AAOF Final Report

Type of Award: Research Aid Award

Name of Principal Investigator: Sneha Oberoi

Title of Project: Compliance Monitoring via a Bluetooth Enabled Retainer: A Prospective Clinical Pilot Study

Period of AAOF Support: 6/2015 to 6/2017

Abstract of Completed Results: Attached

Were the original aims realized?

Yes, the original aims of the proposal were realized. The device was successfully developed, and its accuracy and usability was verified. It is ready for further larger scale clinical studies.

Were the results published?

No. It was submitted to the AJO-DO and Angle Orthodontist; however, it was declined due to the small sample size of the Pilot Study.

Have the results been presented?

Yes. It was presented at the 2016 AAO Annual Session "Residents Presentations." AAOF support was acknowledged on the posterboard. (Posterboard presentation attached)

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

AAOF funding was critical to this project, which gave me a deeper understanding of clinical research and statistics. I am grateful for the support from the AAOF.

Abstract

Introduction: Following orthodontic treatment, it is often critical that patients wear a retainer to prevent relapse. Removable retainers are commonly used, which rely on patient compliance, however it is well known that patients are not always compliant which can lead to a poor outcome. Recent technological advances have led to the development of removable retainers that record compliance, but to date none have incorporated Bluetooth technology to wirelessly transmit compliance information. Such technology would allow a clinician to intervene immediately upon non-compliance to prevent relapse.

Aim: First to develop and conduct preliminary lab testing of the *Innov8* Retainer and to develop the *Innov8* software and webpage database. Then conduct a pilot study to test the clinical efficacy and accuracy of the newly developed Bluetooth enabled retainer and iOS mobile application.

Methods: Following the development and preliminary testing the pilot study was designed. Five subjects were given an *Innov8* Retainer, logbook and iPod Touch with the *Innov8* mobile application (T0). Subjects were instructed to wear the retainer for 12 hours per day, record each time the retainer was inserted or removed and trained to sync the device daily to the mobile application. After the five-day study period (T1), statistical analysis was performed.

Results: The median difference between the self- and device-reported data was 35 minutes or 5.1% and 13 minutes or 1.9% using the adjusted calculation method.

Conclusions: Subjects were able to successfully wear the retainer and use the mobile application. The device showed a clinically acceptable level of accuracy and usability that validates it for further clinical testing.

Compliance Monitoring via a Bluetooth Enabled Retainer: A Prospective Clinical Pilot Study

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ORTHODONTICS IS MY PASSION...

BACKGROUND

- Following orthodontic treatment, it can take up to a year for the periodontal fibers to remodel and adapt to the new tooth positions.[1-3]
- During this time it is essential for patients to have a retainer to prevent relapse. The most commonly used is the Hawley retainer, which requires patient compliance.[4]
- Two retainer devices (SMART® and Theramon®) currently exist to measure orthodontic retainer wear-time. However, both are expensive ($450-600), require in-office visits to download the data (as they are not Bluetooth enabled), and do not provide any feedback to the patient.
- The *Innov8 Retainer* is a newly developed Bluetooth enabled device that can record and transmit wear-time data to (1) the Cloud, (2) a patient's mobile phone and (3) the clinician's computer. (Fig 1, 2)
- This allows early intervention if a patient is not wearing their retainer and direct feedback to the patient.

Figure 1: Innov8 Retainer

Figure 2: Overview of the Innov8 System. (A) Innov8 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

PURPOSE

To conduct a prospective pilot study to test the efficacy and accuracy of the *Innov8 Retainer.*

MATERIALS AND METHODS

- Five orthodontic residents volunteered to participate and were given an *Innov8 Retainer*, logbook and iPod Touch with the *Innov8* mobile application (T0). (Fig 3,4) Subjects were instructed to wear the retainer for 12 hours per day, record each time the retainer was inserted or removed and trained to sync the device daily to the mobile application. After the five-day study period (T1), statistical analysis was performed.
- Wear-time differences were calculated using "unadjusted" and "adjusted" device measurements to account for time lost when the device was taken in and out of the mouth between each ten-minute interval.
  - Adjusted time = (# of times the device was inserted/removed x 5 minutes) + unadjusted time

Figure 3: Screen shot of the Innov8 application's Home Screen

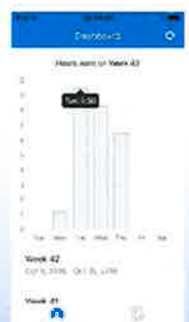

Figure 4: Screen shot of the Innov8 application's Wear Time Dashboard

RESULTS

- From T0 – T1, subjects wore their retainers a median of 11.55 hours per day. The median difference between the self- and device-reported data was 35 minutes or 5.1% and **13 minutes or 1.9% using the adjusted calculation method.**

Subject	Unadjusted difference (minutes)			Adjusted difference (minutes)			Self reported wear time (minutes)	
	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)

Table I: Median difference between the self- and the device- reported data over the five-day study period was calculated for each subject using the unadjusted and the adjusted method

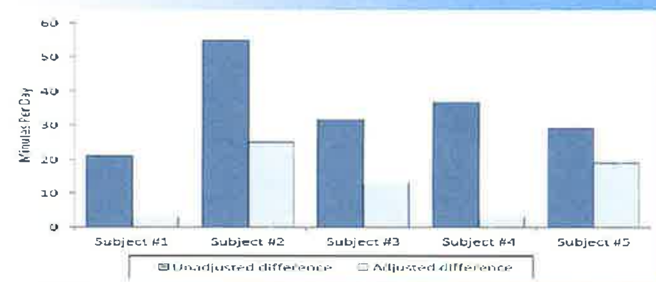

Figure 5: Median difference in self- versus device- reported wear-times between the unadjusted and adjusted method

CONCLUSIONS

- Subjects were able to successfully wear the retainer and use the mobile application. The device showed a clinically acceptable level of accuracy and usability that validates it for further clinical testing.

FUTURE DIRECTIONS

1. Test "Device 2.5" with incorporated light sensor and increased battery optimization
2. Conduct clinical trial with 30-40 patients at the University Clinic

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