CHG use could still be considered regular. It is known that monitoring improves compliance in poorly cooperative patients; if adherence is good, no difference is seen.²⁸ Children in both groups were cooperative, and the disappearance of the possible Hawthorne effect in 6 months was not verified in this study.

This trial also revealed diurnal variability in extraoral traction use. Even if the importance for treatment of wearing CHG also in the early evening hours was emphasized, the average use during 8:00 PM to 12:00 PM was less than 50% of the time in both groups. The adherence was better in the L than in the H group during both school terms and school breaks. During school terms, life is more regulated; children usually go to bed earlier and wake up for school approximately at the same time, whereas during vacations, they can stay up later and sleep longer in the mornings. The use of CHG followed the hours a patient was sleeping. During school breaks, the hours the device was used per day were almost the same as during school terms, but the CHG was used significantly less during evening hours in both groups.

Table 1. Extended

n Valid	Heavy Force (H)							L vs H, <i>P</i> Value
	Mean	SD	Minimum	Maximum	Percentiles			
					25	Median	75	
18	462	66	334	546	423	479	511	**
18	7.76	2.08	2.64	10.08	6.25	8.33	9.44	**
18	34.7	16.1	7.0	59.9	22.6	36.3	46.3	*
18	17.0	19.5	0.3	75.2	3.8	9.5	21.3	NS
18	7.76	2.01	2.35	9.59	6.46	8.47	9.46	***
18	39.8	17.1	9.3	64.8	25.1	41.1	52.3	**
18	16.2	19.3	0.5	77.0	3.9	8.5	22.7	NS
18	7.72	2.42	2.67	10.86	6.33	8.18	9.54	**
18	24.3	14.4	2.0	51.8	10.9	24.8	34.3	*
18	18.9	21.8	0.0	73.4	4.0	13.8	24.2	NS
			NS					

			NS					

In the future, ongoing investigation will focus on the possible effect of different force magnitude on HG on skeletal and dental treatment outcomes.

CONCLUSIONS

- The level of force magnitude in CHG therapy can be adjusted. Children seem to adhere better to instructions at lower force magnitude in CHG therapy. The use of the appliance follows diurnal rhythms during school terms and school breaks.

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