Digital Health & Medical Device Approaches to Improving Patient Compliance & Treatment Efficacy with Orthodontic Appliances

2019 Grants

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Title of Project*

Digital Health & Medical Device Approaches to Improving Patient Compliance & Treatment Efficacy with Orthodontic Appliances

Award Type

Center Award (CA)

Period of AAOF Support

July 1, 2016 through Jun 30, 2024

Institution

University of California, San Francisco

Names of principal advisor(s) / mentor(s), co-investigator(s) and consultant(s)

Snehlata Oberoi

Amount of Funding \$75,000.00

Abstract

(add specific directions for each type here)

Respond to the following questions:

Detailed results and inferences:*

If the work has been published, please attach a pdf of manuscript below by clicking "Upload a file". <u>OR</u>

Use the text box below to describe in detail the results of your study. The intent is to share the knowledge you have generated with the AAOF and orthodontic community specifically and other who may benefit from your study. Table, Figures, Statistical Analysis, and interpretation of results should also be attached by clicking "Upload a file".

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Were the original, specific aims of the proposal realized?*

The specific aims #1 and #2 were able to be realized however during the process of sensor validation, we repeatedly ran into engineering challenges which prevented us from fully developing the sensor.

Specific Aim #1: Software Development

(1-A) Develop a Patient-Facing Mobile Application

Goal: Create a robust mobile app for patients use. Main features include the ability to download sensor data, store it in a local database on the mobile device, and sync the data with a cloud database. The mobile app will also have a user interface for the patient to see their wear- time. Engineers in Dr. Shuvo Roy's lab will develop an iOS application (app) that will wirelessly communicate with the custom Bluetooth Low Energy-enabled wear-time sensor (developed by same engineers). The app will be able to download the data from the sensor device's limited flash memory for storage in a SQL database within the iOS app. The app will have bidirectional data sync capabilities between the database on the iOS app and a cloud database in order to make the wear-time data remotely accessible. Finally, we will create a basic patient- facing iOS app user interface that allows patients to pair the wear-time sensor embedded within their Hawley retainer to the iOS app. Using this, patients will be able to see a summary of statistics, for example, their average daily wear time.

Specific Aim #2: Sensor Testing and Validation

(2-A) Wear-time Temperature Sensor Characterization and Calibration Goal: Calibrate devices to account for between-device variation and determine the optimal threshold for converting body temperature measurement to wear-time. Raw temperature output from sensors is given in bits on an arbitrary range and scale. We will convert raw values to commonly accepted temperature scales (e.g. Celsius) by acquiring calibration curves against a gold standard digital laboratory thermometer. We will study if there is any hysteresis effect in heating and cooling the sensor. Additionally, electronic component tolerances (typically 1-5%) can have a significant impact on the baseline and range of the raw sensor measurement. We will assess the variations between individual devices with respect to increasing temperature. (2-B) Preliminary Human Testing to Assess Objective Wear-time Tracking Accuracy Goal: Validate that our sensor and iOS app system is measuring accurate wear-time information by comparing wear-time data from our sensor with self-reported wear-time in a controlled setting. Dental students, residents, and researchers at UCSF (n=10) will be recruited to wear a Hawley retainer with our embedded wear-time sensor and also be given an iOS app to sync the data. Subjects will simulate a fully compliant patient and wear the modified Hawley retainer during the night for 1 week. Subjects will log all the times at which they wear and remove the retainer. BlandAltman and least squares regression techniques will be used to assess accuracy of measured wear- time from the sensor with subjects' self-reported wear-time.

The specific aim #3 of a pilot clinical study was not realized. Due to the engineering challenges with developing a miniaturized sensor we were not able to conduct a clinical trial that was able to assess the

validity of the device. We are partnering with Theranova to complete the development of the miniaturized senor. However, this will take at least another year to complete.

Were the results published?*

Yes

Have the results of this proposal been presented?* Yes

To what extent have you used, or how do you intend to use, AAOF funding to further your career?*

The Center Award Award from the AAOF has allowed us to develop a custom low-power Bluetooth Low Energy-enabled temperature sensor that can be embedded within a Hawley retainer and act as an objective wear-time monitor. Additionally, this award has allowed us to conduct bench top testing as well as begin preliminary testing of this technology in patients. Following active orthodontic treatment with braces, which usually takes about two years patients' transition to the retention phase of treatment, which typically lasts for at least two years. During this phase patient compliance with wearing removable retainers is critical to prevent relapse and achieve long-term stability. With our custom low-power Bluetooth Low Energy- enabled temperature sensor Innov8 Retainer, orthodontists will be able to measure patient compliance early on and prevent relapse. The long-term goal is to feed the real-time stream of wear-time data into an application that can remind or incentivize patients to wear their orthodontic appliance. A clinician-facing web app will also be developed to enable clinicians to remotely track patient adherence and enable clinician-initiated prophylactic interventions if they deem patient compliance is lacking. We hypothesize that continuous treatment feedback and digital rewards through the patient-facing app will improve patient compliance, and wear-time data accessible through the clinician-facing web will empower clinicians to prophylactically intervene in treatments if compliance is lacking. We thank the AAOF for the continued support that has enabled us to become leader in this field.

Respectfully submitted

Comment: The AAOF commends you and your team on this project's efforts and results to date. We thank you for your contributions to advancing the orthodontic specialty and look forward to seeing the long-term outcomes of this project.

Accounting: Were there any leftover funds? \$0.00

Published

Citations*

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Was AAOF support acknowledged?

If so, please describe: Yes AAOF was acknowledged in the paper.

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Please list titles, author or co-authors of these presentation/s, year and locations:* Northern California Angle Society Meeting 2018

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SUPPLEMENT ARTICLE

Compliance monitoring via a Bluetooth-enabled retainer: A prospective clinical pilot study

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Structured Abstract

Objectives: To conduct a prospective pilot trial to test the clinical efficacy and accuracy of a newly developed Bluetooth-enabled retainer, which was synchronized with an iOS mobile application, cloud database and provider webpage.

Setting and Sample Population: Five orthodontic residents in a university setting.

Material and Methods: At the delivery of the retainers (T0), each participant was given an Bluetooth-enabled retainer, logbook and iPod Touch installed with the mobile application. Participants were instructed to wear the retainer for 12 hours per day and record in the logbook each time the retainer was inserted or removed and trained to synchronize the device daily to the mobile application. After the 5-day study period (T1), statistical analysis was performed comparing the device-reported data to the logbook data using two calculation methods.

Results: From T0 – T1, the participants wore their retainers for a median of 11.55 hours per day and the median difference between the self-reported (logbook) data and the device data was 35 minutes or 5.1% over the 5-day study period. Using an adjusted method to calculate the device-reported wear time, the median error was 13 minutes or 1.9%.

Conclusion: Subjects were able to successfully wear the retainer and upload the data to the mobile application and cloud database. Patient compliance and technical issues could be monitored daily via the provider webpage, and early intervention was possible with reminder messaging. The Bluetooth-enabled retainer showed a clinically acceptable level of accuracy and usability that validates it for future clinical testing.

KEYWORDS

bluetooth, compliance, Hawley retainer, orthodontics

1 | INTRODUCTION

Successful orthodontic treatment frequently relies on patient cooperation and can be most critical during the post-treatment retention period, while the oral soft tissues adapt to the new tooth positions.¹⁻³ Studies have shown it can take up to 12 months for the periodontal soft tissues to re-organize around the final tooth positions.⁴ For this reason, many orthodontists prescribe full time wear of retainers for the first 6-12 months after treatment.⁵ Various retention protocols have been advocated. Both lingual retainers and Hawley retainers have been found to be significantly more durable than other forms of retainers.⁶ While lingual bonded

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retainers are "compliance free," they can occasionally lead to adverse periodontal issues and inadvertent tooth movement.⁷⁻⁹ Therefore, the Hawley retainer is still the most commonly used retainer in the United States.¹⁰ Yet, since the Hawley retainer is a removable appliance, it requires patient cooperation with consistent wear to be effective.

While patients are made aware of the risks of non-compliance, most orthodontists estimate that at least half of their teenage patients do not comply at optimal levels.¹¹ During the retention period, many orthodontists will schedule their patients for long intervals of 6 months or more, leading up to 60%-70% of patients and their parents forgetting the necessity of the retainer.^{12,13} A study in 2018 on reasons for orthodontic retreatment in China showed patient compliance as an important factor.¹⁴ In addition, it is well known that patients will often overestimate wear time when reporting to their orthodontist. Therefore, an objective way to measure patient compliance and a method to remind patients of the importance of compliance during the retention phase are needed.

The idea of objectively measuring compliance has been around since the 1970s.¹⁵ However, due to the limitations of the technology at the time the devices failed to become widely used.¹⁶ Recent technological advances have revived interest in objective compliance monitoring and made it clinically and practically feasible. To date, two micro-sensors (Theramon, Ing. Gerhard Gschladt and Smart Retainer, Scientific Compliance) have been developed to objectively measure orthodontic retainer wear time.^{17,18} Data are stored in the device's onboard memory until the device is synchronized at a reading station and transferred to a computer via USB.¹⁸ In either case, data are only accessible when the patient brings the device to the practitioner's office. In contrast, the incorporation of Bluetooth technology into compliance monitoring devices would enable wireless data transfer to smartphones, iPods and ultimately to a cloud database which could be accessible via a secure webpage. This would allow patients, parents and practitioners to readily monitor compliance daily from a mobile application or web browser.

A questionnaire to gauge adolescent patients and their parents' acceptability towards such a Bluetooth-enabled retainer was given to a consecutive sample of 19 adolescent patients' and 11 parents at a university's orthodontic clinic. Overall, the proposed device was well received among patients and parents, with 87% of those surveyed agreeing or even strongly agreeing that they would use such technology, and 73% of parents and 100% of patients believing that this method of tracking would increase their overall adherence to the prescribed wear time.

The aim of the current study was to test the clinical efficacy and accuracy of a novel Bluetooth retainer, mobile application and provider webpage. We defined clinical efficacy to be adequate subject wear time of the retainer, successful synchronization of the retainer to the mobile application and the capability to view and download the data from the provider webpage. We defined clinical accuracy as an overall median margin of error of 5% or less for the device. Therefore, the first null hypothesis was that not all of the subjects would be able to successfully wear and synchronize their retainer, not all of the data would be accessible via the provider webpage, and the overall median level of error would be >5%. Finally, the second null hypothesis predicted that there would be no difference in the level of error when using the adjusted calculation method.

2 | MATERIALS AND METHODS

2.1 | Subjects

The study was conducted in a university-based orthodontic clinic. Five subjects, who met the inclusion criterion of: (a) being an orthodontic resident; (b) consent to participate; and (c) who met the exclusion criterion of active orthodontic treatment, were recruited. Only five subjects were used for the study because this was a pilot study. The Bluetooth-enabled retainers were fabricated for each subject at Forst Laboratory (Campbell, CA), and each subject was loaned an iPod Touch (Apple Corp, Santa Clara, CA, USA) with the retainer mobile application installed (Figures 1,2,3).

2.2 | Retainer Instruction

At TO, retainers were delivered, individual retainer mobile application accounts were created, and a logbook and written and oral instructions were given to each subject. Each subject was instructed to wear the retainer for 12 hours per day, to remove it when eating and brushing, to record the exact time, as displayed on the iPod, that the retainer was inserted and removed and to synchronize the retainer with the mobile application daily. The data were collected in 7-day increments. Each subject was made aware that both the subject and the study conductor could view their wear time using the mobile application and provider webpage (Figure 4). The retainers, logbooks and iPods were collected at the end of the trial.



FIGURE 1 Bluetooth-enabled retainer

10:45 AM

iPod 🗢



FIGURE 2 Overview of the Retainer System. A, Bluetoothenabled retainer; B, Patient's mobile phone or iPod touch; C, Wear time data stored to the cloud; D, Patient receives real-time feedback, rewards, etc.; E, Secure provider webpage



FIGURE 3 Screen shot of the retainer application's Home Screen

2.3 | Statistical analysis

Statistical analysis was performed using Stata for Windows version 14.2 (StataCorp LP, College Station, TX, USA). The median (interquartile range, IQR) difference in minutes between self-reported device



FIGURE 4 Screen shot of the retainer application's Wear Time Dashboard

use and use as measured by the device itself was determined for each subject across a 5-day period. Differences were calculated using unadjusted device measurements and device measurements adjusted to account for time lost when the device was taken in and out of the mouth in-between each 10-minute interval. The adjusted time was calculated by first taking the number of times the device was taken in and out of the mouth and multiplying it by 5 (minutes). Next, this value of minutes was then added to the unadjusted measurement for each day, yielding the adjusted time. To determine whether the adjusted calculation produced a different result from the unadjusted calculation, we used a non-parametric Wilcoxon matched-pairs signed rank test, as these data were not normally distributed.

3 | RESULTS

The study consisted of five orthodontic residents and all five participants completed the study, including one subject who had a new device delivered after the original device malfunctioned. Two subjects failed to synchronize the device with their iPod within 24 hours, and reminder messages were sent prompting them to synchronize the device. **TABLE 1** Median difference in minutes (per day) using the unadjusted versus the adjusted method. Self reported wear-time data as recorded from each subject's logbook

	Unadjusted difference (minutes)			Adjusted difference (minutes)			Self reported wear time (minutes)	
Subject	Median	(IQR)	% Error	Median	(IQR)	% Error	Median	(IQR)
1	21	(13, 25)	3.3	3	(-6, 5)	0.5	628	(595, 633)
2	55	(45, 70)	7.5	25	(20, 25)	3.4	736	(728, 738)
3	32	(6, 43)	5.3	13	(1, 18)	5.3	608	(413, 612)
4	37	(23, 38)	4.4	3	(2, 22)	4.4	848	(752, 950)
5	29	(22, 64)	4.5	19	(7, 19)	4.5	645	(624, 649)
Total	35	(21, 45)	5.1	13	(3, 23)	1.9	693	(622, 716)

	Unadjusted difference (minutes)		Adjusted difference (minutes)		# of times the retainer was inserted or removed
Subject	Mean	SD	Mean	SD	Total (T0 – T1)
1	19.6	11.78134	3.6	13.33417	16
2	57.4	17.03819	22.4	9.502631	35
3	26.4	20.83987	10.4	10.50238	16
4	30.6	12.77889	9.6	11.92896	21
5	39	23.80126	24	19.46792	15

TABLE 2Mean difference in self-
versus device-reported wear times
between the unadjusted and adjusted
method. Total number of times each
subject inserted and removed the device
during the trial

Figure 4 shows the median difference between the self- and device-reported wear time using the unadjusted and adjusted methods including the IQR, upper and lower adjacent values and the outside values. From T0 – T1, the participants wore their retainers a median of 693 minutes (11.55 hours) per day and the median difference between the self- and the device-reported data over the 5-day study period was calculated for each subject using the unadjusted and the adjusted method (Tables 1, 2). The median difference between the self- and device-reported wear times (percent error) was 5.1% using the unadjusted data with a range of 3.3%-7.5%. Using the adjusted method yielded a per cent error of 1.9% with a range of 0.5%-3.4% (Table 1).

Using a Wilcoxon matched-pairs signed rank test, there was a statistically significant difference (P = 0.04) in the accuracy of the device-reported wear time between using the adjusted vs the unadjusted calculation method (Table 2).

4 | DISCUSSION

This study was novel since it tested a Bluetooth-enabled retainer to monitor compliance. The clinical efficacy of the device was confirmed as all of the subjects were able to successfully wear the retainers, and synchronize them to the mobile application, and the data could be viewed and downloaded from the provider webpage. During the trial, one of the devices malfunctioned shortly after delivery to the subject and a new device was processed and delivered. Malfunctioning of similar compliance monitoring retainer devices has been reported in the literature, and the manufacturers' advise that parafunction such as grinding or vibration can cause failure.¹⁹ In a prospective study by Hyun et al, 4 out of 22 subjects were lost due to device malfunction. In another study by Ackerman and Thornton, 1 out of the 23 subjects in their study was lost due to device malfunction.^{11,19} This error highlighted the need to test each device prior to final retainer processing and for improved quality control in the device manufacturing.

Two subjects had to be reminded via text messaging to synchronize their device with the iPod. This unexpected result demonstrated that subjects could be effectively monitored for compliance on a daily basis and that early intervention was possible when noncompliance was occurring.

From T0 – T1, the median difference between the self and the device-reported wear time for all subjects was 35 minutes or 5.1% (3.3%-7.5%). Therefore, while all subjects were able to successfully complete the study, use the mobile application and and retrieve wear time data, the first null hypothesis could not be rejected as the median level of error was 5.1% which was >5%. However, the underrepresentation of wear time by the device was expected, as a limitation of the device is that it only takes a temperature reading every 10 minutes. This inherently means that the device will under report wear time by up to 10 minutes each time it is inserted or removed from the mouth. For instance, the increased difference in self- vs device-reported wear time for subject two compared to subject one can be explained by the fact that subject two had inserted or removed the device 35 times compared to only 16 times for subject one.

Due to this intrinsic limitation of the device, we developed an adjusted calculation method to improve the device accuracy. This method takes the number of times the retainer was inserted and removed each day, multiplies it by 5 minutes and adds this total number of minutes to the raw data. Application of this method reduced the difference between the self- and the device-reported wear time to just 13 minutes or 1.9% (0.5%-3.4%). The difference between these two calculation methods was statistically significant (P = 0.04) verifying that the adjusted method was more accurate. Therefore, the second null hypothesis was rejected, as the adjusted method was significantly different and the overall median level of error was 1.9%.

There are several limitations of this study that may have impacted the outcomes, and due to the small sample size, the conclusions from the results need to be taken with caution. First, as with any study relying on the use of self-reporting from the subjects, there is the potential for inaccurate reporting. We tried to limit the potential for this error by using orthodontic residents who were given explicit verbal and written instructions on how to record wear time in their logbooks. They were instructed to use the time displayed on their iPod so that the same standardized clock was used by each subject. Secondly, in an effort to verify that none of the subjects faked or simulated wear time; for example, by putting the retainer in a water bath, device temperature recordings were checked via the provider webpage for inaccuracies or unusual readings.

Currently, we are working on Retainerbyte 2.0 which has in addition to the temperature micro-sensor, a light sensor that will help conserve battery life. Additionally, we are targeting to create a device with wireless recharging capabilities in which the retainer case can serve as a charging dock. Through creating the Bluetooth-enabled retainer with recharging capabilities, we have the possibility of creating a "find-my-retainer" feature for locating lost retainers.

5 | CONCLUSIONS

This study showed the device is user-friendly and can be used in a clinical setting as subjects could successfully use the Bluetoothenabled retainer and mobile application and data could be retrieved from the secure provider webpage. Additionally, the provider webpage facilitated early detection of non-compliance that allowed for early intervention through reminder messaging. The adjusted calculation method provided a more accurate devicereported wear time and should be incorporated into the device software in future trials. The Bluetooth-enabled retainer proved to be an accurate device to objectively measure patient compliance with a median error of <2%.

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