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AAO Foundation Final Report Form
(a/o 5/31/2016)

Please prepare a report that addresses the following:

Type of Award, e.g., Orthodontic Faculty Development Fellowship Award, Postdoctoral Fellowship Award, Biomedical Research Award, Center Award, Educational Innovation Award, Program Award, Research Aid Award

Biomedical Research Award

Name(s) of Principal Investigator(s)

Snehlata Oberoi

Title of Project

Improving Orthodontic Appliance Compliance with Gamified Digital Rewards

Period of AAOF Support (e.g. 07-01-17 to 06-30-18):

07-01-13-06-30-17

Amount of Funding

$24,394

Summary/Abstract (250 word maximum)

Ideal orthodontic treatment outcome is partly determined by patient compliance. Due to the large contribution of patient compliance to the ultimate treatment methods to improve patient compliance are constantly being developed and evolving. This study is designed to address the problems of patient compliance through the development of a sensor and mobile application (app) that will work in tandem to objectively collect removable orthodontic appliance (e.g. Hawley retainer) wear-time and use the wear- time data in the mobile app to reward patients when they adhere to treatment. There are four main elements that comprise this study: (1) a small wireless sensor package that can be embedded in the acrylic plastic of an orthodontic appliance, (2) a gamified mobile app that will relay the data into the

cloud as well as present the option to redeem rewards based on wear-time data, (3) a cloud database that will permanently store the wear-time data, and (4) a web application that will present the practitioner with a dashboard and summary of patients' wear-time data. With the experience of Dr. Shuvo Roy's using Bluetooth 4.0 technology, along with our high level of orthodontic clinical expertise, we will develop a miniature sensor package, approximately the size of a dime, which can be embedded within an orthodontic appliance. This would objectively track wear-time and improve patient adherence through a mobile application by offering of digital rewards. We propose the following specific aims: (1) Develop a removable orthodontic appliance with a wireless temperature sensor, (2) Develop a Patient-facing Mobile App (for digital rewards) and Clinician-facing Web Application (for wear-time data), and (3) Perform Acceptability Testing & Preliminary Hardware/Software Testing. We expect to be able to rapidly develop both hardware and software so that we can enter human trials in a year. The long-term goal of this project is to bring to the market our innovative model of patient compliance, so all orthodontists will have the ability to evaluate patient compliance in real time.

Response to the following questions:

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

The specific aims of the proposal were:

Specific Aim #1: Develop a Removable Orthodontic Appliance with Wireless Temperature Sensor

(1-A) *Design and shrink Bluetooth 4.0 temperature sensor electronics into a dime-sized board*
Using the Bluetooth 4.0 Framework, we will prototype several printed circuit boards that comprise of a Bluetooth 4.0 chip, antenna, temperature sensor, micro-energy cell battery, and RFID coil. Designs will differ in physical layout to minimize the size of the electronics. Specific electronic design parameters will be varied to find the optimal tradeoff between size and sufficient battery life for the sensor to last 18-24 months while making battery recharging effortless for the patient.

(1-B) *Create low profile hermetically-sealed mechanical package and embed into orthodontic appliance*
We will encase the sensor board in a hermetically sealed package to isolate harmful battery and electronic chemicals from the patient. The package will be compatible with acrylic plastic and metal wire used in orthodontic appliances. Bench top tests will be performed to ensure the package will not crack under loading (e.g. patient biting) or corrode, and chemicals from within the package will not leach out. **Success Criterion #1-1: electronics in a package less than or equal to the size of a dime that can safely and unobtrusively fit in a Hawley retainer**

(1-C) *Adapt Bluetooth 4.0 framework for removable orthodontic appliances* Microprocessor code previously written for the Bluetooth 4.0 framework can be quickly adapted for the proposed wireless temperature sensor. The basic data transmission code would be largely untouched. However, sensor-specific and application-specific parameters in the code will be adjusted to sample data from the temperature sensor every 15 min. Bluetooth operates at the 2.4GHz bandwidth, which is absorbed by the body. Thus, when the temperature reading is at approximately 36.8°C (device in mouth), sample data will be stored in the on- chip memory. When the temperature reading is lower than approx. 33°C (device out of mouth), all the stored data will be wireless transmitted to an iPod Touch.There is enough on-chip memory for approximately 1

weeks' worth of readings. In the unlikely chance an iPod Touch is not nearby for an entire week, we will compress the existing data on the device to free memory for future readings. Because a majority of battery power is consumed during data transmission, this power management algorithm will lengthen intervals before recharging is necessary. **Success Criterion #1-2: a sensor package that samples temperature data every 15 min. and transmits data only when the device is removed from the mouth**

We have completed Aim 1. We have completed two versions of a Bluetooth enabled sensor that can be hermetically sealed and embedded within a Hawley retainer for clinical testing (Aims 1-A, 1-B, 1-C). The first device (Device 1.0) has been completed, undergone a preliminary clinical test, which has further motivated hardware revisions to produce a second version of the device (Device 2.0) that has an additional light sensor and is further optimized for a battery life that can last up to 1 year without recharging.

Specific Aim #2: Develop a Patient-facing Mobile App and Clinician-facing Web Application

(2-A) *Establish data connectivity between Bluetooth 4.0 sensor package, mobile phone, and cloud database*

In our prior work on the Bluetooth 4.0 framework, we created an iPhone application that can pair with our Bluetooth sensor and act as a gateway for sensor data to flow to the cloud using either Wi-Fi or the cellular network. We will adapt this code to ensure it works on the iPod Touch. We will also setup a dedicated HIPAA- compliant cloud database for this project that can reliably and securely receive data from the sensor and deliver data on-demand when our mobile app or web application. **Success Criterion #2-1: securely and reliably transmit data from the sensor to the cloud storage system**

(2-B) *Develop mobile app for patients with user profile and basic gamification elements* We will create a mobile app that will populate a patient-user's profile based on data stored in the cloud. The profile will utilize game-inspired metrics such as points and levels to visually provide the patient with on-demand feedback that they are progressing with their treatment. This contrasts with the current model of care in which feedback is provided only during orthodontic visits (every 3-6 months apart during post-treatment retention). We believe increased feedback will also increase patient engagement in their treatment. Gamification of the app involves not just an attractive user interface and intuitive layout, but the ability to impose schedules (e.g. continuous, fixed ratio, fixed interval, variable) and define conditions that must be met before points, levels, badges, or rewards are awarded to the user. To do this, we will adapt an existing gamification engine such as Zurmo or Bunchball Nitro. Having control over reward schedules and contingencies will provide great flexibility in designing and refining activity loops to engage the user (i.e. cycles of trigger/motivation, user action, and feedback). Specific design and clinical testing of these activity loops will be a part of future studies, during which we will involve behavioral experts to help create engaging and addictive experiences similar to many web 2.0 and social media products. **Success Criterion #2-2: enable real- time treatment feedback through a gamified system**

(2-C) *Develop system to exchange virtual currency for digital reward goods*

There is no pre-existing service that converts a virtual currency (e.g. points) into digital goods (e.g. music, videos, apps) that normally cost real money to obtain. Using AppleScript on a cloud server, we will develop a system that will subtract virtual currency from the user's account in our app and then gift them the digital goods through iTunes or App Store. Information on the virtual currency transaction

and which digital goods the user owns will be attached to each patient-user account. Recordkeeping of these virtual transactions will be invisible to the users. In the future, we will add support for coupons (e.g. free drink) and integrate these coupons into passbook, which is a new virtual wallet feature in iOS 6. **Success Criterion #2-3: allow patients to exchange virtual currency for digital goods that cost real money**

(2-D) *Web application for orthodontist with dashboards to summarize patient wear-time* We will create a web application for the orthodontist that will populate a wear-time summary dashboard for each patient. In developing this application, we will need to create an authentication system to verify if the user is a valid patient-user or clinician-user. Patient-users and clinician-users will have different permissions to the same data records. For example, patients will only be able to access gamified data (e.g. points, badges, rewards) while clinicians will have access to clinically relevant data (e.g. wear-time data graphs). **Success Criterion #2-4: securely display clinically relevant data to the orthodontist**

We have completed a majority of Aim 2. Specifically, we have developed a fully functional iOS app that is able to communicate with the custom Bluetooth sensor, upload data to a cloud database, and provide a visualization of wear-time to the patient (2-A). This enables patients to track their wear-time and also provides a data collection tool for clinical studies. We have also completed aim 2-D to provide orthodontists a data visualization of patient's wear-time in preparation for a clinical study. We have delayed development of gamification (2-B) and digital reward features (2-C) until after a pilot clinical study in 30 subjects with the app and Device 2.0.

Specific Aim #3: Acceptability Testing & Preliminary Hardware/Software Testing

(3-A) *Patient, parent and orthodontist acceptability surveys*

We will develop surveys to assess patient and parent acceptability of our hardware and software. Prior sensor devices were negatively perceived because they lacked data-transparency to the patient; we will examine if perception changes when patients seek to benefit from incentives and gamified feedback. Patient and parent feedback and concerns will help us better understand user needs while designing the hardware and software, and will also allow us to anticipate concerns in future clinical studies. We will also survey orthodontists to understand any concerns that may bar recommendation of our system to patients. Many orthodontists operate independent practices, which may have particular concerns that differ from an academic medical institution like UCSF. **Success Criterion #3-1: document device acceptability and concerns from patient, parents, and orthodontists**

(3-B) *Bench top testing hardware to detect attempts at "gaming" the system*

Because our wear-time measurement is dependent on temperature, we must take extra precautions in attempts to simulate body temperature in an extraoral environment in order to fool our wear-time measurement. We will test a Hawley retainer with embedded sensor in water baths as well as commercially available products such as toe warmers and compare this data with intraoral data to identify patterns specific to attempts to fool the system. From this, we will set temperature thresholds to distinguish intraoral data from extraoral data and use machine learning to develop algorithms for distinguishing true intraoral wear-time. These algorithms will be tested on both bench top models and a small number (n=3-5) of human subjects (to capture between-subject variations in body temperature). **Success Criterion #3-2: identify attempts to simulate body temperature and fake wear-time**

(3-C) *Test hardware in human subject to ensure expected data functionality is achieved*

We will test the sensor package in a human subject to ensure that the firmware is

operating correctly (e.g. data is only transmitted when the device is taken out of the mouth and no data is lost while transmitting to the iPod touch and cloud database). Initial tests will be with the Hawley Retainer; we will expand to other removable appliances (e.g. Schwartz) to ensure the sensor is as unobtrusive as possible on each of these different appliances. Feedback from these tests will inform iterative prototyping and redesign of what sensor package dimensions would work best in various different types of removable orthodontic appliances. **Success Criterion #3-3: ensure comfort to the patient and broad compatibility of the sensor package dimensions to various removable orthodontic appliances**

(3-D) *Preliminary user testing for mobile app*

We will recruit a small number (n=2-3) of human subjects between ages 7-18 to provide preliminary user feedback on the mobile app and incentives system. Feedback will be used to refine the user interface in order to maximize patient engagement in the app. Furthermore we can begin to get a sense of how often we need to schedule rewards and badges relative to the number of points and levels the user has earned. When testing incentive scheduling, an iPod Touch with our app will be lent to the user for 1-4 weeks. Feedback will be used to refine the software in preparation for a full-length clinical study.

We have completed Aim 3. Acceptability surveys have been completed by patients and parents recruited from the UCSF orthodontics clinic (3-A). Benchtop testing was performed with Device 1.0 and we found that the temperature sensor was sufficiently sensitive for wear-time tracking. To further prevent the ability to cheat the measurement system, we have added a light sensor in Device 2.0 as an additional way to tell if the patient is wearing the retainer (3-B). Initial human testing of Device 1.0 was completed on 5 human subjects who were all able to wear the retainer and use the app without problems (Aims 3-C, 3-D).

2. **Were the results published?**

   Yes, we have submitted our manuscript for publication in The Angle Orthodontist and are awaiting review.

   a. **If so, cite reference/s for publication/s including titles, dates, author or co-authors, journal, issue and page numbers**

We have submitted a manuscript titled “, Compliance Monitoring via a Bluetooth Enabled Retainer: A Prospective Clinical Pilot Study” to The Angle Orthodontist and are awaiting review. The authors are:

Eric J. Castle, [a] Philip Chung, [b] Gerald Nelson, [c] Mohammadhossein Behfar, [b,d] Matthew Chen, [b] Shuvo Roy, [b] Snehlata Oberoi, [c]

[a]Orthodontic Resident, University of California – San Francisco

[b]Department of Bioengineering & Therapeutic Sciences, University of California – San Francisco

[c]Professor of Orthodontics, University of California – San Francisco

[d]Department of Electronics and Communications Engineering, Tampere University of Technology, Finland

   b. **Was AAOF support acknowledged?**

      Yes.

   c. **If not, are there plans to publish? If not, why not?**

NA.

3. **Have the results of this proposal been presented?**

Yes, the results have been presented at national and international scientific meetings and were chosen to participate for some prestigious awards as follows:

Charley Schultz Scholar Award. American Association of Orthodontists San Diego, 2017

   a. **If so, list titles, author or co-authors of these presentation/s, year and locations**

American Association of Orthodontists Orlando, 2016
Eric J. Castle, Philip Chung, Gerald Nelson, Mohammadhossein Behfar, Matthew Chen, Shuvo Roy, Snehlata Oberoi.

American Association of Orthodontists San Diego, 2017
Eric J. Castle, Philip Chung, Gerald Nelson, Mohammadhossein Behfar, Matthew Chen, Shuvo Roy, Snehlata Oberoi.

51st Indian Orthodontic Conference and 8th World Implant Orthodontic Conference, Goa, India, 2016
Snehlata Oberoi, Eric J. Castle, Philip Chung, Gerald Nelson, Mohammadhossein Behfar, Matthew Chen, Shuvo Roy,

   b. **Was AAOF support acknowledged?**

Yes

   c. **If not, are there plans to do so? If not, why not?**

NA

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

The Biomedical Research 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,

Snehlata Oberoi

Please return to AAOF via email attachment to
aaofevp@aaortho.org