Treatment effects of van Beek activator comparing two wear-time prescriptions assessed by microsensors: a randomized clinical trial

Philipp Scaglia
Martin Zimdahl

Supervisor:
PhD Mikael Sonesson, Department of Orthodontics, Faculty of Odontology, Malmö University

Thesis in Odontology (30 ECTS) 
Programme in Dentistry 
February, 2019
ABSTRACT

Aim

The aim of this study was to evaluate the compliance and overjet changes among patients treated with the van Beek activator comparing a twelve- and eight-hours daily wear-time prescription.

Material and methods

The study sample consisted of thirteen patients (4 boys and 9 girls) with a mean age of 10.0 years (SD = 0.9). All patients had a Class II malocclusion and were treated with the van Beek activator. Patients were randomly assigned to two groups with a wear-time of twelve and eight hours respectively. Compliance was measured with the aid of a microsensor (TheraMon®) built into the activator and the overjet and overbite were recorded after the first, third and sixth month.

Results

The mean decrease in overjet among the 8 hours group after six months was 3.4 mm compared to the 3.5 mm overjet reduction recorded in the 12 hours group. The mean wear-time in the 12 hours group and 8 hours group were 8.2 hours (SD = 1.7) and 7.9 hours (SD = 2.6) per day respectively. The overall mean daily wear-time of all patients in both groups was 8.1 hours.

Conclusions

The eight-hours prescription was easier to achieve compared to the twelve-hours. The van Beek activator was effective in Class II correction, no clinically significant difference in treatment effect was observed between the two wear-time prescriptions.
SAMMANFATTNING

Syfte

Syftet med den här studien var att undersöka följsamheten och reduktionen av det horisontella överbettet vid behandling med van Beek-aktivator genom att jämföra en rekommenderad användningstid av tolv och åtta timmar per dag.

Material och metod

Tretton patienter (4 pojkar och 9 flickor) ingick i undersökningsmaterialet med en medelålder på 10,0 år (SD = 0,9). Alla patienter var diagnosiserade med en Angle Klass II-bettavvikelse och behandlades med van Beek-aktivator. Patienterna var randomiserade i två grupper med två olika användningstider (8 timmar och 12 timmar). Följsamheten mättes med hjälp av en mikrosensor (TheraMon®) inbyggd i aktivatorn och det horisontella och vertikala överbettet registrerades efter första, tredje och sjätte månaden. Efter att datan var insamlad gjordes statistisk analys för att påvisa ifall statistisk skillnad fanns mellan grupperna.

Resultat

Medelreduceringen i horisontellt överbett i 8-timmarsgruppen var efter sex månader 3,4 mm jämfört med hos 12-timmarsgruppen som var 3,5 mm. Medelanvändningstiden var i 12-timmarsgruppen och 8-timmarsgruppen 8,2 timmar (SD=1,7) och 7,9 timmar (SD=2,6) per dag respektive. Den genomsnittliga användningstiden för samtliga patienter var 8,1 timmar.

Slutsats

Rekommendation av åtta timmar var enklare att uppnå jämfört med tolv timmar. Van Beek-aktivatorm var effektiv för korrigering av Angle Klass II-bettavvikelser, ingen klinisk signifikant skillnad i behandlingseffekt observerades mellan de två grupperna.
CONTENTS

INTRODUCTION ...................................................................................................................... 4
Malocclusions............................................................................................................................ 4
Prevalence and treatment indications of Class II malocclusion ............................................. 5
Etiology .................................................................................................................................. 5
Treatment of Class II malocclusions ...................................................................................... 6
Van Beek activator ............................................................................................................... 6
Compliance and adherence among patients ........................................................................... 7
Measuring wear-time with TheraMon®.............................................................................. 8
Aim and hypothesis............................................................................................................... 10
MATERIALS AND METHODS ............................................................................................. 10
Instruction protocol .............................................................................................................. 12
Sample size calculation ........................................................................................................ 12
Ethical approval .................................................................................................................... 12
RESULTS ................................................................................................................................. 13
Participation ......................................................................................................................... 13
Data collection ..................................................................................................................... 13
Demographics at baseline ..................................................................................................... 13
Wear-time ............................................................................................................................. 13
Overjet and overbite ............................................................................................................. 16
DISCUSSION .......................................................................................................................... 17
Sleeping time and treatment goals ........................................................................................ 17
Can measuring wear-time contribute to improved compliance? ........................................ 17
Wear-time related to gender and age ................................................................................... 18
Wear-time and compliance ................................................................................................... 18
Hawthorne effect .................................................................................................................. 19
Strengths and limitations ...................................................................................................... 20
Generalization ....................................................................................................................... 21
Suggestion for future studies ................................................................................................ 21
CONCLUSIONS ...................................................................................................................... 21
REFERENCES ......................................................................................................................... 22
INTRODUCTION

Malocclusions

The most common classification system for malocclusions was proposed by the American orthodontist Edward H Angle at the end of the 19th century. It is based on the position and relations of the first permanent molars, canines, and incisors. The central factor in an ideal occlusion according to this definition is the Class I molar relation where the mesiobuccal cusp of the maxillary first permanent molar occludes in the buccal groove of the mandibular first permanent molar. Malocclusion can be defined as any form of deviation from the ideal occlusion and regards the inter- and/or intra-relationship between the maxillary and the mandibular teeth. A perfect relation between the teeth and jaws, also defined as an ideal occlusion, is rarely found within a population (1).

In Sweden, a prevalence of 43 to 78 % has been reported for various malocclusions in children and adolescents, whereas only a mean of 27 % of all children and adolescents qualify for free orthodontic treatment (2,3). Considering the large commonality in variation from an ideal occlusion, it does not as a matter of course, mean that a patient displaying malocclusion would also be in need of orthodontic treatment. The orthodontic treatment is influenced by biological, psychosocial and cultural factors that must be taken into consideration during the treatment. The treatment decision can be based on concerns regarding prevention, function, aesthetics, and psychosocial health, which could affect the patient negatively (4).

Figure 1.

An example of a Class II division 1 malocclusion

![An example of a Class II division 1 malocclusion with prominent upper front teeth and an overjet of 9 mm. Photo was taken from a patient included in the study. Consent has been given in written form.](image-url)
Angle Class II malocclusion can be defined as when the mandibular first molar is in a posterior position in relation to the maxillary first molar in comparison to a class I occlusion. According to the definitions given by Angle, different subsets of Class II malocclusions exists. Angle Class II division 1 is characterized by protrusive and/or proclined incisors commonly associated with incompetent lip closure because of a large overjet. In Class II division 2, there is commonly less narrowing of the maxillary arch and the central incisors are retroclined. Both dental and skeletal factors can affect a Class II malocclusion. Skeletal factors associated with a Class II malocclusion are mandibular retrognathism, maxillary prognathism, or a combination of both (5,6).

**Prevalence and treatment indications of Class II malocclusion**

Reported data regarding the prevalence of malocclusions seem to vary. In Scandinavia, Angle Class II is fairly common (3,7,8). Among schoolchildren in Sweden, 14 to 25 % are diagnosed with this type of malocclusion, depending on the child's age, the early treatment of the latter can have a prophylactic effect on dental health and both reduce negative social experiences and increase the self-esteem of an individual (3,9,10). A clear correlation between large overjets and an increased prevalence of traumatic injury to the teeth of the maxillary central incisors has been found. The absence of effective protection of the upper lip combined with large overjets over 5 mm has been shown to lead to an increased trauma prevalence in front maxillary teeth which vary between 10 to 30 %. The size of the overjet has an impact on the risk of trauma, in fact, the larger the overjet is, more often is the occurrence of trauma to the central and lateral incisors. Most of the injuries occur when the patient is between 8 to 11 years old which is the age where the correction of large overjets is indicated (11–13). The reason for treating a Class II Division 1 malocclusion is not only to prevent traumatic injuries but also in order to obtain improvements in aesthetics and quality of life. Malocclusions with prominent upper front teeth can be perceived as less aesthetically appealing (14) and can in this manner have an impact on the individual oral health-related quality of life (OHRQoL) and self-esteem. Among schoolchildren, there is an association with bullying among teenager with excessive overjet and incomplete lip closure (13).

**Etiology**

Many factors are involved in the etiology of malocclusions, where both environmental and hereditary factors can have an influence (15). Retrognathic facial proportions is a character that tends to be inherited and it has been shown that several of the Class II malocclusions are likely to be genetically controlled (4). In some cases, malocclusions with severe skeletal discrepancies can be related to some genetic syndromes. Anomalies derived from a perturbation of the first branchial arch can cause anomalies in the development of the craniofacial complex, for example, micrognathia which is typically associated with malocclusions (16). To some extent, the prevalence of anomalies depends on exogenous factors such as thumb sucking or muscular forces related to physiologic activity, which could cause malocclusion (3). It has earlier been shown that sucking habits are associated with anterior open bite and posterior crossbite (17). Another important factor that influences the dental equilibrium of an individual is the resting pressure of the lips and tongue. The respiratory pattern can also have an influence on the jaw and tongue posture and in this way possibly alter the equilibrium of forces within the dentoalveolar complex (18).
Treatment of Class II malocclusions

Class II malocclusions are commonly treated in the mixed dentition, different types of removable functional appliances can be used, which utilize the facial growth forces to guide skeletal and dentoalveolar remodeling. The appliances protrude the mandible, which has been hypothesized to lead to a stimulatory effect on mandibular growth and a minor temporary inhibitory effect on maxillary growth (19). Treatment with removable functional appliances on mandibular growth has been shown to produce statistically significant changes in short-term, although contradictory clinical significance has been reported regarding this effect (20,21). Forward positioning of the mandible with fixed appliance has, in studies on rodents, shown stimulation of the condylar growth, leading to an advancement of the mandible (22–25). In another rodent model, both a group with functional appliance and a group with a combination of a functional appliance and growth hormone had a significant stimulatory effect on mandibular growth compared to no intervention, where the group with functional appliance combined with growth-hormone showed the most significant changes (26).

The success of treatment outcome with removable appliances is highly dependent on patient compliance and can, therefore, be challenging for the clinician (27). It is important to have the right timing when treating a malocclusion in order to obtain a successful outcome of the treatment (20).

There are contradictions in the literature regarding the effects on mandibular growth using functional appliances in Class II malocclusions. Some authors have reported that it could have an augmentary effect on total mandibular length, with a significantly higher effect during the adolescent growth spurt (28–30), whereas other authors have reported no clinically significant difference and attributed the Class II correction mainly to dentoalveolar changes (31). This could be related to the individual responses of the patients. In fact, it has been earlier stated that the growth rate in children is not constant and there might be differences in the skeletal maturity and growth potential of a subject (29).

Van Beek activator

The van Beek activator is a modified activator combined with a facebow for extraoral traction with an external headgear. The activator is constructed with palatal coverage, occlusal coverage on the molars and premolars, full acrylic coverage on the maxillary incisors, while no contact on the lingual aspect of the mandibular incisors is present. Full coverage can be seen on the incisal edges in order to prevent labial tipping (32). The intra-oral appliance forces the mandible in to a more anteriorly position. The extraoral headgear connected to the facebow on the van Beek activator improves the retention of the appliance and prevents it from falling out during sleep. When employing heavier forces with the headgear, a larger retruding effect on the maxillary dentition can be seen. The effects of the van Beek activator has been reported to cause retraction and intrusion of upper incisors, proclination and extrusion of lower incisors. Skeletal factors have a minor impact in the correction of Class II malocclusion with inhibition of maxillary growth and augmentation in mandibular growth and temporomandibular joint remodeling and also increase in lower face height (32–34). The reasons for a lack of treatment effects have mainly been attributed to poor patient cooperation, but also factors such as mouth breathing, vertical growth pattern, and lack of sufficient growth are of importance (35–37). It has been previously stated that in some cases wearing the activator in combination with a high-pull headgear can also have some effects on the soft tissue. For instance, significant retraction
of the upper lip and also an anteroposterior growth of the mental regions could be observed in some patients after the therapy (38).

**Figure 2.**
The van Beek activator with an embedded TheraMon®.

![TheraMon® microsensor embedded in the acrylic part of the van Beek activator, lingual placing. Photo: Mikael Sonesson.](image)

**Compliance and adherence among patients**

In the orthodontic setting, factors such as wearing the appliance, maintaining good general oral hygiene and showing up on appointments are of the highest importance, which consequently influences the patient satisfaction and outcome of treatment (39,40). Measuring compliance correctly is important in order to create more individualized recommendations, optimizing treatment planning, and analyzing treatment outcome (41). To improve adherence to the treatment, efforts have been directed toward raising awareness and understanding of the condition and its treatment (42).

Both compliance and adherence are defined by how well a patient follows an authority’s prescription, recommendation or advice, and the two concepts are often being used interchangeably in the literature. The difference is that with adherence, there is an agreement of the prescription between the patient and the clinician. This agreement is not regarded in the concept of compliance where a more authoritarian approach is employed (43).

Removable appliances have many advantages such as the ability to be adjusted extra orally and the ability to be removed in socially uncomfortable settings, although the efficacy of the
treatment is highly dependent on the patient's compliance and wearing time because of the
patient choosing himself to use the appliance or not (44,45). Al-Kurwi et al. studied the van
Beek activator with built-in sensors for monitoring of wear-time and reported significance
overjet reduction with patients wearing the appliance at least 8 hours per day. Another finding
was that none of the patients reached a daily wear-time of twelve hours. A wear-time of fewer
than 8 hours per day resulted in an insignificant overjet reduction (45). The achievement of an
optimal treatment result with functional appliances hinges therefore on good compliance and
good cooperation of the patient. It is crucial for patients to follow the recommended wear-time
in order to obtain a treatment effect. It is expected that children may not necessarily cooperate
and engage with the operators or may not be able to understand the need and the advantages of
treatment. An external motivation may, therefore, be needed by custodians, peers, and clinicians
(46). Factors influencing compliance levels are not fully understood (47,48), but several studies
have shown that custodians relations to the child, their support and involvement in the treatment
can have a positive influence on the child's compliance level (49–52). The headgear can further
challenge the compliance of the patient because of the potential discomfort while wearing it
(52).

In the literature, it appears to be contradictory data regarding gender as a factor that can
influence compliance. While some reports show increased compliance among females (53),
others in males (54), various studies have not been able to demonstrate any gender-related
differences concerning wear-time and behavior (55–57). Neither is there a clear consensus
between socioeconomic status and compliance in orthodontic treatments as many reports show
opposing results (53,58). Regarding age as a potential influencing factor, it can affect the
adherence when using removable appliances. As reported in a systematic review, among
adolescents, the younger subjects reported having a higher wear-time in relation to their older
peers (46).

**Measuring wear-time with TheraMon®**

The self-reported wear-time hours reported by the patient is generally an unreliable source of
data. A systematic review reported that patients generally overestimate their wear-time by five
hours per day regardless of what type of removable appliance was used (46). The data obtained
by the patients time reports cannot be used to evaluate patients compliance in a reliant way
(59,60). It is difficult to obtain an objective wear-time, but this problem has been solved with
the introduction of microsensors that are capable of tracking for how long the appliance has
been worn.

The TheraMon® (Gschladt Company, Hargelsberg, Austria) sensor is a microsensor sensitive
to temperature changes, it records wear-time every 15 minutes for up to 18 months. It is covered
in polyurethane with a small size (12.83 x 8.73 x 4.2mm) that can be embedded into the acrylic
part of various removable appliances. The sensor records the appliance as being used when the
temperature exceeds 35°C. Appliances with TheraMon® microsensor embedded in the acrylic
part have been reported to be well accepted by the majority of patients (61). The accuracy and
reliability of the TheraMon® sensor have previously been studied. High reliability was reported
that satisfies the requirements for use as an objective wear-time tracker for clinical trials (45).
TheraMon® uses an application-specific integrated circuit with a 16-kilobyte internal
electronically erasable programmable memory. The stored data can be transferred to a computer
through a wireless connection between the appliance and a TheraMon® station coupled by a
universal serial bus (USB) connection. The data gets transferred to an online software that stores
and analyses the collected data generating graphs.
of daily wear-time and hours per day over time. This information can be relevant in order to understand the patient’s objective compliance (45,62,63). The software can be accessed remotely and other detailed analyses on the patient's data, i.e. time tracking during a selected time period and correctly worn percentage use of the patient, can be performed.

Making the patient aware of the monitoring can affect wear-time compliance. Some reports state that having a sensor affects the wear-time because there is an awareness of being monitored (55,56), whereas others show no correlation at all (55,56). Worth mentioning is that the use of objective wear-time documentation can provide relevant information to the orthodontist in order to be able to give more individualized wear-time feedback and instructions to the patient (47,48).

It is difficult to find an exact recommendation regarding wear-time of the van Beek activator in the literature. There is insufficient evidence regarding the duration of the prescribed wear-time. Dr. Van Beek recommended a daily wear-time of 12 hours when this type of appliance was first introduced and studied (32).

Ludwig et al. reported among 281 study participants wearing removable appliances (plates and functional appliances) a median of 9 hours wear-time while the prescribed wear-time from the caregiver was 12-15 hours daily (47). Another similar example can be found in a study that tracked the objective wear-time of patients under orthodontic treatment that were instructed to utilize the appliance for 15 hours per day: an average wear-time of 7.9 hours per day was reached by all the participants. A common wear behavior was where patients that missed wearing the appliance on some days, would compensate the low usage by wearing it more on other days (47,48). In most cases, it can become difficult to utilize appliances like van Beek activator for 12-15 hours daily which is used in some clinical settings. (32,35,36,55,56). Wear-time of 7 to 9 hours has been reported to be the average of how much patients wear removable
appliances per day and might be a more realistic goal for patients to achieve. Various studies suggest that treatment with removable devices worn for about 7.9 to 9 hours per day is likely to be successful (47,48,64,65).

**Figure 4.**
Graph displaying a patient's wear-time.

![Graph displaying a patient's wear-time.](image)

**Fig 4.** Wear-time data from the TheraMon® Cloud displaying a patient's wear-time in a graph. The TheraMon® technology gives the possibility to determine the objective patient wear-time more accurately and to generate more interesting findings, i.e. mean wear-times over a specific time period. The diagram is presenting the daily wear-time over a six-month evaluation period. The blue line denotes the minimum wear-time per day. The software shows a diagram of the daily wear-time over a six-month period. Mean wear-time (11.2 hours per day) is clarified by the dotted orange line, the blue bar signifies the prescription of 8 hours per days (45,62,63). The screenshot was taken from the TheraMon® Cloud software.

**Aim and hypothesis**

The aim of this study was to evaluate the compliance and overjet changes among patients treated with the van Beek activator comparing a twelve and eight hours wear-time prescription. The hypothesis for this study was that there is no clinically significant difference in wear-time and treatment progress between recommending a wear-time prescription of twelve and eight hours.

**MATERIALS AND METHODS**

Children between eight and eleven years of age in the mixed dentition with large overjet suitable for treatment with removable appliance were recruited to participate in the trial (Table 1). Both written and verbal information was given to the custodians and the child. After consenting to participate in the study, the children were randomized after gender stratification into two groups; one with twelve hours wear-time per day (evening and nightwear) and the other with 8 hours wear-time per day (night wear only). The randomization was performed using a computer software program generating the random sequence numbers (66).
The patients were treated with the van Beek activator equipped with a microsensor (TheraMon®, Hargelsberg, Austria) in order to measure the wear-time. Treatment was conducted under the supervision of orthodontists at the Faculty of Odontology, Malmö University. Clinical examinations were conducted to assess occlusal changes.

Overjet and overbite were clinically registered according to a standardized protocol with an orthodontic ruler by the students and confirmed by supervisors at the department. Overjet and overbite were registered every first, third, and sixth month.

Evaluation of the overjet and overbite values was performed by analyzing data from the patients’ records, which were collected during the clinical evaluation. Wear-time data from the built-in microsensors was also extracted during each appointment. The collected data was thereafter examined in the TheraMon® Cloud software, visualizing the data as a graph of the patients’ daily wear-time, and the following time intervals were analyzed: one, three, and six months. Regular appointments occurred every six to eight weeks to monitor treatment progress, scan the TheraMon® microsensor, adjust the appliance, and motivate the patient to continue wearing the appliance.

Table 1.
Eligibility criteria.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Children in mixed dentition, dental stage DS2M1 (i.e. eruption of the first molar and anterior incisors has occurred)</td>
<td>- Diseases affecting somatic and/or craniofacial growth</td>
</tr>
<tr>
<td>- Class II malocclusion with overjet &gt; 6 mm</td>
<td>- Medication affecting breathing and/or craniofacial growth</td>
</tr>
<tr>
<td>- Lip incompetence</td>
<td>- Insufficient language understanding (with the patient or parent). Interpreter required.</td>
</tr>
<tr>
<td>- Crowding not exceeding 4 mm per jaw</td>
<td>- Known agenesis (missing tooth/tooth germ) primary or permanent incisors</td>
</tr>
<tr>
<td></td>
<td>- Previous extractions of primary or permanent incisors</td>
</tr>
<tr>
<td></td>
<td>- Dental anterior open bite</td>
</tr>
<tr>
<td></td>
<td>- Previous treatment with removable maxillary expansion appliance</td>
</tr>
</tbody>
</table>

The outcome measures were the reduction in overjet and overbite in mm. The outcome measures were related to the wear-time recorded by the microsensors placed in the appliances. The data were statistically analyzed with the software Statistical Package for Social Sciences (version 22.0.0.0, IBM SPSS Inc., Chicago, Illinois, USA). Apart from the descriptive statistics mean, standard deviation, minimum and maximum values, independent T-test was done to
evaluate if there were any significant differences between the two groups and to see if there were significant changes between start of treatment (T0) at the six month follow-up (T1) in respective groups. Measurements and comparisons will be performed according to the intention-to-treat model (ITT) i.e. all patients randomized to the study will be measured regardless of the outcome.

**Instruction protocol**

After the activators were manufactured and equipped with the activated chip by the dental technician at the department of orthodontics patients were instructed on how to insert and utilize the appliance. The patients had to use the intraoral appliance and headgear daily for twelve or eight hours depending on which group they were randomized into. The force of the headgear was approximately between 230 and 260 g. The patients and the custodians were informed about the wear-time and that they might experience some discomfort at the beginning of the treatment and that the microsensor would register their wear-time of the appliance.

**Sample size calculation**

In the present master thesis, which is a part of a multi-center RCT on wear-time and overjet reduction of the van Beek activator, the included number of patients with matching inclusion criteria was in total thirteen. The initial trial involves two orthodontic clinics, the department of orthodontics at the faculty of Odontology, Malmö University, and at the department of orthodontics Center for Specialist Dental Care in Örebro. The total number of participants required in the initial study was calculated to be 69 with a power set to 90 %. The present report shows data from a smaller sample size and follow-up time of six months.

**Ethical approval**

The project was approved by the Medical Ethical Committee in Uppsala (Dnr 2014-196). The patients and their custodians were informed both verbally and in written form.
RESULTS

Participation

Twenty patients were qualified for participating in the study, where four subjects declined participation. During treatment, three patients discontinued the treatment because of problems related to the appliances; i.e. wear-time less than one hour (n = 1) and due to discomfort (n = 2).

Data collection

TheraMon® data was retrieved from all participants and registered under every appointment at the clinic. One patient had to remake the appliance because of physical damage that occurred, another patient had to change microsensor because of a manufacturing defect that was probably related to a faulty battery. One patient had wear-time data that was excluded from the final analysis due to non-compliance. The mean wear-time of the latter was only 1.3 hours per day. No spontaneous reduction in overjet, during the six-month follow-up period could be observed in this patient.

Demographics at baseline

Between the two study groups, no significant difference in age, gender, overjet, or overbite were found at the start (T0). In the 8 hours group, the mean age was 10.2 years (SD = 0.6) and among the 12 hours group, the mean age was 10.0 years (SD = 1.1). For the distribution of genders, there were predominantly female patients in both study groups.

Wear-time

The results of the descriptive statistics and intragroup comparisons of appointment frequency, together with a mean wear-time and adherence, are presented in Table 3. The follow-up period and intergroup comparison of the changes in overjet and overbite are also presented.
Figure 5.
Flowchart of participation.

Fig 5. Flowchart of the sample between May 2015 and November 2018. Eight participants with matching criteria were assigned a wear-time of twelve hours and five were assigned a wear-time of eight hours. Four patients declined participation and three patients dropped out.

Table 2.
Demographics in age and gender at the start of treatment.

<table>
<thead>
<tr>
<th></th>
<th>Age, years</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>12</td>
<td>8</td>
<td>10.0</td>
</tr>
<tr>
<td>8</td>
<td>5</td>
<td>10.2</td>
</tr>
<tr>
<td>P</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>10.0</td>
</tr>
</tbody>
</table>

SD, standard deviation; NS, not significant (P > 0.05).
Table 3.

Appointment frequency in weeks, wear-time data represented by average wear-time in hours, and adherence (the measured mean wear-time divided by the prescribed wear-time) in percent.

<table>
<thead>
<tr>
<th>Appointment frequency, weeks</th>
<th>12 hours group</th>
<th>8 hours group</th>
<th>8 hours group</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 hours group</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>8</td>
<td>6.6</td>
<td>0.7</td>
<td>5.8</td>
</tr>
</tbody>
</table>

Mean wear-time, hours

| 1 month | 8  | 8.9  | 1.4  | 7.2 | 10.9 | 0.5 | NS            | 5  | 8.3  | 1.1  | 6.6 | 9.3 | 0.5            |
| 3 months | 8  | 8.9  | 1.8  | 7.1 | 11.6 | 0.6 | NS            | 5  | 8.1  | 2.5  | 3.7 | 9.7 | 1.1            |
| 6 months | 7  | 8.2  | 1.7  | 6.7 | 11.7 | 0.6 | NS            | 4  | 7.9  | 2.6  | 4.0 | 9.7 | 1.3            |

Adherence, %

| 1 month | 8  | 74.1 | 11.4 | 60.3 | 91.0 | 40.2 | NS            | 5  | 104.4 | 13.4 | 82.6 | 116.6 | 6.0 |
| 3 months | 8  | 74.1 | 14.9 | 59.3 | 96.9 | 52.8 | NS            | 5  | 100.7 | 31.9 | 45.6 | 121.0 | 14.3 |
| 6 months | 7  | 68.6 | 13.9 | 55.7 | 97.1 | 52.5 | NS            | 4  | 99.3  | 32.9 | 50.4 | 121.5 | 16.5 |

SD, standard deviation; NS, not significant (P > 0.05).

As seen in Table 3, during the first month, the mean correct wear-time in relation to the received wear-time prescription was 104 % (8.3 hours per day) among patients in the 8 hours group. During the three months period, the percentage dropped to 100.7 % (8.1 hours per day), and finally after six months to 99.3 % (7.9 hours per day). When analyzing the data for the 12 hours group 74.1 % (8.9 hours per day), during the three months period the percentage remained constant 74.1 % (8.9 hours per day) and finally decreased again after six months to 68.8 % (8.2 hours per day). The total overall mean wear-time of the two groups was 8.1 hours per day.
Overjet and overbite

Between T0 and T1, the mean follow-up was 5.9 months (SD = 0.6) compared to 6.6 months (SD = 1.2) in the 12 hours group and 8 hours group respectively.

The mean overjet in total for both groups was 6.8 mm at the start of the treatment and 3.2 mm at the six-month follow-up appointment (T1).

Table 4.

Follow-up in months regarding overjet and overbite in mm at T0 and T1, and changes between T1-T0.

<table>
<thead>
<tr>
<th></th>
<th>12 hours group</th>
<th>8 hours group</th>
<th>Std mean err</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>Std mean err</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>Std mean err</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Follow-up, months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>5.9</td>
<td>0.6</td>
<td>52</td>
<td>6.9</td>
<td>0.2</td>
<td>5</td>
<td>6.6</td>
<td>1.2</td>
<td>56</td>
<td>8.7</td>
<td>0.5</td>
<td>5</td>
<td>6.6</td>
<td>1.2</td>
<td>NS</td>
</tr>
<tr>
<td>Overjet (mm)</td>
<td>8</td>
<td>6.9</td>
<td>1.0</td>
<td>50</td>
<td>8.0</td>
<td>0.3</td>
<td>5</td>
<td>6.6</td>
<td>0.5</td>
<td>60</td>
<td>7.0</td>
<td>0.2</td>
<td>5</td>
<td>6.6</td>
<td>0.5</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>3.3</td>
<td>1.4</td>
<td>20</td>
<td>6.0</td>
<td>0.5</td>
<td>5</td>
<td>3.2</td>
<td>1.2</td>
<td>20</td>
<td>5.0</td>
<td>0.5</td>
<td>5</td>
<td>3.2</td>
<td>1.2</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>-3.5</td>
<td>1.3</td>
<td>-10</td>
<td>-5.5</td>
<td>0.5</td>
<td>5</td>
<td>-3.4</td>
<td>1.4</td>
<td>-10</td>
<td>-4.5</td>
<td>0.6</td>
<td>5</td>
<td>-3.4</td>
<td>1.4</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Overbite</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>3.8</td>
<td>1.7</td>
<td>1.0</td>
<td>6.0</td>
<td>0.7</td>
<td>5</td>
<td>4.4</td>
<td>0.9</td>
<td>3.0</td>
<td>5.0</td>
<td>0.4</td>
<td>5</td>
<td>4.4</td>
<td>0.9</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>2.9</td>
<td>1.1</td>
<td>1.0</td>
<td>5.0</td>
<td>0.4</td>
<td>5</td>
<td>2.7</td>
<td>0.8</td>
<td>2.0</td>
<td>4.0</td>
<td>0.3</td>
<td>5</td>
<td>2.7</td>
<td>0.8</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>-0.5</td>
<td>1.6</td>
<td>-2.0</td>
<td>3.0</td>
<td>0.6</td>
<td>5</td>
<td>-1.7</td>
<td>0.8</td>
<td>-2.5</td>
<td>-1.0</td>
<td>0.3</td>
<td>5</td>
<td>-1.7</td>
<td>0.8</td>
<td>NS</td>
</tr>
</tbody>
</table>

SD, standard deviation; NS, not significant (P > 0.05).

Regarding treatment outcomes for the six-month follow-up period, similar results were obtained in both groups. The mean decrease in overjet, among the 8 hours group after six months was 3.4 mm compared to a 3.5 mm decrease in the 12 hours group. Regarding the vertical relations, a reduction of 0.5 mm and 1.7 mm was registered in the 12 and 8 hours group respectively (Table 4).
DISCUSSION

Twenty patients with matching criteria were identified at the Faculty of Odontology. Out of these, thirteen patients with a follow-up of six months could be included in the final analysis. None of the patients in the 12 hours group reached the prescribed wear-time, in contrast to four out of five of the participants in the 8 hours group who reached the target. Considering the overjet, a 2.9% additional reduction was registered among patients in the 12 hours group compared to the 8 hours group. Although the smaller sample size, the initial hypothesis of this study could be confirmed and shows promising support for recommending an eight hours wear-time prescription due to similar results in both occlusal changes and wear-time compared to the original twelve hours wear-time prescription.

In this study, similar to other reports (32,34,45), the focus was put on changes in the sagittal dimension, while vertical changes were registered in order to follow treatment progression among patients.

Sleeping time and treatment goals

A previous study conducted in Sweden in the municipality of Lund documented the sleeping time of schoolchildren between 6 to 16 years. The collected data among ten-year-old children showed that the median sleeping duration during weekdays was 9.5 hours (67). Therefore, prescribing patients to wear the appliance for twelve hours would imply wearing it not only while sleeping but also while the child is awake, thereby affecting the child’s ability to speak and eat. A wear-time prescription that is difficult to fit in with the patient's daily routine can be challenging to reach, whereas a wear-time target that is similar to the duration a child sleep could be more reasonable and easier for patients to achieve. For example, in a previous investigation carried out among children between 7 and 15 years using removable appliances with a microsensor, a median daily wear-time of only 9.7 hours when the prescribed wear-time was 15 hours per day was reported. In the previous study by the evaluated data of the wear-time was limited to the first three months, which, because of the short follow-up, could be a limitation. Although, according to the authors of the study, this generally reflects the long-term wear-behavior of the patient; i.e. patients maintain their initial wear-behavior during the whole treatment (48). In the present study, the follow-up period was six months which might better reflect the progress of the treatment.

Can measuring wear-time contribute to improved compliance?

Because of adherence playing a central part for a successful orthodontic outcome, TheraMon® can be an adequate addition in the treatment with removable appliances in tracking the latter objectively (59,60). It is a relatively cheap technology that can be embedded in the acrylic part of various removable appliances by the dental technician. It is well tolerated by patients and the presence of it is almost no noticeable while worn; in fact, in a questionnaire aimed to study how patients experienced electronic wear-time tracking, 86 % of the participants reported that the comfort of the appliance remained unaffected despite the presence of a microsensor in the appliance (61). A further potential benefit could be the increased motivation from the patient being aware that the usage is being monitored by the orthodontist (55). Thanks to the ability to track temperature changes through the software, it is possible to notice accidental artifacts of
the recordings or eventual manipulations by the patient. This could make the collected data even more reliable and difficult to manipulate.

**Wear-time related to gender and age**

Mean wear-time of both groups were for boys 9.1 hours per day and for girls 8.4 hours per day. In agreement with earlier studies (55–57), no major differences in wear-time between genders in both groups were noticed. It has to be mentioned that there was not an equal distribution of the genders in both groups, which could thereby affect the results. Earlier studies performed with a similar study design have found a correlation between age and headgear wear-time (60,68), assuming that younger children could be more influenced by their custodians compared to older individuals and thereby present an increased wear-time. Thus, younger patients could be more responsive to instructions than older patients. In this study, no analysis of the difference between gender or age was performed due to the small sample size.

**Wear-time and compliance**

A factor that plays an important role in achieving a successful orthodontic treatment result with removable appliances is the compliance of the patient. Some reports have shown how the wear-time of appliances typically decreases over time and that compliance worsens during a prolonged regimen of time (60,69). It is not only important to use the appliance for a certain amount of hours per day but also to follow an adequate total treatment period (44,45). It is clear then how the patients’ compliance can affect the treatment and thereby eventually lead to a smaller reduction in overjet. Similar findings could be noticed when reviewing the collected data. Among the patients that were non-compliant (with an overall wear-time of fewer than four hours per day), no reduction in overjet after the follow-up period of six months was registered.

A normal number of dropouts was experienced, it took longer than expected to recruit patients because of the scarce availability of matching patients that were suitable for this study and in need of Class II treatment. It has to be clarified that it was difficult to obtain an exact follow-up period of six months because of the availability of the patients to visit the clinic. There was a mean follow-up difference between the different groups of two weeks in total.

The van Beek activator requires to have the mouth closed while in use. This implies that food intake and the ability to articulate during the use of the appliances is compromised. Among patients, the main reasons for dropping out and/or not following the instructions, were mostly because of problems during sleeping and breathing because of the discomfort of wearing the appliance.

The mean wear-time between appointments is also important to take into account. It has been reported that a longer average duration between appointments was associated with a significantly increased treatment duration (70). In a report aimed to study the patients’ adherence to orthodontic appointments, one finding was that for every additional six months of treatment duration, the odds of attending appointments had a significant decrease (40). In concordance to a study with a similar design (45), a large variation in the appointment frequency was noted. As shown in Table 3, the overall mean interval between appointments varied from 4.7 to 9.3 weeks. The noticeable variation is mainly due to personal factors related to the single individual that could not be influenced by the examiners or the caregivers.
More precise wear-time documentation aided by the microsensor could eventually help the caregiver to increase the patients' motivation and help to reach the recommended daily wear-time. Thanks to the ability to measure wear-time, the orthodontist could provide more precise wear-time recommendations, empower patients with removable appliances and adjust the wear-time prescription in relation to the wear-time of the single patient (47,48).

By observing the relationship between actual wear-time and recommended wear-time among the participants of the present study a percentage indicating the correct wear-time can be obtained. The 8 hours group had correctly worn the appliance for 99.3% of the recommended time (mean wear-time of 7.9 hours per day) under the six-month period, while among the 12 hours group, the appliances were worn correctly only during 68.6% of the recommended wear-time (mean wear-time of 8.2 hours per day) during the same period. It is clear that an eight hours prescription is easier to reach compared to twelve hours, but this data reflects the actual wear-time of the patient in relation to the wear-time prescription suggested by the orthodontist.

No apparent differences in overjet reduction were noticed when comparing the mean overjet reduction of the two groups even though they received different usage recommendations from the orthodontist. By observing Table 4, where the occlusal relations before and after the six-month period are reported, it can be noted that the 12 hours group had a mean overjet reduction of 3.5 mm while among the 8 hours group a mean overjet reduction of 3.4 mm was measured. This could indicate that no major significant differences exist between the two wear-time prescriptions when looking at overjet reduction, although in order to obtain statistical significance larger patient groups are needed.

**Hawthorne effect**

Our study groups had a follow-up of approximately six months. It should be considered that when patients are included in a trial and know that they are being observed, changes in behaviors and cooperation can occur, this might have some influence on the outcome of the intervention. The Hawthorne effect describes the change in behavior due to the awareness of being observed, and can in some cases affect the outcome of a therapy (71,72). This effect has been reported to last for the first six months for individuals who are involved in a study (73).

Monitoring the wear-time of the patient through a microsensor could in some cases have a similar and an improved effect on compliance during the first six months and could result in false-positive bias (74). It has been shown that orthodontic patients who are aware of being monitored become more motivated to wear the appliance compared to patients who are unaware of the monitoring (55). In contrast to this, there are studies indicating that the wear-time is not altered by this effect (56,75) and that the awareness of being monitored does not directly imply an increase of daily wear-time.

As emerged in earlier reports (46–48), there was a high discrepancy between self-reported and objectively wear-time documentation and both patients and custodians tend to overestimate the wear-time. Wear-time tracking with microsensors can be a beneficial tool during the orthodontic treatment and might aid in increasing the patient's awareness of how well the wear-time recommendation is followed.
Strengths and limitations

Randomized controlled trials (RCTs) are considered being studies of the next highest degree of evidence, next to systematic reviews. Due to its prospective design, having a control group and a randomization process inherently reduces the risk of bias. In some cases, due to ethical aspects, RCTs may be unsuitable, principally when the control group does not receive any treatment that would be needed. A prospective or retrospective study with good design could have the ability to provide valuable evidence within its inherited limitations regarding the risk of bias (76). As an ethical aspect, regarding the present study, being randomly assigned to a wear-time prescription of eight hours instead of twelve hours could potentially be perceived as a worse therapy because of the potential prolongation of treatment. Although, there is insufficient evidence in the literature on why recommending a wear-time prescription of twelve hours would be superior in treatment results.

The study design and method of collecting data are also other important factors in research that can influence the validity of a study and the use of a valid and reliable method is advised (76). By using the TheraMon® microsensor, it is possible to collect more reliable data and avoid potential erroneous data based on self-reported wear-time. Subjectively reported wear-time by the patients has been shown to be frequently overestimated by the patients (46). In this manner, possible social desirability bias that can lead to misleading results can be omitted (77). The Hawthorne effect is another source of bias. Having a follow-up period of over six months could possibly reduce this risk (74).

It is known how examiners can possibly alter the results of an evaluation based on their presumptions, leading to bias. If this person is influenced by the study, he/she could examine the patient differently because influenced by its expectations (78). The authors of this study were not directly involved in any treatments of the study subjects. Further, the measurements were performed by examiners that were not included in the study and carried out the examinations without any influence. This could be seen as a positive factor in order to minimize examiner related bias, but at the same time, it could have a negative impact on the collected data because of the lack of calibration between all the different examiners.

The randomization process was carried out in order to further minimize the eventual bias risk, computer-assisted randomization was used to randomly assign wear-time indications to the patients, this process was performed by an independent subject not involved in the study.

Due to the small sample size, there is a higher risk of random deviations not reflecting the treatment outcome and imprecise estimate of the treatment effect. Although worth mentioning, studies with smaller groups and shorter follow-ups are usually faster to conduct because of the smaller study sample (79), especially in cases that require frequent measurements. Therefore, a study design where a hypothesis can be faster evaluated could lead to improved cost-effectiveness of the research: it is smarter to analyze one therapy among a smaller sample size in order to avoid spending too many resources if there is no proven effect. However, finding an association between the treatment and the results, requires a larger sample size in order to confirm the obtained results.

The examiners carrying out the appointments were aware of the recommended treatment time due to practical reasons, in order to inform and motivate the patient to the correct time protocol recommendation. This could lead to an expectancy bias where the measurements could be skewed towards held assumptions. Interexaminer reliability was not considered when recording
occlusal measurements and the patients were treated in one clinic in an academic setting. The care was provided by multiple care providers under the supervision of an orthodontist.

Some factors affecti ng the data collection of the microsensor exist. For example, losing the appliance, insufficient memory left or physically damaging the sensor can make the data impossible to retrieve. This could also happen if the microsensor’s battery life fails before the data is transferred to the cloud-based system. The TheraMon® sensor has been shown to give different results in wear-time depending on the location of the microchip in the patient's mouth (80). Data loss can be minimized or prevented by reading the data from the microsensor in regularly and verifying that the sensor is functioning.

As previously described, this study is part of a larger multi-center study which also includes a control group with no treatment. At the current clinic, patients were referred from external clinics and presumed to be treated. Due to the shorter time span and difficulty in recruiting patients for control group with no treatment, it was decided to not include this group in the present study.

**Generalization**

The result of the current investigation is based on a small sample size which can affect both its internal and external validity (81). Thus, the results should be interpreted as a description of wear-time patterns in a group of patients and indicate that a wear-time of eight hours can have a good effect in the overjet reduction in comparison to a twelve-hour wear-time prescription. In order to retrieve a higher degree of confidence, a larger sample group and a longer follow-up period combined with a multi-centered design are needed.

**Suggestion for future studies**

Because of compliance being a central factor in orthodontic treatments, future studies could focus on how to increase compliance through the use of microsensors. An example could be the integration of a reward system with the data of the computerized wear-time tracking. A reward system could eventually help the clinician to motivate more patients to comply with the recommended wear-time prescription.

**CONCLUSIONS**

- A wear-time prescription of eight hours demonstrated better adherence compared to twelve hours in the present study.

- The van Beek activator was effective in correcting Class II malocclusions, where no clinical or statistically significant difference in treatment effect was observed between a twelve-hour and an eight-hour wear-time prescription.
REFERENCES


