



## Adherence to the Use of Removable Orthodontic Appliances by Children with Monitoring Microsensor Evaluation

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**ABSTRACT:** The use of removable orthodontic appliances is extremely widespread in Dentistry to correct occlusion and periodic alignment problems. However, patient adherence to treatment remains a significant challenge due to insufficient use of these devices. This Final Course Work proposes a literature review on the use of microsensors coupled to removable orthodontic appliances, focusing on portable electronic systems that allow objective, automatic and continuous monitoring of the time of use. Aspects such as accuracy, functionalities, advantages, benefits, success rates and patient satisfaction will be analyzed. In addition, clinical research will be carried out with 20 patients divided into two groups: 10 will use appliances with microsensors, while the other 10 will only receive guidance on use without electronic monitoring. The objective is to compare treatment adherence and clinical results between the groups. With recent advances in miniaturization technologies and connectivity through the Internet of Things (IoT), wearable devices represent an innovative approach to transforming orthodontic care into a more participatory and preventive practice.

**KEYWORDS:** Orthodontic appliances, wearable devices, internet of things, orthodontic.

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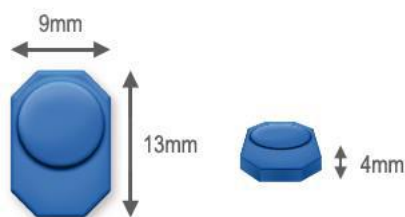
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### I. INTRODUCTION

Patient cooperation is recognized as one of the main success factors in the outcome of orthodontic treatment [1], especially when removable appliances are used. Recent evidence [2-3] suggests that subjective access to cooperation, such as those reported by patients or guardians, is usually unreliable.

The success of an interceptive orthodontic treatment with removable devices depends on the use of at least 13-16 or 24 hours, according to the orthodontist's prescription [4]. However, some studies report that patients usually use it for a little more than 9 hours a day, so the time of use required is rarely satisfactory. Therefore, recording the time of use of the removable appliance is a benefit, as it can help the professional to promptly identify and overcome cooperation problems. In this way, a more efficient and effective result of the treatment is provided.

Due to this great concern in orthodontics, different devices have been introduced to objectively measure the time of use of these appliances [7-8]. The latest device developed for this measurement is the electronic micro sensor called TheraMon [5]. This has been described as reliable and realistic in measuring the time of use of orthodontic appliances [6].



**Figure 1:** Microsensor used in removable orthodontic appliances. Source: Nova Lianka (website).



**Figure 2 and 3:** Representation of the TheraMon® device. Images taken from the company's website (<https://www.thera-mon.com/>).

## II. METHODOLOGY

### 2.1 Ethical aspects

The study was submitted for approval by the Research Ethics Committee (REC), being approved under the Certificate of Presentation of Ethical Appreciation (CAAE) number 82384624.6.0000.5420 and conducted in accordance with the standards determined by the Declaration of Helsinki and by the Resolution of the National Health Council No. 466, of December 12, 2012. For each patient, the Informed Consent Form (ICF) was obtained from all the children's legal guardians, as well as the Informed Consent Form (TALE) from the participants.

### 2.2 Sample calculation

This study was based on a main sample of patients requiring RME for comparison of cross-sectional loss with the use of a removable retainer or retainer with the hyrax expander, both for 6 months.

Thus, the sample size calculated for each group was based on a significance level of 0.05 percent and power of 80 percent (alpha of 1.5 mm) to detect a minimum difference of 1.5 mm ( $SD \pm 1.5$ ) of recurrence of median palatal suture expansion between the groups. The standard deviation was adapted from previous studies<sup>10</sup>. The sample size calculation indicated that 16 patients would be needed in each group. To compensate for dropouts, it was decided to establish a potential loss of 20% in each group, including 4 more patients in each group, totaling 40 patients for the two groups included in the study.

### 2.3 Type and location of study

This is a longitudinal, randomized and controlled clinical study, carried out with children from 6 to 12 years of age, who attended clinical care at the Faculty of Dentistry of Araçatuba (FOA), São Paulo State

University "Júlio de Mesquita Filho" (UNESP), in the discipline of Orthodontics, as well those referred with the need for treatment by the various disciplines, as well as indicated by possible screenings in the municipality.

#### **2.4 Study population**

The study population consisted of children aged 6 to 12 years, of both sexes, who met the following inclusion criteria: Present informed consent form and TAL duly signed by their legal guardian, need for RME, do not have periodontal involvement, do not present contraindications to the treatment itself, patients with incomplete maxillary bone maturation and transverse maxillary deficiency.

For the exclusion criteria, the following were adopted: patients who did not accept the treatment, as well as did not sign the informed consent form and TALE, patients who had previously undergone MRE, bone consolidation of the median palatal suture, and patients with periodontal involvement.

#### **2.5 Data collection**

The clinical examinations to assess the oral condition and assess the need for treatment were performed by a single researcher, a specialist in Orthodontics, with previous experience in diagnosis and treatment, as well as the execution of the same and installation of the proposed appliances, in the FOA/UNESP clinics. When the need for treatment was exposed to the patient's guardian, an anamnesis was instituted, obtaining information on socioeconomic characteristics and medical history, including the variables age, gender, family income, diet, access to dental services, need for special care, eating disorders, use of medications, medical treatment, previous oral health care and/or orthodontic treatment.

#### **2.6 Treatment plan**

Complete orthodontic documentation was requested from the patients, and they should be carried out with their own resources, outside the University, in places indicated for their performance. The patient attended the Faculty after the examination, so that the person responsible for the research could carry out the appropriate treatment plan for the case, which involved the investigation stage with the MRE and subsequent restraint period. The patient continued to be treated at the Faculty after the data collection stage for the present study, in continuation of his orthodontic treatment, in the relative clinics that make up the discipline of Orthodontics.

#### **2.7 Making and installing the appliance**

The Hyrax type Circuit Breaker device was used for the MRE, consisting of a metal expander screw (PecLab, Brazil), which is centered on the palatal roughness of the model obtained in the patient's plaster, or 3D printing with duplication. This device was designed by Biederman and is made entirely of stainless steel and does not include the acrylic palatal plates, which makes it much more hygienic. The device is of the dento-supported type and should be constructed with rigid wires and with a screw as close as possible to the palate, so that the transmitted force is close to the center of resistance of the maxilla. It consists of two orthodontic bands in the first permanent molars, an expansion screw located at the level of the palatine raphe, with 3 mm of separation from the palatine mucosa, and also two palatine and buccal support archwires welded to the bands, which give greater rigidity to the circuit breaker, constituting the modified version of the original, which contained two bands in premolars [11].

#### **2.8 Allocation and initiation of containment**

After the active period of Hyrax breaker use, the patients were randomly allocated, through randomization performed in the "Research Randomizer" ([www.randomizer.org](http://www.randomizer.org)) and the numbers obtained were sequentially placed in brown envelopes, being retrieved at the time of dental treatment, determining which of the two groups the patient will be allocated:

- Group 1: The Hyrax circuit breaker was kept in the mouth as a retainer after screw immobilization for 6 months.

- Group 2: Removal of the Hyrax circuit breaker, alginate molding, obtaining the plaster model, re-cementing the same device in the mouth, until the manufacture of the removable retainer ready for its installation, resulting from the removal of the Hyrax circuit breaker. This period should not exceed 7 days.

In the subdivision for Group 2, verbal instructions were given to 10 patients on the importance of using the retainer for as long as possible, being reminded via WhatsApp message to the others 10 patients, verbally explained the importance of the use, but the Theramon micro monitoring sensor was included in the devices.

The Theramon® sensor used in this study is a small device (12 mm × 8 mm × 2 mm) covered by polyurethane (Figure 1), used to measure intraoral temperature every 15 minutes. The range of temperatures among which the device is considered is from 31.5 °C to 38.5 °C and the sensor is capable of recording temperature with an accuracy of 0.1 °C<sup>12</sup>. The Theramon® software read and interpreted the data (Theramon software, version 1.2.2.26; Handelsagentur, Gschladt, Austria).

### 2.9 Blinding

Due to clinical limitations, only the outcome assessors will be unaware of the groups to which patients were allocated. This applies to the evaluators who will perform the measurements of the Cone Beam Computed Tomography (CBCT) volumes, who are also unaware of the study protocol.

### 2.10 Reviews

Monthly evaluations of patients allocated to both Group 1 and Group 2 were carried out to verify the stability of the devices and reinforce instructions in the first 6 months of retention. After that, patients will come every 3 months to check them, if there are no incidents with the devices, such as the need to re-cement the Hyrax circuit breaker, or make a new removable retainer.

### 2.11 Data analysis

Reports on the use of removable appliances obtained by means of the TheraMon® Microsensor system (MC Technology GmbH, Hargelsberg, Austria), which records intraoral temperature at regular intervals and allows the daily time of use to be objectively estimated, were analyzed. The data refer to seven patients undergoing orthodontic follow-up, whose appliances contained the built-in sensor and were programmed for reading in their own software.

The reports provided contain the variables of interest:

1. Average daily hours of use;
2. Percentage of compliance (percentage of days in which the patient reached the prescribed goal);
3. Number of days recorded;
4. Total hours recorded.

As a clinical reference parameter for adherence, a minimum use of 15 hours/day was considered, according to the prescription established in the treatment protocol. Patients with a daily mean  $\geq 15$  h/day were classified as "adherent".

To characterize the sample, a descriptive analysis was performed: mean, standard deviation (SD), median, interquartile range (IQR), minimum and maximum values, and proportion of adherent patients. The presentation of the results prioritized the detailed description, since the sample size ( $n=7$ ) does not confer robustness for statistical inference with population significance.

## III. RESULTS

The research began with a total sample of 10 (ten) patients using a removable device with a microsensor; however, right at the beginning of the follow-up, there were 3 (three) losses of the device by the patient. This fact explains an interesting condition that draws the attention of professionals regarding the use of removable appliances by children, regarding the impairment of adherence.

Therefore, for the complete follow-up (6 months), 7 (seven) patients were included, with mean values of use ranging from 0.95 to 16.36 h/day. Only two patients (28.6%) reached or exceeded the goal of 15 h/day. The overall mean use was  $11.81 \pm 5.17$  h/day, with a median of 12.43 h/day and IQR of 3.49 h/day.

Table 1 presents the individual data of each patient, including average hours/day, compliance (%) and total days recorded.

Patient	Avg. hours/day	Compliance (%)	Days recorded
P1	15,20	78,29	175
P2	10,75	71,50	193
P3	14,77	87,05	193
P4	12,24	76,34	186
P5	12,43	77,96	186
P6	0,95	22,28	193
P7	16,36	95,85	193

**Table 1:** Individual characteristics of use recorded by TheraMon®.

In the general analysis of the data, for the 7 patients included, the following data were observed:

- Average = 11.81 h/day
- Standard Deviation (SD) = 5.17 h
- Mediana = 12,43 h

- Intervalo Interquartile (IQR) = 3.49 h
- Minimum period of use = 0.95 h
- Maximum period of use = 16.36 h
- Adherents ( $\geq 15$ h/day) = 2 (28.6%)

The following graphs illustrate the distribution of average hours/day and the individual variation in relation to the goal of 15 h/day.

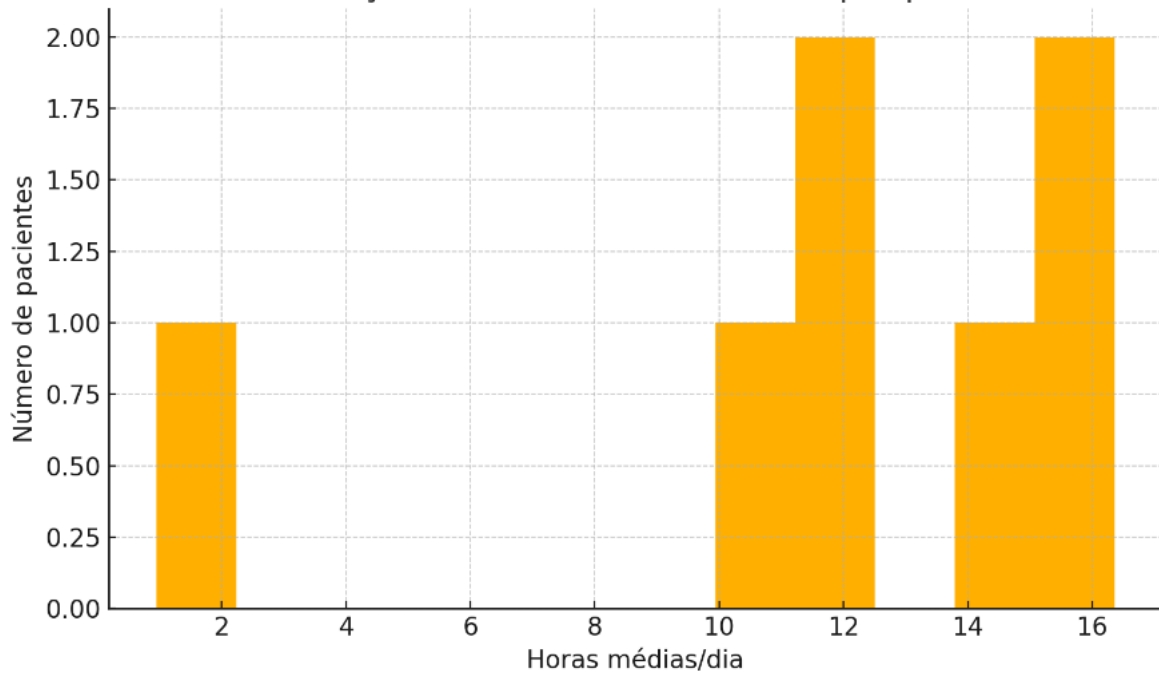


Figure 4: Distribution of average daily hours per patient.

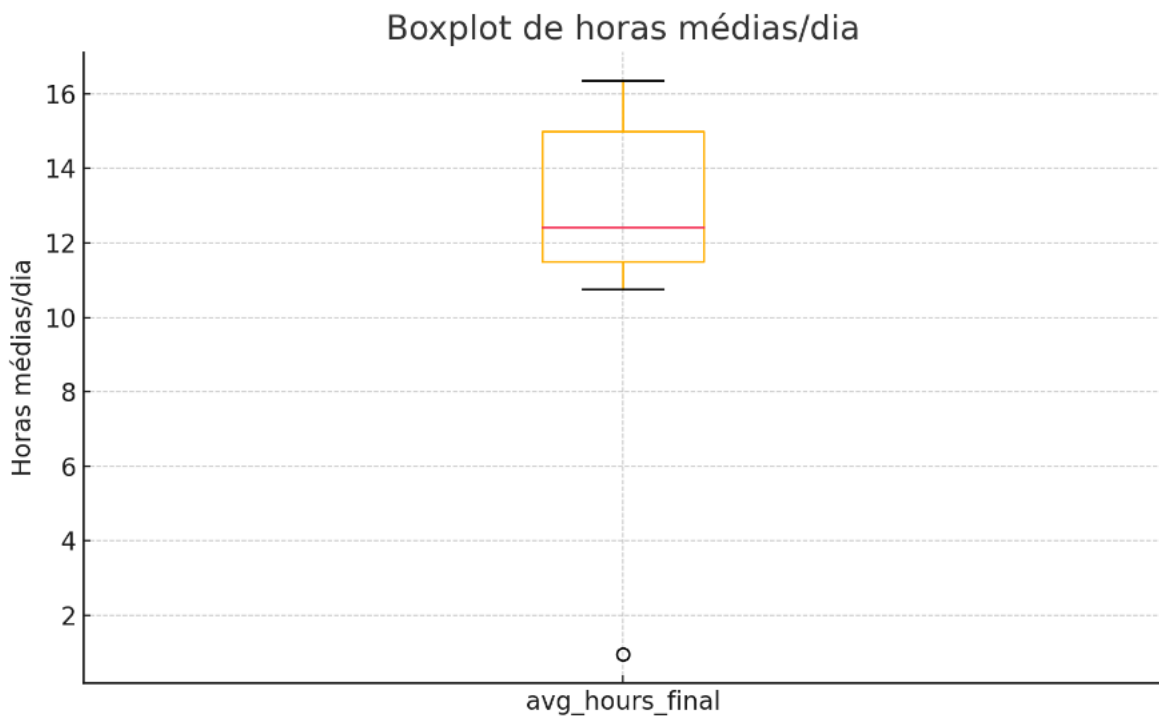


Figure 5: Boxplot of average daily hours per patient.

## V. DISCUSSION

The data indicate that, in this sample, the mean daily use (11.81 h/day) was lower than the clinical goal of 15 h/day. This finding is in line with previous studies that used Theramon® or similar sensors, which often report actual use times below the prescription, with medians between 7 and 12 h/day in larger samples<sup>13-14</sup>. These results reinforce the recurrent discrepancy between the prescribed use and the actual use of removable appliances.

The Theramon® device has been validated as an objective method for monitoring adherence, with studies demonstrating high accuracy in detecting intraoral use<sup>15</sup>. However, technical limitations should be considered: the position of the sensor on the palatal surface may cause under-recording of hours, and reading failures or data loss have already been reported<sup>16</sup>.

Strategies to increase adherence include behavioral interventions such as text message reminders and visual feedback of screen time. Recent studies have shown that sending daily or weekly SMS significantly improves the average time of use of devices such as the Twin Block<sup>17</sup>. The incorporation of TheraMon® into clinical protocols allows for immediate and individualized feedback, favoring patient and family motivation.

In the present study, the low proportion of adherent patients (28.6%) suggests the need for support and follow-up actions, as well as investigations to identify barriers to adherence — for example, discomfort, aesthetic impact, or difficulties in the school routine.

In methodological terms, the small sample size justifies the option for descriptive analysis, as recommended for initial exploratory studies<sup>18</sup>. However, as the present study derives from a total sample section, due to the final comparison between microsensors and reminder by smartphone message, it was justified to initially explore, in a descriptive way, the behavior of children in the use of removable orthodontic devices.

## 6 CONCLUSION

The results demonstrate that TheraMon® is an effective tool to objectively measure the actual use of removable appliances, revealing a significantly lower adherence of the patients present in the study than prescribed. The device's ability to accurately identify the discrepancy between the indicated time and the actual fulfillment of use evidences its clinical value, allowing targeted interventions to improve patient cooperation. This study reinforces the importance of incorporating monitoring technologies into orthodontic treatment, expanding the control and personalization of conducts.

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