
Article:
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How accurate are TheraMon® microsensors at measuring intraoral wear-time? Recorded v actual wear times in 5 volunteers.

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Statement of contributions:
Catherine Brierley was responsible for the study design, gaining approvals, recruitment of participants, data collection, analysis and interpretation and writing the final report. Philip Benson and Jonathan Sandler were responsible for the study design, data analysis and interpretation and revision of the report. All the authors have approved the final report. Catherine Brierley is the guarantor.

Abstract

Background: The TheraMon® microsensor is the most recent device developed to measure the wear-time of removable appliances. The accuracy has not been validated intra-orally.

Objective: To determine if the TheraMon® microsensor accurately records time when fixed intra-orally. We will also examine the effect of the intra-oral location on the recorded time.

Design: A prospective pilot study, using a convenience sample.

Setting: A district hospital orthodontic department.

Participants: 5 non-patient volunteers.

Methods: A prospective pilot study, using a convenience sample, was carried out in a UK hospital orthodontic department. Five non-patient volunteers wore TheraMon® microsensors positioned palatal to an upper molar, and buccal to a lower molar for 7 days, after which they were removed and the data downloaded. Differences between actual amount of wear (24 hours for 7 days) and the wear recorded by each device were calculated. Differences between sites were also examined.

Results: The mean daily wear-time recorded by the upper and lower microsensors combined was 23.0 hours (SD 0.6, 95% CI 22.6-23.4), which is a mean under-recording of 4% (CI 2.5 and 5.8%). The maximum daily under-reporting of wear-times was 5.5 hours. Discrepancies between microsensor locations were also found, with those located in the lower buccal sulcus being closer to actual wear times.

Conclusions: Assumptions made by the TheraMon® microsensors software lead to under-reporting of intra-oral wear-time, particularly when placed palatally. Current discrepancies between actual and recorded intra-oral wear-time could be significant in both clinical practice and research. Adjustment of the microsensor software parameters would improve accuracy, irrespective of the intra-oral location.

Introduction

There have been a number of attempts to develop accurate and reliable devices for measuring the time that patients wear their orthodontic appliances, including headgear (Northcutt 1975; Swetlik 1978; Güray and Orhan 1997; Cureton et al. 1991; Clemmer and Hayes 1979; Lyons and Ramsay 2000; Lyons and Ramsay 2002; Cole 2002; Brandão et al. 2006; Bos et al. 2007) and other removable appliances (Sahm et al. 1990; Ackerman et al. 2009). The latest device, designed to objectively measure adherence to appliance wear instructions, is the TheraMon® microsensor (Handelsagentur Gschladt, Hargelsberg, Austria or Forestadent, Pforzheim, Germany), which has been placed in various removable appliances (Pauls et al. 2013; Schott et al. 2013; Kawala et al. 2013; Tsomos et al. 2014; Schott and Ludwig 2014). The microsensor records the temperature every 15 minutes. At each visit the orthodontist can download the data from the microsensor and use dedicated software to interpret the results by making certain assumptions on wear-time. The software currently 'validates' wear-time as those temperature values which fall between 33.5 to 39°C.

It has been reported that the microsensor accurately records the temperature of a waterbath (Schott and Göz 2010; Schott et al. 2011) and in the mouth (Schott and Goz 2011; Pauls et al. 2013), although the methodology of the *in vivo* investigations is unclear. Tsomos et al. (2014) undertook a cohort study using the TheraMon® microsensor to 'objectively assess the compliance of patients who wore various types of removable orthodontic appliances in the medium/long term'. The authors defined 28°C to 38°C as indicative of wear-time as they felt that this represented the majority of intraoral temperatures in normal conditions. Additionally, the microsensor was placed posteriorly (buccally or palatally) because the authors reported that there was less variation in intraoral temperature at these locations. To our knowledge, this is the only study using TheraMon® which has considered the stability of intraoral temperature in their methodology. Tsomos and colleagues' conclusions about intraoral temperature were based on research by Youngson and Barclay (2000) and Moore (1999).

The aim of this study was to further investigate the accuracy of the TheraMon® microsensor timing when it is fixed in the mouth of five volunteers. There were two research questions:

- Does the TheraMon® microsensor record full time wear (i.e. 24 hours a day) when fixed intraorally?
- Does the location of the microsensor within the mouth affect the recorded time?

Methods

The study was a prospective, cohort design, conducted in the Orthodontic Department of Chesterfield Royal Hospital NHS Foundation Trust. Permission was gained through the local Research and Development Department of CRHT (approval 14 July 2014). A convenience sample of five non-patient volunteers (clinicians, laboratory technicians and dental nurses) was used. There were no data upon which to base a sample size calculation; therefore this study was undertaken to generate some initial data for a descriptive analysis.

Volunteers were eligible for inclusion in the study if they satisfied the following criteria:

- Their oral hygiene was exemplary;
- They were available to attend four appointments over a 4-week period.

Written consent was obtained.

The gender, age, and smoking status of each participant were recorded. Each participant had two microsensors embedded in acrylic and attached to molar bands, cemented in two intraoral locations (Figure 1). The microsensors were left *in situ* for seven days, after which time they were removed and the data downloaded to a computer using a TheraMon® reading station and dedicated software. Figure 2 shows an image of the TheraMon® software analysis for one participant.

[Figures 1 and 2 near here]

Data analysis

Time and temperature data were exported into an Excel® spreadsheet (Microsoft corp, WA, USA). A simple descriptive analysis was undertaken. The discrepancy between actual wear-time and microsensor-recorded wear-time (over- and under-reporting of wear-time) was calculated by subtracting actual wear-time from microsensor recorded wear-time. The mean values, standard deviations (SD) and confidence intervals (CI) of the differences between the actual amount of wear (24 hours for seven days) and the wear recorded by the microsensor were calculated. Any differences in the recordings between the two devices, placed simultaneously in the same mouth, were compared with descriptive statistics and graphs. A one-sample *t* test was used to determine if the difference between the actual wear-time and the recorded wear-time was significantly different from zero (Actual time in minutes – Recorded time in minutes; $p<0.05$). A one-sided test was used because the descriptive analysis suggested that the microsensor consistently under-recorded the time in the mouth, and also because we knew that the microsensor was in the mouth for 24 hours over 7 days, which is the equivalent of 10,080 minutes and it should not have been possible for the microsensor to record a value greater than 10,080 minutes. Pearson product correlation coefficients were used to assess if there was an association between temperatures recorded by the microsensors located in the upper palate and the lower buccal sulcus.

Results

Four females and one male participated. The age range was 19-48 years (mean 35, SD 12.3 years). Four of the participants were non-smokers, one was an infrequent smoker, and did not smoke for the duration of the trial.

The descriptive statistics of the mean recorded wear-time in the five participants, as well as the SD and 95% CI for the upper and lower microsensors, are shown in Table 1. The average daily wear-time recorded by the upper and lower microsensors combined was 23.0 hours (SD 0.6, 95% CI 22.6-23.4), which is a mean under-recording of 4% (CI 2.5 and 5.8%).

Differences between recorded and actual wear-times

The palatal microsensor recorded a mean daily wear-time of 22.8 hours (range 22.0-23.5 hours, SD 0.59, 95% CI 22.2-23.3) in the five participants. The lower buccal sulcus microsensor recorded a mean daily wear-time of 23.3 hours (range 22.5-24 hours, SD 0.57, 95% CI 22.7-23.4). Table 2 shows that on average the upper microsensor underestimated the amount of the time in the mouth by 8.7 hours (95% CI -12.3 to -5.0) over the 7 days (maximum 168 hours) or 1.2 hours per day, whereas on average the lower microsensor had a lower underestimate (mean 5.3 hours out of a maximum of 168, 95% CI -8.8 to -1.7, or 0.8 hours per day,). Both values were statistically significant (upper sensor one-sample *t* test; p value = 0.005; lower sensor p value = 0.022). The range in under reporting over the 7 days was 3.5 to 14 hours for upper microsensors, and 0.3 to 10.5 for lower microsensors.

Overall, microsensors located in the lower buccal sulcus recorded wear-times closer to the actual wear-time compared to microsensors located in the palate. According to the microsensor software fully accurate wear-times of 24 hours were recorded by both intraoral microsensors on only two occasions (day 2 for Participant B, and day 7 for Participant C). The maximum under-reporting of daily wear-times was 5.5 and 4.5 hours for palatally and buccally located microsensors respectively.

Differences between upper palatal and lower buccal recordings

The mean difference between upper and lower recordings was 3.4 hours in 7 days (SD 4.12 hrs; 95% CI -7.0 to 0.2hrs). There was a large range in the difference between upper and lower microsensor recordings (0.0 to 8.3 hrs, out of a maximum of 168 hrs).

Figure 3 shows a scatterplot of the simultaneous upper palatal and lower buccal TheraMon® microsensor temperature readings recorded in the 5 participants, over 7 days. The correlation in the wear-time recorded by the upper and the lower microsensors was very low ($r = 0.025$).

Intraoral temperature recordings

The temperature range recorded for both microsensor locations, among the five participants, was between 25.9 and 43.5°C, with a mean of 35.8°C (SD 1.3). The range in temperatures recorded by

microsensors located palatally was slightly wider (25.9 – 43.5°C) than the range recorded by microsensors located in the lower buccal sulcus (26.1 – 42.6°C). Figure 4 shows boxplots of the data comparing the upper palatal and lower buccal recordings. These indicate that recorded temperatures in the lower buccal sulcus were more stable than in the palate. Despite the similar spread of data between the microsensors in the two locations, more of the temperatures recorded in the palate fell out of the range that TheraMon® software assumes that the microsensor is within the mouth (33.5 – 39.0°C). Interestingly, there was a discrepancy in the wear-times calculated from the upper sensor raw temperature data (data outside the range 33.5 to 39.0°C) and those provided by the software, with a mean under-recording of 2.3 in 24 hours (SD 1.2) from the temperature data and 1.2 in 24 hours (SD 0.8) from the sensor software. There was a minimal discrepancy in the wear-times calculated from the raw temperature data and the software in the lower sensor. It would seem that the sensor software has a 'smoothing' effect on the data, by detecting large discrepancies over short periods of time and assuming these are anomalies; therefore we would recommend using the software values rather than the raw temperature data for more accurate recordings.

To investigate if changing the threshold temperature range would increase the accuracy of the recording, we modelled various ranges against the proportional accuracy of the recording and this is shown in Table 3. This shows that by increasing the threshold range to between 30 and 42°C would increase the accuracy of reported wear-times using the raw temperature data to over 98.8% in all participants, irrespective of microsensor location.

Figure 5 is a graph showing the variation in intraoral temperatures for the 5 participants, over the 7-day period. It can be seen that there was less variability in intraoral temperatures during the hours when participants were likely to be asleep.

Discussion

This prospective *in vivo* study found differences between the recorded intraoral wear-times from a TheraMon® microsensor, using the current threshold temperature range (33.5 to 39°C), compared with the actual wear-times.

Previous validation of the microsensor wear-time has been reported using data following immersion in a waterbath (Schott and Göz 2010; Schott et al. 2011); however this study strongly suggests that a thermostatically controlled water-bath is unlikely to reliably mimic intraoral conditions. Clinical validation studies of the microsensor have relied on patient/participant-reported wear-times to determine the accuracy of the microsensor. Based on the data from our study, Schott and colleagues' (2013) conclusion that 68% of patients cooperated with the prescribed wear-time may be a significant overestimate. Similarly, their conclusion that 8-hours of daily wear, with a removable retainer, is acceptable to patients should be interpreted with caution. (Schott et al. 2013) Similar caution should be applied to more recently published articles using TheraMon® as a measure of compliance with the Frankel II, bionator and face mask (Arreghini et al. 2017) and with the van Beek appliance (Al-Kurwi et al. 2017).

Pauls and colleagues (2013) reported that differences between recorded and reported wear-times decreased when participants were made aware that they were being timed. Their data indicate that an average overestimation of 2.7 hours wear-time per day before being made aware of the presence of the microsensor, reduces to an overestimation of 0.7 hours per day after being made aware. It may be possible to use a TheraMon® microsensor to show a general change in patient reporting behaviour pre- and post-knowledge of wear-time tracking; however following this study, we would recommend caution in interpreting the microsensor quantification of actual hours of wear when using the current assumptions of intraoral temperature. Tsomos et al. (2014) found that despite patients being aware of wear-time monitoring, the median wear per day relative to prescription (14 hours daily wear) was

63% (range: 0-89%) for functional appliances. Patients were, however, found to comply with an 8-hour daily wear retainer prescription.

This study sought to remove potential errors in participants' record of wear-time, by fixing the microsensors intraorally. Following discussion with the developer of the microsensor it became clear that they recommend any appliance containing the microsensor be removed when eating or drinking. This might explain some of the discrepancies in our data between recorded and actual wear-time. In addition, tooth brushing and oral care, when most clinicians would advise the patient to remove the appliance, could also impact on intraoral temperature. It is unlikely however, that the time spent eating, drinking and brushing teeth would have accounted for the 5.5 hours of under-reported wear-time that was recorded for one of the participants in this study. Clinicians who are using the microsensor to assess adherence to wear instructions, and who advise their patients to wear removable appliances full time, including eating, to achieve the most efficient tooth movement, should be aware of this recommendation.

The mean intraoral temperature during our study was 35.8°C, which lies within the range of the software threshold. It also concurs with those reported by previous studies. (Moore 1999; Longman and Pearson 1987; Brown and Goldberg 1966; Spierings et al. 1984; Bergstrom and Varga 1971) The range of temperatures recorded by the microsensors fixed in the mouths of our volunteer participants (25.9 to 43.5°C), however, was much wider than the current software threshold temperature range. According to the data from this study we would recommend that the TheraMon® microsensor software be adjusted to 'validate' wear in the range 30°C to 42°C to increase the accuracy of wear-time reporting to more than 98% irrespective of the intraoral location of the microsensor. Tsomos et al. (2014) chose to define a range of 28°C to 38°C as indicative of wear-time, as they felt that this represented the majority of intraoral temperatures in normal conditions and this is closer to the range that we would recommend.

The range of temperatures recorded in our study was lower than that reported in previous studies when hot and cold drinks were consumed (1°-71.8°C). (Airoldi et al. 1997; Youngson and Barclay

2000; Palmer et al. 1992) There may be a number of reasons for this difference. Firstly, previous studies have used temperature gauges resting on teeth or archwires, rather than a microsensor resting on the mucosa. In addition, the microsensors used in our study were embedded in acrylic, which may have prevented a certain amount of heat conduction. Finally, the previous studies investigating intraoral temperature were undertaken in a laboratory, whereas our study was in a 'real-life' setting, where the temperature of the drinks consumed might have been less extreme.

Tsomos and colleagues (2014) reported that the microsensor should be placed posteriorly (buccally or palatally) because they reported that there was less variation in intraoral temperature at these locations. This study has also showed that the positioning of the microsensor can affect wear-time recording. It would appear that temperatures recorded by the palatal microsensor more frequently fell outside the range the microsensor used to determine wear-time, whereas the recorded wear-times in the lower buccal sulcus were much closer to the actual wear-times. This might be because the lower microsensors were situated between the buccal mucosa of the cheek and attached gingivae, which is a more temperature-stable environment than the palate. At this site there is less exposure to food and drink and when the temperature does change it returns to normal levels more quickly.

Clinicians should be aware that the intraoral location of the microsensor could affect the wear-time data recordings. Most microsensors are placed in the palate, where, according to data from this study, there was a mean daily under-reporting of 1.2 hours. This would equate to approximately 34 hours over the 4 weeks between regular visits to the orthodontist, which might be considered clinically significant, although we are aware that there are limited data confirming a significant relationship between wear-time and rate of tooth movement. A microsensor is less likely to be integrated into a removable appliance in the lower buccal sulcus, where the mean daily underreporting was found to be much less (0.8 hours). Although this difference was statistically significant, it may not be considered clinically significant.

This study did show that there was less variability in intraoral temperatures during the night when participants were likely to be asleep, and more variability during the daylight hours. Reasons for this

might include a lower frequency of food and drink consumption at night, as well as participants undertaking less physical activity. In addition, the ambient temperature might be more constant. Moore (1999), however, reported that ambient temperatures correlate poorly with intraoral temperatures. Whereas, Doyle et al (1992) reported that in ambient temperatures of between -0.5 and 43.5°C, intraoral temperature varied between quite a narrow range (35.3 - 37.7°C).

Another interesting finding, however, was that there was no correlation between temperatures recorded by two microsensors, concurrently recording, in the same mouth. This suggests that temperatures within an individual's mouth can vary according to location, which adds a further complication to the use of intraoral temperature to assess adherence with removable appliance wear.

It is important to state that this study has not shown that the intraoral temperatures recorded by the microsensor are inaccurate. Rather, we believe that the principal reason for the discrepancy between the recorded and actual wear-time is due to the current temperature range used by the software to validate when the appliance is in the mouth. This study has shown that intraoral temperatures are much more variable than the threshold range decided by the developer of the software (33.5 to 39.0°C).

A legitimate criticism is that the study only involved five individuals and the generalisability of the results might be questionable. There were no previous studies, using a similar design, from which data could be used to justify an appropriate sample size; therefore, our initial aim was to generate suitable initial data to undertake a descriptive analysis. However, when we examined the data, the differences were sufficient, with just five participants, to detect a statistically (and, we believe clinically) significant difference between actual and recorded wear-times. We believe that it is unlikely that recruitment of further participants would change the conclusions. It would, however, be beneficial for further investigators, in other centres, to undertake the same design to either confirm or contradict the results of this study.

Schott and Ludwig (2014) suggest that in addition to measuring actual wear-time, as an aid to clinical management, the use of a sensor might help to reduce any strain on the doctor-patient relationship, when discussing suspected non-adherence to removable appliance wear instructions. This study has highlighted potential problems that can occur if the TheraMon® microsensor, with its current software parameters, continues to be used in research and in clinical practice. While the microsensor might provide a general indication of patient wear-time, caution should be exercised when using absolute values to judge a patient's adherence with prescribed wear. To avoid difficulties that may arise if there is conflict between the patient's reporting of wear-time and the microsensor recorded wear-time, the microsensor and current software, should be used as another indicator of wear, alongside clinical judgements. Schott et al. (2013) reported that a majority of parents (74.2%) had no concerns about the use of a microsensor in their child's appliance, presumably because they assumed that the recordings are accurate. It is therefore important to critically evaluate the validity of the microsensor measurements to justify this faith in the measurements, as well as the extra costs of the sensor (approximately 20 GBP or 23 Euros per appliance), software and annual licence (approximately 228 GBP or 261 Euros).

Conclusions

- The mean under-reporting of daily wear-time from a TheraMon® microsensor was 1.2 hours when fixed in the palate and 0.8 hours when fixed in the lower buccal sulcus;
- The maximum under-reporting of wear-time in 24 hours with one microsensor was 5.5 hours;
- Increasing the range of the microsensor software temperature threshold for validating wear to 30C to 42°C would increase the accuracy of wear-time reporting to more than 98% irrespective of the intraoral location.

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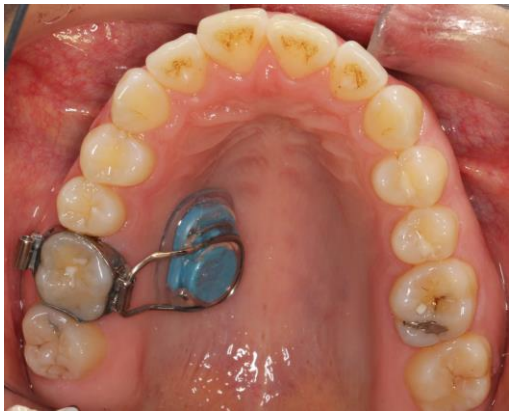
Figures and captions:

Figure 1 - TheraMon® microsensor embedded in acrylic and attached to two intraoral locations:

a) palatally to a molar band on an upper first molar

b) buccally to a molar band on the contralateral lower first molar



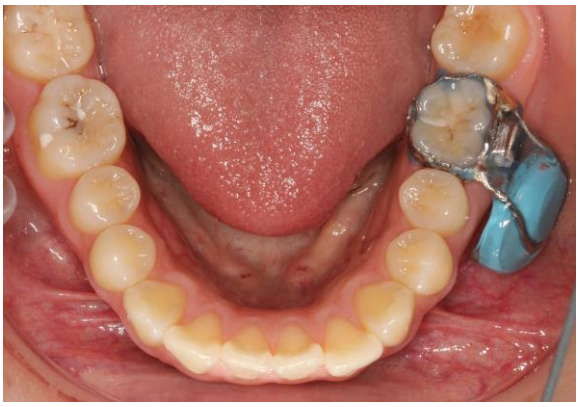


Figure 2 – Image of the TheraMon® software analysis for Participant A (upper)

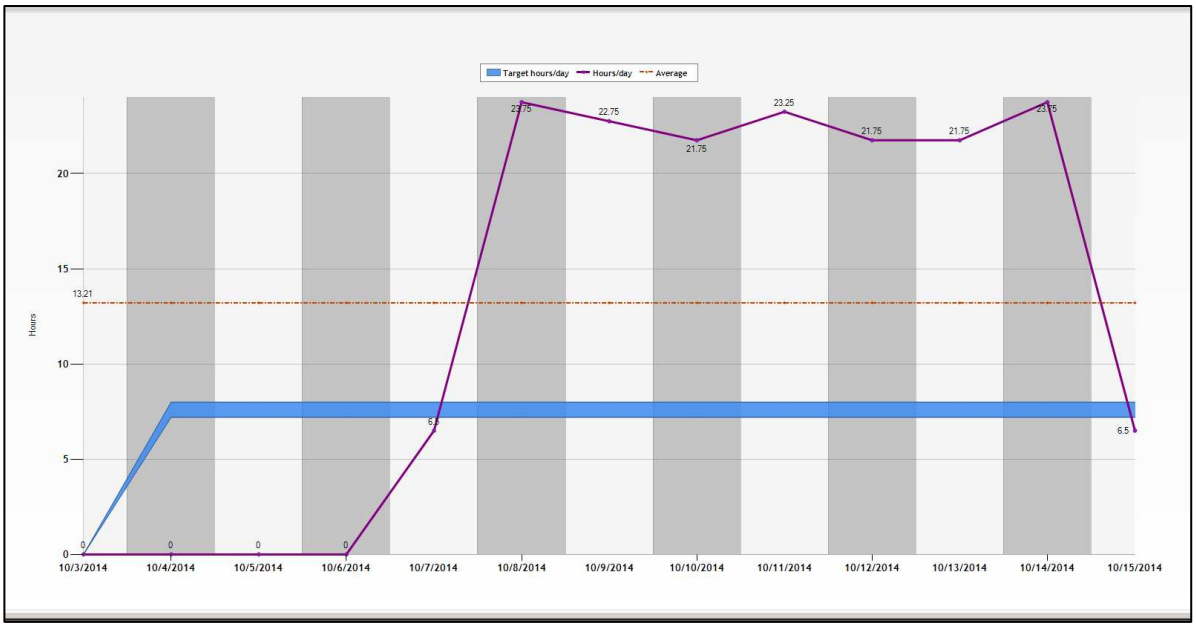


Figure 3 – Scatterplot of the simultaneous upper palatal and lower buccal TheraMon® microsensor temperature readings recorded in the 5 participants, over 7 days

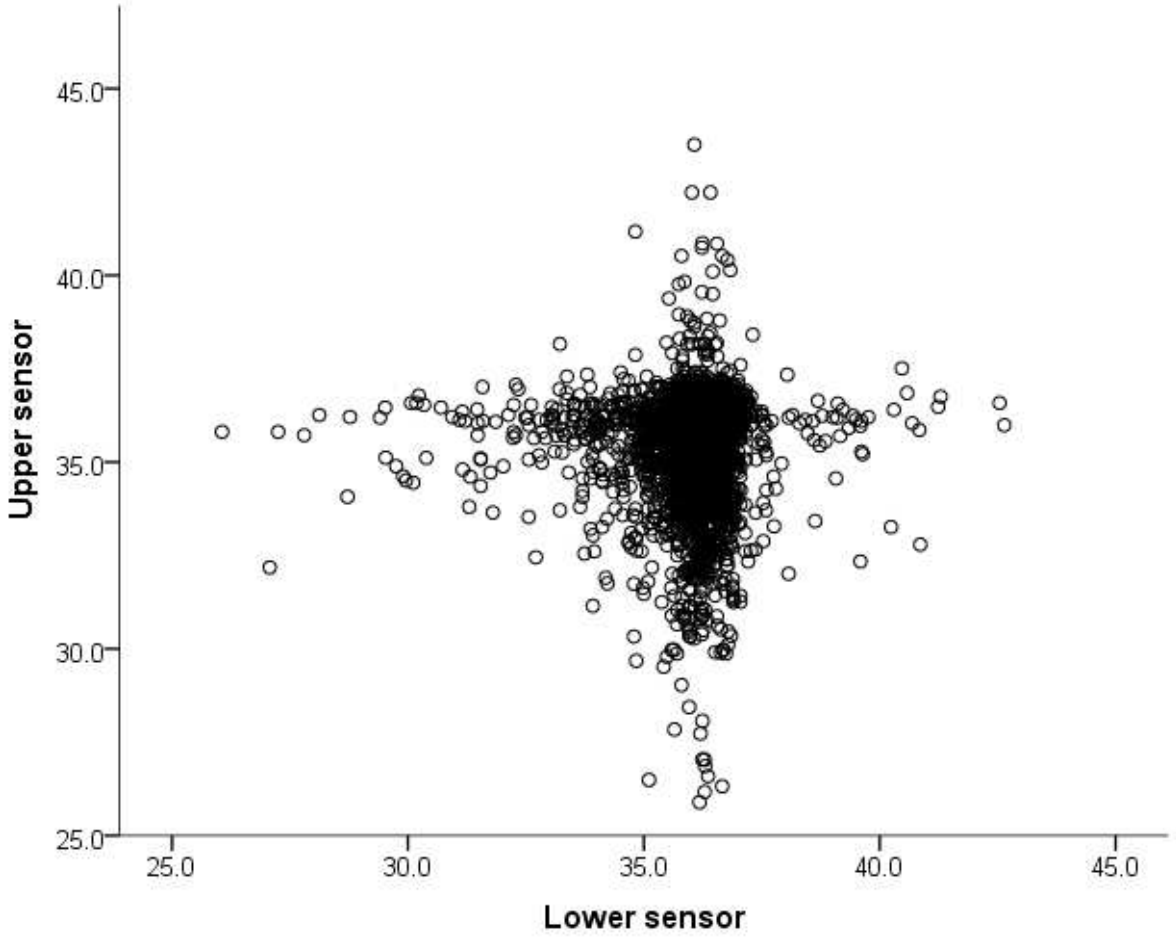


Figure 4 - Boxplot comparing the combined intraoral temperatures measured by microsensors located in the palate and lower buccal sulcus

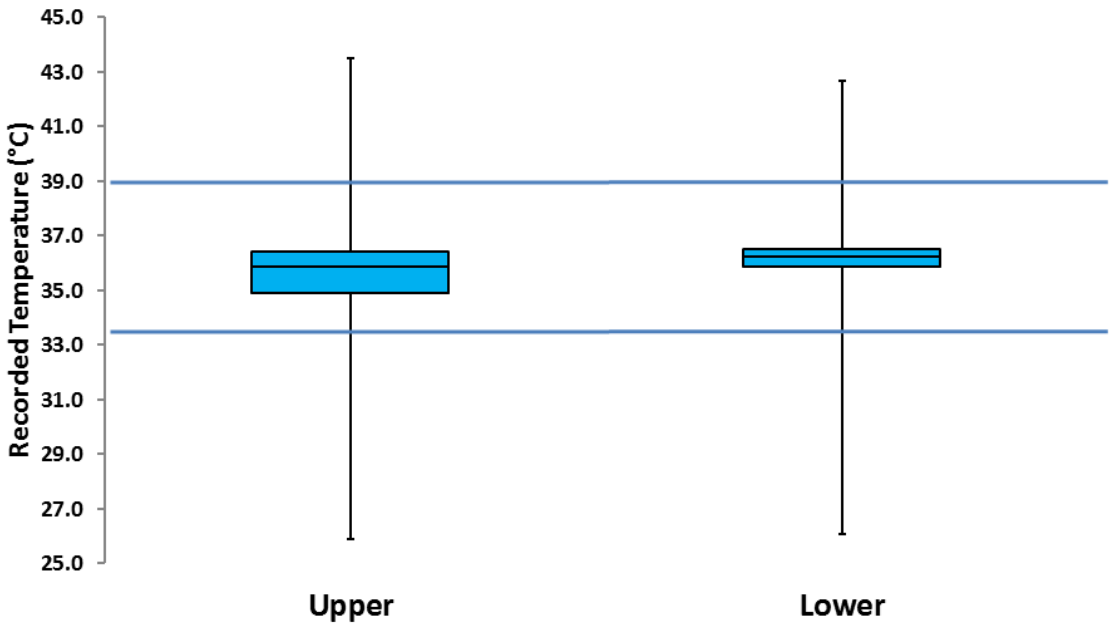
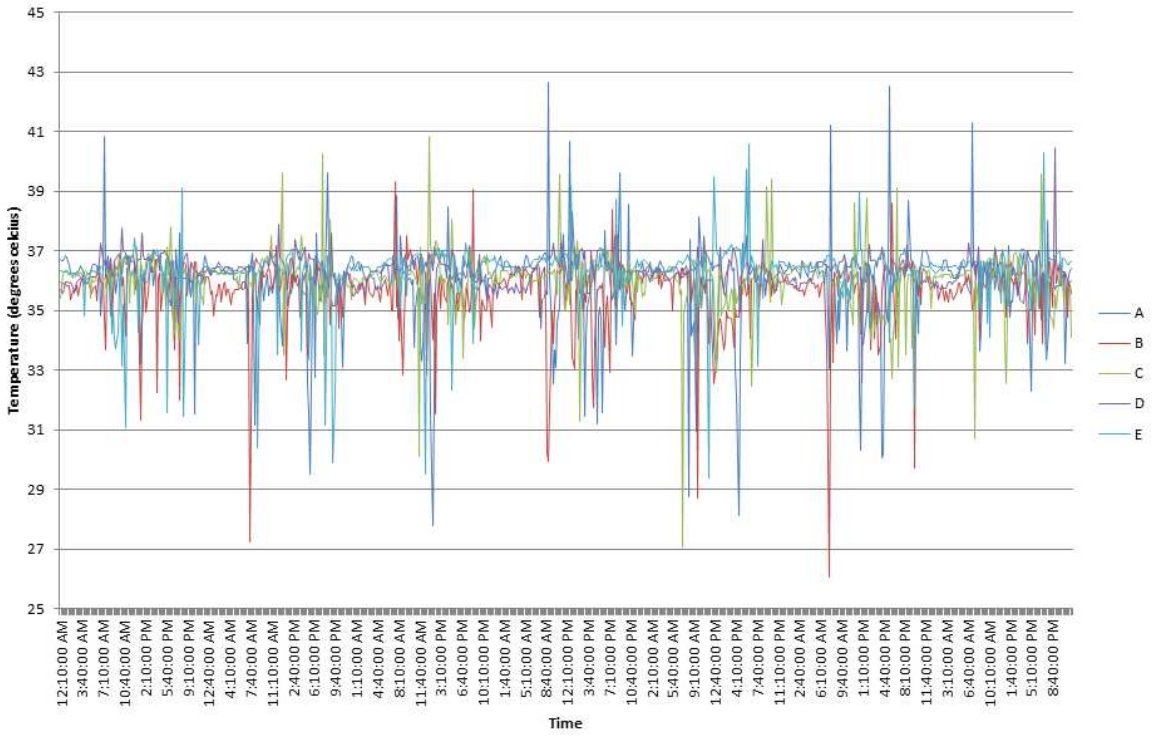


Figure 5 – The variation in intraoral temperatures for the 5 participants, over the 7-day period measured by sensors located in the lower buccal sulcus



Tables:

Table 1 - Descriptive statistics for the mean daily microsensor recorded wear-times in the 5 participants for the sensors placed in the upper palate and lower buccal sulcus, over 7 days.

Participant	Upper Palatal			Lower Buccal		
	Mean	SD	95% CI	Mean	SD	95% CI
A	22.7	0.93	22.0-23.4	22.5	1.52	21.4-23.6
B	23.5	0.60	23.1-23.9	24.0	0.09	23.9-24
C	22.5	1.75	21.2-23.8	23.6	0.24	23.5-23.8
D	22.0	1.81	20.7-23.3	23.0	0.92	22.3-23.6
E	23.2	0.75	22.6-23.7	23.2	0.75	22.6-23.7

Table 2 - Descriptive statistics for the differences between the microsensor recorded wear time and the actual wear time, when placed in the upper palate and lower buccal regions, over 7 days (n = 5).

Sensor	Mean Difference (hours)	SD of mean difference (hours)	95% CI of Differences		P (1-tailed)
			Lower	Upper	
Upper	-8.7	4.1	-12.3	-5.0	0.005
Lower	-5.3	4.0	-8.8	-1.7	0.022

Table 3 – Accuracy of recording intraoral wear according to different temperature ranges for 5 participants

Temperature range for sensor to detect wear (°C)	Location of sensor	Accuracy of wear-time recording for each participant (%)				
		A	B	C	D	E
33.5 to 39	Upper palatal	93.5	93.5	88.5	82.7	94.3
	Lower buccal	93.8	99.6	96.4	97.3	96.7
32 to 40	Upper palatal	97.8	97.8	94.9	95.5	97.0
	Lower buccal	96.9	99.9	98.5	99.1	98.4
30 to 42	Upper palatal	99.4	99.4	98.8	99.1	99.3
	Lower buccal	99.1	100	99.3	99.9	99.6