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Type of Award:
Orthodontic Faculty Development Fellowship Award

Name(s) of Principal Investigator(s):
Hiroshi Ueno (Saint Louis University)

Title of Project:
Headgear Compliance and the Use of Smart Phone App

Period of AAOF Support:
07-01-18 to 06-30-19

Amount of Funding:
$20,000

Summary/Abstract of Completed Project:

Objective: To prospectively assess whether a smartphone application (app) helps: 1) increase compliance with headgear wear, oral hygiene and appointment punctuality; and 2) keep track of headgear wear hours. **Materials and Methods:** The sample included 26 orthodontic patients with Class II malocclusion who were prescribed headgear with the incorporation of a TheraMon® sensor. Participants were assigned to Group 1 with the app (N=11, 2 males and 9 females, 12.37 ±1.09 years) or Group 2 without the app (N=15, 7 males and 8 females, 10.73 ±1.87). Group 1 utilized the app, which had four functions: (1) educational messages, (2) calendar log, (3) reminders and (4) scoring system. The headgear wear hours recorded by the sensor, molar relationships, plaque index and patient punctuality were measured at T1: Headgear delivery day, T2: 1 month, T3: 2 months and T4: 3 months after headgear delivery. The sensor recorded average headgear wear hours, number of headgear wear days, the differences of the molar relationships and plaque index between T1-T2, T2-T3, T3-T4 and T1-T4, as well as the number of late appointments between T1-T4 were compared between the groups. In Group 1, the association between the sensor recorded and the calendar input headgear wear hours was assessed. **Results:** There was no statistically significant difference between the groups regarding the sensor recorded wear hours, number of wear days, plaque index, and appointment punctuality. There was a statistically significant correlation between the sensor recorded wear hours and the calendar input wear hours between T1-T2, T2-T3, T3-T4 and T1-T4 (r=0.94, 0.85, 0.698 and 0,79 respectively). **Conclusions:** The app may help assess headgear compliance with its calendar function; however, it did not produce a favorable statistically significant increase in patient compliance with headgear wear, oral hygiene and appointment punctuality.

Materials and Methods:

Prior to subject recruitment, the Saint Louis University Institutional Review Board approved this prospective study (#27647). Subsequently, orthodontic patients at Saint Louis University were recruited to this study if they were prescribed headgear as part of their treatment plan. The primary investigator evaluated the patient records and medical history to ensure these patients met the following criteria: (1) child or adolescent patients under 18, (2) pre-treatment unilateral or bilateral Class II molar, (3) treatment planned headgear appliance. Patients were excluded for the following criteria: (1) orthognathic surgery, (2) patients with craniofacial deformities, (3) systemic disorders, (4) behavioral or psychiatric disorders.

Prior to participation in this study, informed consent, assent, and HIPAA authorization were obtained from the legal guardian of all participants. Patients were assigned to Group 1 (App group) if they had an iPhone, or if the participant's guardian had an iPhone that the patient could use daily. All other patients were placed in Group 2 (Control group). The information including the demographics of the participants at T1: headgear delivery day are summarized in Table 1.

Table 1. Patient Information at T1

		Group 1 (N=11)	Group 2 (N=15)	Significance
Mean Age		12.37 ±1.09	10.73 ±1.87	0.016*
Male: Female		2:9	7:8	NA
Cell Phone User: Non-user		8:3	3:12	NA
High-pull: Cervical-pull Headgear		1:10	3:12	NA
Phase 1: Phase 2		1:10	8:7	NA
Molar Relationship (Full-step: 2, End-on II: 1, Class I: 0)	Left	1.36 ±0.51	1.27 ±0.59	0.666
	Right	1.09 ±0.83	0.93 ±0.70	0.606
	Average	1.23 ±0.55	1.10 ±0.54	0.566
Plaque Score		1.27 ±0.93	1.17 ±1.17	0.804

NA, not measured
*Independent t-test was significant at the 0.05 level (2-tailed).

Prior to statistical analysis, the groups were determined to have equal variance in terms of the following: Molar relationship right, Molar relationship left, Average molar relationship, and Plaque Score as shown in Table 1.

Calendar @braces Smartphone App

The Calendar @braces smartphone app was developed in 2016 by an independent developer. The app was published to the iOS App Store and made available for free download in 2016. There are four main functions of the app:

1. Patient education:

Patients receive push notifications from the app every six days, beginning on the second day of the study. When the app is opened, the message appears and the patient must exit out of the message before being able to see the home screen (Figure 1). This helps ensure that the patient sees all educational messages. The messages provide written and visual information about the headgear appliance, pain management, and proper oral hygiene. The patient receives a total of 6 headgear educational messages, 3 pain management messages, and 6 oral hygiene messages during 90 days.

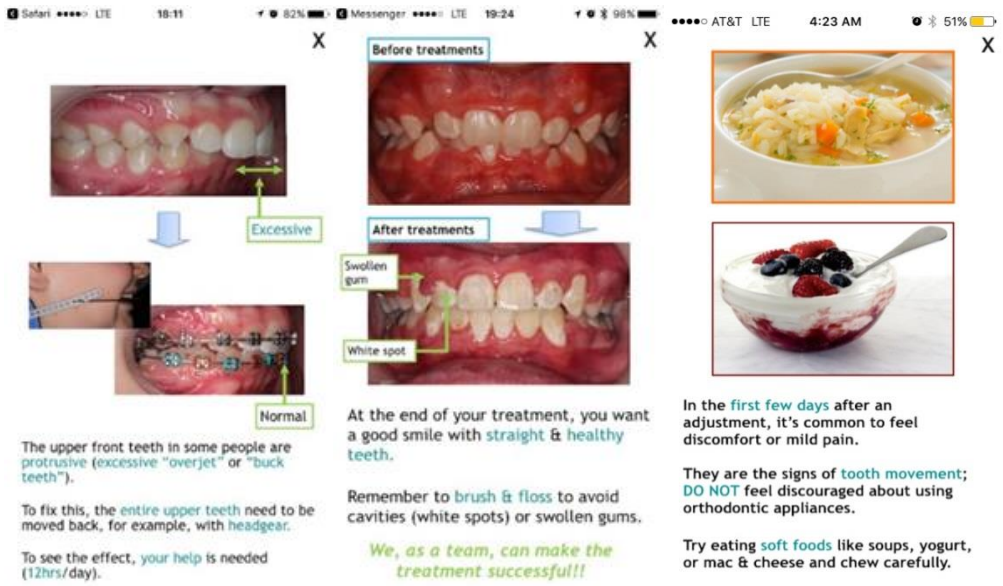


Figure 1. Screenshot of Patient Education Message

2. Calendar log:

Using the calendar function, the patient is able to input the hours of headgear wear each day (Figure 2). Additionally, on Sundays the patient is asked to input a hygiene score from 1-5 and pain score from 0-10 for the previous week (Figure 3). The patient also enters their next orthodontic appointment into the app and the date appears highlighted on the calendar log.

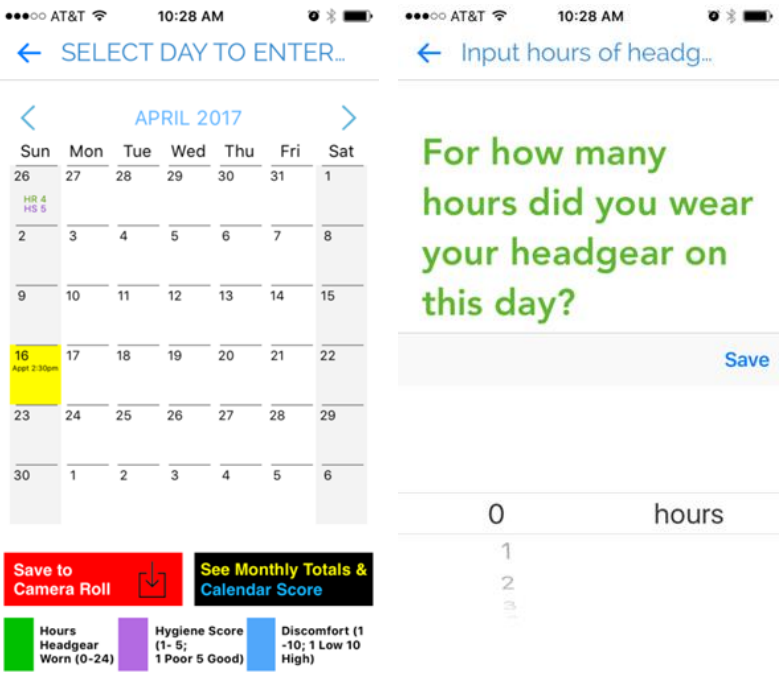


Figure 2. Screenshot of Calendar Log and Headgear Hours Input

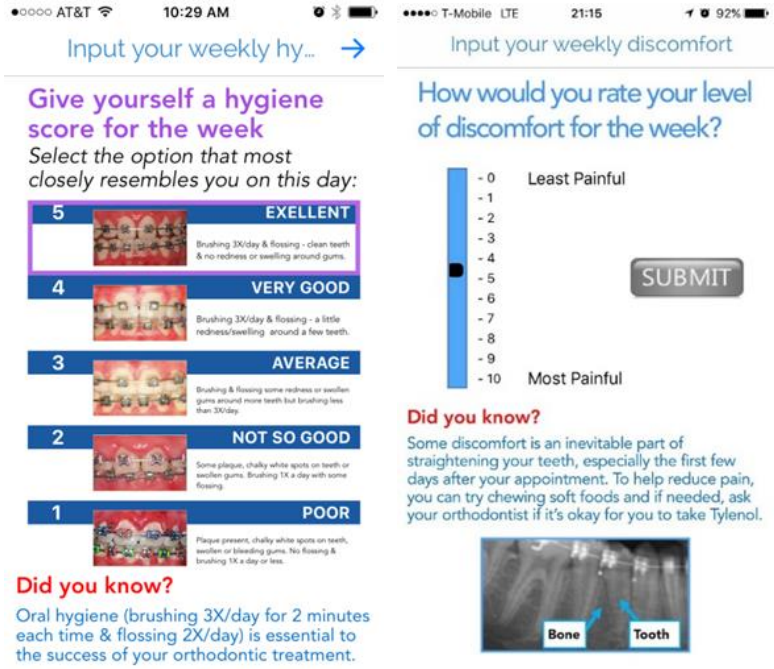


Figure 3. Screenshot of Hygiene and Pain Input

3. Reminders:

The app is designed to send daily push notifications reminding the patient to wear their headgear appliance and to input their hours into the calendar log (Figure 4). In addition to these daily reminders, the patient receives encouragement reminders when the daily input of headgear wear is below 12 hours, the weekly hygiene score is below 4, and pain score is 7 or higher (Figure 5). Thirdly, appointment reminders are sent via push notification to the patient 3 days and 1 day before their orthodontic appointment (Figure 6).

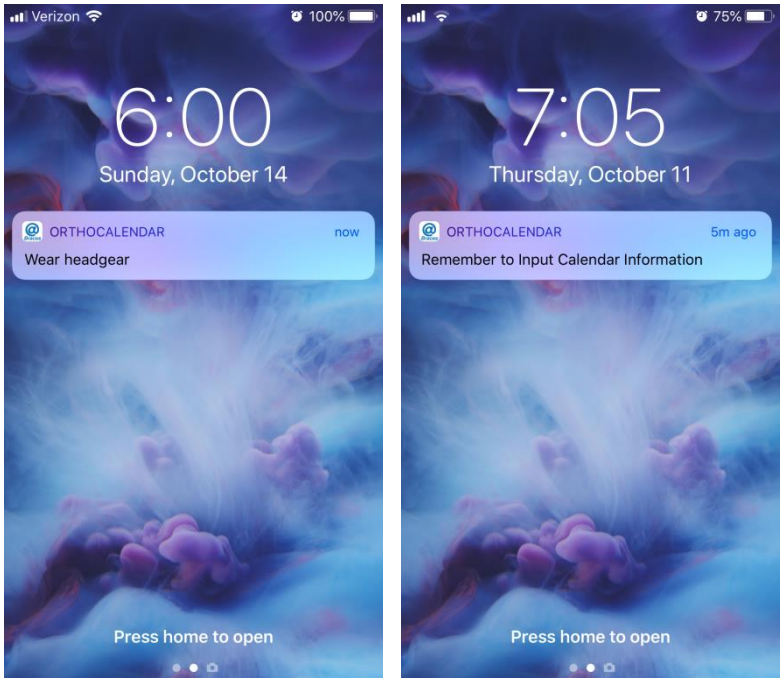


Figure 4. Screenshot of Daily Reminders

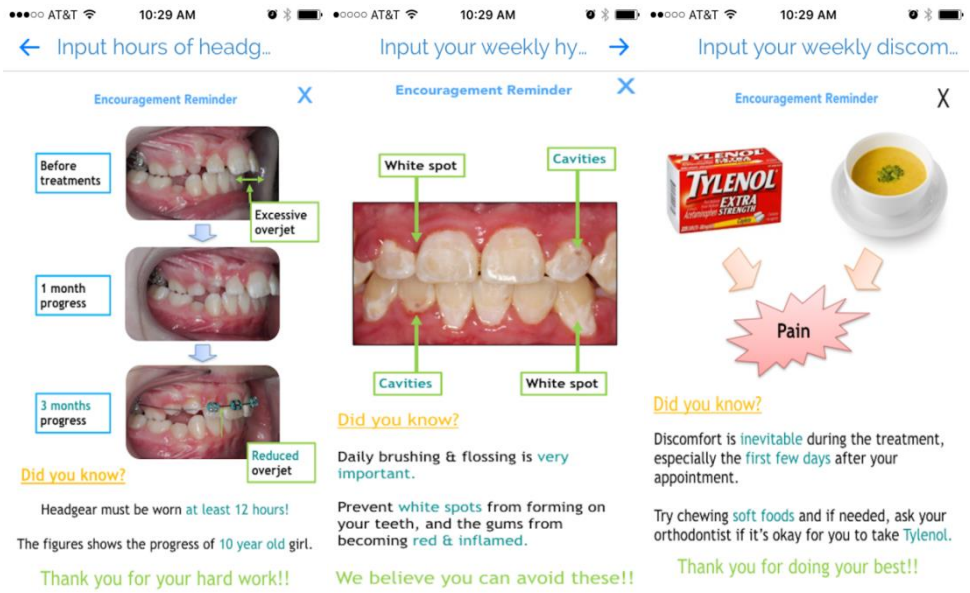


Figure 5. Screenshot of Encouragement Reminders

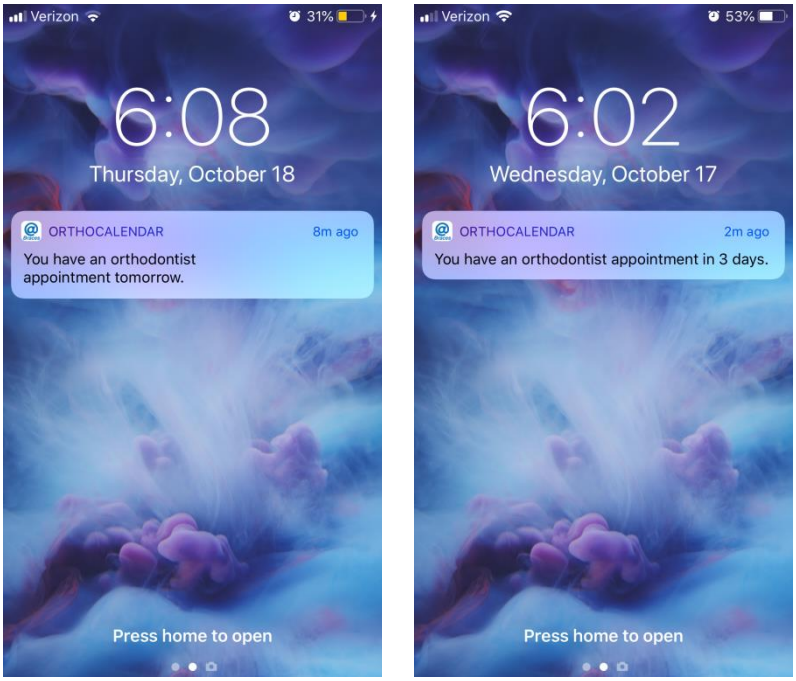


Figure 6. Screenshot of Appointment Reminders

4. Scoring system:

The app also has a scoring feature, which provides the patient with a numeric score based on the hours of headgear worn and the hygiene score for each month (Figure 7). Patients had the opportunity to earn prizes at the end of the study for using the app.

Figure 7. Screenshot of Scoring System

The app was designed to be user friendly, with a simple design and intuitive interface. The information provided in the educational messages and encouragement reminders

incorporated written and visual information specifically made for a child or adolescent to understand. The hygiene score utilized actual photographs to help the patient self-assess their hygiene as well.

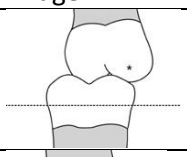
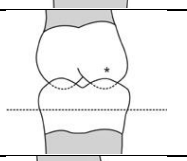
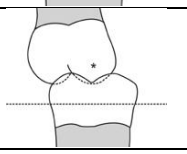
TheraMon® Sensor

The TheraMon® Sensor (Handelsagentur Gschladt, Hargelsburg, Austria) is an FDA approved temperature sensor that has previously been used to objectively measure patient compliance with removable functional appliances, retainers, and facemask.[9-10] Evidence suggests that this sensor is more than 99 percent accurate.[11-12] The sensor takes a temperature reading at 15 minute intervals. Using the TheraMon® reading station, the data contained in the sensor can then be transferred to a computer via radio-frequency identification (RFID) technology. The TheraMon® computer software enables the practitioner to see daily wear time in hours as well as a detailed breakdown of when the appliance was worn. The sensor can store data for up to 100 days and is guaranteed to work for 18 months.

Pilot Study Protocol

The study protocol for the control group and app group was the same. At T1: headgear delivery day, the patient's intial Class II malocclusion was evaluated by scoring molar classification on the right and left sides according to Table 1. Next, the patients were fitted with a headgear facebow that incorporated a TheraMon® sensor (MC Technology, Hargelsberg, Austria). The sensor was attached to the center of the facebow with acrylic resin and adjusted to fit between the patient's resting lips (Figure 9). The accuracy of the sensor was assessed prior to the study. All patients were instructed to wear the headgear for a minimum of 12 hours each day.

Table 2. Molar Classification Scoring System

	Image	Score
Full-Step Class II		2
Half-Step Class II		1
Class I		0

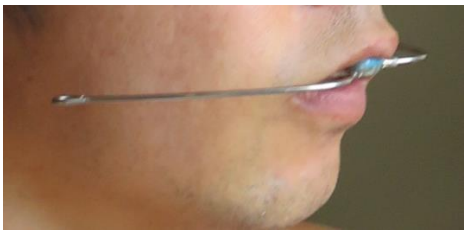


Figure 8. TheraMon® sensor attached to facebow

Patients were assessed for Class II correction and headgear compliance at three monthly intervals, T2: 1 month, T3: 2 months, and T4: 3 months after headgear delivery. The molar classification on the right and left sides were again recorded and the sensor data was transferred to the computer.

Patient's oral hygiene was also assessed from T1 to T4 using the Modified Quigley-Hein Plaque Index (Table 2 and Figure 9). The PI mainly evaluated the six maxillary anterior teeth, if present, prior to the patient brushing. The individual tooth scores were then averaged to provide an average plaque score at T1, T2, T3 and T4.

Table 3. Modified Quigley-Hein Plaque Index Scoring

Score	Criteria
0	No plaque
1	Separate flecks of plaque at the cervical margin of the tooth
2	A thin continuous band of plaque (up to 1mm) at the cervical margin of the tooth
3	A band of plaque wider than 1 mm but covering less than one-third of the crown of the tooth
4	Plaque covering at least one-third but less than two-thirds of the crown or plaque around the bracket
5	Plaque covering two-thirds or more of the crown of the tooth

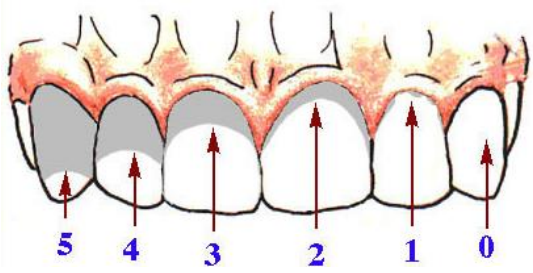


Figure 9. Modified Quigley-Hein Plaque Index

Finally, appointment punctuality was recorded at T1, T2, T3 and T4. At the end of the study the number of late appointments were calculated for each patient. For this study, a late appointment was defined as a patient who arrived any time after their scheduled appointment time.

At T4, both groups completed a questionnaire. Participants answered questions using a Likert scale to self-assess their knowledge about headgear wear, oral hygiene, pain, and appointment attendance. Answers ranged from 1 = strongly disagree to 5 = strongly agree. In addition, the app group completed a second questionnaire which asked questions related to what motivated or prevented the patient from using the app and about the different app features.

Data Reduction

Statistical analysis was completed using the SPSS software program (version 25, SPSS Inc., Chicago, IL). In order to compare between Group 1 and Group 2, independent samples t-test was applied to the sensor recorded average headgear wear hours, number of headgear wear days, the differences of the molar relationships and plaque index between T1-T2, T2-T3, T3-T4 and T1-T4, as well as the number of late appointments between T1-T4. Differences between Group 1 and Group 2 with $p \leq 0.05$, were considered statistically significant. Paired samples correlations were used to compare sensor recorded hours of headgear wear to hour of headgear wear input in the app. Independent samples Mann-Whitney U tests were used to compare questionnaire responses between the groups.

Detailed results and inferences:

Headgear Wear

There was no statistically significant difference between the app group and the control group regarding average sensor recorded hours of headgear wear during each time interval or for the overall study duration: First month (T1-T2), second month (T2-T3), third month after headgear delivery (T3-T4), and the entire study duration (T1-T4). In addition, the percentage of days headgear was worn showed no significant difference between the two groups (Table 4 and Table 5).

Table 4. Comparisons of Headgear Wear, Molar Changes, Plaque Score Changes between Group 1 and Group 2 (T1–T2, T2-T3, T3-T4)

		Group 1 (N=11)			Group 2 (N=15)			Significance		
		T1-T2	T2-T3	T3-T4	T1-T2	T2-T3	T3-T4	T1-T2	T2-T3	T3-T4
		Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD			
HG	Average Hours Worn	7.71 ±3.28	6.07 ±3.53	5.21 ±3.46	7.64 ±3.22	6.20 ±4.00	5.27 ±4.29	0.96	0.93	0.97
	Days Worn (%)	80.68 ±23.61	71.43 ±35.44	68.12 ±33.32	86.30 ±19.50	71.22 ±31.46	61.21 ±39.49	0.51	0.99	0.64
Molar	Left	-0.27 ±0.47	-0.36 ±0.51	-0.09 ±0.30	-0.13 ±0.35	-0.2 ±0.41	-0.20 ±0.41	0.39	0.37	0.47
	Right	-0.36 ±0.51	-0.18 ±0.41	-0.36 ±0.51	-0.13 ±0.35	-0.2 ±0.41	-0.13 ±0.35	0.18	0.91	0.18
	Average	-0.32 ±0.46	-0.27 ±0.41	-0.23 ±0.34	-0.13 ±0.30	-0.2 ±0.32	-0.17 ±0.31	0.23	0.61	0.64
Plaque Score		-0.67 ±1.16	-0.24 ±0.77	-0.14 ±0.61	-0.20 ±0.93	-0.24 ±0.68	-0.07 ±0.64	0.27	1.00	0.81

HG, headgear

Table 5. Comparisons of Headgear Wear, Molar Changes, Plaque Score Changes, Number of Late Appointments between Group 1 and Group 2 (T1-T4)

		Group 1 (N=11)	Group 2 (N=15)	Significance
		Mean ±SD	Mean ±SD	
Headgear	Average Hours Worn	6.25 ±3.27	6.47 ±3.54	0.88
	Days Worn (%)	72.76 ±30.94	73.16 ±26.24	0.97
Molar	Left	-0.73 ±0.65	-0.60 ±0.51	0.58
	Right	-0.73 ±0.79	-0.53 ±0.52	0.46
	Average	-0.82 ±0.46	-0.57 ±0.37	0.14
Plaque Score		-0.88 ±1.40	-0.58 ±1.39	0.60
Number of Late Appointments		0.45 ±0.69	0.93 ±0.96	0.17

Molar Classification

There was no statistically significant difference between the app and the control group regarding average molar classification changes, molar classification changes on the left side, or molar classification changes on the right side during any of the time intervals or the study duration. A negative change in molar classification was considered improvement (Table 4 and Table 5).

Headgear Input

For the app group, the hours each patient input into their calendar was recorded and compared with the sensor recorded headgear wear hours from the TheraMon® Sensor. As shown in Table 6, Table 7, Figure 10 and Figure 11, there was a strong positive correlation between the recorded headgear wear hours and app input headgear wear hours at T1-T2, T2-T3, T3-T4 and T1-T4 (r=0.94, 0.85, 0.70 and 0.79 respectively). There was also a strong positive correlation between the percentage of sensor recorded days the patient wore headgear and the percentage of days the patient input headgear wear at T1-T2, T2-T3, T3-T4 and T1-T4 (r=0.93, 0.89, 0.69 and 0.62 respectively).

Table 6. Headgear Wear Hours Compared to App Calendar Input Hours in Group 1 (T1-T2, T2-T3, T3-T4)

		Average Sensor Recorded Wear Hours			App Input Wear Hours			Correlation (Significance)		
		T1-T2	T2-T3	T3-T4	T1-T2	T2-T3	T3-T4	T1-T2	T2-T3	T3-T4
		Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD			
HG	Average Hours Worn	7.71 ±3.28	6.07 ±3.53	5.21 ±3.46	9.39 ±3.21	9.24 ±4.05	7.75 ±6.57	0.94 (<0.01**)	0.85 (0.001**)	0.70 (0.017*)
	Days Worn (%)	80.68 ±23.61	71.43 ±35.44	68.12 ±33.32	85.59 ±24.83	82.01 ±32.50	84.72 ±32.10	0.93 (<0,01**)	0.89 (<0.01**)	0.69 (0.02*)

HG, headgear

** Paired samples correlation test for equality of means was significant at the 0.01 level (2-tailed).

* Paired samples correlation test for equality of means was significant at the 0.05 level (2-tailed).

Table 7. Headgear Wear Hours Compared to App Calendar Input Hours in Group 1 (T1-T4)

		Average Sensor Recorded Wear Hours	App Input Wear Hours	Correlation (Significance)
		Mean ±SD	Mean ±SD	
Headgear	Average Hours Worn	6.26 ±3.27	7.82 ±6.53	0.79 (0.004*)
	Days Worn (%)	72.76 ±30.94	83.64 ±30.00	0.62 (0.043*)

** Paired samples correlation test for equality of means was significant at the 0.01 level (2-tailed).

* Paired samples correlation test for equality of means was significant at the 0.05 level (2-tailed).

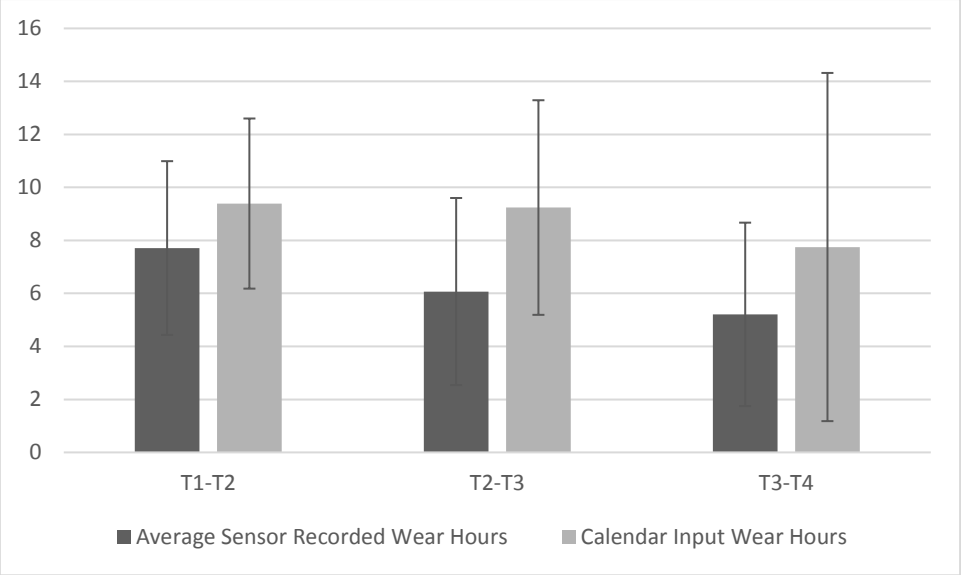


Figure 10. Headgear Wear Hours Compared to App Calendar Input Hours in Group 1 (T1-T2, T2-T3, T3-T4)

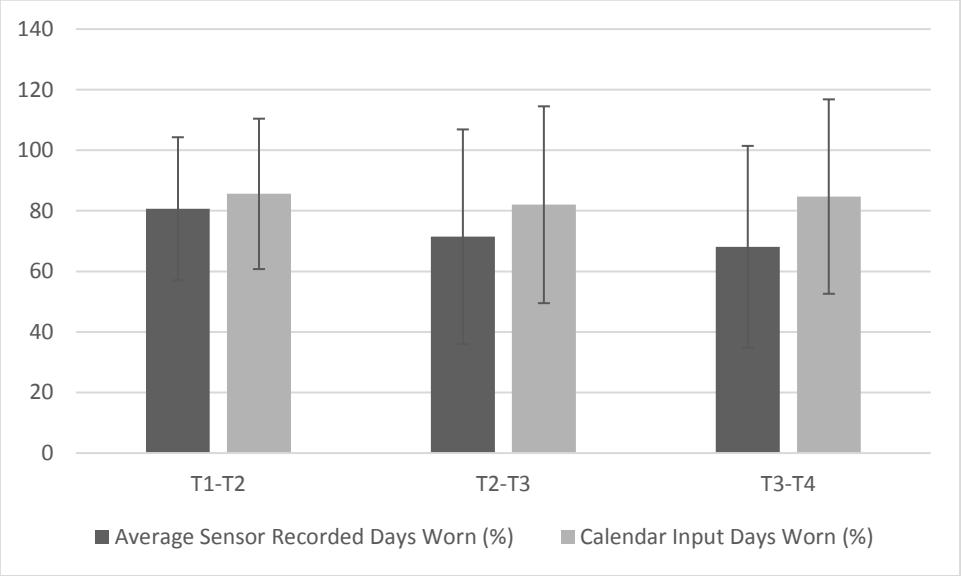


Figure 11. Sensor Recorded Headgear Wear Days (%) Compared to App Calendar Input Wear Days (%) in Group 1
(T1-T2, T2-T3, T3-T4)

Hygiene

There was no statistically significant difference between the control and app group regarding oral hygiene during each time interval. The change in plaque score during each time interval was compared, where a negative value shows improvement in plaque score (Table 4 and Table 5).

Appointment Punctuality

There was no statistically significant difference between the number of late arrivals for appointments during the 3 month study interval between the control group and app group (Table 5).

Questionnaire

There was no statistically significant difference between the control group and app group responses to the questionnaire.

Interpretation of Data

Limitations

One of the major limitations of this study was the small sample size. Due to this limitation, the validity of the results is undermined. The results should be interpreted with caution and conclusions should not be applied to all individuals.

Another limitation of this study was that randomization of the groups was not feasible. Patients who had an iPhone were automatically placed in the app group and patients who did not use a smartphone or had an Android phone were placed in the control group. As a result of this sampling bias, the average age of the patients in the app group was statistically significantly higher than the control group (12.37 ±1.09 years and 10.73 ±1.87 respectively). It is possible that iPhone users have a higher socioeconomic status than Android users, and this difference may have been evident between the two groups, although it was not evaluated. Due to this limitation, the results of this study must be interpreted with caution.

Another limitation of this study was the evaluation of the molar classification and oral hygiene, which was performed by multiple evaluators. The PI was not able to be at each time interval for all patients and because evaluation was completed chair side, there was no inter-rater reliability or intra-rater reliability.

The patient guardians were all told about the TheraMon® sensor and asked not to tell their child about it to minimize the Hawthorne Effect. However, the researcher was unable to know if the guardians followed through with this request. In addition, the sensor was visible to the participant, and it is possible that some of the participants concluded on their own what the sensor did.

Finally, the level of engagement with the app is unknown for each participant in the app group. It was assumed that the patient read the educational messages and entered their hours daily, however there is nothing that prevents the patient from entering all the monthly data right before coming in for their appointment. In addition, some of the participants used the app on their parent's phone and it is possible they did not see all the educational messages and reminders. The PI was also not able to be at each time interval for all patients to use the app as a communication tool, such as looking at the calendar with the patients or the scores they have earned and give them feedback.

Questionnaire

All participants responded to a questionnaire at the end of the study to assess their knowledge on headgear, pain, oral hygiene, and appointments. For all of these questions, the median scores among both groups agree or strongly agree. For the question of how many consecutive days was the patient unable to wear headgear, if applicable, the most common response was 2-3 days. Interestingly, only 3 out of the 15 control group patients and 4 out of the 11 app group patients reported never missing 2 or more consecutive days of headgear wear. Among the app group, the most common reasons were broken or distorted headgear or left headgear at home during a trip (Figure 10). The most common reason for not wearing headgear among the control group is shown in Figure 11, with the top reasons being pain and lack of sleep.

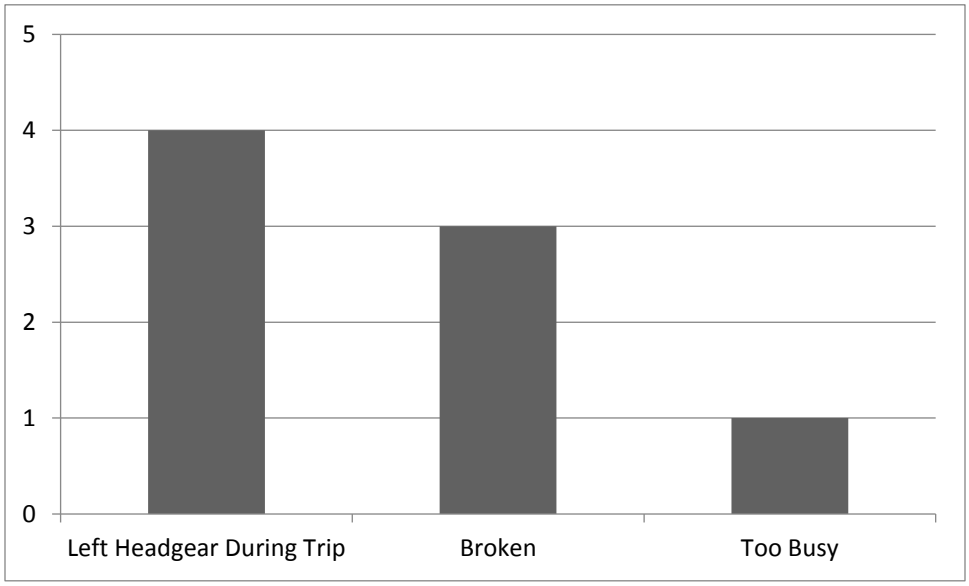


Figure 12. Top Reasons Participant was Unable to Wear Headgear – Group 1

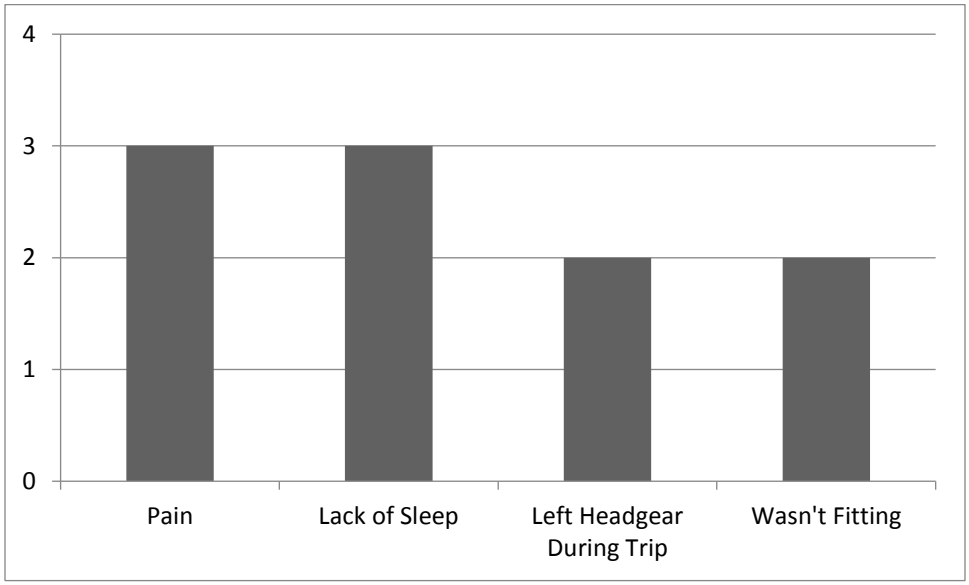


Figure 13. Top Reasons Participant was Unable to Wear Headgear – Group 2

Patients from the app group were asked to complete a second questionnaire to gather information about the app itself. The feedback about the app was generally positive. Patients strongly agreed that the app was easy to use and the texts and pictures were easy to read and understand. They also agreed that the log of headgear, hygiene, appointment reminders, and educational messages were helpful. Despite this, the median responses to the questions “I wore my headgear because of the app” and “I was better off with the app than without during treatment was neutral”, suggesting that the app features need to be improved. The top reason participants used the app was the simple and easy layout and functions. The top 3 ways patients felt they could be motivated to use the app were with better

prizes, fun games within the app, and more interactive features, also suggesting that the app system should be improved. Finally, the top reason for participants to not use the app was "I was too busy and forgot to use the app."

Results Compared to Literature

Cureton found that patients who kept a headgear calendar wore their headgear significantly more than those who did not.[13] However, in this study, there was no statistical difference in sensor recorded headgear wear between the app group that kept a headgear calendar and the control group that did not. In Cureton's study, he found that the average headgear wear was 7.9 hours for those that kept the headgear calendar and 5.3 hours for those that did not.[13] This study found that the average hour of headgear wear was 6.26 for those that kept the calendar log and 6.47 hours for those that did not, which were quite similar. This may be due to the fact that the average age of the app group was significantly higher, because, in general, it is more difficult to achieve compliance from older adolescent patients.

As shown in Table 6 and Table 7, there was a strong, positive correlation between the recorded headgear wear hours and app input headgear wear hours at T1-T2, T2-T3, T3-T4 and T1-T4 (r=0.94, 0.85, 0.70 and 0.79 respectively). This suggests that an orthodontist can use the calendar log in the app as useful tool to keep track of how many hours the patient actually uses headgear. If the patient does not use headgear sufficiently, the orthodontist needs to think about the alternative. However, there is a tendency that as time went by, the differences between the sensor recorded hours and the calendar input hours increased during the 3 month observation period, suggesting that the patients input more hours than actual wear hours.

A systematic review in 2018 found that reminders resulted in significant improvement in oral hygiene and appointment attendance.[5] Several other studies by Eppright, Bowen, and Cozzani also found that text message reminders significantly improved patient compliance with oral hygiene.[2-4] This same result was not found in the present study. There was no statistically significant improvement in oral hygiene or appointment punctuality between the app group that received reminders to their smartphone and the control group.

Several recent studies by Zotti, Alkadhi, and Li have evaluated the influence of smartphone apps on orthodontic patient compliance with oral hygiene, broken brackets, and appointment attendance.[6-8] All three studies found a statistically significant improvement in patient compliance with the use of a smartphone app. In contrast, this study did not find that the use of a smartphone app had any significant effect on increasing patient compliance.

Further Investigation

Further investigation of this topic is needed with a larger sample size to draw accurate conclusions. In addition, control variables such as age, socioeconomic status, and type of treatment should be better controlled. This may be possible by limiting participants to only Phase II, cervical-pull headgear patients and only iPhone users. To minimize the potential Hawthorne effect, it may be possible to incorporate the TheraMon® sensor in the neck strap where it is not visible.

Based on the results of this study and a 2017 study by Allahdina, the use of a smartphone app did not increase patient compliance with oral hygiene and appointment attendance.[9] Therefore, it would be best to focus further studies on only headgear wear.

Self-monitoring is the basis for the use of a calendar log to increase patient compliance with headgear wear. By requiring patients to log their hours each day, the patient is able to visualize their level of compliance. Studies have shown that this self-monitoring of headgear wear, specifically with the use of a manual calendar, does have a positive influence on patient compliance.[10] Self-monitoring has also been used to effectively change behavior, specifically with physical activity using activity trackers.[11-12]

A 2016 systematic review found that wearable activity trackers may be effective at increasing activity levels of children and adolescents through self-monitoring and goal setting.[13] This same idea may be an area for further investigation in behavior change of child and adolescent orthodontic patients with respect to headgear wear. As previously mentioned, the main reason for lack of compliance with the app was patients were too busy or forgot to use it. Incorporating a temperature sensor that automatically uploads wear hours to the patient's app would minimize this burden and allow patients to more consistently and effectively self-monitor their wear and set goals.

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Response to the questions:

1. The original, specific aims of the proposal were realized. The objectives described below that I set for this fellowship were successfully fulfilled.

A. Objective 1 (ABO certificate):
I took the ABO clinical exam in February 2019, and successfully passed it.

B. Objective 2 (Educational and Teaching skills):
I actively joined many other instructors' and speakers' lectures, and the AAO educational leadership conference. This helped improve the quality of my lectures, although my responsibility increased substantially ever since a new program director came.

C. Objective 3 (Clinical skills):
I actively participated in and conducted many "Clinical Case Conference" sessions. I learned a variety of techniques, how the diagnosis and techniques worked in order to further improve my clinical skills and patient care.

D. Objective 4 (Resident Theses):
I provided four residents in Class 2018 with research ideas and supported them as committee chair. All of them successfully achieved Master of Science. I am currently serving as committee chair for five residents in Class 2019.

2. The project results have not been published, but it was documented as a thesis project, upon which one resident acquired Master of Science. It was presented by Dr. Michelle Clinton at Saint Louis University with a title "Assessment of Patient Compliance during Headgear Treatment with the Use of a Patient-Education Smartphone Mobile App" in December 2018. The sample size was 26 as of October 2019. Therefore, I have been recruiting more patients before publishing it with acknowledgement for the AAOF support. The entire funding was used as a salary supplement to achieve my academic career objectives.