

The Effect of Text Message Reminders on Patient Compliance with Functional Appliance Therapy as Measured by Theramon[®] Sensors

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requirements of the degree of Doctorate in Dental
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Declaration

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Summary

Aims: The aim of this study was to evaluate whether text message reminders have an effect on patient compliance with twin block appliances. A secondary aim was to determine whether text message reminders influenced the number of days where over 18 hours or 8 hours of wear was recorded. Orthodontic patients who present with class II skeletal discrepancies are often treated with a functional appliance to correct their anteroposterior relationship before proceeding to fixed appliances. Although reminders have been associated with increased compliance in the dental and orthodontic setting, this is the first study to examine the effect of text message reminders with the twin block appliance.

Materials and Methods: A consecutive sample of 59 patients between 11-15 years of age and with a 5a Index of Orthodontic Treatment Need (IOTN) were recruited. These patients were randomly allocated into the control group (CG) and study group (SG). Both groups received a standardised twin block design with a thermosensitive sensor (Theramon®) embedded in the maxillary block. Both groups were asked to wear their appliances full time, excluding during eating, cleaning and contact sports. The CG received verbal instruction as well as a leaflet instructing them on how to wear and care for their appliances. In addition to the same verbal and written instruction received by the CG, the SG received text message reminders to wear their appliances every 3 days. At each visit, data on wear-time was

uploaded from the Theramon® sensors onto cloud software. Patients in both groups were asked to fill out wear diaries and submit these at each visit. The follow-up period was 4 months in duration.

Results: The median hours/day of wear recorded was 13.77 (IQR 10.19) in the CG and 17.72 (IQR 5.62) in the SG. There was no statistically significant difference between the CG and SG for wear times reported by the Theramon® sensors ($p=.16$). There was no statistically significant difference in the number of days where over 18 hours or 8 hours of wear was recorded. Insufficient completed wear diaries were returned and therefore it was not possible to carry out a formal analysis on the data.

Conclusions: The study concluded that text message reminders have no statistically significant influence on patient compliance with twin block appliances. In addition, text message reminders have no statistically significant influence on the number of days where over 18 hours or 8 hours of wear is recorded. Wear diaries are not a useful mechanism for measurement of subjective wear times and consideration should be given to the use of intraoral sensors to more reliably measure compliance.

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1.0 Literature Review

1.1 Introduction

A functional appliance is an appliance which makes use of facial muscles and muscles of mastication to produce changes in the occlusion.

Functional appliances have been used to treat lower face skeletal discrepancies since the late 1800's, with the first "bite jumping" appliance being described by Kingsley in 1880 (Kingsley, 1880). The twin block appliance is a functional appliance that was first described by Clark in 1984 and later published in the American Journal of Orthodontics (Clark, 1988). It is the most widely used functional appliance in the UK (Chadwick et al., 1998). Twin blocks work by posturing the mandible into a forward position. The stretch on the adjacent muscles of mastication and soft tissues creates a force which is transferred to the dentition via the appliance and elicits an effect on the dentition. The net result of this is a reduction in overjet.

1.1.1 Short-term Effects

Initially it was thought that functional appliances could "grow" the mandible due to their effects on condylar remodelling (McNamara and Bryan, 1987, Stöckli and Willert, 1971, Moyers et al., 1970). Nelson and Harkness noted an increase in mandibular length and gonial angle when comparing the Harvold appliance and Frankel Appliance II with untreated controls (Nelson et al., 1993). More recent studies have shown that the

effects of functional appliances are primarily dentoalveolar, with a small amount of skeletal change (Lund and Sandler, 1998, Mills and McCulloch, 1998, Keeling et al., 1998). Studies reported by Tulloch et al. have found that there is an average of 0.6mm additional mandibular growth in the short-term during functional appliance therapy (Tulloch et al., 1997, Tulloch et al., 2004). A more recent, well-designed randomized controlled clinical trial examined the effectiveness of early treatment with twin block appliances. It found that 73% of the change in anteroposterior skeletal relationship was due to dentoalveolar changes, with the remaining 27% being due to skeletal changes. The study reported functional appliance therapy resulted in an additional 1mm of mandibular growth which accounted for 14% of overjet correction. Forty four percent of overjet correction was attributed to upper incisor retroclination. It concluded that there was no additional benefit associated with early treatment of class II division I malocclusions with twin block appliances (O'Brien et al., 2003a, O'Brien et al., 2003b). Early treatment is defined as treatment when the patient is between 7-10 years of age and in the mixed dentition, with a further second phase of fixed appliances when the permanent dentition is established. The alternative is to wait until the late mixed dentition or transitional dentition and undergo growth modification as part of one course of treatment. The results of this study are in line with findings by a recent Cochrane study which found no advantages to early treatment of class II division I malocclusions with functional appliance therapy, apart from a reduction in the incidence of incisal trauma (Batista et al., 2018).

These results correlate with a study by Baccetti et al. who concluded that treatment during the pubertal growth spurt was more effective at reducing overjet than early or pre-pubertal treatment (Baccetti et al., 2000).

1.1.2 Long-term Effects

The long-term effects of functional appliance therapy have long been disputed. It is now broadly accepted that the skeletal change associated with functional appliances is minimal in the anteroposterior direction. One study in a series by Tulloch et al. concluded “the skeletal effects of early treatment are not maintained”. Early treatment was carried out on patients in the mixed dentition with an mean age of 9.9 years (range 7.7-12.4) (Tulloch et al., 1998). There are few studies that compare treatment with functional appliance therapy with untreated controls, possibly due to the ethical problems encountered with leaving class II skeletal patterns untreated. One retrospective study compared treatment with Frankel II appliances with untreated controls and found that for all parameters including ANB values and dentoalveolar change the group treated with the functional appliance had more favourable correction of their malocclusion than untreated controls. However due to the retrospective nature of this study, and the fact that cephalometric landmarks were used for comparison, the results should be interpreted with caution (McNamara et al., 1985). It is now accepted that functional appliance therapy is effective at reducing large overjets in mild to moderate skeletal class II cases.

1.1.3 Twin Block Design and Wear Protocol

The original Twin Block design advocated by Clark included Adam's cribs on the upper and lower first permanent molars to aid retention (Figure 1). He also advised the use of interdental ball clasps in the lower anterior region. The upper bite blocks extended to the mesial ridge of the upper second premolar. The lower block extended to the distal marginal ridge of the lower second premolar. In deep-bite cases, the lower molars were not clasped, and left uncovered by acrylic to allow for passive eruption of these teeth. Clark recommended that the bite registration should be taken such that initial activation of the blocks reduced the overjet by 5-7mm with 3-5mm of interocclusal clearance in the first premolar region. Reactivation of the blocks can be achieved by addition of cold-cure acrylic to the mesial inclined plane of the upper blocks if required (Clark, 1988).

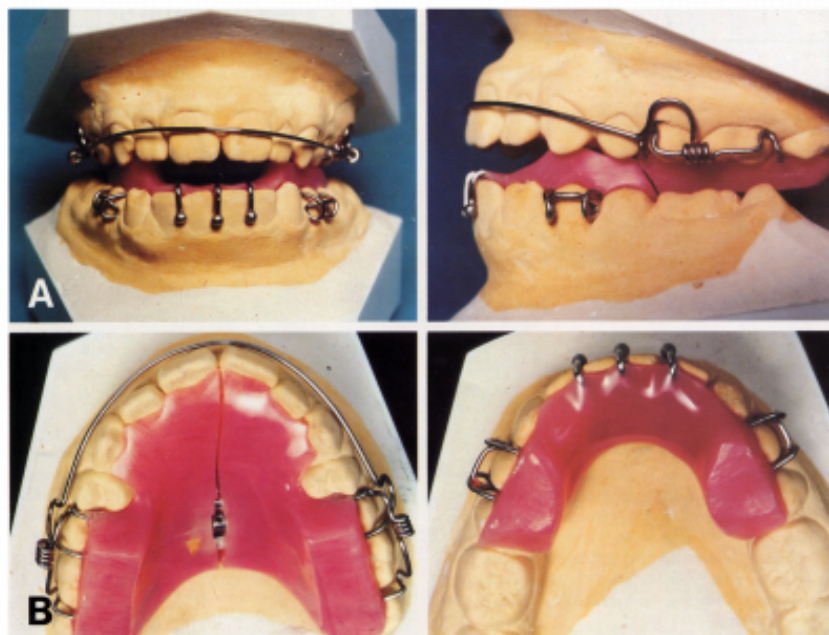


Figure 1: The original twin block appliance designed by Bill Clark in 1988 (Clark, 1988).

Different modifications to the initial twin block design have been examined in various studies. A study by Yaqoob et al. found no statistically significant differences in maxillary incisor retroclination, skeletal change or rate of overjet reduction between twin blocks incorporating a labial bow and those without (Yaqoob et al., 2012). The discontinuation rate in this study was 6.25%, which would suggest that the incorporation of a labial bow has no effect on the patient's willingness to wear the appliance. Harradine and Gale found no differences in overjet reduction when comparing twin blocks with torqueing spurs versus those without. They found that torqueing spurs reduced upper incisor retroclination and extrusion during overjet reduction. Lower incisor proclination was similar in both groups. (Harradine and Gale, 2000). In this study, 17.5% of patients failed to reduce their overjet below 4mm and 9% failed to reduce their overjet below 6mm. This compares favourably with other studies such as that by Cohen (1981) who used the same criteria to denote failure (overjet greater than 6mm) and had a failure rate of 65% by this criteria (Cohen, 1981). One randomized clinical trial with a sample size of 52 patients compared the effect of including Southend clasps on upper and lower incisors to those without and found that there was less upper and lower incisor tipping along with greater skeletal change in the Southend clasp group. However, 11 patients were lost to follow-up or dropped out and an intention to treat analysis was not carried out. In addition, the age range included in this study was large, with inclusion criterion including patients between the ages of 9-30. This could have an impact on the skeletal

change measured as we know that older patients react less favourably to treatment aimed at correcting skeletal relationships. (Trenouth and Desmond, 2012).

Acrylic blocks are generally fabricated to an edge-to-edge incisor position or a position of maximum protrusion. No significant differences in clinical outcome have been found in those that are incrementally advanced versus single advancement techniques (Banks et al., 2004). Incremental advancement requires addition of acrylic gradually to achieve an edge-to-edge incisor position, rather than achieving edge-to-edge incisor position in one movement. For Banks' study, blocks were incrementally added to by 2mm at 6-weekly intervals. Studies by Lee et al. have looked at the hard and soft tissue changes seen with single step or incremental block advancement. They found that incremental advancement is not associated with greater mandibular growth, nor does it result in less lower incisor proclination (Gill and Lee, 2005). In terms of soft tissue changes, they found that the single advancement technique resulted in a greater change in soft tissue profile than the incremental advancement technique. However, there was a great degree of individual variation in response to twin block therapy (Sharma and Lee, 2005).

Clark himself felt that twin block appliances should initially be fixed inside the mouth for the first two weeks to overcome any problems in co-operation with the appliance in these crucial early weeks (Clark, 2010).

Clark also advocated full-time appliance wear to maximise clinical

outcomes. A recent, well-designed study by Parekh et al concluded that there is no difference in skeletal or dental changes between full-time and part-time wear regimens. It must be noted that patients in both groups wore their appliances for less than the prescribed time. Patients in the part-time group were asked to wear their appliances for 12 hours per day and recorded only 8 hours per day of wear. Those in the full-time group were asked to wear their appliances for 22 hours per day and recorded only 12 hours per day of wear (Parekh et al., 2019). A single-centre study designed to examine compliance concluded that 24-hour wear was not necessary. The authors determined that the threshold for effective outcomes was a wear-time of 9 hours per day. Below this time they found that treatment was less effective (Charavet et al., 2019).

One study comparing twin block and Dynamax appliances showed that the greatest degree of skeletal and dentoalveolar change occurred in the first 6 months of treatment, and if treatment was withdrawn after this amount of time there was a high rate of relapse (Lee et al., 2007). This study was a prospective, randomized controlled trial comparing these two appliances. They assessed both hard and soft tissue changes using cephalometric landmarks and optical surface laser scanning (Figure 2). They found that the soft tissue pogonion advanced by 4mm in the first 6 months in both groups, 1.5mm in the next 3 months and -0.65mm in the final 3 months post-treatment. However, as the sample size was calculated to assess the primary outcome of differences between the appliances of one standard deviation and not calculated to assess changes in values over time, the

results must be interpreted with caution. In addition, the sample size required per group was 32, however only 31 per group were recruited and there were 6 dropouts. Animal studies such as that by Rabie et al. found that bone formation was not complete after 5 months of treatment, and unstable type III collagen remained. This is the human equivalent of 1 year of treatment and suggests that at least this amount of time in functional appliance treatment should be achieved before any results can be considered stable (Rabie et al., 2003).

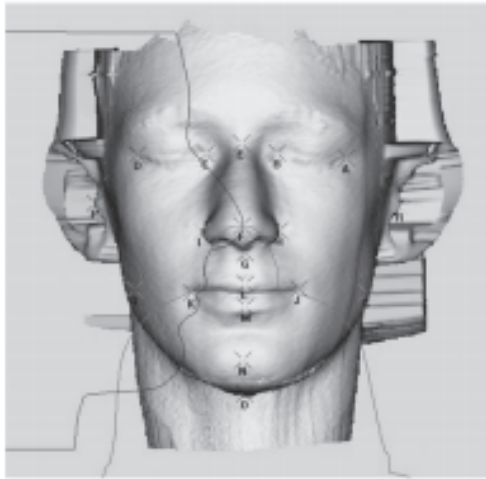


Figure 2: Optical laser scanning of soft tissue landmarks used by Lee et al (Lee et al., 2007).

1.2 Functional Appliance Compliance

The primary drawback of using twin blocks is their removable nature.

Bishara and Zjaja suggested that the success of twin block therapy was mainly determined by patient compliance (Bishara and Ziaja, 1989). Many studies have reported different levels of compliance with twin block appliances. In general, the appliance has high compliance rates in comparison with other functional appliances such as the Bass or Frankl Functional Regulator appliances. The failure rate in the study by Parekh et al. was 9.7% and they noted a higher drop-out rate in the full-time versus part-time wear group (Parekh et al., 2019). The O'Brien study found a discontinuation rate of 33% with twin blocks used in adolescents. This reduced to 16% in the pre-adolescent group (O'Brien et al., 2003b). These results are similar to those found in a study by Banks et al. who found a discontinuation rate of 30% in those with single advancement blocks and 19% in those with incremental advancement of the blocks (Banks et al., 2004). The lowest rate of discontinuation was found by Yaqoob et al. in 2012 who noted a discontinuation rate of 6.25% (Yaqoob et al., 2012). The discontinuation rate of Functional Regulators can be up to 42% (Ghafari et al., 1998).

The definition of compliance varies in the literature. Sometimes non-compliant patients are considered those who have had to discontinue treatment, however some feel that these patients are only a subset of non-compliant patients. Others consider compliance in terms of how much

the patient adheres to the treatment prescribed by the clinician. In the O'Brien study patients were classified as non-compliant if there wasn't a 10% reduction of overjet within 6 months. They also classified as non-compliant any patients who repeatedly broke their appliances or refused to wear their appliance. In this study, failure and discontinuation were considered to be the same (O'Brien et al., 2003b). Harradine and Gale defined successful treatment as those who reduced their overjet to under 4mm. In this study, the difference between failure and discontinuation was not the same, as treatment was continued in 9% of patients who failed to reduce their overjet to below 6mm (Harradine and Gale, 2000).

1.2.1 Influences on Functional Appliance Compliance

When predicting patient compliance, we need to identify patient characteristics that are strongly linked with compliance (Caldwell and Cook, 1999). Negative patient co-operation can be the difference between excellent and un-acceptable orthodontic outcomes (Klaus et al., 2017). The orthodontist-patient relationship has more of an influence on patient satisfaction after orthodontic treatment (Bos et al., 2005b). In addition, patients who are actively involved in the decision-making process tend to be the most satisfied (Nel and Dawjee, 2012). Studies measuring compliance in orthodontics are largely related to oral hygiene practices, headgear compliance and compliance with retainer regimens. A recent qualitative study identified several positive and negative influences on treatment that are outlined below (El-Huni et al., 2019).

1.2.1.1 Age

Objective assessments of compliance have determined that children between the ages of 6-8 years of age are more likely to comply with appliance therapy than those between 12-15 years of age (Arreghini et al., 2017). This study was a pilot study consisting of a small sample size of 30 patients. In addition, 4 different types of appliances were used (Bionator, Frankel II, Rapid Palatal Expansion and Protraction Facemask) and therefore there were many other variables which may have influenced wear-time and compliance. A retrospective cohort study looked at various removable appliances including Frankel, Hawley and Essix appliances and found that compliance decreased from early childhood up to early adulthood (Tsomos et al., 2014). There is weak to moderate evidence that age influences compliance with removable appliance wear regimens. Studies into compliance with headgear and functional appliance wear protocols found that compliance was higher in younger children (Bos et al., 2007, Brandao et al., 2006, Schott and Menne, 2018). The study by Bos et al. was carried out in an academic research facility with a sample size of 56 patients undergoing headgear therapy. However, no sample size calculation was carried out and there was a short follow-up period of 29 days. The results are similar to other studies who found that compliance decreased with increasing age although with a low level of significance (Allan and Hodgson, 1968). Schafer et al. carried out a prospective cohort study examining the influence of age, gender, health insurance and type of

device on socioeconomic status. They placed Theramon[®] sensors into functional appliances and maxillary expansion plates to objectively measure wear time (Figure 3). The study was well designed with a good follow-up period of 3 months and a large sample size of 141 participants (Schafer et al., 2015). The results of this study are in contrast to an observational study assessing compliance which found no differences in compliance between the ages of 11-14 and 15-17. It involved monitoring 252 participants in active treatment over the course of 1 year. The orthodontist then assigned them to one of three groups depicting compliance: good, fair and poor. Participants were then asked to complete three different surveys relating to self-concepts and socioeconomic status. The authors concluded that age had no influence on compliance, however the mean ages of patients in each group were very similar, and the study was not powered to determine the influence of age on compliance (Cucalon and Smith, 1990). Other studies also found age had no influence on compliance rates (Nanda and Kierl, 1992, Agar et al., 2005). The study by Nanda and Kierl looked at several possible influences on compliance including operator-patient relationship, age, gender and socioeconomic status. As it was prospective in nature the results are not as susceptible to bias.



Figure 3: An example of a functional appliance and a maxillary expansion plate used in a study by Schafer et al. investigating influences on compliance (Schafer et al., 2015).

1.2.1.2 Gender

Some studies have shown no differences between compliance in male and female patients (Arreghini et al., 2017, Tsomos et al., 2014, Clemmer and Hayes, 1979). Other studies found that female patients demonstrated higher rates of compliance than males (Cucalon and Smith, 1990, Starnbach and Kaplan, 1975). One survey-based study aimed to evaluate and quantify retainer compliance. They surveyed 1085 patients who were between 6 months and 6 years out of treatment. They concluded that females are more likely to wear their retainers than males. However their response rate was only 25.8% and therefore this data may not be representative of the population as a whole (Pratt et al., 2011). A cross sectional study found that although self-reported wear-times were the same in females compared to males, females wore their retainers for longer (Mirzakouchaki et al., 2016). The fact that this is self-reported wear, which is often overestimated, means that these results should be interpreted with caution. Schafer's study found that females wore their appliances on average 1.3 hours/day longer than males (Schafer et al.,

2015). This may be due to the fact that in general, girls are more concerned about their dental attractiveness than boys (Shaw, 1981). One study concluded that males are more compliant than females, however this study was poorly designed, with a sample size of only 45 patients. In addition, the mean age for boys in the study was lower than that of girls and therefore it may be that age was the primary influencer of compliance rather than gender (Kawala et al., 2013).

1.2.1.3 Duration of Treatment

Objective assessments of compliance found that it is stable during the first five months of treatment and then reduces slightly (Arreghini et al., 2017). A cross sectional study found that decreasing compliance occurs as a result of increased duration of treatment (Bartsch et al., 1993). However, patients enrolled in this study were followed-up for only 3.9 months and increasing age could be considered a cofounder for compliance. These results are supported by other studies examining the effect of treatment duration on compliance however these studies generally had short follow-up periods (from 1-3 months) and as a result the effect of longer duration of treatments was not established. (Bos et al., 2007, Murray, 1989, Schott and Menne, 2018). Furthermore, a retrospective study found poor compliance can result in increased treatment times of approximately 1.4 months, potentially worsening further compliance (Skidmore et al., 2006). This study was carried out using clinical notes, records and cephalometrics from 366 patients treated under one operator. The large sample size lends

credence to the results, however the study was not clear on what constituted non-compliance and was highly reliant on retrospective interpretation of clinical records.

1.2.1.4 Functional and Social Impairments

Many studies have noted the functional limitations experienced by patients undergoing fixed appliance therapy (Lena et al., 2017, Sergl et al., 1998). One qualitative study found that patients with functional appliances found it took longer to eat meals and were sometimes distressed when eating with the appliance in place. They determined patient perceptions of orthodontic appliances through focus groups and semi-structured interviews. Participants felt that eating packed lunches rather than school dinners made eating easier, and they found that removal of functional appliances was considered messy (Carter et al., 2015). Functional and social impairments were also noticeable in the cohort of patients who participated in semi-structured interviews as part of another qualitative study by El-Huni et al. The impairments were considered at their most debilitating at the beginning of treatment and included pain, difficulty with eating and speech changes. This resulted in a temporary decrease in wear and compliance in the initial stages of treatment until a normal pattern of wear was recorded (El-Huni et al., 2019). Whilst fixed appliances are more associated with a painful experience, removable appliances are primarily associated with functional restrictions including breathing and swallowing. Acceptance of these appliances is determined by patients' attitudes

towards discomfort (Doll et al., 2000, Sergl et al., 1998). In one study pain was highlighted by 28% of patients as being a reason for non-compliance with elastic or headgear wear and was considered highly influential on compliance (Egolf et al., 1990). This qualitative study consisted of a subjective assessment by the treating clinician of 100 patients undergoing orthodontic treatment regarding compliance with elastics or headgear wear. It also utilised a patient questionnaire investigating general beliefs and attitudes towards health. It concluded that patients who are stoic or self-confident will comply with the wearing of elastics and headgear despite discomfort. Although retrospective, it highlights interesting patient-related factors that influence compliance. A study comparing compliance with Bionators and headgear found that despite the increased pain associated with headgear, it did not cause significantly less compliance with the device (Johnson et al., 1998).

1.2.1.5 Patient Attitude

There is a significant interrelationship between patient attitude and self-motivation towards treatment and the level of compliance that is demonstrated (Sergl et al., 2000, Bartsch et al., 1993, Clemmer and Hayes, 1979). A study by Brattstrom et al. determined that lack of motivation was the main reason for discontinuation of treatment. In addition, lack of information on the pain and effects of orthodontic appliances are a primary cause of drop-outs (Brattstrom et al., 1991). Another study applied the Millon Adolescent Personality Inventory to a cohort of

orthodontic patients and concluded that rebelliousness was the most influential personality characteristic that determined non-compliance (Southard et al., 1991). Albino et al. determined that patient attitudes towards treatment were the greatest indicator for compliance in the early stages of treatment and although this study had a small sample size of 39 patients, the follow-up was significant, allowing them to assess compliance over time (Albino et al., 1991). In the latter stages of treatment, patients with a greater amount of self-motivation were more compliant than those that relied on external motivation for compliance (El-Mangoury, 1981). This was also confirmed by Egolf et al. who found that those patients who are internally motivated are more capable of dealing with the demands of orthodontic treatment and will react better to their environment. Those who have an external locus of control feel powerless over events and are less likely to be compliant. They concluded that the most important factors that determine compliance are personality type, pain, functional limitations and self-consciousness about malocclusion (Egolf et al., 1990). A more recent pilot study used robust psychological evaluation on patients and their caregivers and objectively measured twin block compliance using TheraMon® sensors. They concluded that personality traits associated with patients and their caregivers strongly influenced compliance. Although the sample size in this study was small (38 participants) and the follow-up period was short (9 months), the results are interesting and the psychological testing involved was robust (Sarul et al., 2017b). These results are echoed by other studies that have concluded that patient

personality characteristics could be used to predict compliance in orthodontics (Bos et al., 2003, Robertson and Maddux, 1986, Sergl et al., 1992). However they are in contrast to one study which concluded that compliance could not be predicted by personality traits determined through psychological testing (Nanda and Kierl, 1992). It is difficult to predict what exact traits of patient behaviour will predict compliance, and this is generally due to the large degree of individual variation (Agar et al., 2005).

1.2.1.6 Operator Influence

Sinha et al. highlighted the importance of the orthodontist-patient relationship in the success of orthodontic treatment. One hundred and ninety-nine patients undergoing orthodontic treatment with 8 different operators were asked to fill out a questionnaire 8-12 months into their orthodontic treatment. Orthodontists were also asked to rate patient adherence via a patient co-operation score. Despite the subjective nature of assessment of patient adherence, the study was well designed. Patients felt that the most important aspect of the consultation was the perception that the orthodontist listened to what the patient had to say. Smiling, friendliness and making the patient feel welcome were also reported as being important. The most important orthodontist behaviours associated with patient adherence were politeness and communication (Sinha et al., 1996). Overjet measurements can be used as a positive motivating tool

when encouraging compliance in patients undergoing functional appliance therapy and operator enthusiasm can have an influence on this (Figure 4).

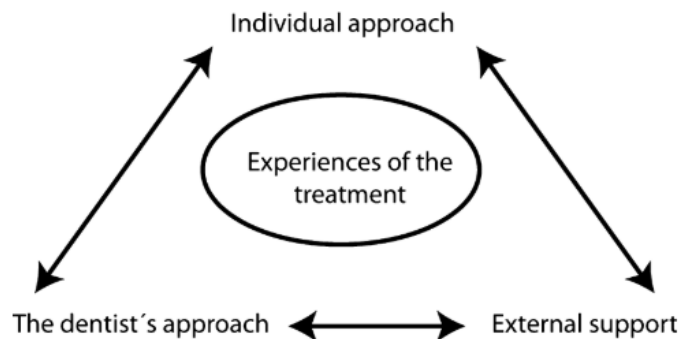


Figure 4: Schematic representation of partial influence of operator approach on patient experience (Cirgic et al., 2015).

Similarly, a feeling of “not being listened to” by the clinician can have a negative influence on compliance. The clinician’s ability to listen, pass on information and encouragement can influence patient adherence (Cirgic et al., 2015, Mirzakouchaki et al., 2016). A good patient-clinician relationship can be established by explaining the nature of the malocclusion and why twin block therapy is being considered as well as being supportive and informative of treatment progress throughout treatment (El-Huni et al., 2019).

1.2.1.7 External Influence

An interview study showed that for younger patients (6-13 years of age), enthusiastic parental involvement can be a predictor for compliance. The authors suggested that if the parents were not likely to be enthusiastic and involved in their child’s treatment, it may be better to delay treatment

until the child is older. Older children had more internal motivation for treatment, and were therefore less reliant on parental influence when it came to compliance (Trulsson et al., 2004). This is in line with two other studies which found that parental involvement was considered to be a positive influence on compliance in adolescents (Cirgic et al., 2015, Sarul et al., 2017b). The qualitative study by Cirgic et al. aimed to explore and describe adolescent experiences with functional appliances via a semi-structured interview. Twenty-one patients were divided into “success” and “failure” groups and correlations determined between outcome and influences. External support in the form of parental encouragement was one of five categories influencing treatment success. Experiences with functional appliances did, however, have a great degree of variation. A well-designed, prospective, randomised controlled trial examined the use of images highlighting the consequences of poor compliance with Hawley retainers. This trial had a large sample size of 302 participants and a follow-up period of 3 months. The control group were given routine verbal instruction on retention after removal of their braces. In the first intervention group, patients were given standard instructions and were shown pictures of dentitions with relapse resulting from poor compliance. In the second intervention group, patients were given standard instructions and both patient and parent were shown pictures of dentitions with relapse resulting from poor compliance. When these pictures were shown to patients and parents, they were more effective in improving compliance than when shown to patients alone, which suggests

that parents play an active role in compliance (Lin et al., 2015). Gross et al. examined a modified behavioural method involving a reward system, along with parental observation. This was shown to have a positive influence on patient compliance and a beneficial effect on child-parent relations (Gross et al., 1985). Similar results were found by Richter et al. who found that feedback and rewards in the form of coupons resulted in improved compliance in below-average compliers, although rewards had no effect on compliance in average or above-average compliers. This study had a smaller sample size than the one carried out by Lin et al. and was more subject to bias as the clinicians recording compliance were not blind to the patient allocation (Richter et al., 1998). More recently, a randomised trial by Stefanovic et al. concluded that parental perception about their child's emotional wellbeing was the strongest predictor of compliance, which increased compliance by 3.4 times (Stefanovic et al., 2021).

Peers can have a positive or negative effect on patient compliance. In many instances orthodontic treatment is considered the "norm" by patients of a particular age, and the feeling of social acceptance can encourage compliance (Shaw, 1981). Conversely, negative attitudes by peers towards orthodontic treatment can have a negative influence on self-esteem and confidence which adversely effects compliance. Social concerns regarding the risk of bullying or negative comments can affect

compliance especially at the beginning of treatment (Cirgic et al., 2015, El-Huni et al., 2019).

1.2.1.8 Socioeconomic Status

Socioeconomic status (SES) has a bearing on compliance, with increased compliance being associated with higher economic status (Cucalon and Smith, 1990, von Bremen et al., 2018, Schafer et al., 2015, Rölling, 1982). The studies by von Bremen et al. and Schafer were well designed in that Theramon® sensors were used to objectively describe wear-time and therefore compliance (Figure 5). However, the follow-up period in Schafer's study was short (3 months) and in both studies the exact socioeconomic backgrounds of patients was not determined. Von Bremen used BMI to assume the SES of his patient cohort and this is not a reliable method of determining SES.

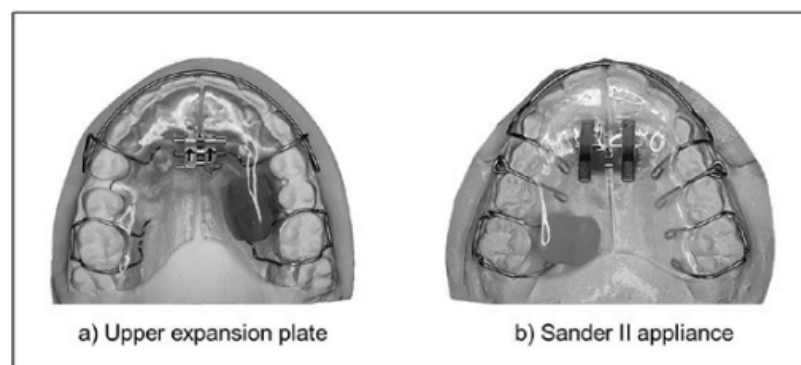


Figure 5: Theramon® sensors used by von Bremen to objectively measure wear-time and compliance (von Bremen et al., 2018).

One study analysed influencers of compliance with removable retainers using sensor devices as a quantitative measure. They found that socio-

economic status, as measured by health insurance status, was a greater influence on compliance than age or sex and those with statutory health insurance more commonly associated with lower levels of income had higher compliance rates in the first 3 months of retention. The differences were not statistically significant, possibly as the study was not sufficiently powered to detect a difference (Schott et al., 2013a). Other studies have found that children who performed well in school and had positive academic and social ratings by teachers demonstrated better orthodontic compliance than those achieving lower grades (Al-Jewair et al., 2011, Sergl and Zentner, 2000). A retrospective study examined the difference in compliance between self-pay and state-subsidised patients. It found that patients undergoing state-subsidised orthodontic treatment had on average 3 more missed appointments than the self-pay cohort and were 4 times more likely to be dismissed from treatment due to poor compliance (Wilson and Harris, 2015). Conversely, Starnbach and Kaplan found that middle lower or lower classes had higher levels of compliance (Starnbach and Kaplan, 1975) and another well-designed study found that SES could not be used to predict whether or not a child would complete treatment. This sufficiently sampled study examined multiple possible influences on compliance including age, gender, SES, type of appliance and pre-treatment Index of Orthodontic Treatment Need (IOTN) score. Pre-treatment IOTN Aesthetic scores were examined and compared to clinical notes recording whether treatment was completed and if not, why not. They found that IOTN scores and quality of life measures were not useful

for predicting which patients will complete treatment (Mandall et al., 2008). The IOTN was examined in one study to see if it predicted compliance and although they found that more severe IOTN scores were associated with increased compliance, they concluded that the degree of compliance is unpredictable in those with higher IOTN scores (Sarul et al., 2017a).

1.2.1.9 Pragmatic Issues

Egolf's study found that 9% of patients cited forgetfulness as the most common reason for forgetting to wear their elastics (Egolf et al., 1990). Many patients develop strategies, such as leaving appliances in visible places, to enable them to wear their appliance as per the prescribed protocol (Cirgic et al., 2015). In the El-Huni study, some participants found the full-time wear regime to be more advantageous, as they did not have to remember to put their appliance in at certain times. Patients in this group felt that reminding tools would well be well supported by adolescents (El-Huni et al., 2019). One interview-based study found that patient perception about the severity of malocclusion is a strong predictor of compliance (Cirgic et al., 2015).

1.2.2 Improving Compliance

Recommendations suggested to improve compliance include effective communication, tailoring wear regimes to individual patients, modifying appliances to suit patients' individual needs and considering the use of

reminding tools to encourage wear. A double-blind, randomized clinical trial examined the effect of supplemental information (leaflets) on patient anxiety, motivation and apprehension towards treatment and compared it to patients who had received verbal information alone. It concluded that patients who are provided with visual as well as verbal information on treatment during the consent process show increased compliance and motivation. Those in the intervention group had higher motivation scores after consenting to treatment. However, these scores were only higher for the first four weeks of treatment and did not equate to fewer missed appointments or breakages (Wright et al., 2010). Patients must be included in open conversations about their treatment, a view encouraged by Schott and Goz. After surveying a cohort of orthodontic patients, they found that only 20% accepted wear-times spread over day and night. Seventy-five percent accepted wearing their devices at night-time only. This means that orthodontists may have difficulty motivating their patients to wear their appliances the required amount of time (Schott and Goz, 2010b). Another method involves the use of class II non-compliance appliances. These are fixed devices and thus more under the control of the orthodontist (McSherry and Bradley, 2000).

The Hawthorne Effect is the inclination of people who are the subjects of an experimental study to change or improve the behaviour being evaluated only because it is being studied and not because of changes in the experiment parameters or stimulus. One study examined the intentional use of the Hawthorne effect on oral hygiene practices in

orthodontic patients. The 6-month, single blinded, quasi-randomized trial found that the group that were aware that they were being monitored had significant improvements in oral hygiene at the 3- and 6-month evaluation (Feil et al., 2002). If we could estimate compliance prior to embarking on treatment and predict the likelihood of compliance, we could adapt our treatment protocols to the needs and characteristics of our patients. This would reduce treatment times, reduce treatment cost, and potentially improve the orthodontist-patient relationship.

1.3 Measuring Compliance

1.3.1 Self-reported Wear

Although this is an important part of the exchange of information and feedback between the patient and orthodontist, self-reported wear has been shown to be unreliable. Patients, parents, and orthodontists tend to over-estimate the amount of time appliances have been worn. Patients with a high compliance rate wear their appliance 80% of the time they report. Those who are poorly compliant tend to grossly exaggerate their wear. Objectively-measured wear time has been shown to be on average 55-66% of reported wear time (Sahm et al., 1990b). A study by Bos et al. found that patients reported wearing their headgear 3 hours more than was recorded by a sensor embedded in the headgear appliance (Bos et al., 2007). These results are supported by studies examining the accuracy of patient reporting as an indication of compliance (Cole, 2002, Cureton et

al., 1993a). These studies were all carried out using objectively measured wear time as an indicator of compliance (Figure 6).



Figure 6: The Thermochron i-Button sensor used by Bos et al. to examine subjective and objective reports on compliance with headgear therapy (Thermochron i-Button, DS1921G; Maxim Integrated Products, Sunnyvale, Calif) (Bos et al., 2007).

The studies by Bos and Cureton examined headgear compliance, whilst the study by Sahm looked at compliance with Bionator therapy. Follow-up information was only available for the studies by Bos and Cureton, who followed-up their patients for 3 months and 1 month respectively. None of the studies carried out sample size calculations, and the sample sizes ranged from 28-56 participants. Therefore, the results from these studies are not conclusive, however they go a long way to suggest that patients, parents, and orthodontists tend to overestimate compliance. A systematic review concluded that the mean difference between patient-reported

wear and objectively measured wear was 5.02 hours (95% CI 3.64-6.40) (Al-Moghrabi et al., 2017).

1.3.2 Wear Diary

Self-monitoring can be an effective way to improve compliance. It allows the patient to take responsibility for the wear of their appliance, and immediate information on their wear pattern is available. Cureton et al. found that patients who kept a daily headgear calendar wore their headgear more often than those that did not. They were also more likely to report hours of wear that were the same as wear-time measured by sensors embedded into the headgear strap. This study examined the same cohort of patients as Cureton's previous study examining the accuracy of self-reported wear. Although the study was well designed, the sample size is very small (28 participants) and follow-up limited (3 months) as previously mentioned (Cureton et al., 1993b).

1.3.3 Extraoral Sensors

Early sensors were developed for use to monitor headgear compliance. The first sensors were developed initially by Northcutt and further modified by Cureton in the United States and Guray & Ohan in Turkey (Guray and Orhan, 1997). They were initially designed to monitor pressure changes around the neck strap of the headgear. Northcutt found that patients reported wearing their appliances 11 hours per day when they actually wore it 6.5 hours per day (Northcutt, 1974). These results are

similar to the study by Guray & Ohran who carried out a clinical study on a small cohort of patients (10 participants) and found that patients wore their headgear for 63% of the time prescribed. Similar differences between reported wear and actual wear were noted by Cureton (Cureton et al., 1993a). A recent study measuring headgear compliance shows us that not much has changed, and patients still only wear their headgear 50-55% of the prescribed time. This prospective, clinical cohort study examined 20 patients over an 8-month period, fitted with headgear incorporating a pressure and temperature sensor. The patients were aware that they were being timed. As well as highlighting lack of compliance, they concluded that daytime wear of headgear appliances was 60% of the prescribed time and compliance dropped during the summer months. There was no control group in this study, and the sample size was calculated for a separate primary outcome that was being reported in a paper by Bos et al. and therefore the results may not be sufficiently powered (Huanca Ghislanzoni et al., 2019). The results are in line with other studies evaluating objective measurement of wear-time with sensors (Sahm et al., 1990a, Clemmer and Hayes, 1979, Schott et al., 2017). The results of studies using headgear timers may be subject to inaccuracies however, as Banks & Read concluded that only 4 of 13 headgear timers evaluated in vitro had greater than 90% accuracy. (Banks and Read, 1987).

1.3.4 Intraoral Sensors

The recent development of temperature-sensitive recording devices has introduced new opportunities for objective measurement of compliance. These devices measure compliance by recording the amount of time an appliance is worn in the mouth. The sensors are designed to measure their surrounding temperature between a range of 31-38 degrees Celsius, which is the temperature intra-orally. This is measured every 10-15 minutes. There are two brands available; SMART Retainer® and Theramon® sensors. Studies have shown that these sensors display an acceptable level of accuracy, with Charavet et al. reporting that:

“Theramon microsensors provided an objective, reliable and accurate assessment of patient compliance” (Charavet et al., 2019).

This is in contradiction with a study by Brierley et al. who found that sensors that were fixed palatally under-reported wear by an average of 1.2 hours per day. They concluded that increasing the range of the software temperature threshold for validating wear time would increase accuracy to more than 98% (Brierley et al., 2017).

Although followed-up over a short period of time (3 months), a study by Schafer et al. examined wear times of patients using functional appliances and expansion appliances embedded with Theramon® sensors and found that patients wore their appliances 64.7% of the prescribed time (Schafer et al., 2015). Studies by Schott et al. into the use of microsensors have found that these sensors can be used to objectively

measure wear times and may be useful for customizing wear protocols for individual patients. One study used a prototype Theramon® in 20 patients and assessed its ability to record wear-time (Schott and Goz, 2011b). They concluded that 92% of patients do not comply with a wear regimen of 12-15 hours/day and are most likely to wear their appliances for 9 hours/day and most patients display discontinuous wear behaviour (Schott and Ludwig, 2014). Despite wearing their appliance for the required time, patients with discontinuous wear behaviour are unlikely to achieve the constant pressure that are required for biomechanical tooth movement (Proffit et al., 2013). Schott and Goz also compared the SMART Retainer® and Theramon® sensors in an in vitro study using a thermostatic water bath and found that the Theramon® system had several advantages over the SMART Retainer® system. One of these advantages was that the Theramon® sensor was smaller in size and therefore could be incorporated into a broader range of orthodontic appliances. The Theramon® had a higher concordance between programmed water-bath temperature and registered wear time. No conflicts of interest were reported in this study (Schott and Goz, 2010a).

A pilot study investigated the use of SMART® sensors to measure compliance with removable Hawley retainers over a period of 12 weeks. They found that patient compliance was better in patients who were aware that their compliance was being monitored. Patients who were unaware that the sensor was monitoring their wear were less compliant (Hyun et al., 2015). Similar results were reported in earlier studies into

compliance by Northcutt and Guray and Ohran. This shows that the aforementioned “Hawthorne Effect” of using sensors in patient appliances which can potentially be used to increase compliance. This view has been supported by Brandao et al. who found that those who knew they were being monitored by sensors had a compliance rate of 62.7% compared to a cooperation rate of 56.7% in those who were unaware they were being monitored (Brandao et al., 2006). It is in contrast to results obtained in a clinical trial which found that patients who knew they were being monitored had better subjective estimations of wear time, however this did not increase the actual amount of time the patients wore their appliances. This clinical trial examined 32 patients undergoing treatment with removable appliances and retainers fitted with Theramon® sensors over a period of 6 months. No information is given on sample size calculation, randomisation or blinding, meaning there could be potential bias influencing the results (Pauls et al., 2013). Al-Moghrabi et al. concluded that compliance can be improved if patients are made aware that they are being monitored (Al-Moghrabi et al., 2017).

A survey concluded that patients are supportive of the use of such sensors, with 26.8% of patients recommending the use of sensors during treatment. 86% of respondents reported that the comfort of wearing their appliances was not adversely affected by the sensor (Schott et al., 2013b).

1.3.5 Bluetooth-enabled Sensors

A recent pilot study examined the effectiveness and accuracy of Bluetooth-enabled sensors embedded into removable Hawley retainers. The data from these sensors can be uploaded to a mobile application supported by Apple software. They found that difference of wear-time reported by the sensor in comparison with self-reported wear was 5.1% or 35 minutes over a 5-day period. Participants were surveyed about their use of such a device. Eighty-seven per cent of participants agreed or strongly agreed that they would use such technology and 100% agreed that it was likely to increase their compliance. The technology has an added benefit that reminders can be sent if non-compliance is demonstrated and data can be uploaded to a cloud database which can be accessed by both patient and practitioner. Although this was a pilot study and the data must be approached with caution, it provides information on a technology that can be more thoroughly assessed in future studies (Castle et al., 2019).

1.3.6 Coloured Compliance Indicators

These were introduced by Align™ technology to indicate how much patients were wearing their orthodontic aligners. There has been conflicting evidence relating to this method of measuring compliance. One study concluded that it was a safe and effective way of measuring compliance. However, this study was carried out on a small sample of patients undergoing evaluation as part of another clinical trial, and no information is given on statistics used or scientific methodology employed

(Tuncay et al., 2009). An in vitro study concluded that the fading pattern of the indicator was not an objective measurement of wear-time and could be influenced by other factors including pH and temperature (Schott and Goz, 2011a) .

1.4 Effects of Mobile Phone Applications/Text Messages on Compliance

1.4.1 Smartphones

With the development of smartphones comes new opportunities to incorporate smartphone technology into daily practice. The use of text messages and mobile applications has been used to enhance compliance in different parts of healthcare (Fenerty et al., 2012). A mobile application is a computer program or software application designed to run on a mobile device such as a phone, tablet, or watch.

A recent Ofcom study found that 83% of 12-15 year olds and 35% of 8-11 year olds have their own smartphone, and this opens up opportunities for us to directly influence the compliance of these patients (Ofcom, 2019).

Smartphone functions have been shown to improve glycaemic control in patients with diabetes, and positively influence physical activity of patients with coronary heart disease (Bin Abbas et al., 2015, Thakkar et al., 2016).

Reminders can come in the form of text messages or more interactive mobile applications. There is limited evidence available with regard to what types of reminders patients prefer to receive (Nelson et al., 2011),

however a survey of parents found that they would prefer their adolescent children to be contacted by phone call rather than by text, with only younger parents preferring text messages (Rand et al., 2015). Attitudes may well have changed with the advent of more secure messaging platforms. Studies have shown that patients are generally supportive of the use of mobile application reminders and feel that these would improve compliance (El-Huni et al., 2019, Henzell et al., 2013). A systematic review concluded that “a simple intervention such as a reminder targeting patients of a low socioeconomic background may provide the maximum benefit” (Mohammed et al., 2019).

1.4.2 Mobile Applications (Apps)

These can provide patients with helpful information on their condition in the form of videos or diagrams and they can also act as reminders via push notifications. There are many orthodontic applications available both to clinicians and patients. According to Gupta and Vaid, there are 354 orthodontic-related apps available, with 62 of these being aimed at patients (Gupta and Vaid). A recent UK-based study found that there are 305 available orthodontic apps. Many of these are focussed on gaming rather than behaviour change (Siddiqui et al., 2019). Despite this, a recent survey of 100 orthodontic patients in the UCLH Eastman Dental Hospital found that even though 90% of patients had access to a smartphone, only 7% were aware of the availability of orthodontic apps (Sharif et al., 2019).

Orthodontic apps such as Brace Accelerator, MyBraces Reminders and Rubberband Reminder are designed to remind patients to wear their elastics. Those such as iBraces™ Help and Learn about Braces™ are designed to provide patients with information about orthodontic treatment. The Invisible Orthodontist™ and Align Remind™ are designed to track orthodontic progress (Baheti and Toshniwal, 2014).

Dental patients tend to perceive dental apps in a positive way, and they are associated with improved health literacy (Bohn et al., 2018, Marchetti et al., 2018) The use of 3D apps for educational purposes has been shown to improve patient knowledge and insight into procedures(Pulijala et al., 2016).

A single-blind, randomised controlled trial investigated the effects of using mobile application reminders on the oral hygiene of patients undergoing orthodontic treatment in comparison to verbal reminders alone. The app contained informative videos as well as message reminders encouraging patients to practice oral hygiene tasks. The control group received only verbal oral hygiene instructions. They found a significant reduction in plaque index and gingival index in those receiving mobile application reminders after 4 weeks. Although the follow-up was short in this study, the study was well designed and further periods of follow-up could provide more convincing results (Alkadhi et al., 2017). Kay et al. investigated the effect of the Brushlink mobile app and found that use of the app was twice as effective in plaque reduction than oral hygiene advice alone (Kay and

Shou, 2019). The Brushlink app is synchronized with a smart toothbrush to given patients real-time information on their brushing time and performance. The WhiteTeeth™ mobile application has recently been introduced by clinicians in Amsterdam. This application not only provides patients with information on oral hygiene but addressed the psychosocial factors that influence oral health behaviour. The techniques it uses includes coping mechanisms, goal setting, reminders, feedback, and practical support. A single-blind, randomised controlled trial found that use of this app resulted in a significant reduction in gingival bleeding and dental plaque after 12 weeks of follow-up. The frequency of tooth-brushing did not increase, however the technique of those in the intervention group improved in comparison to the control group, who received only verbal oral hygiene instructions (Scheerman et al., 2019). The benefit of mobile applications over text messages is that they are easily accessed, more interactive, constantly available and can provide tailored feedback to patients (Wang, 2016). The disadvantages of using apps is that their content is generally unregulated. The quality and reliability of information provided by the apps have a high degree of variability (Parker et al., 2019). In order to combat this, the UK National Health Service (NHS) has produced a list of reliable apps that can be recommended by clinicians. The sole dental app on this list is the Brush DJ© app (Figure 7). There is a great need for quality control systems to be put in place to ensure that apps developed provide only evidence-based health information (Yetisen et al., 2014).



Figure 7: Brush DJ© app symbol (<https://www.brushdj.com/>).

1.4.3 Text Messages

These are less interactive than mobile applications but are useful to encourage compliance in orthodontic patients. They have the benefit of being relatively cheap and easily customised. They have been used to encourage compliance with oral hygiene, improve attendance rates, encourage elastic wear, and reduce post-treatment pain and anxiety in orthodontic patients. A randomised controlled trial found that text message reminders sent to parents of patients undergoing orthodontic treatment resulted in improved oral hygiene compliance. However, the trial had short follow-up, and no information was given on blinding or allocation concealment. No sample size calculation was carried out. They went so far as to say that reminders should be included as part of the basic protocol for providing any compliance-based treatment to patients, a view that is supported by Mohammed et al. who carried out a systematic review of the effect of reminders on oral hygiene and attendance rates (Eppright et al., 2014, Mohammed et al., 2019). These results are similar to

studies investigating the effect of text messages on compliance in non-orthodontic patients (Bowen et al., 2015). Hashemian et al. found that text message reminders sent once daily for 7 days resulted in increased compliance with flossing regimens and improved oral-health related knowledge in mothers. However there was a very short follow-up of 7 days, and therefore long-term retention of information was not confirmed (Hashemian et al., 2015).

Text messages have been used to improve attendance rates in orthodontics and other medical specialties. Downer et al. found that text message reminders improved attendance rates to hospital outpatient appointments (Downer et al., 2005). This is similar to results in other studies examining the effects of text message reminders on attendance rates (Foley and O'Neill, 2009, Chen et al., 2008, Prasad and Anand, 2012).

Contrasting results in a randomized controlled trial concluded that reminders of any form did not improve attendance rates in orthodontic practice. This study included a sample size of 301 subjects who were divided into 4 groups. Three of the groups received one form of reminder to attend their appointment, either by telephone, mail, or SMS. The control group did not receive any reminder. There were no differences in attendance rates, and 20% of participants in this study felt that reminders were a waste of time and money and would not affect attendance. The results of this study may be affected by the fact that the overall failure rate at the department was 4% which is already low, therefore a larger sample

size may have identified a difference between the groups (Bos et al., 2005a).

One study found that patients who received text messages after placement of fixed appliances reported lower levels of pain than those that did not. This suggests that text message reminders can reduce subjective pain experience and therefore possibly improve compliance (Keith et al., 2013).

There are limited studies into the effects of the frequency of reminders on compliance. A well-designed, blinded randomised clinical trial concluded that daily reminders were more effective at improving oral hygiene compliance than weekly reminders. Patients were randomly allocated to one group receiving daily text message reminders and one group receiving weekly reminders. There was no control group in this study. Over a period of 2 months, patients who received daily reminders had lower scores for bleeding, plaque and gingival indices than patients receiving weekly reminders (Ross et al., 2019). A systematic review by Fry & Neff concluded that periodic reminders are effective in behaviour change interventions. Although meta-analysis was not possible due to the heterogeneity of the data. They concluded that effectiveness was enhanced if the prompts were frequent however there was insufficient evidence to suggest a particular time interval (Fry and Neff, 2009).

1.4.4 WhatsApp

Seventy-three percent of UK internet users use mobile messaging, and WhatsApp is the number one app in terms of monthly active users and by downloads (Hootsuite & We Are Social (2019), "*Digital 2019 Global Digital Overview*" retrieved from <https://datareportal.com/reports/digital-2019-global-digital-overview>). WhatsApp has been used as a messaging platform for patient reminders as an alternative to conventional text messages. A prospective, randomised controlled trial used WhatsApp messages twice weekly to remind patients to wear their elastics. The trial had a total of 42 participants and compared those who received two WhatsApp messages per week to those who did not. Those that received reminder messages achieved 3.7 times greater class II improvement than the control group (Leone et al., 2019). The results are similar to a study by Pinchani et al. who compared compliance with elastic wear between a group who received daily reminders and a group that didn't. They concluded that this method was highly effective. However, their measure of compliance related to how many used and unused elastics patients went through over a period of 30 days and this measure is subject to great manipulation by the patient cohort (Pinchani et al., 2016). Another prospective randomised controlled trial by Li et al. examined the effect of regular WeChat messages on the duration of treatment. This non-blinded study found that those patients receiving regular informative and reminder messages had a shorter duration of treatment by on average 7.3 weeks. However, other

influences on duration of treatment such as age or mechanics used were not accounted for in the study. They also found that bond failure and failure to attend rates were lower in the intervention group. The plaque and gingival indices of the intervention group was the same as the control group (Li et al., 2016). Contrastingly, a study by Zotti et al. used a WhatsApp group chat where patients could share anonymous “selfies” and messages to encourage patients to improve their oral hygiene. In comparison to the control group, the intervention group had better oral hygiene compliance and fewer white spot lesions at the end of the study (Zotti et al., 2016). A similar pilot study found that engaging with adolescents via WhatsApp improved their compliance with removable retention and resulted in better orthodontic stability and fewer changes in intercanine widths 1 year after debond (Zotti et al., 2019). With the advent of systems such as WhatsApp comes security concerns regarding data. According to a review paper, data transfer on WhatsApp is at risk at many levels, including during transmission and storage. The authors advocated the introduction of patient consent specifically for data transferred via instant messaging systems (Morris et al., 2018).

1.5 Developments

Telecommunication in medicine has been used to inform patients, diagnose disease and educate clinicians (Pande et al., 2003). Its use in orthodontics to date has been limited however a small study investigated the use of videocalls in the management of orthodontic emergencies. The

study included 10 patients, each of whom were given information on breakages and a mobile phone with access to video calls after the placement of fixed appliances. Most emergency calls made were due to loss of elastic ligatures, however other topics included mucosal irritation or bracket debond. They concluded that videocalls were a suitable way to manage orthodontic emergencies, with 5 out of 10 patients effectively dealing with the emergency without attending the orthodontic practice. It must be noted that no control group was included in this study. The patients were positive towards the use of telecommunication in orthodontics. This is an area where further research may be possible in the future. In this era of data protection, telecommunication in the healthcare field has implications in terms of security and integrity of patient data. This is especially pertinent for orthodontic patients, who tend to be below 18 years of age and are therefore considered children (Favero et al., 2009).

A qualitative study into the use of an interactive mobile app with cloud services (Dental Calendar) to remind patients of appointments and communicate with patients about their treatment in real-time found that these technologies can improve overall dental care and provide both dentist and patient with economic benefits (Lin et al., 2014).

1.6 Summary

The positive effects of twin block therapy are well documented in the literature. Due to the time-specific nature of twin block therapy, enhancing compliance at the outset is an important part of successful treatment.

Influences on compliance can be internal or external, with patient personality a strong determinant of compliance. External factors such as parent involvement, operator influence, and social norms can also have a positive or negative effect on compliance. Methods to measure compliance initially focussed on patient-reported wear along with subjective measurements by clinicians. These have gradually evolved to include more sophisticated objective measurements by sensors. These sensors have given us an opportunity to investigate the effect of reminders on compliance and wear-time. Patients are generally in favour of these reminders, and the methods available to us include simple text messaging or more complex mobile applications with the ability to synchronise with cloud databases. These provide us with a potential resource to help improve compliance in patients, along with tailored wear regimens and targeted behavioural therapy.

2.0 Aims and Null Hypotheses

2.1 The aims of this study were:

- To evaluate the effect of text message reminders on compliance of patients with twin block appliances.
- To compare patient-reported wear times and objectively recorded wear times.

2.2 The objectives were to:

- Objectively measure appliance wear-time in the CG and the SG.
- Subjectively measure appliance wear-time in the CG and SG.
- Compare both subjective and objective reports of wear times in the CG and SG.
- Compare the number of days with over 8 hours of wear between the CG and the SG.
- Compare the number of days with over 18 hours of wear between CG and the SG.

2.3 Null Hypotheses

- There is no statistically significant difference in twin block compliance between those who receive regular text message reminders and those that do not.
- There is no difference between objectively and subjectively reported wear times.

3.0 Materials and Methods

3.1 Study Design

This was a prospective, single blind, randomized controlled trial with a 1:1 allocation ratio investigating the effects of text message reminders on patient compliance with twin block appliances as measured by wear-time. Wear time data was collected using Theramon® micro sensor technology (Theramon System, Gschlady, Hargelsberg, Austria) embedded in the patient's twin block appliances as well as wear diaries completed and returned by the patients. The study lasted a total of 9 months, with 5 months assigned for patient recruitment and 4 months assigned for data collection.

3.2 Ethical Approval

Ethical approval was sought from Tallaght University Hospital (TUH) / St. James's Hospital (SJH) Joint Research Ethics Committee (REC) and approval was granted on the 13th February 2020 (Appendix 1).

3.3 Sample

The sample consisted of 59 patients who were recruited from the functional appliance waiting list of the HSE Orthodontic Unit. They were assigned to this list after initial examination revealed an overjet of greater than 9mm, resulting in an IOTN score of 5a.

3.3.1 Inclusion Criteria:

- Patients with a class II division I malocclusion.
- Aged between 11-15 years.
- Having an overjet of greater than or equal to 9mm.
- Planned for twin block therapy.
- Patients must own their own smartphone with capability to receive text messages.

3.3.2 Exclusion Criteria:

- Patients undergoing functional appliance therapy with other functional appliances.
- Patients who have had a pre-functional phase of fixed appliances.
- Patients who do not own their own smartphone.

The sample size calculation was carried out using G*Power 3.1.9.2

(Buchner, A., Erdfelder, E., Faul, F., Lang, AG. (2007) G*Power (Version 3.1.9.2) Accessed on: 17/12/2018). A sample size calculation of 52 patients was determined sufficient to yield a power of 80% and an alpha of .05. This was calculated using a medium effect size of 0.8 based on a clinically significant difference in wear time of 4 hours per day (SD 7.9). This was based on previous studies comparing full-time and part-time wear of twin block appliances (Parekh et al., 2019). Recruitment of 59 patients allowed for a drop-out rate of 10% without affecting the power of the study. The sample was divided into two groups, with 30 in the CG and 29 in the SG. The SG received a text message reminder to wear their appliance on every third day during treatment. Both the study and control group received verbal information and an information leaflet regarding wear protocol. Both groups received wear diaries for completion and return at the

following visit. The distribution of participants among the clinicians is outlined in Table 1.

Clinician 1	Clinician 2	Clinician 3	Clinician 4	Clinician 5
11	14	10	9	15

Table 1: Number of research participants seen by each clinician.

3.4 Recruitment of Participants

Patients were enrolled in the study as they reached the top of the functional appliance waiting list. This was done by the gatekeeper who identified these patients as they became eligible for treatment. Ethical approval was dependant on consent being obtained from the parents of the patients and assent from the patients themselves. Clinicians informed the patients and parents about the study and their role as subjects.

Patients and parents were given information leaflets (Appendix 2) and were asked to study these over a period of two weeks. After two weeks, patients and parents were asked to return and written consent was obtained by the treating clinicians (Appendix 3).

3.5 Randomization & Allocation

After consent was obtained, the gatekeeper was asked to allocate the patients to either the intervention or control group. A computer generated unstratified allocation sequence was used to randomize the patients (Urbaniak, G.C., & Plous, S. (2013). Research Randomizer (Version 4.0).

Accessed on: 19/02/2020, from <http://www.randomizer.org>).

The sequence was kept in opaque, tamper-proof envelopes in a secure location until the allocation was required. The envelope was opened by the patient and the group was revealed. At this point the gatekeeper noted the group in a secure document that was not provided to the research lead or treating clinician.

3.6 Blinding

It was not possible to blind the patient to the research group. Clinicians responsible for patient treatment were blinded as to the research group and during data input the principal investigator was blinded as to research group. The research group was revealed to the principal investigator prior to data analysis.

3.7 Interventions

The intervention in this study was a text message sent to the patient's phone to remind them to wear their appliance. Messages were sent using a web-based Short Message Service (SMS) platform (3Communicate software, Version 12.5.18, Three Ireland (Hutchison) Limited, Sir John Rogerson's Quay, Dublin, Ireland). These messages were sent every three days at three different times: 09.00, 14.00 or 17.00. These times were chosen to ensure maximum effect of the text message reminders. They were sent at times during which the patients may be likely to have removed their appliances, for example, during school or weekend activities. The text messages differed and were not the same. An example

of the text messages sent can be found in the information leaflet in Appendix 2. Text messages were sent directly to patient phones as it was thought that communicating directly with patients at these specific times would increase the impact of the reminders.

3.8 Twin Block Design

A standardised twin block design was used in this study (Figure 8). Wax records were taken with patients occluding edge to edge. The twin block design included: Adam's clasps on upper first premolars and first molars, an upper midline expansion screw, Adam's clasps on lower first premolars and first molars, anterior ball-ended clasps and acrylic blocks of 6mm with anterior opening of 2-3mm. These twin blocks were made by the same lab technician, who is highly experienced in placing Theramon® sensors.

Clinicians were informed that if additional active components such as z-springs or additional clasps were required that it was at their discretion as to whether these were included in the design. Single-step advancement was advised to achieve edge-to-edge occlusion however clinicians were advised if this was uncomfortable for the patient incremental advancement could be employed.

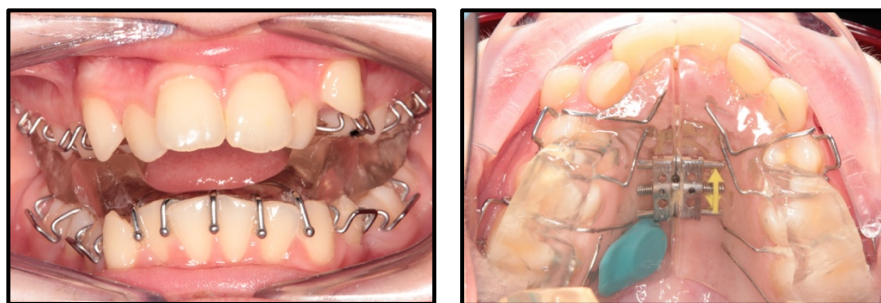


Figure 8: Modified twin block design with embedded Theramon® sensor.

3.9 Data Collection

Wear-time data were collected in two ways. Patients were asked to maintain a wear diary and to bring it with them to every visit. An example of the wear diary can be found in Appendix 4. Data was also collected from the Theramon® sensor.

The Theramon® sensor used in this study was a small (12mm x 8mm x 2mm) device covered by polyurethane. It used an application-specific integrated circuit with 16 kilobyte internal Electronically Erasable Programmable Read-Only Memory (EEPROM-memory). The sensor was embedded into the removable appliance by the technician. It measured the temperature within the mouth every 15 minutes. The range of temperatures between which the appliance is deemed to be worn is 31.5°C- 38.5°C and the sensor is capable of recording the temperature with an accuracy of $\pm 0.1^{\circ}\text{C}$ (Schott and Goz, 2010a). The data were transmitted to a computer using a wireless connection between the removable appliance and a readout station coupled by a universal serial bus (USB) connection. The Theramon® software read and interpreted the

data (Theramon software, version 1.2.2.26, Handelsgentur, Gschladdt, Austria). A diagram with the relevant information was then generated.

Patient manipulation, for example, using a water bath with temperature control or putting the appliance on a heater, can be revealed by viewing the temperature curves in detail. Figure 9 illustrates a typical reading from the Theramon® sensor.

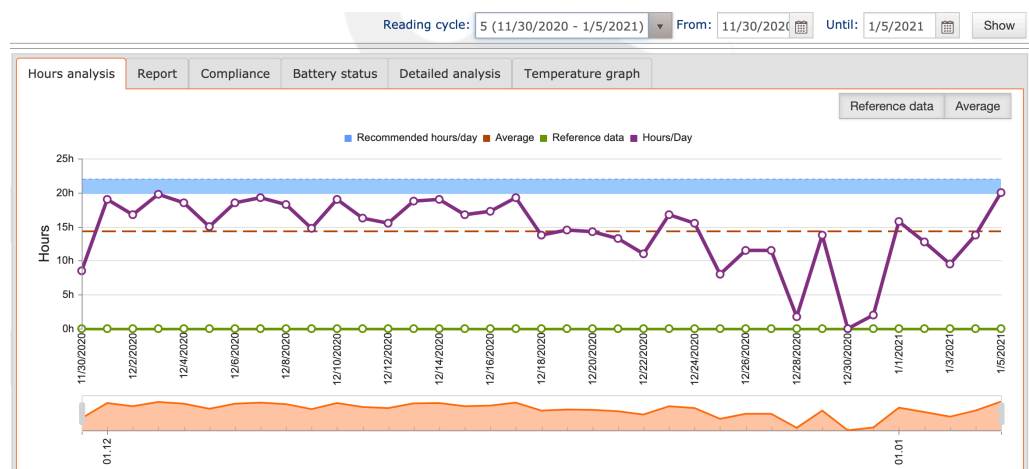


Figure 9: Data output illustrating hours of daily wear.

3.10 Data Collection Sequence

3.10.1 Visit 1

- Patient information leaflets and verbal study information were given.
- Clinical records were obtained: photographs, radiographs, and impressions for study models. Photographs taken included full face, full face smiling, three quarter profile, profile, anterior view, buccal right and left views and occlusal upper and lower views.
- Clinical parameters such as overjet, reverse overjet, overbite, molar relationship, and canine relationship were noted in the patient record.

3.10.2 Visit 2

- Consent for treatment and inclusion in the study was obtained from parent and assent from patient.
- Impressions were taken with patient protruding into an edge-to-edge incisor position.
- Twin block standardised design was sent to the lab with instructions to include incorporation of Theramon® into the maxillary portion of the appliance.

3.10.3 Visit 3

- On return of the twin block the sensor number was assigned to the patient on their electronic chart.
- Patient was allocated to control or study group.
- Twin blocks were fitted.
- Twin block instruction leaflets were given to all participants as per usual protocol.
- Standard advice on wear was given to all patients – 18-22 hours/day of wear. Patients were advised to take the appliance out only for eating, cleaning and contact sports.
- Patients were asked to start wearing the appliance full-time immediately with no period of build-up to full time wear.
- Patients were booked in for a review after 8 weeks and asked to contact if there were any problems.
- Patients in both groups were given wear diaries and asked to complete and return these at the next visit.

3.10.4 Visit 4 (8 weeks after start of twin block therapy)

- Wear diaries were collected and new diaries distributed to patients.
- Data were uploaded from the sensor onto the cloud software.
- Expansion of the midline screw was started at this visit, if required.

3.10.5 Visit 5 (16 weeks after start of twin block therapy)

- Wear diaries were collected.
- Data were uploaded from the sensor onto the cloud software.
- Patients were advised that the research study has concluded and thanked for their participation.

Patients underwent the remainder of their treatment as normal with the twin block appliance after conclusion of the study. However, patients in the intervention group no longer received text messages.

3.11 Patient Records and Stopping Rules

Wear diaries were collected at each visit and data uploaded from the Theramon® sensor at each visit. There were no stopping rules identified for this trial as twin block appliances are a commonly used appliance to correct anteroposterior skeletal discrepancies and no special problems with this appliance were foreseen.

3.12 Method Error

Systematic error was reduced by ensuring that both the treating clinician and the examiner analysing the wear time data were blinded to the allocated group for each patient.

3.13 Statistics

Data analysis was carried out using SPSS software (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp) and RStudio Team

(RStudio: Integrated Development for R, Version 1.4.1717. Boston, MA:

PBC). The level of statistical significance was predefined at $p < 0.05$.

3.13.1 Baseline Data

Simple descriptive statistics were used for baseline data comparison. Chi-square test was used to test categorical data (gender). The groups were assessed for normality with Shapiro-Wilk and Mann Whitney U test was used to determine whether there were any statistically significant differences between the groups with regard to age.

3.13.2 Objective Wear Data (Theramon®)

The mean hours/day of wear for both groups was determined using data from the Theramon® sensor and was calculated by dividing the number of hours of wear per day by the number of days the appliance was prescribed. The Shapiro Wilk test for normality was used to determine whether the data was parametric or non-parametric. Linear regression was carried out to determine the effect of age and gender on wear time. When the assumption of normality was not satisfied, the generalised linear modelling approach used was gamma regression with the log link. Levene's test for variance was carried out to test for variance and homogeneity of data across the groups. Mann Whitney U test was used to compare the groups as data was not normally distributed.

3.13.3 Subjective Wear Data (Wear Diary)

The mean hours/day of wear for both groups was calculated by dividing the number of hours of reported wear per day by the number of days the appliance was prescribed. This was determined using data from the wear diaries from both

the CG and SG. Due to the limited number of completed wear diaries returned, it was not possible to carry out a formal analysis comparing the CG and SG.

3.13.4 Compliant Days (Theramon®)

The number of days where over 18 hours or 8 hours of wear was recorded were calculated for both the CG and SG. Negative binomial regression analysis was used to compare the groups as data were not found to satisfy criteria for Poisson analysis.

3.13.5 Objective versus Subjective Wear

The wear data for the objective and subjective measurements was compared to determine if there were any notable differences in average wear reported across the sample. Unfortunately, due to a large amount of missing data in the wear diary group it was not possible to carry out statistical analysis on objective and subjective wear times. The number of participants who over and underestimated their wear times by over 1 hour was also noted.

4.0 Results

4.1 Participant Flow

The flow of patients through the study can be found on the CONSORT diagram (Figure 10). Overall, 59 participants were randomly allocated to either the intervention or control groups. 29 were allocated to the CG and 30 were allocated to the SG. There was a total of 27 females and 32 males with an average age of 13.9 (SD 0.57) years.

Four of the sensor batteries failed in the CG and one sensor was not possible to read due to an inability to connect to the software server as a result of a nationwide cyberattack. The cyberattack affected the Health Service Executive (HSE) Information Technology system nationally and resulted in an inability to access electronic systems and patient records. Therefore, data for 24 participants were analysed. In the SG, sensor battery failure rendered an incomplete dataset for 1 participant and therefore the data of 29 participants were analysed. In total, the data of 53 participants were analysed. A complete case analysis was carried out whereby incomplete data was not included in statistical analysis.

CONSORT 2010 Flow Diagram

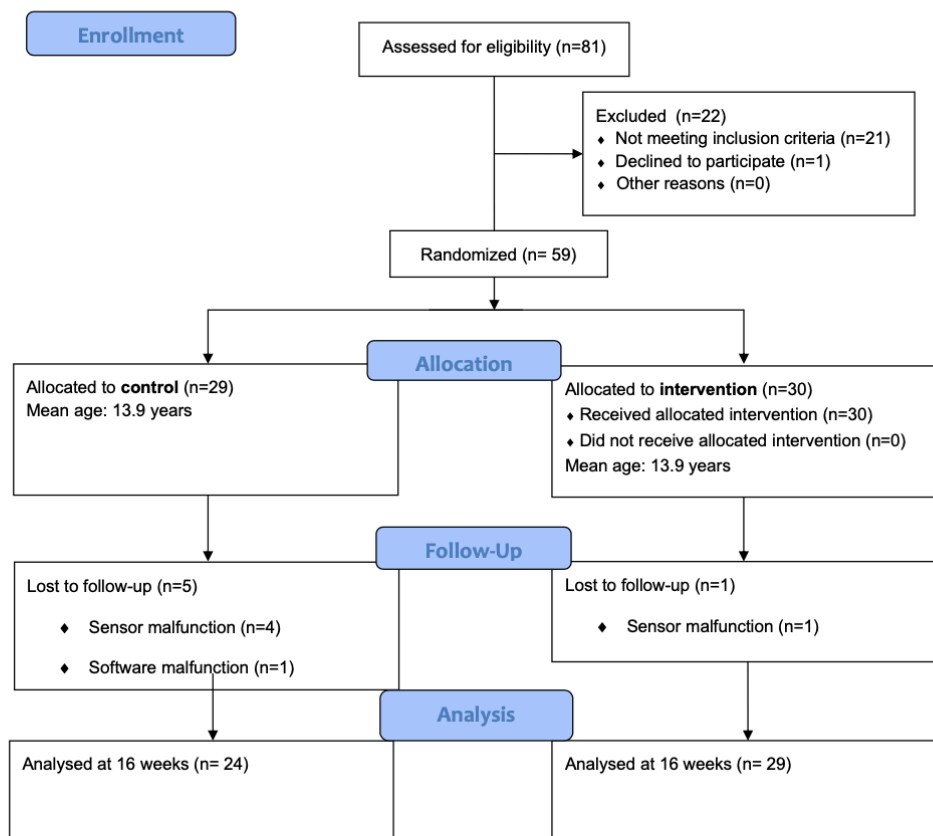


Figure 10: Flow of participants through the study.

4.2 Baseline Data

Both groups were well matched for age at baseline with the average age of both groups being 13.9 years. Figure 11 and Table 2 illustrate age distribution among the control and study group.

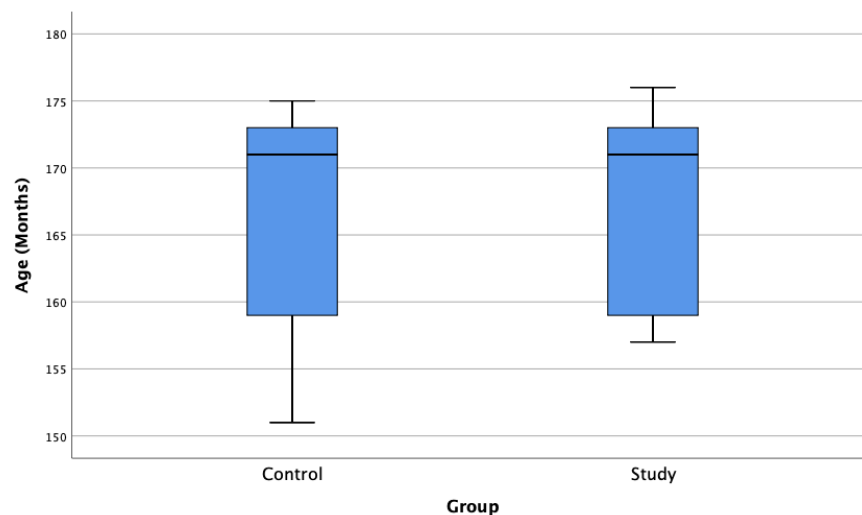


Figure 11: Age distribution among the control and study groups.

Group	N	Mean	Std. Deviation	Median	IQR
Control	24	167.7	7.29	171.0	14
Study	29	167.3	6.73	171.0	14
Total	53	167.5	6.93	171.0	14

Table 2: Mean and median age (in months) of participants.

Shapiro Wilk reports for normality determined that the data were not normally distributed (Figure 12). Independent samples Mann Whitney U test showed no statistically significant age differences between the CG and SG ($p=.98$).

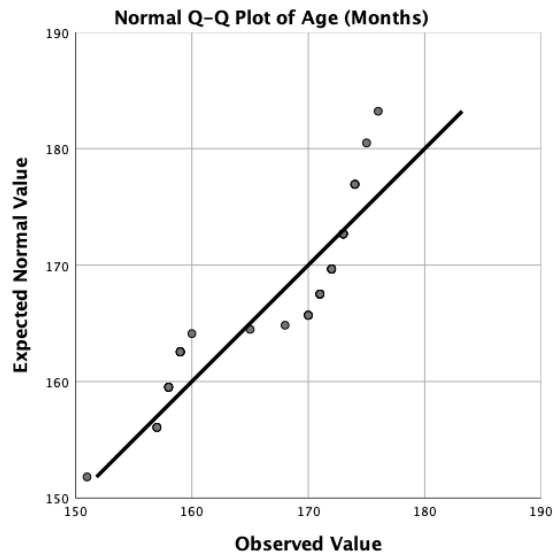


Figure 12: Q-Q plot of age distribution.

The sex distribution was relatively well balanced in the CG although there was a preponderance of males in the SG (Table 3).

Group	Male (%)	Female (%)
Control	11 (45%)	13 (55%)
Study	19 (65%)	10 (35%)
Total	30 (56%)	23 (44%)

Table 3: Gender distribution between groups.

Chi-square test was used to determine whether the differences between the groups was significant. Table 4 illustrates the results of Chi-square analysis which concluded that there were no significant differences in gender distribution between the groups ($p=.15$).

Pearson Chi-Square Analysis		
Value	Degree of Freedom	P value
2.07	1	.15

Table 4: Chi-square analysis for gender differences between the control and study group.

4.3 Objective Wear Data (Theramon®)

Linear regression analysis was carried out to determine the effect of age and gender on wear time. Levene's test for homogeneity of variance concluded that the variance between the groups was constant and data was homogenous across ($p=.15$). The Shapiro-Wilk test was used to test for normality and this concluded that the data did not satisfy the assumption of normality ($p=.21$). Outliers were present in the SG and the sample data did not have the normal bell shape distribution (Figure 13). Non-parametric analysis was therefore chosen to compare the distribution of values between the groups.

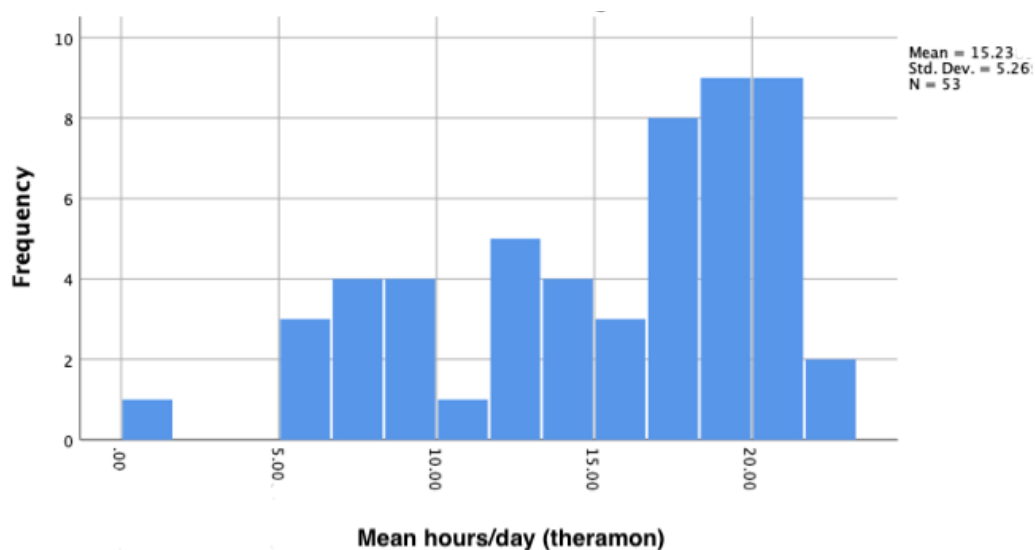


Figure 13: Histogram displaying non-normal distribution of data for the overall sample.

Group	Mean Hours/Day	SD	95% CI	Median Hours/Day	IQR
Control	13.91	5.69	11.51-16.32	13.77	10.19
Study	16.33	4.71	14.54-18.12	17.2	5.62
Total	15.23	5.26	13.75-16.69	16.82	7.59

Table 5: Mean and median hours of wear for control and study groups. (Theramon®).

Mann Whitney U test for unpaired groups was used to test for differences in the distribution between the samples. The results are illustrated in Figure 14 and demonstrate no statistically significant differences between the CG and SG ($p=.16$).

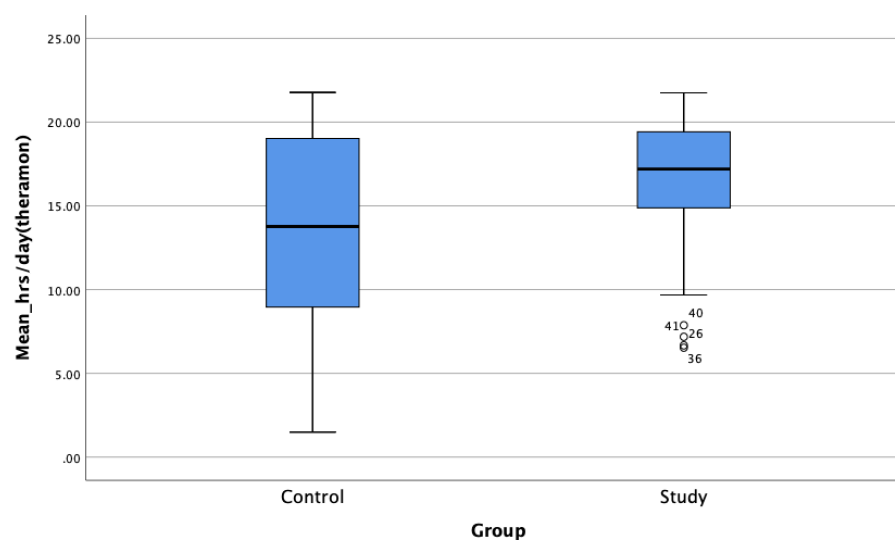


Figure 14: Boxplot illustrating comparative wear time in the control and study groups (Theramon®).

Linear regression concluded that the data did not satisfy the assumption of normality (Appendix 5) and therefore gamma regression was used to determine the effect of age and gender on the average hours/day recorded in the CG and SG (Table 6).

	Estimate	Standard Error	95% CI	P Value
Age	0.002	0.007	0.98 –1.01	.76
Gender	0.01	0.1	0.83-1.23	.85

Table 6: Gamma regression for average hours (Theramon®).

4.4 Subjective Wear Data (Wear Diary)

Wear diaries were returned by 28 of the sample. Of these, only 5 were completed in full (16 weeks of data). 14 were returned with 8 weeks of data and 9 were returned with 14 weeks of data. Therefore, only descriptive statistics were used for the subjective data and no statistical analysis was carried out compare the CG and SG. The subjective reported wear times are outlined in Table 7.

Group	Mean Hours/Day	SD	95% CI	Median Hours/Day	IQR
Control	18.11	3.91	15.74-20.47	19.44	6.58
Study	19.26	3.95	17.07-21.45	20.35	3.07
Total	18.72	3.9	17.21-20.24	19.78	3.38

Table 7: Differences between hours of wear for control and study groups (wear diary).

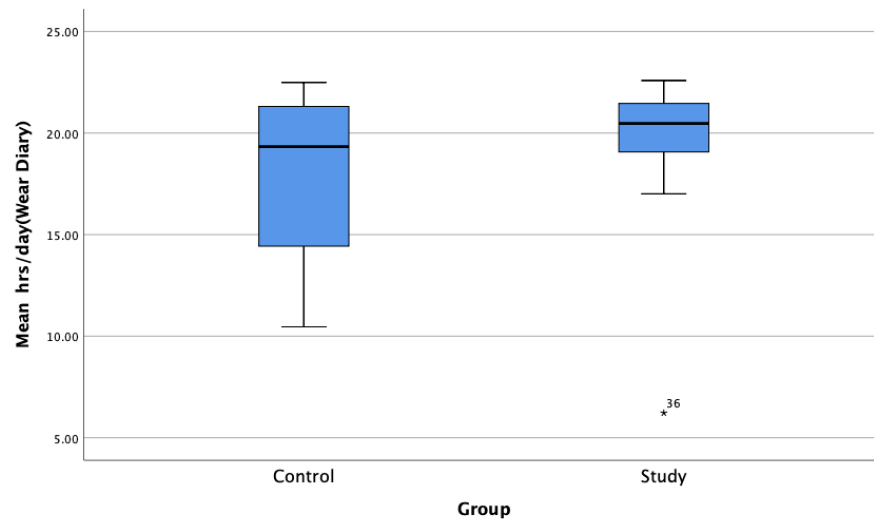


Figure 15: Boxplot illustrating comparative wear time in the control and study groups (wear diary).

4.5 Compliant Days

The mean number of days where greater than 18 hours of wear was recorded by the Theramon[®] sensor across all groups was 53.5 out of the 111 days of the observation period (SD 40.35). This increased to 95.3 (SD 24.61) for days where over 8 hours of wear per day was recorded. This was considered as the minimum daily wear time to be considered “compliant”.

In the CG patients wore their appliances for greater than 18 hours a day for a mean of 43.9 days (SD 41.37) and greater than 8 hours per day for a mean of 90.3 days (SD 20.14). In the SG, patients wore their appliances for greater than 18 hours a day for a mean of 61.5 days (SD 38.3) and greater than 8 hours per day for a mean of 99.4 days (SD 28.77).

Poisson regression was used to assess count data and dispersion test found that the data were over dispersed. Therefore, negative binomial regression was used to determine if group or gender had an effect on the

number of days where over 18 or 8 hours of wear was recorded. The results are outlined in Table 8 and conclude that neither group nor gender had an effect on the number of compliant days recorded.

	Variable					
	Days over 18 hours of wear			Days over 8 hours of wear		
Group	IRR	95% CI	P value	IRR	95% CI	P value
	1.39	0.76-2.52	.26	1.11	0.93-1.33	.22
Gender	1.01	0.55-1.82	.97	0.93	0.77-1.11	.44

Table 8: Incidence rate ratio (IRR), 95% Confidence Intervals (CI) and P values for differences between group and gender and recorded days over 18 and 8 hours of wear.

4.6 Objective versus Subjective Wear

Table 9 shows the mean and median wear times reported by Theramon® and wear diaries for the 28 participants for whom this information was available.

Measuring device	Mean Hours/Day	SD	95%CI	Median Hours/Day	IQR
Wear Diary	18.73	3.90	17.21-20.24	19.78	3.38
Theramon®	16.14	5.21	14.12-18.17	17.35	7.29

Table 9: Mean and median wear times reported by Theramon® and wear diary.

Unfortunately, due to the small number of completed wear diaries returned, it was not possible to complete a formal analysis of the objective and subjective hours of wear recorded.

In the CG, seven out of a total of 13 participants overestimated their wear time by over an hour. Two participants underestimated their wear and four correctly estimated their wear times. In the SG, 11 out of a total of 15 participants overestimated their wear time by over an hour. Four participants correctly estimated their wear times, and no participants underestimated their wear times.

5.0 Discussion

5.1 Validation of Wear Time Measurements

Previous studies support the view that orthodontists, patients and parents tend to over-estimate wear (Sahm et al., 1990b, Bos et al., 2007, Al-Moghrabi et al., 2017). It is important that any device designed to objectively measure wear-time is accurate and valid. Validity is a measure of the accuracy of a method in measuring what it is intended to measure. The Theramon[®] sensor has been shown to accurately measure wear time, judged by higher concordance between programmed water-bath temperature and registered wear time. The temperature reported by the Theramon[®] sensor (34.5 °C -35.2 °C) coincided very closely to those of the water bath (35 °C) (Schott and Goz, 2010a). Brierley et al. concluded that increasing the temperature range within which wear time is validated can help to improve the accuracy of intraoral wear recordings. The range of temperatures in this study was 31.5°C – 38.5°C rather than the 33.5°C-39°C used previously. Therefore, Theramon[®] sensors were considered a reliable method of measuring patient wear time and compliance for the purpose of this study. Further increasing the range of temperature threshold for validation of wear to 30°C-42°C would increase the accuracy to 98% (Brierley et al., 2017).

There were five instances of battery failure in this cohort which amounts to 8% of the sample. This was not reported in the literature but should be borne in mind when planning future studies with Theramon® sensors.

5.2 Mean Wear Time

The mean overall objective wear time was 15.23 hours (SD 5.26). This is higher than that reported in the literature. The randomized controlled trial by Parekh et al. in which patients who were asked to wear their appliances for a minimum of 22 hours/day wore them for only 12.38 hours, or 51.6% of the time (Parekh et al., 2019). Schafer et al. had slightly more success with maxillary expansion devices and concluded that patients wore their appliances for 9.7 hours (64%) of the 15 hours prescribed. (Schafer et al., 2015). Schott and Ludwig concluded that 92% of patients did not comply with a wear regimen of 12-15 hours/day and most patients displayed largely inconsistent wear behaviour (Schott and Ludwig, 2014). The current study demonstrated overall average wear time that is higher than that reported in the literature. This may be due to the short duration of the study, as increasing duration of treatment corresponds with a reduction in compliance. This study was carried out during the COVID-19 global pandemic and as part of the Health (Preservation and Protection and Other Emergency Measures in the Public Interest) Act 2020, restrictions were placed on Irish citizens to limit virus transmission. These meant that children were unable to socialise with their peers and were obliged to remain at home for their schooling (Health (Preservation and Protection

and other Emergency Measures in the Public Interest) Act 2020). This may have reduced the external influence of peer pressure on their compliance and resulted in increased compliance in all cohorts.

The mean subjective wear time was 18.72 hours (SD 3.9). This amounts to an overestimation of wear time by 3.49 hours. This is less than that reported by Al-Moghrabi et al. who compared patient-reported wear to objectively recorded wear found that patients over-reported their wear by 5.02 hours (Al-Moghrabi et al., 2017). It is, however, in line with a study by Bos et al. who reported a difference of 3 hours between patient-reported wear and wear-time measured by sensors placed in headgear straps (Bos et al., 2007).

Seventy-three percent of participants in the SG overestimated their wear time, compared to 63% in the CG. Patients who keep wear diaries are more likely to report wear more accurately than those who do not. It is important to remember that only 9.4% of the sample returned completed wear diaries. Forty-three percent of participants returned incomplete wear diaries. This suggests that paper diaries are less relevant to younger patients in a digital world and some form of electronic recording may be better suited to this generation. The formation of an interactive mobile App with push notifications to encourage engagement may be a solution for this and this may be an interesting topic to investigate in future studies.

5.3 Mean Wear in Control and Study Groups

Text messages are a cheap and reliable way of encouraging compliance with oral hygiene, improving attendance rates, encouraging elastic wear, and reducing post-treatment pain and anxiety in orthodontic patients. The systematic review by Mohammed et al. concluded that text messages should be included as part of the basic protocol when dealing with patients from whom compliance is required for orthodontic treatment (Mohammed et al., 2019). Eppright et al. examined the oral hygiene levels of patients who received regular reminders over a 5-month period and found improved oral hygiene compliance (Eppright et al., 2014). The follow-up period in this study was slightly shorter, however and although the group who received text message reminders displayed an increase in average objective wear times, these were small and not statistically significant ($p=.16$). Therefore, the study fails to reject the null hypothesis whilst acknowledging the risk of type II error.

5.4 Mean Compliant Days

Few studies are available with data regarding compliant days. A compliant day in this study is a day where the patient wears their appliance for the prescribed time. The prescribed time in this study was 18 hours/day. This was to allow for removal of the appliance during mealtimes and when playing contact sports. Analysis was also carried out on the days where over 8 hours of wear was recorded. This was chosen as the mean wear time of the part-time functional appliance group in the study by Parekh et

al. was 8.78 hours (SD 3.77) and this group displayed similar clinical results to the full-time regimen group (Parekh et al., 2019). Charavet et al. concluded that in their study, anything under 9 hours of wear was considered insufficient (Charavet et al., 2019). Schott and Ludwig reported inconsistent wear patterns in their study, with some days of zero wear compensated for by days of above-average wear. This highlights the importance of not only assessing average daily wear but total days of compliant wear in order to adequately assess wear behaviour. The mean number of days where over 18 hours of wear was recorded was 58.5 (SD 40.35). This increased to 95.3 (SD 24.61) for days where over 8 hours was recorded. These figures suggest that on average, patients wore their appliances as per the prescribed regimen on just over half the days they were observed. There was no statistically significant difference in the number of days where over 18 hours or 8 hours of wear was recorded between the CG and SG ($p=.26$ and $.22$, respectively).

5.5 Limitations of Study

Twin block treatment normally occurs over a period of 9-12 months depending on patient compliance and growth. Relapse is more likely when treatment lasts under 6 months and the greatest degree of skeletal and dentoalveolar change occurs in this time (Lee et al., 2007). Objective assessments of compliance have found that it is relatively stable in the first 5 months of treatment and declines thereafter (Arreghini et al., 2017). Many studies examining the effect of treatment duration on compliance

have short follow-up periods of 1-5 months. The follow-up period in this study was 4 months which is under half of the duration of normal twin block treatment. This negates the effect of increasing age on compliance, however further studies may benefit from a longer follow-up which would better establish long-term compliance.

Although there was no statistically significant difference between the CG and SG in terms of gender. There was a preponderance of males in the SG. There is some evidence, albeit inconclusive, that females display higher levels of compliance than males. The preponderance of males in the SG may have influenced the data on wear-time in this group. This could have been minimised by carrying out a stratified randomisation. This wasn't carried out as prior to randomisation the sample was well balanced with regard to gender.

Operator influence has been identified as an influencing factor when it comes to patient compliance. Clinicians' ability to listen, encourage and pass on information about treatment can influence patient compliance with treatment (Cirgic et al., 2015). There were five treating clinicians in this study, which may have an influence on the amount of patient compliance recorded. A more standardized approach, assessing the patient cohort of only one clinician, would reduce the influence of operator influence on compliance. In order to recruit sufficient numbers into the study in a limited time, it was decided to include multiple operators.

Clinical parameters were not influenced by wear time in a randomized controlled trial by Parekh et al. Outcomes such as reduction in ANB angle, overjet and overbite were not clinically significant between the part-time and full-time wear groups. The part-time group only wore their appliances for 8 hours, and the full-time for approximately 12 hours. Therefore, both groups could be considered to be in a part-time wear regimen, which may account for the lack of statistically significant clinical outcomes (Parekh et al., 2019). Whether the higher wear times in this study have a clinically significant effect would be more thoroughly assessed by examining clinical outcomes of treatment rather than solely wear times. This was initially planned in this study however the influence of the COVID-19 pandemic resulted in alterations to the study protocol and follow-up periods which mitigated against the collection of clinical outcome data.

A complete case analysis was carried out whereby incomplete data from participants who had Theramon® sensor malfunction was not included in statistical analysis. This was done because there was only a small proportion of data missing, the mechanism causing missing data was not dependent on the observed data nor the missing data and data were only missing for the dependant variable (Jakobsen et al., 2017). This was not possible for the wear diary data as too much data was missing from the dataset. Although resulting in a less biased analysis of the data, omission of incomplete datasets reduces statistical power of the study which increases the risk of type II error. This could result in an incorrectly failing

to accept the null hypothesis. Increasing the sample size of the study would mitigate against the risk of type II error.

5.6 Implications for Future Research

Although there was no statistically significant difference in wear times reported by those patients receiving text messages and those not, a small difference was noted. This may become more pronounced as treatment duration increases when patient compliance gradually reduces. Longer follow-up protocols may reveal a more pronounced positive effect over time.

The results presented also reinforce the fact that wear diaries are not accurate in their depiction of wear time and patient compliance.

Integration of the wear diary into an interactive mobile app such as the Dental Calendar may help improve patient interaction with the resource and result in more accurate recording of wear time. Alternatively, the accuracy of the Theramon® sensor in its ability to record wear-time and the user-friendly cloud interface makes it useful tool for objectively measuring compliance. Future research examining the compliance of patients with removable and functional appliances would benefit from the use of objective measuring devices such as intraoral sensors.

6.0 Conclusions

The following conclusions can be drawn from this investigation:

1. Text message reminders have no statistically significant influence on patient compliance with twin block appliances in the first four months of treatment.
2. Text message reminders have no statistically significant influence on the number of days where over 18 hours or over 8 hours of wear is recorded.
3. Subjective analysis of wear time using wear diaries is not a useful method of assessing compliance.
4. Consideration should be given to the use of intraoral sensors for measuring compliance.

7.0 Appendices

Appendix 1: Ethical Approval

SJH/TUH Research Ethics Committee Secretariat
email: researchethics@tuh.ie

JREC Reference: 2020-02 Chairman's Action (54)

Ms Emily Higgins,
Dublin Dental Hospital,
Lincoln Place,
Dublin 2

13th February 2020

REF: The Effect of Text Message Reminders on Patient Compliance with Functional Appliance Therapy as Measured by TheraMon Sensors

REC: 2020-02 Chairman's Action (54)

(Please quote reference on all correspondence)

Date of Valid Submission to REC: 15.05.2019

Date of Ethical Review: 12.02.2020

Research and Innovation Number: N/A

Dear Ms Higgins,

The Chairman, Prof. Richard Deane, on behalf of the Research Ethics Committee, has reviewed correspondence you submitted to the SJH/TUH JREC and has given **FULL** approval for the above study to proceed in the **HSE Orthodontic Dept, SIMMS Building**. The following comments were made:

The following documents were reviewed:

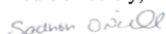
- Standard Application Form
- Updated Information Leaflet and Consent form
- Updated Assent Form
- TheraMon Information booklet

Please note that ethical approval for this study is only active under the following conditions:

1. *Applicants must submit an annual report for ongoing projects.*
2. *Applicants must submit an end of study declaration/end of study report upon completion of the study.*
3. *All adverse events must be reported to the JREC.*
4. *All changes (minor and substantial) to documentation/study must be submitted to the JREC using the amendment request form and the changes must be tracked/highlighted clearly. Approval from the JREC is required before implementation of the changes.*

It is the responsibility of the researcher/research team to ensure all aspects of the study are executed in compliance with the General Data Protection regulation (GDPR), Health Research Regulations and the Data Protection Act 2018.

Yours sincerely,



The SJH/TUH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.

Appendix 2: Parent Information Leaflet

1



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

INFORMATION SHEET – PARENTS

Principal Investigator:

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Your son/daughter is being invited to take part in a research study to be carried out at the HSE orthodontic department, Tallghat by Dr. Emily Higgins. Before you decide whether or not you wish them to take part, you should read the information provided in this leaflet carefully. Take time to ask questions – don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for them. You may wish to discuss it with your family and friends.

What is the purpose of this study?

The purpose of this study is to examine whether text message reminders have an effect on how well patients wear their braces. Twin Block appliances are removable braces given to patients as part of their orthodontic treatment to help correct prominent front teeth. As part of this study, patients will be sent text message reminders, to help remind them to wear their Twin Block. Our aim is to see how effective these text messages are at improving the amount of time patients wear their Twin Blocks.

Why has your son/daughter been asked to take part?

Your son/daughter has been chosen because they will be having orthodontic treatment in the HSE Orthodontic Unit in SIMMS Building, Tallaght Cross West, Tallaght. You are being asked to consent to their participation in this study, but your son/daughter's assent to take part is an important part of this process, and their wishes will be taken into account.

Do they have to take part in this study? What if they say no? Can they withdraw?

Your son/daughter doesn't have to take part in this study. If they decide not to take part it won't affect their current or future orthodontic care. They can change their mind about taking part in the study and opt out at any time even if the study has started. If they decide to opt out, it won't affect their current or future orthodontic care. They don't have to give a reason for not taking part or for opting out. If they wish to opt out, please contact the principal researcher; Emily Higgins (Emily.higgins@dental.tcd.ie) who will be able to organize this for you.

What does this study involve?

Your son/daughter is scheduled to have a Twin Block brace as part of their orthodontic treatment. We plan to divide all patients in this study into 2 groups. One group will get text reminders to wear the Twin Block. The second group will have a Twin Block but no text reminders. We call this the control group. When they enter the study they will be assigned randomly to one of the groups. They will then be provided with a Twin Block brace with a timer incorporated into it. The timer measures how long they wear their brace for each day. The group that receives a text message will get a message twice a week, reminding them to wear their appliance. If they are in group that doesn't receive a text reminders, they will still get reminders and encouragement from their orthodontist at their regular visits. Their treatment will progress as normal regardless of what group they're in. An information leaflet on the twin block brace will be provided to you with this form. It is important that you read this to understand how this brace works. There will be 60 people in total taking part in the study. An example of the texts that will be sent are illustrated below.

"Don't forget to wear your twin blocks!"

"Just a reminder, wearing your twin blocks all the time will help produce the perfect smile!"

What will happen if I agree to take part?

If you agree for your son/daughter to take part you will be asked to attend the orthodontic clinic to have a Twin Block brace made for them. This involves taking some photographs and some dental impressions so that the brace can be made to fit specifically to their mouth. This happens with all patients getting Twin Block braces, regardless of whether they take part in research or not. You will meet the orthodontist who will talk you and your son/daughter through the study. He/she will ask your son/daughter to wear their brace all the time, except for eating and cleaning. This is a normal part of treatment with the Twin Block brace. The timer works automatically, and does not require you or your son/daughter to do anything. Your son/daughter will be asked to keep a wear-diary, which is calendar that they will fill in every day to write down how many hours they wore their brace for. The study will last approximately 6 months. At the end of the study another set of dental impressions will be taken to use for comparison to the first set.

What are the benefits of taking part?

In taking part you and your son/daughter are providing us with valuable information as to the influence of text message reminders on how well patients wear their braces. This will help us to improve our treatment of patients with these braces and will help improve outcomes for these patients.

What are the possible risks/side effects of taking part?

There are no risks/side effects to Twin Block therapy. Twin block braces are very safe and are worn by many patient's to help correct their bite. The timer is covered in the plastic coating on the brace and will not be in contact with anything in the mouth.

Will I be told the outcome of the study?

You will not be told directly of the results of the study. The results will be presented by Dr. Emily Higgins as part of her thesis submission. Results may also be presented at conferences or published in a journal article. At all times your son/daughter's information will be kept strictly confidential.

What happens at the end of the study?

At the end of your son/daughter's Twin Block therapy they will progress to the next stage of their orthodontic treatment, regardless of the results of the study.

PART 2 – DATA PROTECTION

What information about my son/daughter (personal data) will be used as part of this study?

Information that will be used in this study will include certain measurements relating to how their teeth meet and how often they are wearing their Twin Block brace. Their medical records will not be assessed.

What will happen to their personal data?

After collection this data will be fully anonymised before being analysed. Their information will not be identifiable from the data collected. Only information required to complete the study will be analysed. The data will be stored according to the Data Protection (Health Research) Regulations 2018.

Who will have access to their information?

Their information will be examined by the researcher for the study. Some of their information may also be analysed by the hospital statistician. Their name and other details will not be written on the information collected.

Will information be kept confidential? How will their information be kept safe?

Their information will be stored on secure software on a password-protected computer in the orthodontic clinic in Tallaght. Some information may be transferred to secure computer in the Dublin Dental Hospital. Any sheets of information collected will be stored in a locked cabinet at the orthodontic clinic. All procedures are in place to make sure their information will be stored correctly. When presenting the study results, their information will not be identifiable. When the study is complete, anonymised data will be stored securely for a period of time before being destroyed.

What is the lawful basis to use my son/daughter's personal data?

This study fulfils the lawful basis for use of your son/daughter's personal data as outlined in Article 6 and Article 9 of the EU GDPR legislation:

- Explicit consent will be gained relating to the processing of personal data.

What are my son/daughter's rights with regard to accessing data?

- Right to access data held
- Right to restrict the use of the data held
- Right to correct inaccuracies
- Right to have information deleted
- Right to data portability
- Right to object to profiling

PART 3 – COSTS, FUNDING & APPROVAL

Will it cost me anything to take part?

No, taking part in this study is free.

Who is funding this study?

The study is being funded by the Dublin Dental University Hospital Research fund. The results will not be used for commercial purposes and researchers are not being paid to carry out the research.

Has this research been approved by a research ethics committee?

This study has been approved of by the Research Ethics Committee of the Clinical Research Facility at St. James' Hospital, Tallaght University Hospital, Tallaght, Dublin 24. This approval was given on 13th February 2020.

PART 5 – FURTHER INFORMATION

Where can I get further information?

You can get further information from Dr. Emily Higgins, Postgraduate in Orthodontics, Dublin Dental University Hospital, Lincoln Place, Dublin 2. Her email is Emily.higgins@dental.tcd.ie.

What happens if I wish to make a complaint?

If you wish to make a complaint you can do so to the principal researcher, who's details are mentioned above.

Will I be contacted again?

You will not be contacted again in relation to the study.

Appendix 3: Consent Form



CONSENT FORM



The effect of text message reminders on patient compliance with functional appliance therapy as measured by TheraMon® sensors.

Researcher: Dr Emily Higgins

To be completed by the parent/legal guardian of the participant:

I have read and understood the information leaflet.	YES ☐	NO ☐
I have had the opportunity to discuss the study, ask questions about the study and I have received satisfactory answers to all my questions.	YES ☐	NO ☐
I have received enough information about this study.	YES ☐	NO ☐
I understand that I am free to withdraw from the study at any time without giving a reason and this will not affect my future medical care.	YES ☐	NO ☐
I agree to allow the researchers use my child's information (personal data) as part of this study as outlined in the information leaflet.	YES ☐	NO ☐
I consent for my child to take part in this research study having been fully informed of the risks, benefits and purpose of the study.	YES ☐	NO ☐
I give my explicit consent to have my child's data processed as part of this research study'	YES ☐	NO ☐

Child's Name:	
Parent/Guardian Name (Block Capitals):	
Parent/Guardian Signature	
Date:	

To be completed by the **RESEARCHER**:

I have fully explained the purpose and nature (including benefits and risks) of this study to the participant and participant's parent/legal guardian in a way that he/she could understand. I have invited him/her to ask questions on any aspect of the study.	YES ☐	NO ☐
I confirm that I have given a copy of the information leaflet and consent form to the participant and parent/legal guardian.	YES ☐	NO ☐

Researcher's Name (Block Capitals):	
Researcher's Title & Qualifications:	
Researcher's Signature:	
Date:	

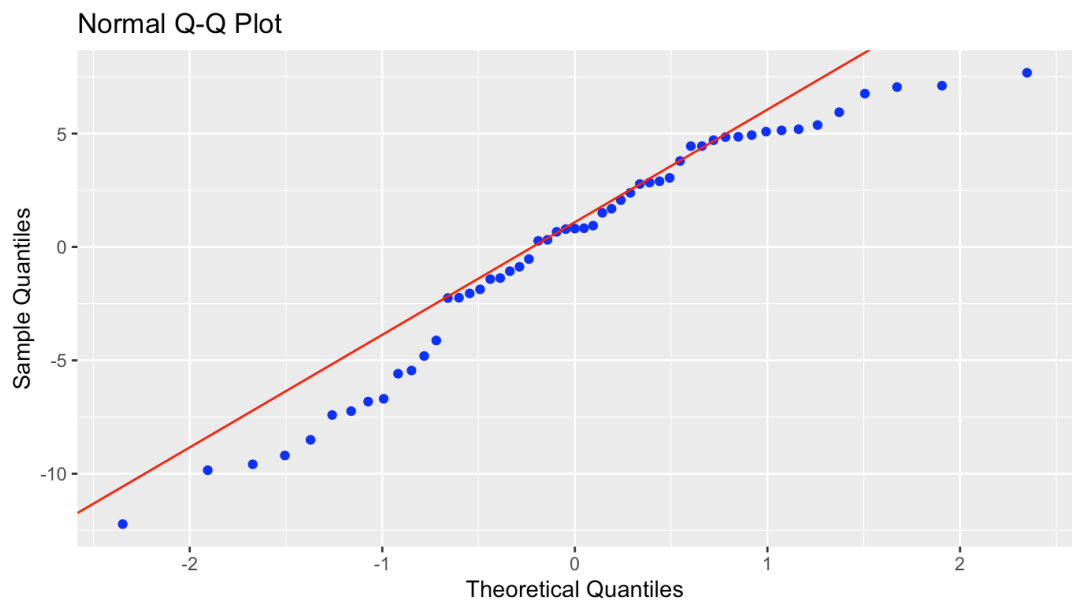
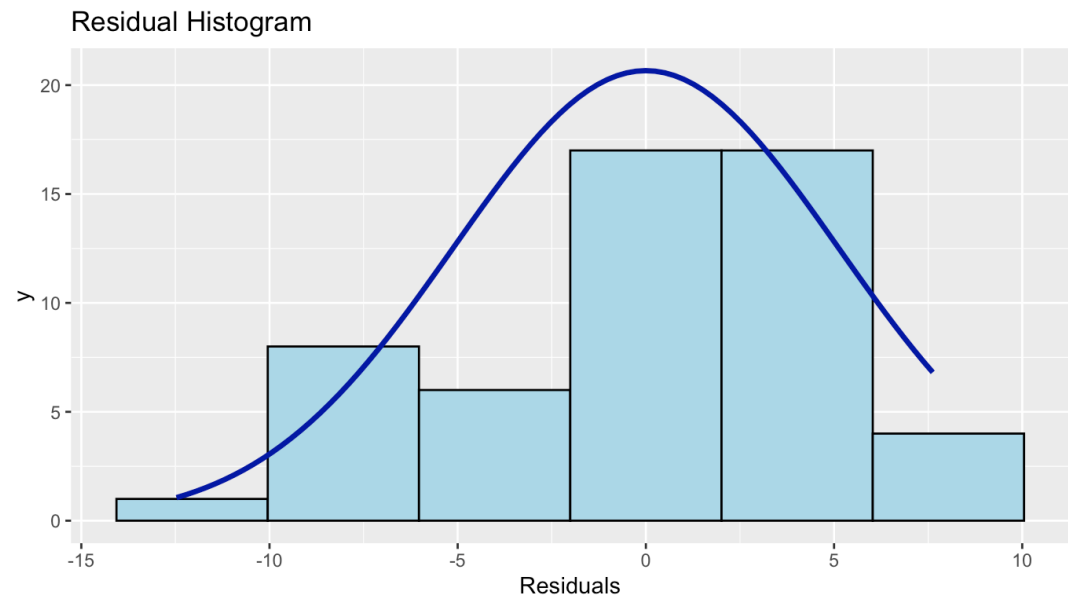
Appendix 4: Wear Diary

Chart of use

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1	h min	h min	h min	h min	h min	h min	h min
Week 2	h min	h min	h min	h min	h min	h min	h min
Week 3	h min	h min	h min	h min	h min	h min	h min
Week 4	h min	h min	h min	h min	h min	h min	h min
Week 5	h min	h min	h min	h min	h min	h min	h min
Week 6	h min	h min	h min	h min	h min	h min	h min
Week 7	h min	h min	h min	h min	h min	h min	h min
Week 8	h min	h min	h min	h min	h min	h min	h min
Week 9	h min	h min	h min	h min	h min	h min	h min
Week 10	h min	h min	h min	h min	h min	h min	h min
Week 11	h min	h min	h min	h min	h min	h min	h min
Week 12	h min	h min	h min	h min	h min	h min	h min

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Appendix 5: Histogram and Q-Q Plot for Test of Normality with Linear Regression for Age and Gender and Mean Hours/day recorded with Theramon®



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