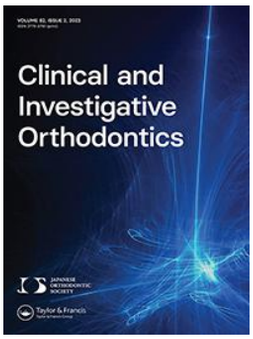

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# Effects of wear time monitoring devices on patient's compliance: a systematic review and meta-analysis

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# Effects of wear time monitoring devices on patient's compliance: a systematic review and meta-analysis

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**ABSTRACT**

**Objective:** To determine and analyse the effects of wear time monitoring devices on patients' compliance with removable orthodontic appliances.

**Methods:** A literature search was performed using PubMed, Central of the Cochrane Library and Google Scholar databases. Unpublished literature was searched on ClinicalTrials.gov. A Manual search was undertaken in orthodontic journals. The revised Cochrane risk-of-bias tool for randomized trials (RoB 2) was used for Randomized Controlled Trials and the ROBINS-I tool was used for non-Randomized Controlled Trials. The meta-analyses, using a random-effects model, were applied with RevMan 5.4.

**Results:** Studies that showed the effect of wear time measurement devices on patient compliance were selected. Twenty-five (7 RCTs and 18 nRCTs) articles were selected for the final systematic review. Nine studies were included in the meta-analysis. The average daily wear time of the appliance was higher in the subjects who were aware of being monitored as compared to those subjects who were kept blind (unaware) regarding monitoring status, with a mean difference of 2.62 (95% CI = 0.06 to 5.17; Z value = 2.01).

**Conclusion:** Compliance with removable appliances increases when patients are made aware of being monitored by wear time measurement devices. Patients tend to overestimate the duration of wear time hence wear time measurement devices should be used to assess compliance with removable orthodontic appliances.

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**KEYWORDS**
Compliance; sensor; wear time

## Introduction

Compliance is the extent to which a person's behaviour coincides with medical or health advice [1]. Concerning the branch of Orthodontics, compliance describes patients' behaviour to follow instructions given by the Orthodontist [2]. In contemporary orthodontic therapy, patient compliance is required for general tasks such as maintaining oral hygiene, following certain dietary restrictions and in terms of removable orthodontic appliances patients are expected to follow the prescribed wear time regimen suggested by their Orthodontist to achieve optimal therapeutic progress. In Orthodontics a patient with good compliance will achieve better treatment results than a patient with poor compliance is conceivably an unwritten dictum. Poor compliance can result in slow treatment progress, increased chair side time and compromised treatment outcomes [3]. Sometimes Patients are unrealistic and not very honest when it comes to their reported wear times [4]. With the patients themselves being less realistic or truthful monitors of their behaviour, self-reporting questionnaires also fail to adequately assess compliance. In this regard, parents also tend to overestimate the amount of time their child wears the appliance [5]. Objective measurement of wear time has been a demand in Orthodontics for a long time as it allows a more realistic view of compliance by patients and orthodontists [6]. There is a lack of evidence regarding the effect of wear time assessment on the levels of compliance hence, this systematic review aimed to identify, summarize and evaluate whether electronic wear time measurement device has an influence on compliance in patients treated with removable orthodontic appliances.

## Materials and methods

### *Protocol*

The research protocol was registered at the National Institute for Health Research, Prospero international prospective register of systematic reviews (registration number: CRD42021257563) is designed according to the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) guidelines 2020.

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### Eligibility criteria

The following selection criteria were applied for the review

(1) Studies conducted between 2000 to 2021 on orthodontic patients irrespective of their age group. Studies assessing objective compliance levels. Studies that showed the effect of wear time measurement devices on patient compliance.
(2) The intervention was removable orthodontic appliances incorporated with a sensor.
(3) Outcome measures were the wear time measured by the sensor, the patient reported wear time and awareness of the patient about being monitored.
(4) The study designs were randomized controlled trials (RCTs), non-randomized controlled trials (nRCTs) and cohort studies.
(5) Exclusion criteria were studies conducted before the year 2000, studies published in a language other than English, animal studies, studies that failed to mention the effectiveness of wear time measurement on compliance and studies that have assessed the effect of factors other than wear time measurement on compliance.

### Information sources, search strategy, and study selection

A literature search was performed independently by two reviewers using the following databases: PubMed, Central of the Cochrane Library and Google Scholar. A hand search was undertaken in orthodontic journals. Unpublished literature was searched on ClinicalTrials.gov. The database was searched from 2000 till November 2021 with no specific filter applied during the search. An additional search was also carried out on review articles, bibliography and related journals. A comprehensive search was conducted on electronic databases, additionally as by manual search, to spot all relevant studies. Articles were found using equation #1 ('removable orthodontic appliances' OR 'removable appliances' OR 'orthodontic appliances' OR 'functional orthodontic appliances' OR 'orthodontic retainers' OR 'Orthopedic appliances') AND #2 ('sensor' OR 'microsensor' OR 'microelectronic sensor' OR 'wear-time documentation' OR 'electronic wear-time measurements' OR 'microelectronic wear-time device' OR 'microelectronic wear-time documentation')

Study selection was performed by two independent authors and any discrepancy was resolved by the third author. Any possible discrepancies encountered during this process that is, inclusion or exclusion criteria, were resolved by discussion between the reviewers who selected the included studies. If a disagreement persisted, the judgement of a third reviewer was considered decisive. Two authors collected the data independently from the included studies. Disagreements were solved by consensus with a third author.

### Risk of bias/quality assessment in individual studies

To evaluate the risk of bias in individual studies, different tools were used for randomized controlled trials (RCTs) and non-randomized controlled trials (NRCT).

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) [7] was used for Randomized Controlled Trials and ROBINS-I (tool for assessing the risk of bias in non-randomized studies of interventions) [8] was used for non-Randomized Controlled Trials.

### Analysis of data

The meta-analyses, using a random-effects model, were applied with RevMan 5.4 (RevMan 5.4, The Nordic Cochrane Centre, Copenhagen). Heterogeneity was assessed by a Q test and quantified with $I^2$ statistics. Data on mean and standard deviation were obtained from selected studies. Average daily wear time (hours/day) was considered the main outcome. Two separate comparisons were performed: Comparisons of average wear (hours/day) time between aware and unaware subjects, and comparison of average wear time (hours/day) between time recorded by the sensor and time reported by patients, using mean difference (MD) for wear time. For analyses, if the test showed substantial heterogeneity ($I^2$ >50%), a random effects model was applied, or else ($I^2$ ≤50%), a fixed effects model would be used.

### Summary measures and approach to synthesis

The primary objective was to determine and analyse the effects of wear time monitoring on patients' compliance with removable orthodontic appliances. The secondary objective is to objectively analyse patient's compliance with removable orthodontic appliances, in the included studies.

## Results

### Study selection

The initial search strategy brought forth a total of 604 results including the studies obtained from Google Scholar. After duplication removal, 585 articles were assessed for their abstracts and full texts. Finally, after strict and meticulous application of the inclusion and exclusion criteria, 25 articles [5,9–32] were selected for the final systematic review. Of these, 9 studies were included in the meta-analysis(quantitative analysis).

Meta-analysis was conducted using 5 studies [10,11,14,20,24] for comparison of average wear time (hours/day) between subjects aware and unaware regarding wear time monitoring devices. Another meta-analysis was conducted using 5 studies [14,16,22,30,32] for comparison of average wear time (hours/day) between time recorded by the sensor (objective) and time reported by patients (subjective). One study [14] was common for both the meta-analysis. The PRISMA flowchart of the literature search and selection process is summarized in Figure 1;

### Study characteristics

The studies were conducted from 2002–2020. All the studies were heterogeneous in study designs, seven were RCTs [20,24,26,27,29,30,32] and eighteen were Non-RCTs [5,9–18,20–23,25,28,31]. The patients in individual studies ranged from 7–21 years. A cumulative total of 1555 patients were included in the 25 studies. Seven studies [5,9–11,24,28,30] have assessed compliance with extraoral appliances such as headgear and two studies [24,30] amongst them included intraoral as well as extraoral appliances. The remaining studies [12–14,16–27,29–32] included intraoral appliances such as retention plates, myofunctional appliances, expansion plates and OSA appliances. The types of wear measurement devices used were different with a majority of studies using TheraMon sensors. The measurement of wear time as an indicator of patient compliance was the outcome of interest in the majority of studies, whereas one study evaluated overjet reduction along with wear time measurement as a means of patient compliance. (Tables 1 and 2)

### Risk of bias within studies

Amongst RCTs random sequence generation was adequately reported in all six studies except one study where it was only mentioned that patients were randomly allocated to two groups, but the details of allocation procedure were not mentioned (unclear). Allocation concealment was adequately reported in only three studies. Patients were kept blinded about being monitored in four studies; however, examiners could not be kept blind to the intervention groups because of the nature of the intervention. One study reported missing participants but did not mention

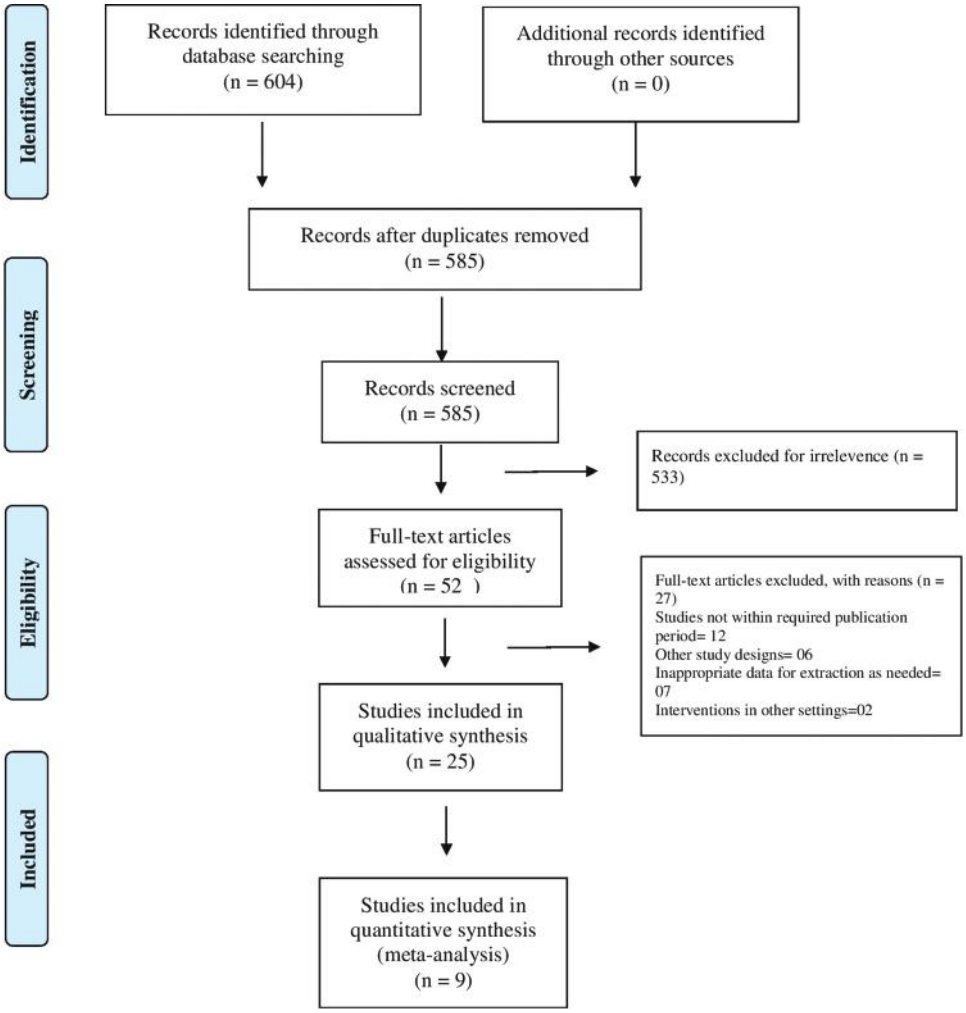


**Figure 1.** Prisma flow diagram of study selection.

**Table 1.** Characteristics of the included studies.

| Sr. No | Author/Year of publication | Sample size | Age | Study design | Appliance | Wear time recorder |
|---|---|---|---|---|---|---|
| | William A. Cole [9] | 20 | 12 ± 8 Years | Non RCT | Headgear | Timing headgear (Compliance Science System, Ortho Kinetics, Vista, Calif) |
| | Cenk Doruk et al. [10] | 46 | 13 Years | Non RCT | Cervical pull headgear | Electronic module timer (Ortho kinetics corporation, Vista, California, USA) |
| | Márcia Brandão et al. [11] | 21 | 14 years | Non RCT | Headgear | Compliance Science System, Ortho Kinetics, Vista, Calif |
| | Annemieke Bos et al. [5] | 56 | 10 to 22 years | Non RCT | Headgear | Thermochron i-Button, DS1921G; Maxim Integrated Products, Sunnyvale, Calif |
| | Beata Kawala et al. [12] | 45 | 9.2 years | Non RCT | Shwartz plates | TheraMon sensors |
| | Marijke Dieltjens et al. [13] | 51 | 49 ± 10 years | Non RCT | A custom-made titratable mandibular advancement device (RespiDent Butterfly®, Dormoco, Belgium) | TheraMon-microsensor (Handelsagentur Gschladt, Hargelsberg, Austria) |
| | Pauls A et al. [14] | 32 | 12.76 years | Non RCT | Removable appliances, bite-jumping appliances, activators, and plates | TheraMon-microsensor (Handelsagentur Gschladt, Hargelsberg, Austria) |
| | Timm Cornelius Schott et al. [15] | 100 | 13 and 20 years | Non RCT | Hawley retainers | TheraMon-microsensor |
| | Olivier M Vanderveken et al. [16] | 51 | 47 ± 10 years | Non RCT | Custom-made titratable mandibular advancement device | TheraMon-microsensor |
| | Timm Cornelius Schott et al. [17] | 281 | 6 and 18 years | Non RCT | Removable plates or functional orthodontic appliances | TheraMon-microsensor |
| | Timm Cornelius Schott et al. [18] | 28 | Above 18 years | Non RCT | Transverse maxillary expansion plate | TheraMon-microsensor |
| | George Tsomos et al. [19] | 45 | 11.8 years | Non RCT | Removable appliances | TheraMon-microsensor |
| | Paul Hyun et al. [20] | 22 | 15.44 years | RCT | Hawley retainers | SMART sensor |
| | Katharina Schäfer et al. [21] | 141 | 7 to 15 years | Non RCT | Functional appliances (standard activator or Class III activator | TheraMon-microsensor |
| | Timm Cornelius Schott et al. [22] | 109 | 6–20 years | Non RCT | 33 expansion plates, 34 functional appliances 42 retention plates | TheraMon-microsensor |
| | Ali S. A. Al-Kurwi et al. [23] | 28 | 11.60 years | Non RCT | van Beek activator | TheraMon-microsensor |
| | Arreghini A et al. [24] | 30 | 6–15 years | RCT | 11 Frankel 3 Bionator 16 Face mask | TheraMon-microsensor |
| | Charavet C et al. [25] | 69 | 7.8 years | Non RCT | Planas functional appliances | TheraMon-microsensor |
| | Georgia Vagdouti et al. [26] | 77 | 14.8 years | RCT | Hawley or vacuum-formed retainers | TheraMon-microsensor |
| | Dalya Al-Moghrabi et al. [27] | 84 | 12–21 years | RCT | Thermoplastic retainers | TheraMon-microsensor |
| | Luis Huanca Ghislanzoni et al. [28] | 20 | 8–12 years | Non RCT | Headgear | Temperature- and force-sensitive module (Smartgear, Swiss orthodontics AG, Cham, Switzerland) |
| | Jeet Parekh et al. [29] | 62 | 10–14 years | RCT | Twin block | TheraMon-microsensor |
| | Heidi Arponen [30] | 52 | 12.6 years | RCT | Headgear activator and twin-block | TheraMon-microsensor |
| | Michał Sarul et al. [31] | 55 | 10.4 years | Non RCT | Twin block | TheraMon-microsensor |
| | Cansın Kutay et al. [32] | 30 | 10–15 years | RCT | Monoblock and twin block | TheraMon-microsensor |

**Table 2.** Results of the included studies.

| Sr No. | Study | Appliance | Stipulated wear time (hours/day) | Self reported wear time (mean in hours/day) | Objective wear time (mean in hours/day) | Awareness of the patient about being monitored |
|---|---|---|---|---|---|---|
| 1. | William A. Cole [9] | Headgear | 10–12 | 8.89 | 6.78 | Unaware |
| 2. | Cenk Doruk et al. [10] | Cervical pull headgear | 16 * | - | Cooperative<br>T1: 18.41 ± 0.36<br>T2: 18.94 ± 0.48<br>T3:18.25 ± 0.44<br>Uncooperative<br>T1: 9.53 ± 0.89<br>T2: 13.97 ± 0.95<br>T3:15.42 ± 0.97 | T0: Unaware<br><br><br><br>T1: Unaware<br>T2<br>T3 |
| 3. | Márcia Brandão et al. [11] | Headgear | 14 | 13.6 | T1: 5.6<br>T2: 6.7 | T1: Unaware<br>T2: Aware |
| 4. | Annemieke Bos et al. [5] | Headgear | 12 | 11.02 | 6.71 | Unaware |
| 5. | Beata Kawala et al. [12] | Shwartz plates | 9 | - | 8.3 | Aware |
| 6. | Marijke Dieltjens et al. [13] | A custom-made titratable mandibular advancement device | 8 | 7.3 | 6.4 ± 1.7 | Aware |
| 7. | Pauls A et al. [14] | Study group:<br>Activator-5<br>Bite jumping appliances-9<br>Removable plates-4 | 15 | T1:10.8 ± 2.3<br>T2:9.2 ± 2.5<br>T3: 9.1 ± 2.5<br>T4: 8.8 ± 2.0 | T1:8.1 ± 2.3<br>T2:8.4 ± 2.78<br>T3: 8.2 ± 2.36<br>T4: 8.1 ± 2.19 | T0 – Unaware<br>T1<br>T2<br>T3<br>T4 |
| | | Control group:<br>Activator-7<br>Bite jumping appliances-3<br>Removable plates-4 | 15 | - | T1:6.7 ± 2.06<br>T2:7.4 ± 2.17<br>T3: 7.9 ± 2.17<br>T4: 8.1 ± 1.72 | Aware |
| 8. | Timm Cornelius Schott et al. [15] | Hawley retainers | 8 | - | 7.7 | Aware |
| 9. | Olivier M Vanderveken et al. [16] | Custom-made titratable mandibular advancement device | 8 | 7.5 ± 0.9 | 6.7 ± 1.3 | Unaware |
| 10. | Timm Cornelius Schott et al. [17] | Removable plates and functional orthodontic appliances | 12–15 | | 9.35 median hours/day | Aware |
| 11. | Timm Cornelius Schott et al. [18] | Expansion plates | 15 | - | T1:12.8 ± 3.8<br>T2:13.3 ± 3.9<br>T3:12.7 ± 4.8 | Aware |
| 12. | George Tsomos et al. [19] | Group 1:<br>Active appliances | 14 | - | 10.1 median hours/day | Aware |
| | | Group 2:<br>Passive appliances | 14 | - | 8.1 median hours/day | |
| 13. | Paul Hyun et al. [20] | Group 1: Hawley retainers | 19 | - | T1: 16.3 ± 4.39<br>T2: 15.6 ± 4.77 | Aware of monitoring from start of study |
| | | Group 2: Hawley retainers | 19 | - | T1: 10.6 ± 5.36<br>T2: 11.1 ± 6.08 | Aware of monitoring at T1 |
| 14. | Katharina Schäfer et al. [21] | Group 1:<br>Functional appliances: | 15 | - | 9.5 | Aware |
| | | Group 2:<br>Maxillary removable appliances: | 15 | - | 10.1 | |
| 15. | Timm Cornelius Schott et al. [22] | Maxillary removable appliances:<br>Functional appliances:<br>Hawley's retainer: | 15.1 ± 0.9<br>15.2 ± 0.5<br>13.4 ± 2.7 | 12.0 ± 3.0<br>12.2 ± 3.6<br>10.1 ± 3.8 | 11.9 ± 3.0<br>10.2 ± 3.3<br>9.0 ± 4.9 | Aware |

(*Continued*)

**Table 2.** (Continued).

| Sr No. | Study | Appliance | Stipulated wear time (hours/day) | Self reported wear time (mean in hours/day) | Objective wear time (mean in hours/day) | Awareness of the patient about being monitored |
|---|---|---|---|---|---|---|
| 16. | Ali S. A. Al-Kurwi et al. [23] | Van Beek activator | 12 | - | 6.77 | Aware |
| 17. | Arreghini A et al. [24] | Group 1: Frankle and bionator | 13 | - | 9.4 ± 2.6 | Aware |
| | | Group 2: Frankle and bionator | 13 | - | 8.1 ± 3.2 | Unaware |
| 18. | Charavet C et al. [2] | Planas functional appliances | 24 | - | 15.8 ± 5.2 | Not stated |
| 19. | Georgia Vagdouti et al. [26] | Group A: Hawley retainer: | 24 | 20.0 median hours/day | 15.3 median hours/day | Aware |
| | | Group B: Vacuum-formed (thermoplastic) retainer: | 24 | 20.7 median hours/day | 18.3 median hours/day | |
| 20. | Dalya Al-Moghrabi et al. [27] | Intervention group: Received access to 'my retainer' mobile application | 8 | | 7.25 | Aware |
| | | Control group: Did not receive access to 'my retainer' mobile application | 8 | | 6.21 | |
| 21. | Luis Huanca Ghislanzoni et al. [28] | Headgear | 12 | | Including days of non-use: 6.4<br>Excluding blank days: 8.7 | Aware |
| 22. | Jeet Parekh et al. [29] | Part time: Twin Block | 8 | - | Part time: 8.78 | |
| | | Full time: Twin Block | 22 | - | Full time: 12.38 | |
| 23. | Heidi Arponen [30] | Headgear Activator | 12 | 9 | 5.8 | Unaware |
| | | Twin Block | 18 | 11 | 7.3 | |
| 24. | Michał Sarul et al. [31] | Twin Block | 12–14 | | 7.60 ± 3.12 | |
| 25. | Cansın Kutay et al. [32] | Group 1: Monoblock | 15 | 14.08 ± 2.94 | 10.33 ± 3.51 | Unaware |
| | | Group 2: Twin block | 15 | 14.78 ± 3.16 | 11.02 ± 4.40 | |

*Patients were divided at the end of T1 in to two groups cooperative and uncooperative.

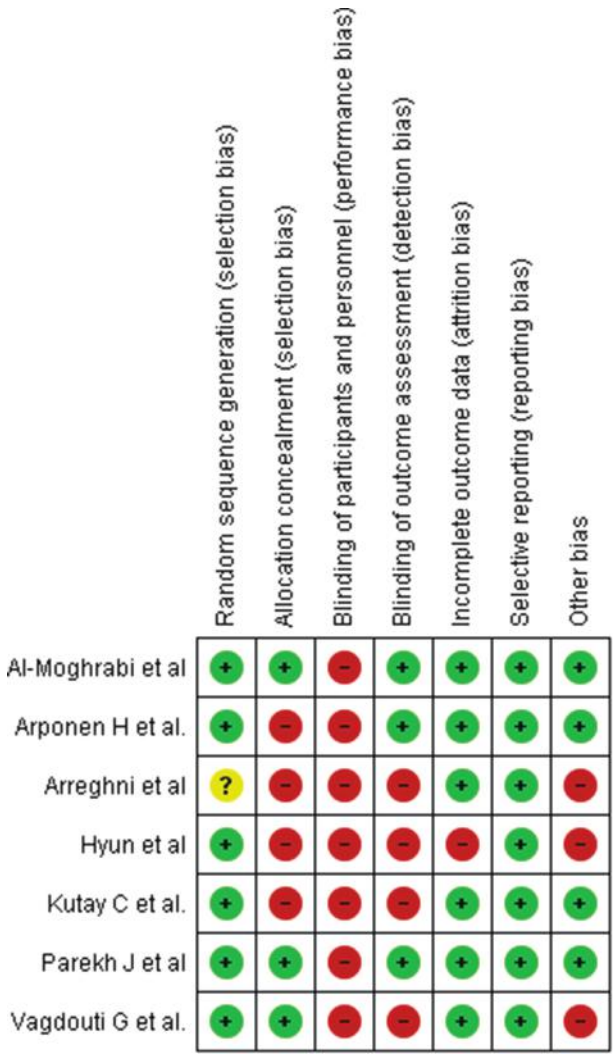


**Figure 2.** Risk of bias summary.

measures taken to compensate for missing data. Selective reporting was avoided in all the studies. Other unspecified types of bias were also considered as associated with the lack of information on sample size estimation and mention of baseline demographic and clinical variables. Two studies did not report sample size calculation. Two studies showed fair and five showed poor Risk of bias. (Figures 2 and 3) (Table 3)

For nRCTs, the assessment of the risk of bias was performed using the risk of bias in the non-randomized studies of intervention (ROBINS-I) tool. (Table 4) It includes a risk of bias due to confounding factors, selection of participants into the study, classification of interventions, deviations from intended intervention, missing data, measurement of outcomes, and selection of the reported results. Eighteen studies were assessed using the checklist for possible bias. All studies showed a low risk of bias.

## *Results of meta-analysis*

### *Comparison of average wear time (hours/day) between aware and unaware subjects (Figure 4)*

Five studies [10,11,14,20,24] were included in the meta-analyses comparing the wear time between aware and unaware subjects. The other studies were excluded as the data reported could not be analysed. The results of the overall comparison have been depicted as a forest plot. With the meta-analysis conducted for selected studies, heterogeneity was more than 50% ($I^2 = 89\%$); hence, a random effect model was applied. The average daily wear time of the appliance was higher in the subjects who were aware of being monitored as compared to those subjects who were kept blind (unaware) regarding monitoring status, with a mean difference of 2.62 (95% CI = 0.06 to 5.17; Z value = 2.01). This difference in daily average wear time (in hours/day) between the two groups was statistically significant ($p = 0.04$).

### *Comparison of average wear time (hours/day) between time recorded by the sensor (objective) and time reported by patients(subjective) (Figure 5)*

Five studies [14,16,22,30,32] with fourteen comparisons were included in the meta-analyses comparing average wear time (hours/day) between the time recorded by the sensor and the time reported by patients. The other studies were excluded as the data reported could not be analysed. The results of the overall comparison have been depicted as a forest plot. With the meta-analysis conducted for selected

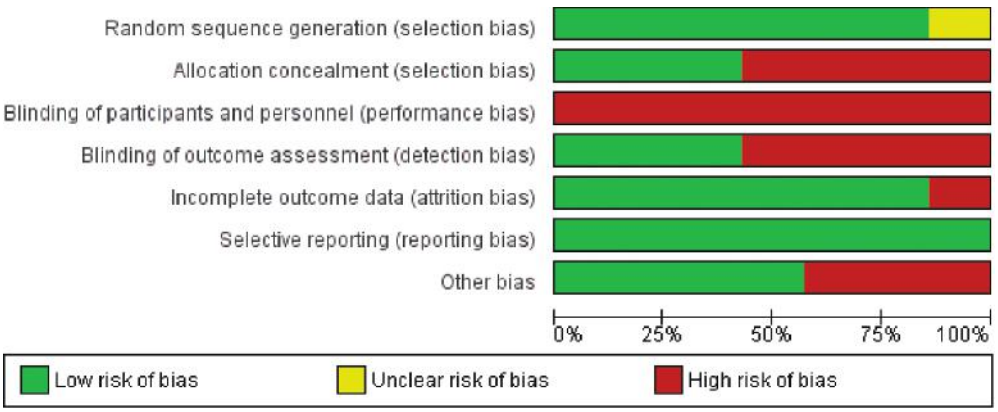


**Figure 3.** Risk of bias graph.

**Table 3.** Risk of bias assessment – for randomized control trials.

| Sr. No. | Study | Random sequence generation | Allocation Concealment | Blinding of participants and personnel | Blinding of outcome assessment | Incomplete outcome data assessment | Selective reporting of outcome | Other source of bias | Risk of bias (Methodological)Adequacy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Paul Hyun et al. [20] | Low risk | High risk | High risk | High risk | High risk | Low risk | High risk | Poor |
| 2 | Arreghini A et al. [24] | Unclear | High risk | High risk | High risk | Low risk | Low risk | High risk | Poor |
| 3 | Georgia Vagdouti et al. [26] | Low risk | Low risk | High risk | High risk | Low risk | Low risk | High risk | Poor |
| 4 | Dalya Al-Moghrabi et al. [27] | Low risk | Low risk | High risk | Low risk | Low risk | Low risk | Low risk | Fair |
| 5 | Jeet Parekh et al. [29] | Low risk | Low risk | High risk | Low risk | Low risk | Low risk | Low risk | Fair |
| 6 | Heidi Arponen [30] | Low risk | High risk | High risk | Low risk | Low risk | Low risk | Low risk | Poor |
| 7 | Cansın Kutay et al. [32] | Low risk | High risk | High risk | High risk | Low risk | Low risk | Low risk | Poor |

**Table 4.** Risk of bias assessment for nRcts.

| Sr. No. | Study | Bias due to confounding | Bias in selection of participants into the study | Bias in classification of interventions | Bias due to deviations from intended interventions | Bias due to missing data | Bias in measurement of outcomes | Bias in selection of the reported result | Risk of bias |
|---|---|---|---|---|---|---|---|---|---|
| 1. | William A. Cole [9] | No | No | No | No | Yes | No | No | Low |
| 2. | Cenk Doruk et al. [10] | No | No | No | No | No | No | No | Low |
| 3. | Márcia Brandão et al. [11] | No | No | No | No | No | No | No | Low |
| 4. | Annemieke Bos et al. [5] | No | No | No | No | No | No | No | Low |
| 5. | Beata Kawala et al. [12] | No | No | No | No | No | No | Yes | Low |
| 6. | Marijke Dieltjens et al. [13] | No | No | No | No | No | No | No | Low |
| 7. | Pauls A et al. [14] | No | No | No | No | Yes | No | No | Low |
| 8. | Timm Cornelius Schott et al. [15] | No | No | No | No | No | No | No | Low |
| 9. | Olivier M Vanderveken et al. [16] | No | No | No | No | No | No | No | Low |
| 10. | Timm Cornelius Schott et al. [17] | No | No | No | No | No | No | No | Low |
| 11. | Timm Cornelius Schott et al. [18] | No | No | No | No | No | No | No | Low |
| 12. | George Tsomos et al. [19] | No | No | No | No | No | No | No | Low |
| 13. | Katharina Schäfer et al. [21] | No | No | No | No | No | No | No | Low |
| 14. | Timm Cornelius Schott et al. [22] | No | No | No | No | No | No | No | Low |
| 15. | Ali S. A. Al-Kurwi et al. [23] | No | No | No | No | No | No | No | Low |
| 16. | Charavet C et al. [25] | No | No | No | No | Yes | No | No | Low |
| 17. | Luis Huanca Ghislanzoni et al. [28] | No | No | No | No | No | No | No | Low |
| 18. | Michał Sarul et al. [31] | No | No | No | No | Yes | No | No | Low |

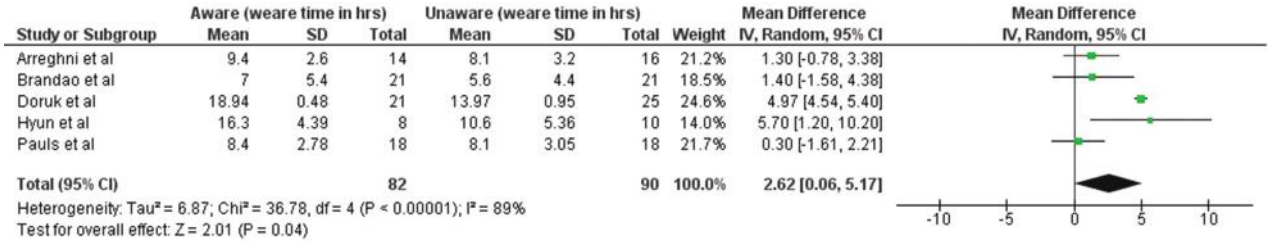


**Figure 4.** Forest plot evaluating difference of compliance between subjects aware about wear time measurement device vs unaware about wear time measurement device.

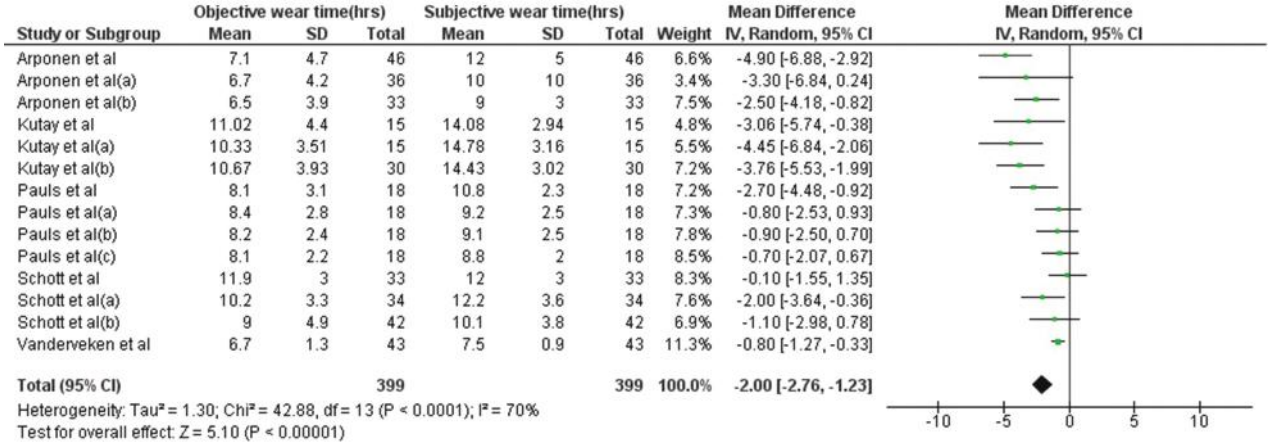


**Figure 5.** Forest plot comparing objective vs subjective wear time.

studies, heterogeneity was more than 50% ($I^2 = 70\%$); hence, a random effect model was applied. The average daily wear time of the appliance as reported by the patients was significantly higher than the actual time recorded by the device, with a mean difference of −2.00 (95% CI = −2.76 to −1.23; Z value = 5.10); and this difference in daily average wear time (hours/day) between time recorded by the sensor and time reported by patients was statistically significant ($p < 0.00001$).

## Discussion

### *Summary of evidence*

Removable appliances have been widely used in orthodontics, either for correcting malocclusion or for retention of treatment results. In orthodontic treatment, patient compliance is of crucial importance for successful outcomes, especially when removable appliances are used. Subjective methods lead to overestimation of compliance by patients, parents as well as orthodontists [5]. Studies have shown that subjective compliance measurements were almost two times greater than the compliance assessed objectively [11]. The evolution of wear time measurement devices over the years seems to revolutionize Orthodontics. An electronic wear-time measurement is a profitable tool for identifying non-compliance. Researchers across the studies have based their hypothesis on wear time obtained from wear time measurement devices incorporated in the removable appliances. Out of 25 studies, 9 studies were acquired for quantitative analysis of outcomes conducted with meta-analysis. The results showed patients tend to cooperate more when they are aware of wear time monitoring. On average aware patients wore their appliances 2.6 hours more than unaware patients. Objective wear time was less as compared to the subjective wear time, indicating that the patient compliance was lower and ephemeral to that predicted by the orthodontist.

### *Compliance with extraoral appliances*

The present systematic review contains 7 studies that assessed compliance levels with extraoral appliances. Of these 4 studies have assessed objective wear as well as self-reported wear. According to these studies, patients report more headgear wear time than actual. Patients and their parents overestimate the wear duration. However, orthodontists also tend to overestimate the wear duration of their patients [5].

Bimodal distribution (good compliance group and poor compliance group) of compliance was observed in the study population [9]. The good group had an

average compliance level of 92.8%. The poor group had an average compliance level of 34%. The average compliance level was 74.5%. It was found that when an uncooperative group of patients was informed about wear time monitoring, about 80% of them improved the use of headgear [10]. The compliance rate was average during the night and poor during the day. Appliance wear during the night was over 50 % whereas during the day it was almost zero, especially for hours ranging from 11 am to 8 pm. Effective headgear wear was 8.7 hours/day (73%) [28].

### *Compliance with intraoral appliances*

Twenty included articles studied compliance with removable intraoral appliances. All these studies, collectively concluded that patients wear removable appliances for a shorter time than recommended. A statistically significant difference was found in compliance depending on the gender of patients. The statistical analysis showed that boys are more compliant, however, the statistical significance was not large. In a study by Beata Kawala et al [12], 50% of boys followed the wear time regimen prescribed by their clinician whereas only 33.3% of girls followed recommended wear time regimen.

Patients when unaware of wear time monitoring tend to overestimate their wear time by approximately 33%. When patients are made aware of their objective wear times their subjective estimations of wear time become more accurate [14]. A clinician can better understand possible obstacles during the treatment by knowing compliance. More transparency regarding patient compliance can be achieved by making the patient aware of wear time monitoring. However, knowing that wear time is being recorded does not necessarily increase the amount of wear time. Pauls A et al [14] have shown that compliance was insufficient despite being informed about wear time recording for functional appliances, yet for retainers the compliance was sufficient.

In contrast with the above results, Paul Hyun et al [20] have shown that the study group which was aware of the wear time documentation wore their appliance more than the non-aware group, and the difference was statistically significant. However, before and after becoming aware of the use of microsensors the non-aware study group did not show a significant change in wear time. During the retention phase wear time of about 8 hours for removable retainers was accepted and followed for several months by most of the patients [15]. Microelectronic quantification of wear time and wear behaviour offers a new medical and technical aid for efficient and individualized orthodontic treatment with removable appliances [17]. Indirect wear-time evaluation cannot be recommended for reliable determination of wear time anymore. Objective documentation of wear time makes it easier to determine factors affecting the treatment progress, especially in cases of uncertainty over following the wear time regimen [22].

For the Twin Block appliance daily wear time threshold was found 8 hours for achieving adequate treatment results as well as compliance [31]. Patients tend to accept and follow a wear time of about 9 hours for several months [21]. However, for optimal treatment outcomes, adequate wear time duration for functional appliances still needs to be established.

### *Comparison of compliance with extraoral vs intraoral*

Two [24,30] out of 25 studies assessed compliance with extraoral as well as intraoral appliances There was no difference in compliance between intraoral and extraoral appliances [24]. Compliance levels are not dependent on the type of appliance prescribed. Nonetheless, it was found that the average actual appliance wear time was half of that prescribed in patients with Twin Block appliances and even less in those with Headgear Activator [30].

### *Limitations*

Studies incorporated in this systematic review had substantial heterogenicity in the study design as well as the types of interventions used. Since we aimed to focus on appliance wear rate, we incorporated both randomized and nonrandomized studies. Nonrandomized studies have a greater inherent risk of bias. Nevertheless, the methodology was inadequate for certain studies included. Since data were heterogeneous, the number of studies included in the meta-analysis were less. Wear time measurement devices can be a potent tool to have good compliance. However, to establish the actual influence of wear time measurement devices on compliance further research is still needed.

## Conclusion

Wear time measurement device is an effective tool to determine as well as enhance compliance with removable orthodontic appliances. Patients tend to overestimate the duration of wear time hence wear time measurement devices should be used to assess compliance with removable orthodontic appliances. Compliance with removable appliances increases when patients are made aware of being monitored, still, more RCTs with appropriate study designs should be carried out in the future to evaluate the effect of being monitored on patient compliance.

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Author 1: Literature search, Study selection, Analysis, Collection and interpretation of data, Review writing, Bias Assessment.

Author 2: Conceptualization, literature search, Supervision.

Author 3: Supervision, Resolve disagreement and critical appraisal.

Author 4: Visualization.

Author 5: Validation.

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