

Compliance of children with removable functional appliance with microchip integrated during covid-19 pandemic: a systematic review

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Treatments with removable appliances are widely used in Europe to correct dento-skeletal dysgnathia in the growth phase that is a period of poor cooperation of the patients. Adherence to the wear-time prescription is often not achieved and it represent the main argument against the use of removable devices. Suspected non-compliant behavior with the wear time prescription is often the subject of medico-legal disputes, which can deteriorate doctor-patient relationship. The use of microchips allows to document objectively and clarify the patient's behavior. To conduct a systematic review of the orthodontic literature to identify the factors associated with compliance in orthodontic treatment. We conduct a systematic review that aimed to identify the factors associate with compliance in orthodontic treatment. The main purpose was to assess the objective levels of time of use of the removable appliances and the self-reported levels. A literature search was conducted by the electronic databases PubMed and Cochrane Library. The following search terms were used: compliance functional removable orthodontic appliance. Randomized and nonrandomized controlled trials, prospective cohort studies, case series, qualitative and mixed-methods studies objectively assessing compliance levels were included in the study. A total of 94 articles were identified by PubMed and 14 articles by Cochrane. The papers selected were included for the qualitative analysis and categorized according to the subjects age, the clinical appliance, compliance factors, wear time and monitoring. Removable appliances are an important part of orthodontic treatment, used in growth phase of the patient. Collaboration with removable functional devices determines success / failure in treatment.

The British Orthodontic Society (2008) defined orthodontic treatment as 'a specialized branch of dentistry concerned with development and management of deviations from the normal position of the teeth, jaws and face (malocclusions) (1). Functional removable orthodontics appliances are

devices used for orthognathic treatments (2) in order to correct skeletal dysgnathia, to guide the maxillary and mandibular growth of the small patient and to stimulate bone expansion (3–6). The early interceptive orthodontic treatment aims to prevent and correct dental/skeletal malocclusion and is based

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on the principle that correction should be performed before an abnormality has fully developed (7–9).

Early interceptive orthodontic treatment with removable functional appliances in deciduous teeth and in mixed dentition reduces the needs of a succeeding fixed appliances treatment, avoids skeletal asymmetry (TMJ or maxillary arch, basicranial skeletal asymmetry) and pathogenetic masticatory function. The great advantage of removable appliances lies in the ability to expand the bone and change the direction of growth (10–17). The functional appliances are designed to develop forces on the teeth or jaws, modifying the balance between the muscles, arches and tongue, so as to facilitate the movement of the teeth. Its use also corrects bad habits such as oral breathing and atypical swallowing (18, 19). The mobile device is made with the medical prescription in the dental laboratory on the patient's dental impressions and is made up of an acrylic resin part and metal wire elements, important for its stability in the oral cavity, for tooth displacements and for muscle correction.

The success of early orthodontic treatment with removable appliances is highly dependent on patient compliance (20), defined as the patient's behavior matches the doctor's recommendations. According to O'Brien et al. (2003), early functional treatment increases the self-esteem (21) and reduces negative social experiences. Compliance is a key concept in health care and affects all areas of health care.

The orthodontic successful treatment depends on a variety of factors. Compliance in orthodontic treatment was mentioned over 2000 years ago by Aulo Cornelio Celso²² (25 a.C.-50 d.C.), in his 'De Re Medica', when he suggests to stimulate the eruption of permanents in the right position, with constant pressure of a finger. He advised patients to use continuous finger pressure to move their teeth to a more desirable position, but he noted that patients who did not comply with the doctor's instruction failed to achieve successful results (22). In December 2019 a novel β -coronavirus (SARS-CoV-2) first reported in Wuhan, Hubei province, China caused pneumonia and rapidly spread to other provinces of China and other countries (23–28).

During the pandemic period, there were also urgencies related to orthodontics. In particular, there were problems related to the management and control of children with removable functional devices. In case of breakage of the appliance or pain, it was recommended to suspend the use of the appliance for the moment, in order to reduce emergencies that cannot be managed in the doctor's office (29). Furthermore, it has been seen that the oral cavity has a high expression of the ACE-2 receptor, considered the main cellular receptor of the host for the SARS-CoV-2 virus (30–32). An objective, reliable and accurate control system is currently available in clinical practice, which is based on a microchip integrated in the appliance. The system is called TheraMon® (Therapeutisches Monitoring). In this way the thermo-sensitive microchip ($\sim 35^{\circ}\text{C}$) records the time spent in the oral cavity and the result is read by a reading station. The microchip is heat sensitive and reacts to the temperature of the oral cavity. Daily Wearing times, measured in hours, were recorded with the aid of the TheraMon® microsensor (Fig. 1).

Patient's compliance was objective assessed, relative to medical wear prescription. Wear-time documentation is well accepted by patients, as shown in a questionnaire study (33) and, when the patient is aware of microchip, this has a positive effect on treatment adherence (34, 35). Other innovative technologies that can be used to bio stimulate the bone formation, produce an antimicrobial effect on different pathogens and also to ameliorate the pain is the laser

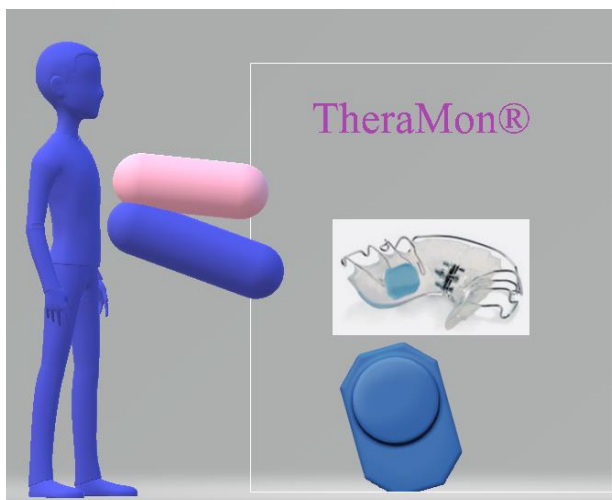


Fig. 1. Representation of TheraMon® system.

(36–39). The aim of the present investigation was to perform a systematic literature review to identify the factors associated with wearing compliance and treatment acceptance in orthodontic.

MATERIALS AND METHODS

The PRISMA guidelines was followed in order to perform the present review (40). Randomized studies, non-randomized controlled clinical trials, prospective cohort studies, case series and observational studies with and without control groups (cohort, case-control, cross-sectional) were included for the qualitative analysis. Studies that were not included were literature reviews, editorial letters, short communications, book chapters. The inclusion criteria for the selection of the articles in this study were: appliance type: removable appliances, removable retainers, objective measure used, factors influencing compliance levels. Regarding the participants: patients of any age treated with removable appliances were eligible.

The exclusion criteria were: patients treated with fixed orthodontic appliance with intraoral elastics, headgear, protraction facemask, chin cup, fixed retainers, OSAS appliance, Herbst, Forsus.

The search was performed in PubMed and the Cochrane Library. The last updated search was performed on 22 January 2021. In PubMed and Cochrane Library, the following search query was used: ["compliance functional removable orthodontic appliance" (Mesh)]. No limits were applied to the search for language, year of publication, or methodology.

Study selection

The titles, abstracts, and full texts were screened independently by two reviewers according to the pre-established protocol and the inclusion and exclusion criteria mentioned above.

Eligibility

Quantitative studies including randomized, non-randomized controlled clinical trials, prospective cohort studies and case series on compliance were eligible. Qualitative studies exploring patients' views and experiences of removable orthodontic appliances were included. Mixed-methods studies in which

quantitative or qualitative components met the above criteria were also included.

RESULTS

The present investigation included both randomized and non-randomized studies to identify publication bias. Non-randomized trials have a higher risk of bias; however, as our primary focus was patient-reported compliance and observed outcomes, this was appropriate.

The search yielded a total of 103 articles and after searching for duplicates (no duplicates), 103 studies had been found. Of these, 78 studies were excluded based on title and abstract. The full texts of 25 studies were assessed in more detail, and 8 were subsequently excluded. After screening the reference lists of the remaining 17 articles. The flowchart of the search is presented in Fig. 2. A total of 17 studies met the inclusion criteria and were processed for critical appraisal and data extraction.

Characteristics of the studies included

The main characteristics of the studies included were summarized in table I according to the patients age, appliance, compliance factors, wear time and monitoring. Several studies reported an increase of self-motivation, authority influence, quality of life evaluation, perceived treatment progress, and pragmatic and recall issues were evaluated (41–43). Charavet et al evaluated the intercanine and intermolar maxillary expansion of 4.4 ± 1.9 mm and 4.6 ± 2.0 mm and the mandibular canine and molar distances were 5.3 ± 2.0 mm and 4.7 ± 2.3 mm with wear time of 9 hours/day (44). Several studies reported a similar wear time of about 9 hours/day (45–49), while Tsomos et al and Sahm et al. reported on a few subjects a wear time range between 2–8 hours/day (50, 51). Serogl et al reported that the acceptance and wear time difference could be determined by various types of functional appliances (52). A significant higher wear time of about 9.2–11.2 h/d were reported with various color groups for the functional devices (53). No significantly differ between groups of overall wear time (54–56). De Bittencourt reported a significant improvement of the

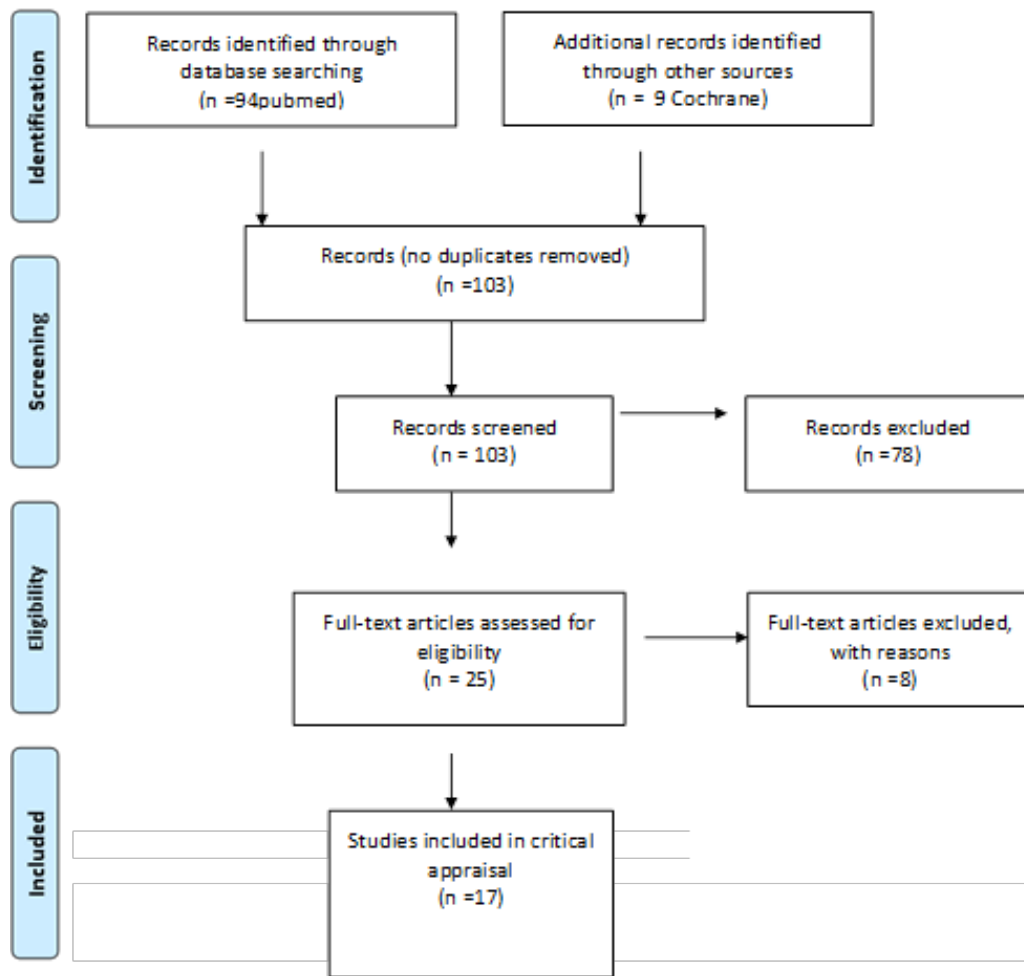


Fig. 2. PRISMA Flow Diagram of the studies selection.

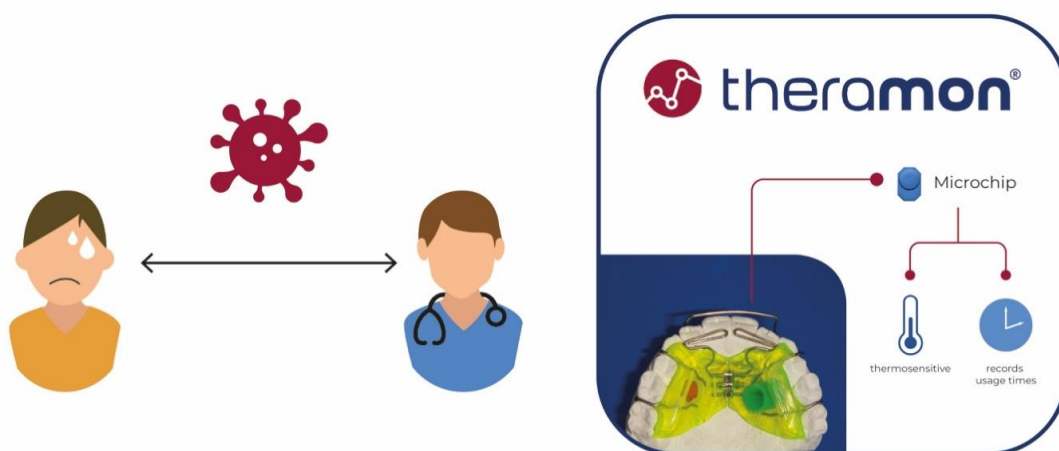


Fig. 3. Present and future.

acceptance and skeletal, dental and profile aspects after interceptive orthodontics (57).

DISCUSSION

The use of removable functional appliances can successfully correct skeletal dysgnacies. It is necessary a correct diagnosis and an optimal compliance, respecting the prescription of the orthodontist (5). This systematic review analyzed many articles and the large compliance difference was not due to the type of appliance, but was strongly influenced by factors such as patient, parents and microchip monitoring. Age and gender also influence compliance. Many authors have found that female patients are more diligent than males and that prepubescent people collaborate more than adolescents (16).

According to Bartsch et al. (58), no linear relationship between age and compliance levels and no effect of sex on compliance levels were reported. Patients in early stages of treatment are

more compliant. Parental supervision and social motivation from friends are positively correlated with compliance. Compliant patients report high results at school and are motivated to orthodontic treatment also by parents (58). Sahm et al. (59) followed 53 patients between 9 and 14 years of age, in treatment with Bionators. The authors reported that the youngest patients more compliant than older groups. In particular, the patients under 11-years-old wear appliance 8.87 h/d, patients of 12- to 13-years-old wear 6.81 h/d and patients over 13 years-old wear in mean 6.97 h/d. The females were more compliant than males (M: mean, 7.38 h/d and F: mean, 7.95 h/d). Patients in early stages of treatment are more compliant (less 3 months: mean, 8.29 h/d, 4-12 month: mean, 7.24 h/d and over 12 months: mean, 5.76 h/d). Moreover, a strong correlation that exists between compliance and patient credibility was reported, because the “*poor compliant patient*” over-estimate the wearing time. Factors such as operator-patient interaction, regularity of wear and

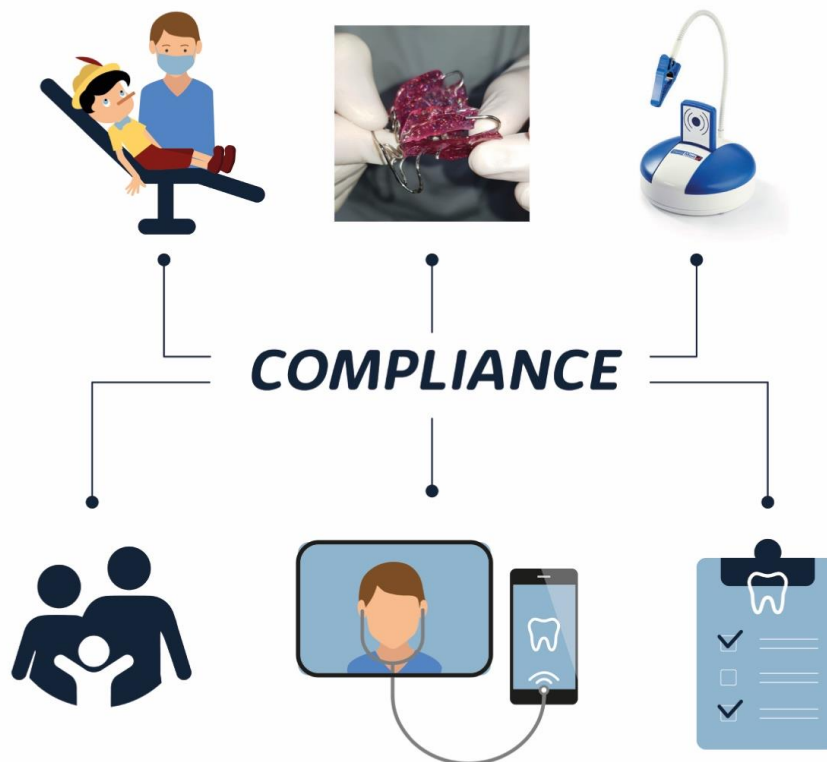


Fig. 4. Compliance factors.

Table I. Summary of the studies included for the qualitative review according to the patients age, appliance, compliance factors, wear time and monitoring.

AUTHORS	AGE	APPLIANCE	COMPLIANCE'S FACTORS	WEAR TIME	MONITORING
El-Huni A, Colonio Salazar FB, Sharma PK, Fleming PS ⁴¹ .	22 -adolescent mean age was 12.5 years at the time of interview.	Twin-block	Self-motivation, effective communication, perceived treatment progress, professional and parental influence, social influence, quality of life impairment and adaptability	one-to-one semistructured interviews	Tape recorded interview and notes TheraMon® microsensor data taken in those not responding to treatment. Participants who had been wearing the appliance for ≥ 3 months were considered for inclusion
Charavet C, Le Gall M, Albert A, Bruwier A, Leroy S. ⁴⁴	69 - mean age was 7.8 ± 1.1 years	Planas appliances	Age, gender, and presence of parents at visits did not modify compliance.	on average 15.8 ± 5.2 h/d	TheraMon® microsensor Patients were followed up for a period of 9 months
Schott TC, Schlipf C, Glasl B, Schwarzer CL, Weber J, Ludwig B. ⁵⁴	100 - 13-20 years	removable Hawley retainers and functional appliance retainers	no influence by device type. Age, sex, place of treatment, and insurance status produced changes in the median wear time of up to 50%	prescribed wear time of 8 hours or more per day. Real median wear time 7.0 hours per day	TheraMon® microsensor at least 90 days of wear-time documentation.
Arreghini A, Trigila S, Lombardo L, Siciliani G. ⁴⁵	30 -aged between 6 and 15 years (mean age 9.8 years)	Class 2 (Frankel or Bionator) or a class 3 appliance	Age, monitoring awareness	for 8 months (8.6 ± 2.9 hours, far lower than the 13 hours Prescribed)	TheraMon® microsensor: 14 were informed and 16 were not informed The mean observation period was 8 months (range 2–16 months).
Tsomos G, Ludwig B, Grossen J, Pazera P, Gkantidis N. ⁵⁰	45 The median age of patients with 14 h/d prescription wear was 11.8 years and that of the 8 h/d prescription wear group was 12.7 years).	removable orthodontic appliances	strong negative correlation of age, not difference sex	14 active (14h/d) 31 passive (-24 8h/d -7 14h/d) patients' actual median wear time was 9.00 h/d	TheraMon® microsensor During a median observation period of 186 days (range, 55–318 days)

Schott TC, Meyer-Gutknecht H, Mayer N, Weber J, Weimer K. 42	109 - aged 6-20 years (12.3±2.9 years)	33 expansion plates, 34 functional appliances, and 42 retention plates	depending on the type of appliance	The prescribed mean wear time for all treatments was 14.5±1.9 hours per day compared to a practitioner-estimated mean daily wear time of 10.6 (± 3.3) hours and a patient-reported mean wear time of 11.3 (± 3.6) hours per day. The mean objective daily wear time measured with the microelectronic sensor was 10.2 (± 4.1) hours	TheraMon® microsensor and questionnaire (mean treatment duration: 59,1 days functional, 63,4 days plate,102,8 retainers)
Schott TC, Menne D. 53	117 -4-14 years	active removable plate or functional appliances	not significantly influenced by the patient-selected colors. median wear times involved an age-related decrease by 0.56 h/y	The longest median wear times were recorded in the blue and green groups (≈11 h/d) and the shortest ones in the red and pink groups (≈9 h/d)	TheraMon® microsensor 90-day study period.
Schott TC, Ludwig B. 47	281 -6-17 years	removable appliances	Wear Behavior variable	9.0 hours per day, compared with the 12 to 15 hours per day prescribed	TheraMon® microsensor wear time for a period of at least 6 months
Čirgić E, Kjellberg H, Hansen K, Lepp M. 48	21 -mean age 13.2 years	prefabricated appliance (Myobrace) and a modified Andresen activator	parents' involvement, dentist, discomfort and pain, active involvement, internal motivation and external support listen and understand adolescents' needs and requirements	Participants were instructed to use the appliance nightly and 2 hours during the day for a total of 12–14 hours.	interviews tape-recorded 'Can you please tell me about your experiences of the treatment with and using your removable functional appliance?' a 1-year follow-up
Gross AM, Samson G, Dierkes M. 49	Pre-adolescent Limited numbers of subject (numbers not specified)	removable appliance	behavior in function of environment. Renforce /punishments Parents-child relationship	Patients instructed to wear appliance 20 h/d Compliance 90%	Patients monitored in a period ranging from 2 to 10 weeks

Sahm G, Bartsch A, Witt E. ⁵¹	18 -9-14 years	Bionator	fulfilling only 50-60 per cent of the orthodontist's requirements	over a period of 3-6 months averaged 7.65 hours per day of wear	Timing device (magnet system) the wearing time was measured on the average for 4.5 months
Witt E, Bartsch A, Sahm G. ⁴³	172 orthodontists who treat and follow patients	Schwartz plates in an average of 43.7%, functional orthopaedic appliances in an average of 37.6% of the cases, the classical activator (61.1%) and the Bionator (58.7%)	Wear times actually, prescribed average 15 (functional appliances) and 16 hours (plates) daily, while the minimum wear time considered necessary for successful treatment averages 12.8 for functional appliances and 13.9 for plates.	Particular times of day or night are prescribed as wear times by some 60% of responders, while others prescribe merely a certain number of hours of daily wear.	Questionnaire
de Bittencourt Neto AC, Saga AY, Pacheco AA, Tanaka O. ⁵⁷	5 - Growing patients at different phases	Klammt's elastic open activator (KEOA)	reducing the risk of trauma involving maxillary incisors labially proclined and providing patients with psychological benefits and self-esteem	10 to 15 hours a day during 1.5 to 2 years	Appointments were scheduled every 15 days, with monthly activations of coffin springs skeletal, dental and profile aspects (cephalometric analysis and photographs)
Sergl HG, Zentner A. ⁵²	10 -18-32 years	Bionator, functional corrector FR-I and elastic open activator	influence of shape and design, acceptance of an orthodontic appliance	12h/d Effects of appliances on speech, acceptance, assessed by means of standardized tests	considerable difference in acceptance of various types of functional appliances
Pauls A, Nienkemper M, Panayotidis A, Wilmes B, Drescher D. ⁵⁵	32 - between 6.42 and 21.25 years	removable appliances/retainers	Overestimation, more realistic once they know wear time is being monitored	15 hours per day	TheraMon® microsensor: patients were asked about their subjective wear time and afterward were told about the objective wear time wear- time data for each patient for a total of 168 days.
Schäfer K, Ludwig B, Meyer-Gutknecht	141 -7-15 years	active removable appliance	age, gender, type of device, location of treatment, and health insurance status	The median daily wear time was 9.7 hours/day for the entire cohort, far less than the 15	TheraMon® microsensor 3 months

H, Schott TC. ⁴⁶			orthodontist- patient relationship	hours/day prescribed.	
M Saleh, MY Hajeer, A Al-Jundi ⁵⁶	33 - average age: 7.5 ± 1.33 y	Removable Mandibular Retractor (RMR).	significant decrease in the levels of pressure, impaired speech, impaired swallowing and lack of confidence in public was observed two weeks following appliance insertion. Mandibular constraint feeling required three months to decrease significantly		Pain and discomfort were assessed using standardised questionnaires at the following assessment times: 7day (T1), 14 day (T2), 6 weeks (T3), 3 months (T4) and 6 months (T5) after appliance insertion.

duration of treatment are the most influential (59). El-Huni (41) analyzed the factors influencing compliance in adolescents treated with a Twin-block appliance: self-motivation and Self-perception of malocclusion, effective communication, perceived treatment progress, attitude toward orthodontic treatment, professional and parental influence. Patients with Planas appliances monitored with TheraMon® wore their appliance on average 15.8 h/d though 24 h/d was prescribed. Age, gender and presence of parents at visits did not modify compliance. A 24 h/day wear time prescription was not necessary to achieve efficacy (44). Another study (45) with TheraMon® microchip shows that the average compliance recorded was 8.6 ± 2.9 h, less than the 13 h prescribed. The younger patients showed greater compliance, respect the adolescent. Compliance is generally poor in young patients, regardless of their gender and psychological maturity. Monitoring awareness doesn't increase compliance but provide dentist with objective information about their patients' compliance (45). Also, Schäfer (46) quantified daily wear time of active removable appliances using integrated microelectronic sensors. The age is an important factor, because youngest patients more compliant than older (7-9 years old: median 12.1 h/d, 10-12 years old: median 9.8 h/d, 13-15 years old: median 8.5 h/d). Girls are more compliant (M: median 9.3 h/d and F: median 10.6 h/d). The authors reported higher compliance levels in patients with private insurance. (Statutory health insurance: median, 9.6 h/d, Private health insurance: median, 11.4 h/d).

The relationship between orthodontist and patient

seems to play a key role in patient adherence (46). Tsomos (50) highlights a strong negative correlation age-daily percentage of wear time per day. Sex did not have significant influence on compliance. Compliance was insufficient for functional treatment (14 h/d prescription), while it was sufficient for retention purposes (8 h/d prescription). Microchips can help to assess compliance with removable orthodontic appliance (50). Serogl (52) examine the influence of the shape and design of different types of functional appliances on their patient acceptance. The results indicate a notable difference in the acceptance of various types of functional appliances. Bionator, the FR-I and the elastic open activator showed the highest acceptance by the test subjects. Colored removable appliances may improve treatment acceptance, but do not improve wear time behavior (53). Pauls (55) reported that patients overestimate their wear times but become more realistic once they know wear time is being monitored. TheraMon® allows a realistic view of compliance by patient and orthodontist. Saleh (56) observed no difference between males and females with regard to acceptance. It is necessary to improve compliance with TheraMon® microchips and TheraMon® RPB (Remote Patient Box), also in relation to the COVID-19 pandemia. During the lockdown, dental remote assistance has reduced patients' outpatient visits, allowing virtual monitoring, avoiding compromising therapy, especially in orthodontic treatments. telemedicine is now recognized as part of health care also by the World Health Organization (WHO) (60). Also, the

disinfection of the dental clinic is important during this period as mentioned in the article of Scarano et al. (61). Tele-dentistry reduces appointments thanks to long-distance monitoring of patients. The goal was to reduce patient outpatient visits by maintaining regular monitoring without compromising outcomes (62). The TheraMon® microsensor offers a new perspective for prescription monitoring. The microsensor is a reliable method of cooperation control, motivate parents and patients and make an objective evaluation of the collaboration (63).

The new Theramon® RPB is an accessory placed in the patient's home and connected to the home WiFi. Data that analyzes and records compliance is available to the clinician in near real time without seeing the patient. Theramon® RPB can also store data when not connected to wi-fi. Additionally, Theramon® RPB charges the chip battery when the device is placed inside. A UV light inside the Theramon® RPB helps to fight germs and bacteria (64).

CONCLUSIONS

The success of the orthodontic treatment with removable appliances is correlated to multiple factors, (diagnosis, prescription, selection of devices collaboration/compliance, patient's behavior, parents). According to the evidence of the present review, the subject's compliance with removable functional orthodontic appliances is often inferior compared to the orthodontist prescription. In fact, the patients tend to overestimate the wearing time of the appliance. The quantification of wear time offers medical support and allows to personalize orthodontic treatment with removable appliances. The patients monitored with the Theramon® microchip demonstrated greater collaboration, aware of being monitored. Patients who receive better information are encouraged and demonstrate more collaboration. The success of orthodontic practice depends on the interaction, communication between the orthodontist and the patient.

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