Objective evaluation of compliance after orthodontic treatment using Hawley or vacuum-formed retainers: A 2-center randomized controlled trial over a 3-month period

Georgia Vagdouti,[a] Effimia Karvouni,[b] Elias Bitsanis,[a] and Despina Koletsi[a,c]
Athens and Volos, Greece, and Zurich, Switzerland

Introduction: The aim of this 2-arm parallel trial was to assess patient compliance objectively with Hawley or vacuum-formed retainers in the maxillary arch in a 3-month period after active orthodontic treatment through the use of the thermosensitive microsensor TheraMon. **Methods:** Patients who had just completed orthodontic treatment in the Postgraduate Orthodontic Clinic, School of Dentistry, National and Kapodistrian University of Athens and in a private orthodontic practice were randomly allocated to either the Hawley or vacuum-formed group for retention. Eligibility criteria included patients aged 12-18 years who had undergone orthodontic treatment in both arches for ≤ 5 years. The main outcome was the average objective daily difference in compliance measured with TheraMon between patients receiving either Hawley or vacuum-formed retainers in the maxillary arch for 3 months. Secondary outcomes pertained to the average objective difference in compliance between the 2 retainers for the first month in retention and the association between objective measurements of compliance and diary-reported duration of wear for both the first and 3- month periods. Randomization was implemented with a computer-generated randomization list; allocation was concealed in sequentially numbered, sealed, opaque envelopes. Blinding to the study protocol was not feasible either for the patient or orthodontist. Patients were instructed to wear the retainer full-time. Data were analyzed using nonparametric statistics and linear regression with standard errors based on the bootstrap method. **Results:** Seventy-seven patients (median age 14.8 years; interquartile range 1.5; range 12.1-17.6) were randomized in a 1:1 ratio to either a Hawley or vacuum-formed retainer. Baseline characteristics did not present significant differences between groups. One patient from the Hawley group was excluded from 3 months' follow-up owing to a microsensor fault. Objectively assessed median daily wear time for the Hawley group was 15.3 hours (interquartile range 6.8), whereas for the vacuum-formed group it was 18.3 hours (interquartile range 4.6) for the 3-month interval. Patients allocated to vacuum-formed retainers had higher wearing values of 2.10 h/d compared with the Hawley group, after adjusting for trial settings (mean difference 2.10; 95% confidence interval 0.32-3.89; $P = 0.02$). Patients from private orthodontic practice had an increased potential for compliance of 2.16 h/d compared with university settings after adjusting for type of appliance (mean difference 2.16; 95% confidence interval 0.34-3.97; $P = 0.02$). A significant correlation was detected between objective assessment and self-reported compliance for both retention protocols in the first and 3-month intervals. No harm was observed during follow-up. **Conclusions:** This study found relatively high compliance in the short-term retention phase for both appliances. Vacuum-formed retainers were better accepted by adolescent patients, whereas those proceeding to private orthodontic practice were more compliant. There was a positive and statistically significant correlation between objective and subjective measures of compliance. **Registration:** This trial was registered in ClinicalTrials.gov: NCT03683862. **Funding:** No funding or conflict of interest to be declared. **Protocol:** The protocol was not published before trial commencement. (Am J Orthod Dentofacial Orthop 2019;156:717-26)

[a]Department of Orthodontics, School of Dentistry, National and Kapodistrian University of Athens, Athens, Greece.
[b]Private practice, Volos, Greece.
[c]Clinic of Orthodontics and Pediatric Dentistry, School of Dental Medicine, University of Zurich, Zurich, Switzerland.
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Address correspondence to: Georgia Vagdouti, 2 Thivon Str, Goudi, Athens 11527, Greece; e-mail, georgiavagd13@hotmail.com.
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The importance of retention has long been identified by Reitan[1]: "treatment of a patient consists not only of active treatment but also includes the retention period." There are a number of reasons why stability of post-orthodontic treatment outcome may be compromised, leading to relapse after active orthodontic treatment.[2] The most predominant are rearrangement of the gingival and periodontal tissues, the adaptation of muscle function, and further long-lasting growth increments.[2-5] During the retention phase, increased remodeling of the supporting structures has been identified, with the principal fibers of the periodontal ligament being rearranged within approximately 3 months. On the contrary, the elastic supra-alveolar fibers are slower respondents and require increased time to reorganize; this may take up to 12 months and be linked to the initial tooth movement.[1,4,6,7] Muscle adaptation and orofacial soft tissue function is related to normalization and achievement of equilibrium to the new posttreatment environment.[1,8] Further growth increments within retention and postretention treatment phases are also strong determinants of relapse and stability. It has been shown that dentoalveolar and maxillomandibular alterations may present in patterns of high- or low-level predictability within both retention and postretention treatment phases.[9]

Retention strategies used by clinicians in everyday practice vary largely and the ultimate selection of the appliance and protocol of wear was previously justified in terms of working experience or obtained knowledge through the academic years.[5,10] Apparently, scientific data and relevant literature are not unanimous and describe retention protocols that may vary between fixed and removable appliances of various types as well as across prescribed timing of wear, namely across night-only wear to 3-6 months of full-time wear, followed by night-wear.[5,10,11] Retention in the maxillary arch has been frequently provided to young patients through the use of removable adjuncts, because these are considered less prone to breakages and require minimum chair time compared with their fixed counterparts. In addition, removable appliances maintain high levels of oral hygiene.[12,13] Two of the most commonly used removable retainers are the Hawley-type appliance and the thermoplastic one, also known as vacuum-formed retainer. The latter is more easily acceptable by patients and is reported to result in fewer breakages than the former.[14,15]

Whichever the retention strategy followed, patient compliance with the prescribed scheme is pivotal to the long-term success of the orthodontic treatment. Lately, new technologies have allowed for objective quantification of compliance with removable adjuncts, used either during or after orthodontic treatment, through the fabrication and embedding of thermosensitive microsensors within the adjuncts.[5,10,16-19] A recent systematic review[20] on the level of compliance of orthodontic patients with removable appliances in general reported suboptimal compliance and further concluded overestimation of the duration of wear on patients' part. Nevertheless, only 1 clinical trial[21] could be identified that gauged the difference between patients who were aware and unaware of being monitored for compliance through the use of a Hawley retainer with an embedded microsensor. There is a lack of previous well-conducted clinical trials on the comparative objective assessment of patients' compliance on different retention schemes.

Specific objectives or hypotheses

The aim of this study was to assess patients' compliance objectively with vacuum-formed or Hawley retainers after active orthodontic treatment though the use of a thermosensitive microsensor (TheraMon, MC Technology GmbH, Hargelsberg, Austria) and for a period of 3 months. The null hypothesis was that there would be no difference in the level of compliance between the 2 retention schemes (Hawley-type and vacuum-formed), after objective evaluation.

METHODS

Trial design and any changes after trial commencement

This was a randomized, active controlled trial with a 1:1 allocation ratio (on a simple randomization basis). No changes occurred after trial commencement.

Participants, eligibility criteria, and settings

Patients were recruited from the Postgraduate Orthodontic Clinic, School of Dentistry, National and Kapodistrian University of Athens and a private orthodontic practice in Volos, Greece, from January 2018 to November 2018. Recruitment and intervention administration dates were the same, whereas data for the last recruited participant was collected in February 2019.

To be eligible for the study, patients had to be aged 12-18 years and to have just completed orthodontic treatment with fixed appliances in both dental arches, with a duration of $\leq$5 years. Patients with systematic diseases, syndromic patients, and pregnant women were excluded from the study. Furthermore, patients who were unwilling to participate in this research project, those who had been retreated, or those with physical

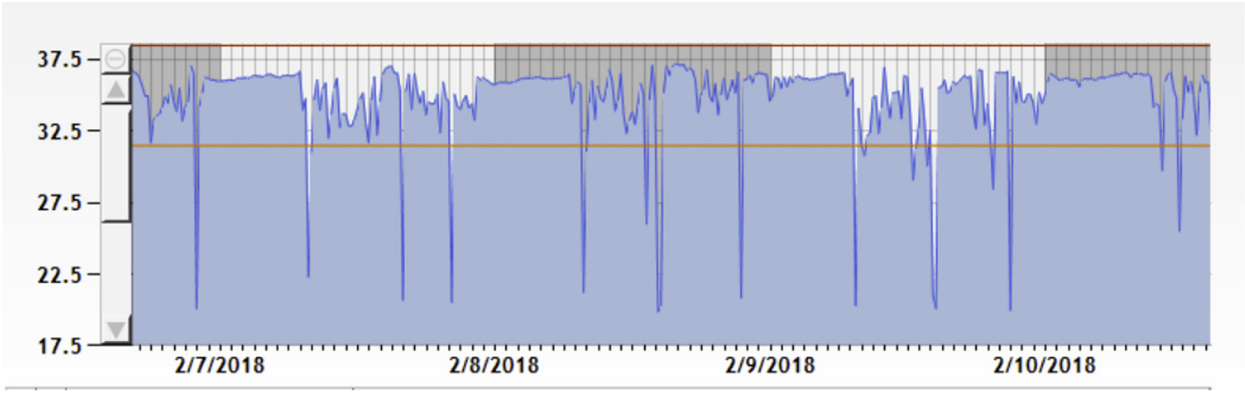

Fig 1. Example of TheraMon microsensor reading cycle with relevant daily temperature recordings.

or mental disabilities that could compromise dexterity or compliance with treatment were also excluded.

The Ethics Committee of the School of Dentistry, National and Kapodistrian University of Athens, reviewed and approved the study protocol (Reference Protocol Number 341/10.07.17).

An informed consent form was handed to patients and their parents and was obtained during the appointment when the fixed orthodontic appliances were removed and before recruitment.

Interventions

Group A was allocated to the Hawley retainer and group B to the vacuum-formed (thermoplastic) retainer for the maxillary arch. The Hawley retainer was constructed according to its typical structure and was composed of an acrylic covering the palatal region, a stainless-steel labial arch at the frontal region (0.032 in) and Adams clasps at the first molars (0.028 in). The vacuum-formed retainer was constructed to be 1.0 mm thick and was trimmed to a gingival edge width of 2-3 mm. Both groups received a fixed retainer in the lower arch. A TheraMon microsensor was used to gauge compliance levels of patients objectively in terms of appliance wear for 3 months after the removal of fixed orthodontic appliances. The TheraMon microsensor was embedded in acrylic resin and incorporated in both appliances in the right posterior palatal region. This region has been shown to have limited variation in intraoral temperature. TheraMon works by measuring the intraoral temperature every 15 minutes and transforms this information into wearing time, when the temperature ranges between 2 recordings[16,17,22,23] (Fig 1).

Patients were informed about the presence of the microsensor and its use and were instructed to wear the appliance full-time except when having meals and brushing their teeth. The retainer was delivered the day of bracket removal, after alginate impression and cast construction. The same laboratory technician was responsible for constructing both appliances. Patients were also instructed to fill in a diary with the hours they were actually wearing the appliance every day and to present it to the orthodontist each month.

Outcomes (primary and secondary) and any changes after trial commencement

The primary outcome of this study was the average difference in compliance (in daily recording), as objectively measured with the aid of TheraMon, between the Hawley retainer and vacuum-formed retainer in the maxillary arch over a period of 3 months after treatment. Patients were advised to visit the orthodontist in monthly scheduled appointments when data derived from the microsensor were recorded and an average wear time was calculated.

Secondary outcomes were the following: (1) the average difference in compliance for the 2 retainers over 1 month; (2) the association between objective assessment of compliance and diary-reported hours by patients over a 3-month period; and (3) the association between objective assessment of compliance and diary-reported hours by patients for the first month after treatment.

Sample size calculation

Based on previous research,[24] we assumed that a mean difference of 4 hours' daily wear of the appliances would be clinically relevant for detection (mean 1: 9 h/d vs mean 2: 13 h/d; standard deviation 4.9 h/d). Alpha was set to 0.05 and power to 90%. Sample calculation indicated that 33 participants would be recruited in each arm. To account for a 5% loss to follow-up, and because this study did not involve a relatively

long-term evaluation period, we rounded up the numbers to 35 participants per group.

Interim analyses and stopping guidelines

Not applicable.

Randomization

Simple randomization was implemented through a computer-generated randomization list. Allocation concealment was guaranteed through sequentially numbered, sealed, opaque envelopes prepared before participant recruitment. For each participant who was entered in the study, the next-in order envelope was drawn and identification data (baseline information) was written outside the envelope before this was opened. A secretary was responsible for the randomization procedure and implementation.

Blinding

This was an open-label randomized controlled trial (RCT) because it was not possible to blind either the patient or orthodontist to the study protocol.

Statistical analysis

Normality assumptions were checked through Shapiro-Wilk test and visual inspection through Q-Q plots. Because of the non-normal distribution of residuals, nonparametric statistics were employed. Descriptive statistics were used to present baseline data and average daily compliance hours in retainer wear, as recorded by TheraMon and diaries both at 1- and 3-month intervals and by intervention. Univariable and multivariable linear regression with observed coefficients and 95% confidence intervals (CIs) was used to assess the effect of type of appliance on average compliance hours per day at 3 months after treatment. Standard errors were calculated using the bootstrap method with 10,000 replications (n = 76). In addition, independent predictors (age, sex, and setting [ie, university or private practice]) were inserted sequentially in the initial model and retained in the final multivariable model if $P < 0.10$. A likelihood ratio test for interaction between type of appliance and setting was performed. Scatterplots were constructed and a Spearman rho correlation coefficient was calculated for the association between TheraMon and diary-reported wear duration across 1 and 3 months in retention.

The level of statistical significance was prespecified at $P < 0.05$. Statistical analyses were performed with Stata software (version 15.1, Stata Corporation, College Station, TX).

RESULTS

Participant flow

Seventy-seven patients (median age 14.8 years; interquartile range [IQR] 1.5; range 12.1-17.6) were randomized in a 1:1 ratio to either a Hawley or vacuum-formed retainer (Fig 2). Patient recruitment started in January 2018 and ended in November 2018. One patient from group A did not contribute data for the 3-month follow-up interval for reasons unrelated to the assigned intervention or outcome. Data on diaries for self-reported outcomes were returned by 68 patients at 3 months.

Baseline data

At baseline, data on age, sex, and setting (university or private practice) were collected for all included patients. Table I lists baseline characteristics across groups.

Numbers analyzed for each outcome, subgroup analyses

Objectively assessed median daily wear time for the Hawley retainer at 3 months' retention was 15.3 hours (IQR 6.8), whereas that for the vacuum-formed appliance was 18.3 hours (IQR 4.6). According to patient-reported diary compliance, at 3 months, patients in group A (Hawley) reported wearing the retainer for a median time of 20.0 hours (IQR 5.5), whereas in group B (vacuum-formed), patients reported similar hours with a median of 20.7 hours (IQR 4.0). Diary return rates ranged from 88.3% to 97.4% for the 3- and 1-month intervals, respectively (Table II; Fig 3).

Analysis for the primary outcome was based on a per-protocol scheme because only 1 patient was lost to follow-up and we did not expect deviations from an intention-to-treat approach. According to the multivariable model, patients allocated to the vacuum-formed retainer were recorded to present a higher mean time of wear of 2.10 h/d compared with those allocated to the Hawley retainer, after adjusting for setting (mean difference 2.10; 95% CI 0.32-3.89; $P = 0.02$). Likewise, after adjusting for the type of retainer, patients proceeding to private practice had an increased potential for compliance of 2.16 h/d compared with those in the university setting (mean difference 2.16; 95% CI 0.34-3.97; $P = 0.02$) (Table III; Fig 4).

A significant correlation was observed between objective assessment and patient-reported compliance for both retainer adjuncts across 1 and 3 months in retention (1 month: Spearman rho [Hawley] 0.81, $P < 0.001$; Spearman rho [vacuum-formed] 0.78,

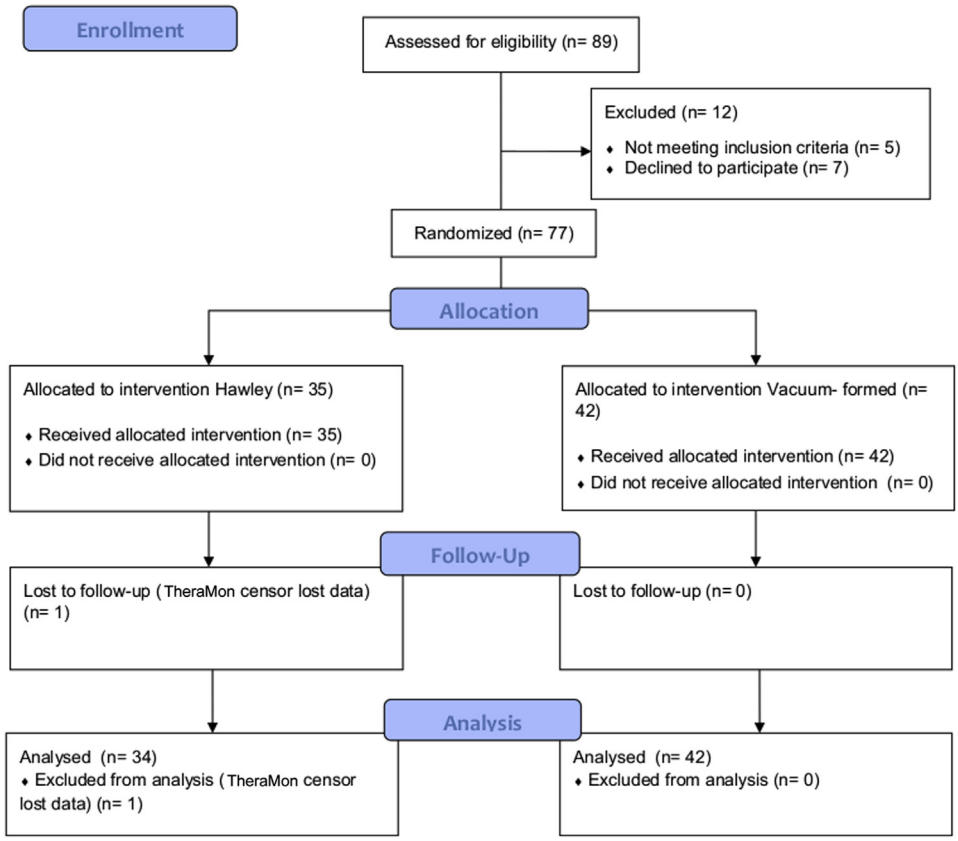

Fig 2. Flow diagram of patient recruitment.

Table I. Baseline characteristics of sample by intervention group (n = 77)

	Hawley	*Vacuum-formed*	*Total*
Baseline characteristics	*n (%)*	*n (%)*	*n (%)*
Sex			
Girls	22 (62.9)	18 (42.9)	40 (52.0)
Boys	13 (37.1)	24 (57.1)	37 (48.0)
Setting			
University	19 (54.3)	15 (35.7)	34 (44.2)
Private practice	16 (45.7)	27 (64.3)	43 (55.8)
Total	35 (100.0)	42 (100.0)	77 (100.0)
Age	*Median (IQR)*		*Median (IQR)*
	14.8 (1.5)		14.6 (2.0)

P <0.001; 3 months: Spearman rho [Hawley] 0.79, P <0.001; Spearman rho [vacuum-formed] 0.82, P <0.001) (Figs 5 and 6).

Harms

No harm was observed during the period of intervention.

DISCUSSION

Main findings in the context of the existing literature, interpretation

The current study was composed of an objective evaluation of adolescent patients' compliance during the early retention phase with 2 commonly used adjuncts, the Hawley- type and the vacuum-formed retainer. Patients were more likely to wear the thermoplastic vacuum-formed retainer according to the prescribed hours for retention. In addition, we concluded that private practice settings promote better compliance with wear duration of the retainers.

The breadth of the existing literature on objective evaluation of compliance included studies on removable functional appliances, Hawley retainers, or headgear appliances, which were classified as prospective cohort studies or even retrospective ones.[16,21,24-26] We are aware of only 1 previous RCT with a limited number of participants who were allocated to being aware or unaware of being monitored for wear duration of a Hawley retainer.[21] To the best of our knowledge, this is the first RCT on the comparative assessment of

Table II. Descriptive data for average daily compliance hours, as recorded by TheraMon and diaries at 1- and 3-mo intervals

	Hawley				*Vacuum-formed*			
Method of assessment	*Median*	*IQR*	*Minimum*	*Maximum*	*Median*	*IQR*	*Minimum*	*Maximum*
TheraMon								
1 mo	15.8	7.3	4.2	22.0	17.9	5.2	8.7	22.0
3 mo	15.3	6.8	5.4	22.8	18.3	4.6	10.5	22.4
Diary								
1 mo*	19.8	6.6	3.9	23.4	20.7	4.2	10.4	23.1
3 mo†	20.0	5.5	8.6	23.6	20.7	4.0	9.7	23.1

*Data based on 75 patients who returned diaries (34 Hawley and 41 vacuum-formed); †Data based on 68 patients who returned diaries (29 Hawley and 39 vacuum-formed).

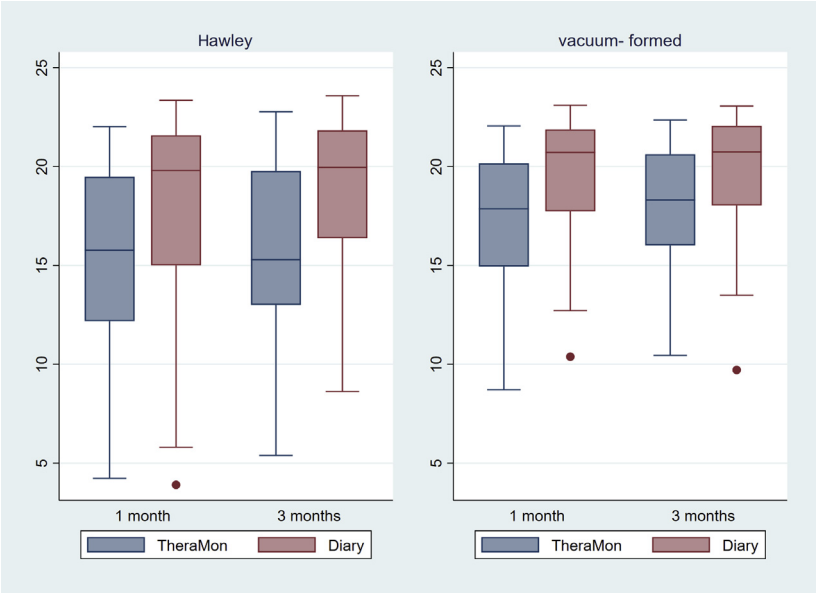

Fig 3. Box plots for average daily compliance by type of retention (Hawley or vacuum-formed) according to TheraMon or diary recordings and across time.

compliance with 2 commonly used removable adjuncts, supplemented by a subjective evaluation by patients.

The TheraMon microsensor was selected to detect daily wear duration because it was previously identified as a reliable and accurate device in addition to being a manageable size for incorporating into retainers.[16] In fact, the accuracy of 3 thermosensitive microsensors (the TheraMon; Air-Aid Sleep, Air Aid GmbH & Co. KG, Frankfurt, Germany; and DentiTrac, Braebon Medical Corporation, Kanata, Ontario, Canada) has been assessed in vivo and in vitro, and all 3 were found to be highly accurate and reliable in recording the wearing duration of removable appliances.[27] In particular, regarding TheraMon, a recent pilot study[28] revealed a mean under-recording time of 4% (95% CI 2.5-5.8%) in hours; however, those results were related to both the upper and lower arch. Evidence from an in-vitro study[18] showed that the TheraMon appliance demonstrated increased versatility compared with other thermosensitive microelectronic sensors such as the SMART Retainer (Scientific Compliance, Atlanta, GA) while being substantially accurate in terms of documentation of wear duration of the retainers.

Regarding documented compliance and wear duration of the appliances, high levels of compliance were detected overall. This may be because patients were aware of being monitored, which rendered them more motivated toward the prescribed retention scheme.[21,26,29] In addition, monthly scheduled appointments were conducted with the intention of

Table III. Univariable and multivariable linear regression with observed coefficients and 95% confidence CIs for effect of method of retention (Hawley or vacuum-formed) on objectively recorded (through TheraMon) average daily hours of compliance 3 mo after treatment

	Univariable			*Multivariable*		
	Observed coefficient (β)	*95% CI*	P *value*	*Observed coefficient (β)*	*95% CI*	P *value*
Intervention						
Hawley	Reference			Reference		
Vacuum-formed	2.47	0.60 to 4.35	0.01	2.10	0.32 to 3.89	0.02
Age						
Per unit	−0.49	−1.20 to 0.23	0.18			
Sex						
Girls	Reference					
Boys	0.55	−1.36 to 2.45	0.57			
Setting						
University	Reference			Reference		
Practice	2.52	0.61 to 4.43	0.01	2.16	0.34 to 3.97	0.02

Standard errors were calculated using the bootstrap method with 10,000 replications (n = 76). Likelihood ratio test for interaction (intervention × setting), $P = 0.92$.

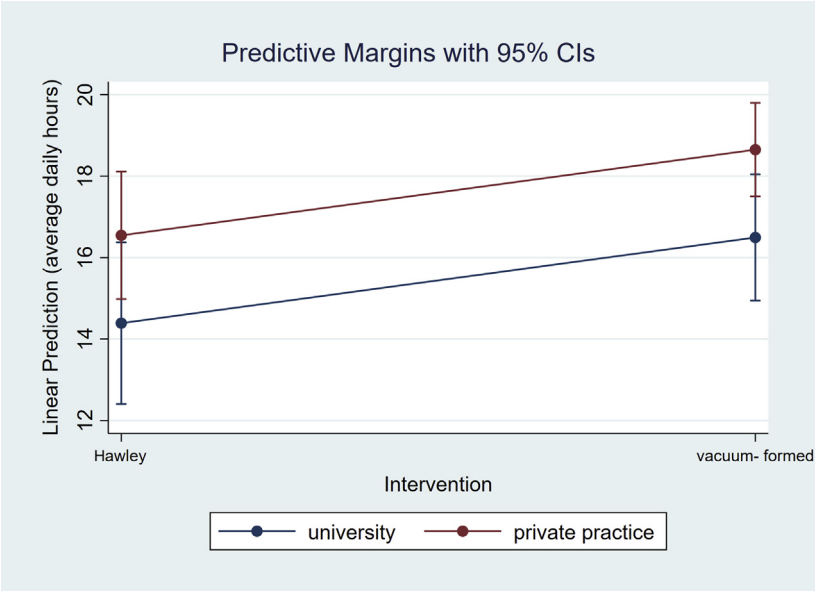

Fig 4. Predictive margins with 95% CIs for effect of type of retention on average compliance 3 months after treatment, across different settings.

enhancing patients' motivation and instructions for full-time wear of the appliance. Similar retention schemes for full-time wear of the appliance, especially in the short term after treatment, were previously described. The results of those studies were not been unanimous; recorded compliance was slightly lower (approximately 15-16 h/d) for vacuum-formed retainers,[30] whereas it was documented as being on comparable levels for Hawley-type retainers.[21] Nevertheless, a number of studies described instruction schemes for removable appliances wear pertaining to part-time daily wear, from 8 to 15 h/d.[10,16,24,31] Indeed, those studies did not involve exclusively retention appliances; adjuncts were used during the course of active orthodontic treatment. Thus, the results of the studies cannot be compared directly with our findings.

Self-reported assessment of compliance revealed a high degree of correlation with objectively detected patterns in the current study. Nevertheless, we recorded a nonnegligible overestimation of the daily wearing times

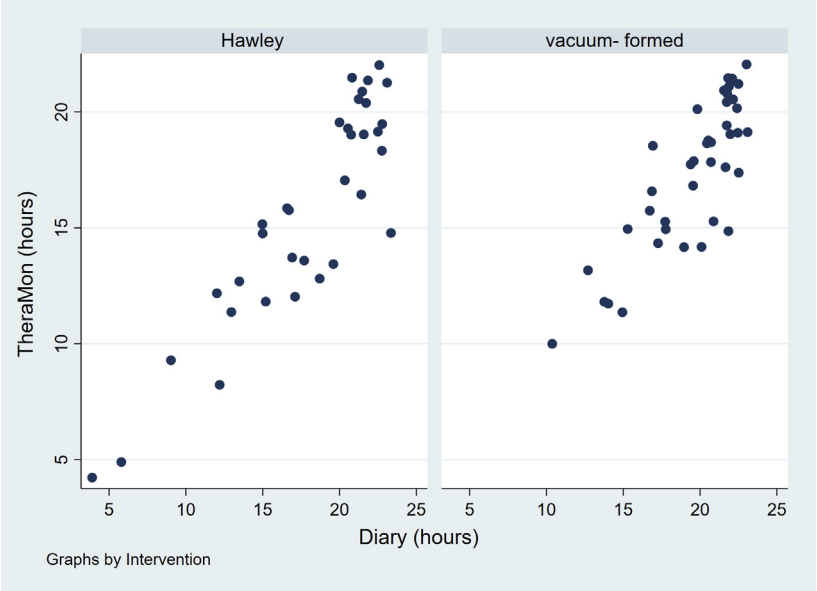

Fig 5. Scatterplot for association between objectively recorded TheraMon hours of compliance and diary claims at 1 month after treatment, by intervention.

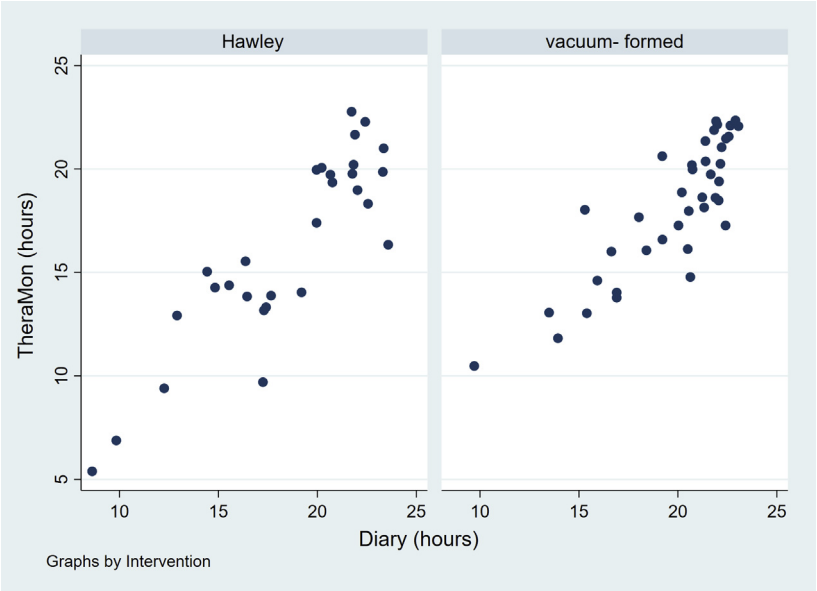

Fig 6. Scatterplot for association between objectively recorded TheraMon hours of compliance and diary claims at 3 months after treatment, by intervention.

within 2.4-4.7 median h/d at 3 months after treatment. This is in accordance with a recent cohort study[30] on vacuum-formed appliances that used self-completed reports as a supplementary method of assessment. The identified subjectively reported wearing times are slightly lower than those reported in the latest systematic review on the topic,[20] which identified a difference of approximately 5-6 hours. Such a difference may be attributed to the fact that the latter figure may represent reported compliance with appliances other than purely removable retainers. However, overall, the recorded discrepancies between objective and subjective methods of evaluation of compliance may reflect the potential for survey bias. It was suggested that adolescents may feel anxious about the appearance of their teeth or adherence to the prescribed guidance and may deliberately

overreport wearing hours in an attempt to preempt the doctor's judgment.[32]

Age and sex constitute 2 commonly addressed factors in studies of patients' compliance with orthodontic removable appliances. Although our study revealed no significant difference for either factor and was in accordance with previous research,[30,33] younger patients were reported to be more compliant overall when it comes to wearing duration of removable appliances in general,[16] with decreasing levels of compliance from late childhood onward. However, the current trial invited patients aged 12-18 years to participate. Controversial findings were documented in the existing literature regarding sex; some studies did not record significant differences between boys and girls,[16,30,34] whereas others have reported increased wear duration times for girls compared with boys, assessed objectively or through the aid of questionnaires.[6,10,26] Given the potential differences in populations studied in age and type of appliance across these studies, it is possible that some or all of these factors interacted with sex and that this interaction might have either masked or stressed the potential effect of sex on the documented compliance.

Trial settings appeared to pose a significant role in compliance after the end of active orthodontic treatment in the current RCT; patients proceeding to private practice were more cooperative with the prescribed retention schemes. This factor was previously evaluated through studies in university, hospital, and private practice settings, objectively and subjectively. Private practice settings were shown to have an equally effective role in compliance of retainer adjuncts with university or hospital settings.[10,30,34] However, this finding may be uniquely specific to the setting or location. Future attempts evaluating multiple location settings are probably required to confirm the direction of this effect on patients' compliance.

Overall, the documented difference in compliance between the 2 commonly used adjuncts, with the superiority of vacuum-formed retainers, may be particularly useful for patients who are not typical to prescribed orthodontic treatment schemes during active treatment and ultimately are not expected to be highly compliant during the retention phase. Clinicians should be critical and aware of their patients' potential for compliance during and after orthodontic treatment and to perceive their patients' capability in terms of maintenance for the orthodontic treatment outcome.

Limitations

The current RCT may have been prone to certain limitations. First, a simple randomization scheme was followed across both centers involved in the trial. As a result, inequality in treatment groups was detected in terms of participant allocation to either the Hawley or vacuum-formed retainers. However, no serious imbalances were confirmed, whereas all potential baseline predictors were weighed against in the statistical analysis. Second, a separate randomization list within each center might have also been appropriate to allocate participants and ensure stratum-specific equalities; nevertheless, there were no indications or previously existing evidence that patients were significantly different in terms of demographic or baseline characteristics across the different settings. Third, not all participants returned the diaries with the subjectively recorded wearing duration times. However, we preferred to report findings for these secondary outcomes for each protocol, because there were no severe losses to follow-up, all of which were unrelated to the study's outcomes or interventions. For the primary outcome, we lost data for only 1 patient on a 3- month recall basis, which was unrelated to the study's rationale, interventions, or outcomes. Finally, we did not involve an independent investigator, unaware of the trial's aims and scopes, to perform the outcome assessment. Given our trial design, the clinician could not have been blinded with regard to the reading times of the appliances, because the microsensor embedded within the appliance had to be secured to the TheraMon evaluation system linked to a computer to read each patient's compliance performance. However, the analyst of the data was unaware of the allocated interventions.

Generalizability

The generalizability of the findings of the current RCT might be limited to adolescents aged 12-18 years, whereas the findings might be applicable to both university and private practice settings. Notwithstanding, more clinical trials in various settings are required to confirm the findings (See Supplementary Table, available at www.ajodo.org).

CONCLUSIONS

This RCT concluded that both retainers achieved relatively high levels of compliance, apparently lower than prescribed, whereas vacuum-formed retainers were better accepted by adolescent patients. Participants proceeding to private practice settings appeared to be more cooperative, although they tended to overreport wearing duration times for both retention adjuncts.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.ajodo.2019.07.008.

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Supplementary Table. CONSORT 2010 checklist of information to include when reporting a randomized trial*

Section/topic	*Item no*	*Checklist item*	*Reported on page no*
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2,3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4,5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6,7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	7 N/A
Randomization			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomization; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	8
	13b	For each group, losses and exclusions after randomization, together with reasons	8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8,9
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	13

Supplementary Table. Continued

Section/topic	*Item no*	*Checklist item*	*Reported on page no*
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9,10,11,12
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, noninferiority and equivalence trials, nonpharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.