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Cervical headgear effectiveness in distalizing molars in relation to patient compliance.

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Ειδίκευση: **Ορθοδοντική**

Τίτλος Μεταπτυχιακής Διπλωματικής Εργασίας

Η αποτελεσματικότητα του εξωστοματικού αυχενικής έλξης στην άπω μετακίνηση γομφίων σε σχέση με τη συνεργασία των ασθενών.

Ονοματεπώνυμο μεταπτυχιακού/ής φοιτητή/τριας
Γρατσία Σοφία
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Βασταρδή Ελένη, Αναπληρώτρια Καθηγήτρια, Επιβλέπων/ουσα

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Το ερευνητικό πρωτόκολλο της παρούσας μελέτης, με αριθμό πρωτοκόλλου 329/23-02-17, εγκρίθηκε από την Επιτροπή Δεοντολογίας Έρευνας του Τμήματος Οδοντιατρικής ΕΚΠΑ στη συνεδρίαση στις 23/02/2017.

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Περίληψη

Τα εξωστοματικά μηχανήματα αυχενικής έλξης χρησιμοποιούνται ευρύτατα στην ορθοδοντική πράξη, ιδίως για τη θεραπεία ασθενών με ΙΙη Τάξη κατά Angle, με σκοπό τον περιορισμό της αύξησης της άνω γνάθου, καθώς και την προς τα άπω μετακίνηση των πρώτων μόνιμων γομφίων της άνω γνάθου. Ποικίλοι παράγοντες αναφέρεται ότι επηρεάζουν το επίπεδο συνεργασίας του ασθενούς, όπως η σχέση του με το θεράποντα, η διασαφήνιση των στόχων της θεραπείας από τον ορθοδοντικό και η κατανόησή τους από τον ασθενή, η ηλικία και το φύλο του ασθενούς. Η έλλειψη μιας αντικειμενικής μεθόδου μέτρησης των πραγματικών ωρών χρήσης του εξωστοματικού μηχανήματος καθιστά αδύνατη την αξιολόγηση της αποτελεσματικότητάς του σε σχέση με τις ώρες που εφαρμόζεται ημερησίως. Στο παρελθόν, ποικίλες μέθοδοι και συσκευές χρησιμοποιήθηκαν σε μια προσπάθεια προσδιορισμού και αντικειμενικής εκτίμησης του επιπέδου συνεργασίας των ασθενών, παρ’ όλα αυτά, το αυξημένο μέγεθος των συσκευών αυτών καθώς και η μειωμένη ακρίβεια και αξιοπιστία των μετρήσεων που παρείχαν, οδήγησαν στο να απορριφθούν από κλινική πράξη και έρευνα. Πρόσφατες έρευνες οδήγησαν στην κατασκευή ηλεκτρονικών μικροαισθητήρων, οι οποίοι καταγράφουν θερμοκρασία περιβάλλοντος (στόματος, δωματίου κλπ.) και παρέχουν έτσι τη δυνατότητα μέτρησης των πραγματικών ωρών χρήσης του μηχανήματος από τον ασθενή. Ειδικά, ο μικροαισθητήρας Theramon®, έχει αποδειχθεί ότι πλεονεκτεί σε σχέση με άλλους μικροαισθητήρες που υπάρχουν στην αγορά λόγω του μικρότερου μεγέθους του και μεγαλύτερης συχνότητας των μετρήσεων που καταγράφει. Έτσι με τη χρήση του μικροαισθητήρα Theramon® καθίσταται πλέον δυνατή η αντικειμενική μέτρηση και αξιολόγηση της συνεργασίας των ασθενών, αναφορικά με τις ημερήσιες ώρες εφαρμογής του εξωστοματικού μηχανήματος. Πρωταρχικός σκοπός αυτής της κλινικής μελέτης ήταν η μέτρηση της αποτελεσματικότητας του εξωστοματικού μηχανήματος αυχενικής έλξης για την προς τα άπω μετακίνηση των πρώτων μόνιμων γομφίων της άνω γνάθου ανάλογα με τις πραγματικές ώρες χρήσης του μηχανήματος από τον ασθενή.

Το δείγμα της έρευνας αυτής αποτέλεσαν οι ασθενείς που προσέρχονταν για ορθοδοντική θεραπεία στη μεταπτυχιακή κλινική του εργαστηρίου Ορθοδοντικής του Πανεπιστημίου Αθηνών και έχρηζαν θεραπείας με εξωστοματικό μηχάνημα αυχενικής έλξης. Τα κριτήρια επιλογής ασθενών ήταν να είναι ασθενείς Καυκάσιας φυλής οι οποίοι δεν έχουν λάβει ορθοδοντική θεραπεία στο παρελθόν, δεν παρουσιάζουν σύνδρομο ή/και σχιστίες, είναι

ηλικίας 9-15 ετών, έχουν συγκλεισιακή ανωμαλία ΙΙης Τάξης κατά Angle (σχέση πρώτων μόνιμων γομφίων άνω και κάτω γνάθου ≥ φύμα-φύμα) και το σχέδιο θεραπείας τους περιελάβανε την εφαρμογή εξωστοματικού μηχανήματος αυχενικής έλξης χωρίς άλλα ακίνητα ή κινητά ορθοδοντικά μηχανήματα που θα ήταν δυνατό να μεταβάλλουν τη θέση των πρώτων μόνιμων γομφίων της άνω γνάθου, πριν και κατά τη διάρκεια της περιόδου παρακολούθησης. Στους ασθενείς δόθηκε εντολή να φοράνε το εξωστοματικό τους για τουλάχιστον 12ώρες ημερησίως και ένας μικροαισθητήρας TheraMon® τοποθετήθηκε στην αυχενική ταινία του μηχανήματος με σκοπό την αντικειμενική καταγραφή των ωρών χρήσης του μηχανήματος. Για να μετρήσουμε την μετακίνηση των άνω 1ων μόνιμων γομφίων χρησιμοποιήσαμε και αλληλεπιθέσαμε τα τρισδιάστατα ψηφιακά εκμαγεία της άνω γνάθου που δημιουργήθηκαν με τον ενδοστοματικό σαρωτή (3D scanner) iTero πριν και μετά τη χρήση του εξωστοματικού μηχανήματος. Η αλληλεπίθεση και ο υπολογισμός της μετατόπισης και της στροφής των γομφίων κατά μήκος και γύρω από τους άξονες X,Y,Z έγινε με τη βοήθεια του λογισμικού προγράμματος Viewbox4 (dHal Software, Kifissia, Greece).

Η αξιοπιστία του ίδιου του εξεταστή αλλά και μεταξύ των εξεταστών (intra- & inter-examiner reliability) αξιολογήθηκε με την ανάλυση Bland Altman. Ένα γραμμικό μοντέλο (General Linear Model) χρησιμοποιήθηκε για να αξιολογήσει την επίδραση της κάθε ανεξάρτητης μεταβλητής (φύλο, ηλικία, στάδιο κατά Nolla, κατάσταση ανατολής 2ου άνω γομφίου, ώρες χρήσης της συσκευής) στην άπω μετακίνηση του γομφίου στο οπισθο-πρόσθιο επίπεδο καθώς και την άπω απόκλιση και την άπω στροφή του γύρω από τον κατακόρυφο άξονα του δοντιού. Το επίπεδο σημαντικότητας ορίστηκε σε α=0.05 και όλες οι δοκιμές εκτελέστηκαν με το IBM SPSS® Statistics έκδοση 26.

Η μέση διάρκεια θεραπείας ήταν 130 ημέρες και ο μέσος συνολικός χρόνος χρήσης του μηχανήματος 55 ημέρες, που σημαίνει 10.1ώρες ανά ημέρα. Κατά την διάρκεια αυτής της περιόδου, η άπω μετακίνηση του γομφίου ήταν κατά μέσο όρο 1.75χιλ αλλά με μεγάλη μεταβλητότητα, με ελάχιστο λιγότερο από 0.2χιλ και μέγιστο περισσότερο από 4.5χιλ. Η άπω απόκλιση και άπω στροφή ήταν κατά μέσο όρο 5 μοίρες. Η συνολική διάρκεια εφαρμογής του εξωστοματικού είχε ισχυρή συσχέτιση με την άπω μετακίνηση του γομφίου (r-squared 0.32, $P < 0.002$), την άπω απόκλιση (r-squared 0.27, $P < 0.01$) και την άπω στροφή του (r-squared 0.20, $P < 0.05$).

Τα αποτελέσματα υποδεικνύουν ότι η άπω μετακίνηση του γομφίου επηρεάζεται ισχυρά από τις συνολικές ώρες χρήσης του μηχανήματος και ο παράγοντας της συνεργασίας είναι καθοριστικός για την επιλογή του κατάλληλου σχεδίου θεραπείας και την επίτευξη κλινικού αποτελέσματος. Η χρήση του μηχανήματος ανά ημέρα ήταν ασθενέστερος παράγοντας συσχέτισης όσον αφορά στην επίτευξη του θεραπευτικού αποτελέσματος.

Λέξεις Κλειδιά: Εξωστοματικό, Άπω μετακίνηση, Συνεργασία.

Abstract

Objectives: The purpose of this study was to measure the effectiveness of the cervical headgear for distalizing first permanent maxillary molars in relation to hours of use.

Methods: This was a one-centre, prospective, clinical study, conducted at the Orthodontic Department of the National and Kapodistrian University of Athens. Participants (N=26; 17 females, 9 males) were patients with no history of orthodontic treatment, no syndromes or clefts, and Angle's Class II malocclusion where the treatment plan included a cervical headgear. They were instructed to wear the appliance for at least 12 hours per day. A TheraMon® microsensor was embedded in the headgear's strap to objectively measure wear-time. To measure tooth movement, pre- and post-treatment digital models were superimposed, using the palate as a reference area; translation and rotation were measured along three axes. Superimposition and movement measurements were made with the Viewbox 4 software.

Results: Average treatment time and headgear wear was 130 days and 55 days respectively, i.e., 10.1 hours/day. During this period, distal movement averaged 1.75 mm with high variability (min 0.2 mm, max 4.5 mm). Distal tipping and rotation had an average of approximately 5 degrees. Cumulative headgear wear was significantly correlated with distal movement (r-squared 0.32, $P < 0.002$), distal tipping (r-squared 0.27, $P < 0.01$) and distal rotation around the long axis of the tooth (r-squared 0.20, $P < 0.05$).

Conclusion: Compliance is critical for having a successful clinical outcome. Distalization of the molar with a cervical headgear is correlated with the cumulative hours of appliance use, with hours per day being a weaker predictor.

Keywords: Headgear, Distalization, Compliance.

Introduction

Headgear appliances are well known in orthodontic practice, especially for treatment of patients with Class II malocclusion, to limit the growth of the maxilla and distalize the maxillary first molars. (1) A minimum wear of 12 hours per day is considered necessary for the desired dentoalveolar and/or skeletal changes, (2,3) so patient cooperation is essential. (4)

However, several factors affect cooperation, such as the patient-doctor relationship, the orthodontist's clarification of treatment goals, patient's understanding, age, and sex. (5-11) Patients' reports about appliance wear-time do not seem to be accurate, nor is the doctor's subjective evaluation, (9,12,13) making it hard to assess headgear effectiveness. In the prospective clinical study of Ghislanzoni et al. (14), compliance was measured during an 8-month observation period by a temperature-sensitive recording device. On the days that the appliance was used, wear time was on average 8.7 hours, instead of the 12 hours prescribed. However, the appliance was not used at all for 30 per cent of the total period, dropping the average compliance to 6.4 hours per day. In another recent systematic review, Al-Moghrabi et al. (15) reported that, for removable appliances in general, there was a substantial difference of 5 hours per day between wear-time reported by the patient and that objectively measured by the orthodontist. The average headgear use reported by this review was 5.8 hours per day. Nahajowski et al. (16), in their systematic review, also mentioned that, irrespective of whether the appliance was extra- or intra-oral, the average wear time was shorter than the prescribed, although patients with intraoral appliances had better time scores.

A variety of methods and devices have been used to determine and objectively assess the level of patient cooperation. Electronic microsensors, such as the Smart Retainer® and Theramon® system, when incorporated in removable appliances, record ambient temperature, and thus enable accurate measurement of appliance usage. The Theramon® microsensor is reported to have an advantage over the Smart Retainer®, due to its smaller size and higher rate of recorded measurements. (17,18) The use of the above devices makes it possible to objectively evaluate patient cooperation, find factors that potentially affect patient compliance to instructions, as well as measure the effectiveness of the appliance.

The primary purpose of this clinical study was to measure the effectiveness of the cervical headgear for distalization of the first permanent maxillary molars during the correction of Angle's Class II malocclusion, in relation to hours of usage of the appliance.

Methods and Materials

This was a one-centre, prospective, clinical study, carried out at the Orthodontic Department of the National and Kapodistrian University of Athens.

The sample included patients who attended the Postgraduate Orthodontic clinic and whose treatment plan included the use of a cervical headgear appliance, without the need for other fixed or removable orthodontic appliances that could affect the position of the first maxillary molars during the study period. The patients also fulfilled the following inclusion criteria: no prior orthodontic treatment, no syndromes, or clefts, aged 9-17 years, with Angle Class II malocclusion (first permanent maxillary and mandibular molar relation ≥ flush terminal).

Patients fulfilling the inclusion criteria were consecutively recruited between January and May 2019 and data were collected between January and September 2019. Patients and their guardians were informed orally and in writing about the research and their written consent was obtained. However, they were not informed about the incorporated microsensor in the headgear strap until the end of the study. For blinding, one researcher (SG), was responsible for collecting, anonymizing, and coding the data, which were statistically analysed by another researcher (DH).

To estimate the required sample size, we conducted a power analysis using G*Power software (version 3.1.9.6; Franz Faul, Kiel University, Germany). (19) Our primary objective was to determine the regression between time of use and molar distalization, so we selected the “t test: Linear Regression (size of slope, one group)” test, setting alpha to 0.05 and power to 0.80. The expected distal movement of the maxillary molar shows wide variation (3,20,21), so we estimated an average value of 2 mm and standard deviation of 1 mm. The standard deviation of patient compliance in hours/day was estimated at 2.5, based on previous data, and the slope of the regression to be detected was set to 0.2, corresponding to 2.4 mm distal movement per 12 hours per day of headgear wear. Total sample size was computed at 26 patients.

Patients were instructed to wear the cervical headgear appliance for at least 12 hours per day, a time-period considered necessary for the desired dentoalveolar and/or skeletal changes. (2,3) The headgear was adjusted to exert a force of 4.4-4.9N and the long outer bows were not angulated. (2,3) Embedded in the headgear's strap, the Theramon® microsensor (MC Technology GmbH, Hargelsberg, Austria) was used to objectively measure wear-time. The microsensor recorded the temperature every 15 minutes. (22) Data collected were downloaded via the reading station to the TheraMon Viewer® for further analysis. The iTero intraoral 3D scanner (Align Technologies Inc., Milpitas, CA, USA) was used for intraoral scanning and for creating 3D digital records of the upper arch. For analysis and superimposition of the pre- and post-treatment 3D digital models we used the Viewbox 4 software (dHal Software, Kifissia, Greece).

At the first visit, orthodontic bands were placed on the maxillary first molars and an intraoral scan of the upper dental arch and palate was performed. Afterwards, the appliance was adjusted, and the patient was instructed to use it for at least 12 hours per day, without being aware of the existence of the embedded microsensor. The patient was also asked to record in a calendar the days and hours of usage of the appliance. During re-examinations, the relationship between the first permanent molars was examined, the calendar was reviewed and the measurements from the Theramon® microsensor were extracted. Duration of participation in the study varied, depending on when a Class I molar relationship was achieved or whether it was deemed necessary to proceed to the next stage of treatment by adding mechanisms that might affect molar response. At the last evaluation, a final intraoral scan of the upper arch was performed. The initial and final 3D models of the upper arch were processed with the Viewbox4 software to evaluate the 3D movement of the first permanent maxillary molars.

Measurements

The hours of use were defined as the hours during which the microsensor recorded elevated temperatures, the range of which was individualized. (9,23,24) From the collected temperature recordings we created a temperature curve for each patient. On placement of the headgear, the temperature increased, to return to room temperature levels on removal. (Figure 1) Depending on the time of year (different environmental temperature), the temperature diagram had a different shape and the lowest and highest peaks changed. (Figure 2) Based on findings from the diagrams, the threshold temperature classifying whether the headgear was worn was set to the average temperature of the minimum of the high peaks and the maximum of the low peaks. (Figure 2)

Pre- and post-treatment 3D models were superimposed using the palate as a reference area. (Figure 3) The reference area included the palatal rugae and palatal slope, except for a 2.5 mm border along the gingival margins of the teeth and did not extend distally beyond the line joining the distal surfaces of the contralateral first premolars or the deciduous first molars, depending on the phase of the dentition. (25)

Superimposition measurements were made with the software Viewbox 4. At first, we superimposed the final 3D model to the initial using the abovementioned reference area of the palate. As a second step, we isolated the first permanent molar of the initial digital cast as an independent object and set it at an axis system (x/sagittal axis, y/anteroposterior axis, z/vertical axis) with the center of the molar being the origin (0,0,0). Afterwards, we set the final position of the molar (1st permanent molar of the final 3D model) as a reference area and superimposed the isolated molar to this area. The new coordinates of the isolated molar represented the amount of movement from the initial to the final position. The movement was calculated for translation and rotation along the three axes. (Figure 4, 5) Positive values were considered the distal, buccal and extrusion movement of the molar and the distal rotation along z axis, the distal rotation along the x axis and buccal rotation along the y axis. These measurements were made on both sides, separately for each molar. Also, these measurements were made independently by two examiners (SG and DH) who were blinded to the hours of appliance use, as mentioned in the calendars or in the Theramon® recordings. Each of the researchers repeated the measurements twice.

The Nolla stage of development of the second maxillary molars was recorded from available panoramic radiographs. (26) Eruption status was noted from the dental casts and radiographs and recorded as a binary variable (erupted / not erupted). No eruption or, clinically and radiographically, no contact point between the first and second molars was recorded as ‘‘Not erupted’’ in eruption status. Presence in the oral cavity, with an interproximal contact point between the first and second molars, both clinically and radiographically, was recorded as ‘‘erupted” in the eruption status. (27)

Statistical Analysis

Movement of the molar was calculated for translation and rotation along the 3 axes (Y-position, X-position, Z-position and Y-rotation, X-rotation, Z-rotation), and the measurements were registered as Ypos, Xpos, Zpos, Yrot, Xrot and Zrot accordingly. Treatment time and cumulative headgear wear were entered in hours (TotalTime, HGwear), and hours per day (Hours/Day) were computed from these by simple reduction to a 24-hour basis. (Table 1)

Descriptive statistics were computed for all variables. Inter- and intra-observer error was evaluated using the Bland-Altman method. The molar movements were compared between the right and left sides using the Bland-Altman method and paired t-tests. General Linear Models were used to assess the effect of the independent variables (sex, age, Nolla stage, eruption phase of second molars, and each of HGwear and Hours/Day) on molar distalization, as measured by Ypos, Xrot and Zrot. We used these 3 measurements as the most representative and clinically relevant for the molar's distal movement. All tests were performed using SPSS 28 (IBM ® SPSS® Statistics 28.0, Chicago, Illinois, USA) with level of statistical significance set at 0.05. Plots were drawn using Microsoft Excel and PowerPoint (Microsoft®, Redmond, Washington, USA).

Results

Initially, 28 patients who matched the inclusion criteria were recruited in the study. After excluding two patients because of missing data and withdrawal from treatment, analysis was based on 26 patients (17 females, 9 males).

Inter- and intra-observer agreement was evaluated by the Bland-Altman method. No statistically significant bias was found, except for Ypos, right side, for observer 2. Random error was small; the 95% Limits of Agreement (LoA) for Ypos were below 0.3 mm and the LoA for angular measurements were below 0.6 degrees. The Bland-Altman plots showed that the differences were uniform across the range of measurements. Since no significant differences between observers, or between the 1st and 2nd measurement of each observer were found (Table 2), we averaged the 4 measurements and used the averages for all subsequent analyses.

Differences between the left and right sides were tested using the Bland-Altman method of agreement. The largest difference between the two sides in molar distalization was 2.1 mm and the largest angular difference was almost 9 degrees. Although there was a trend for the right molar to distalize more than the left, no statistically significant bias was found (Table 3). The Bland-Altman plots showed that the differences were uniform across the range of measurements.

Since no statistically significant differences were found between the right and left sides, these were averaged, and the averages were used for further analysis. Descriptive statistics are shown in Table 4. Average treatment time was 130 days and average headgear wear was 55 days, i.e., 10.1 hours/day. During this period, distal movement averaged 1.75 mm but showed high variability, with a minimum of less than 0.2 mm and a maximum of over 4.5 mm. Distal tipping and rotation had an average of approximately 5 degrees. Eruption status of the second molar was almost equally split in the sample. Nolla development stage had an average of 8.4, corresponding to completion of at least two thirds of the root. Thirteen second molars had a status of "erupted" on the left side and thirteen on the right side. There were four patients who had a different 2^{nd} molar status between the two sides and three patients with a different Nolla stage between the two sides.

Bivariate correlations were computed for all variables (Table 5). Ypos, Xrot and Zrot were correlated mainly with HGwear and less with TotalTime and Hours/Day. No significant correlation was found with Age, Sex or second molar development (Nolla) and eruption status (Mstatus). Ypos was significantly related to Xrot but not to Zrot. Simple bivariate linear regression plots of Ypos, Xrot, Zrot against HGwear and Hours/Day are shown in Figures 6-11 and relevant results are reported in Table 6.

A General Linear Model was run for each of the dependent variables (Ypos, Xrot, Zrot) and the variables Age, Sex, Nolla, Mstatus and HGwear (TotalDays and Hours/Day were not included due to high collinearity). The only significant parameter was HGwear. Corresponding models substituting Hours/Day in place of HGwear did not reach statistical significance (results not shown).

Discussion

The present study objectively evaluated patient compliance with the headgear appliance and measured the movement of the first maxillary molars in relation to appliance wear-time. Our results agree with other studies' findings, that most patients do not follow the wear-time instructions and wear-time is suboptimal. (11,12,14-16,28,29) In this study, the TheraMon® microsensor was selected as the most appropriate temperature-sensitive recording device to detect daily appliance wear because it has been acknowledged as a reliable and accurate time-measurement device. (9,17,22-24) In addition, the Theramon® microsensor is of a manageable size and easy to incorporate in the headgear strap without the patient being aware. A calendar log, where patients recorded their daily headgear use, was also used. Unfortunately, the logs contained incomplete data so could not be used to detect differences between the objectively measured wear time and the calendar recorded one. The literature reports many benefits from using self-monitoring techniques. (30) Cureton et al. (31) mention that patients who keep a headgear calendar meet the prescribed wear time more than those who are not self-monitored (7.9 hours compared to 5.3 hours). All age groups in that study, except for the >16-year-olds, wore their headgear more when they used a calendar for self-monitoring. In the same study, although there was a high degree of correlation ($r^2 = 0.60$) between the calendar recorded hours and the actual hours of headgear wear in the calendar group, there was no significant correlation ($r^2 = 0.02$) between the hours reported to the attending doctor, and the objectively measured ones, in the group without the calendar. (31)

As already mentioned, an important factor in reaching treatment goals with removable appliances is patient cooperation. (9,11,15,32) Age and sex represent two important parameters when it comes to treatment depending on patient compliance. Several studies report that females are more compliant, (4,5,7,11,33) but others show no correlation between sex and compliance (6,8,13,24,34-37) and one even shows that cooperation was better in boys than in girls, without, however a large difference. (28) As to age, some studies show no substantial impact on patient cooperation, (6,24,34,35,37) but others conclude that pre-adolescent patients are most of the times more compliant than when they go into puberty, when compliance usually drops because of teenagers' psychosocial and behaviour issues. (8-10) Parental control may play a significant role in this age-related difference. (6)

To calculate tooth movement, pre- and post-treatment 3D models were superimposed using the palate as a reference area. Studies that have examined the suitability of the palatal rugae area as a reference for 3D superimposition have found it to be stable for measuring changes in tooth position, especially mesiodistal ones. (38-42) However, during adolescence, changes in rugal dimensions may occur because of differential growth of the alveolar and basal bone. (43) In our study, the observation period was short, and it was safe to use the palate as a reference area.

A limitation of studies which investigate cervical headgear effectiveness is the difficulty to measure the exact force applied to the molars by the appliance throughout the day. Talvitie et al. (44,45), by continuously measuring force magnitude, concluded that there is substantial variability in force levels during wear. They also report that force fluctuations of about 1.5N did not have a clinically significant effect on treatment results. (44) Variation of headgear force is associated with changes in head posture during sleep. (46,47) For example, a downward tilt of the head reduces headgear force magnitude (46) potentially leading patients to intentionally alter their head position to avoid neck pressure. (48)

The rate of tooth movement shows high individual variation, depending on bone density, bone metabolism, and turnover in the periodontal ligament, and not exclusively on force magnitude. (49-51) This agrees with the concept of "slow and fast movers" (49,52) and with the observation that age is also a determinant factor, with subjects under 16 years old showing higher amount of experimentally stimulated tooth movement as compared to subjects over 16 years old. (52,53) High inter-individual variation was clearly evident in our results, especially between patients who had many cumulative hours of wear. For example, at 2000 hours, the minimum and maximum distal translation was approximately 1 and 4.5 mm, respectively (Figure 9). This difference could not be explained by the other factors that were included in the statistical model. Among those, we didn't find a correlation between the presence of second molars and the rate of movement of the first molars. Existing literature on this factor is conflicting, with some studies reporting that the presence of the second molars results in distalization at a slower pace (27,54), while others showing no such correlation. (55,56)

A noteworthy strength of this clinical trial was that the actual movement of the upper first molars with the cervical headgear was evaluated based on the actual wear-time, as objectively recorded, and not on the overall treatment period, the prescribed wear-time, or the patient-reported wear-time. We found an average distal molar movement of 1.8 mm over 4.3-months, within the range of 1 to 2 mm previously reported. (3,20,57)

Conclusion

Compliance is critical for a successful clinical outcome. Distalization of the molars using the headgear appliance is correlated with total hours of appliance use during treatment, with hours per day being a weaker predictor.

Conflict of interest

This research did not receive any grant from funding agencies in the public, commercial, or not-for-profit sectors.

Clinical Registration

This trial was not registered.

Ethics Approval

The study protocol was reviewed and approved by the Ethics Committee of the School of Dentistry, National and Kapodistrian University of Athens (Reference Protocol Number 329/23-02-17).

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Figures

Figure 1: Theramon data of a patient for a 10days period.

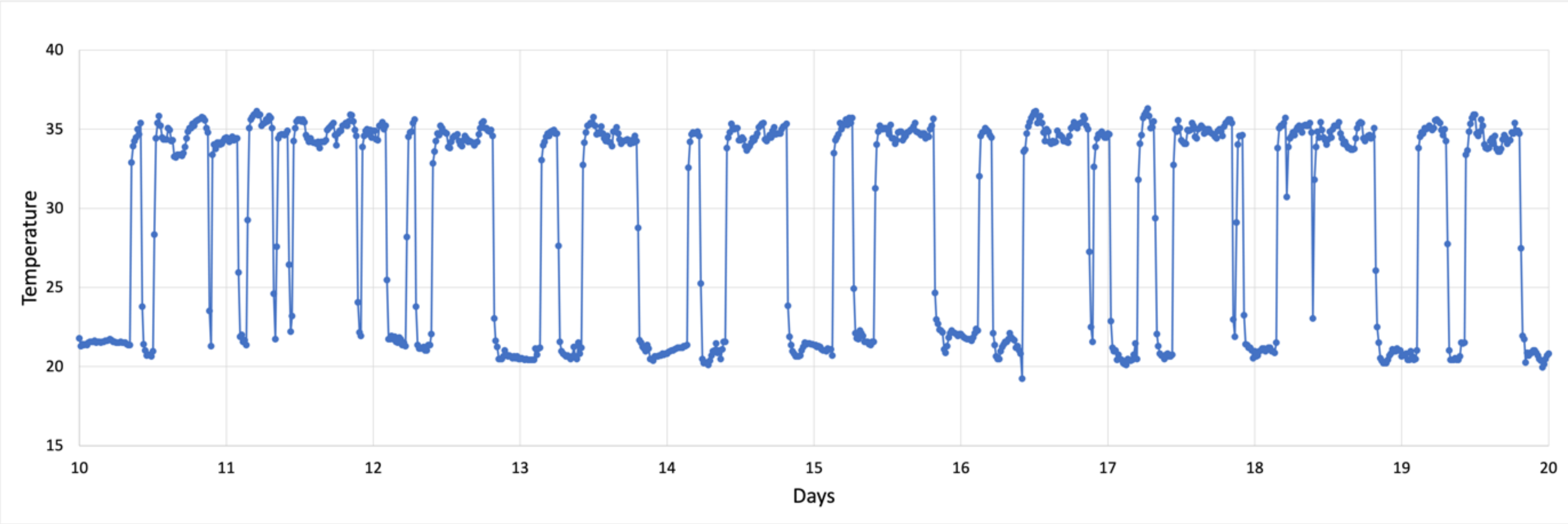


Figure 2: Theramon data of a patient for his 126-days observational period.

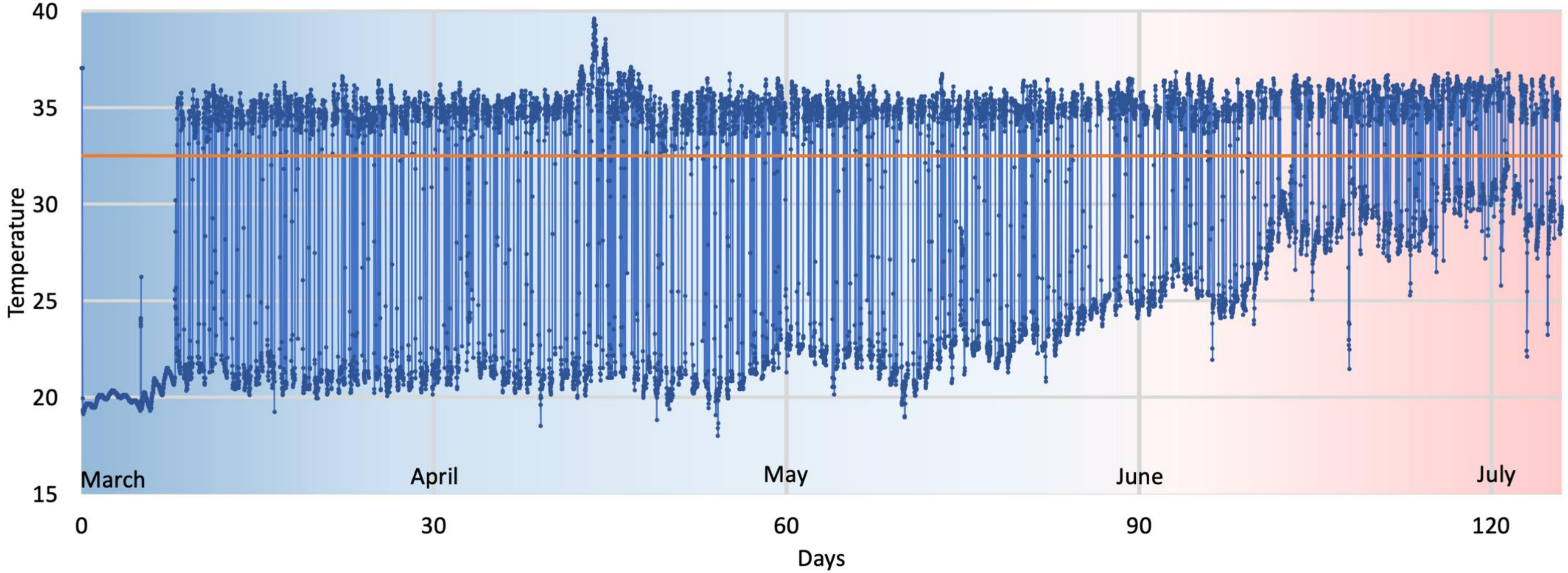


Figure 3: Pre-and post-treatment 3D models superimposition using the palate as a reference area.

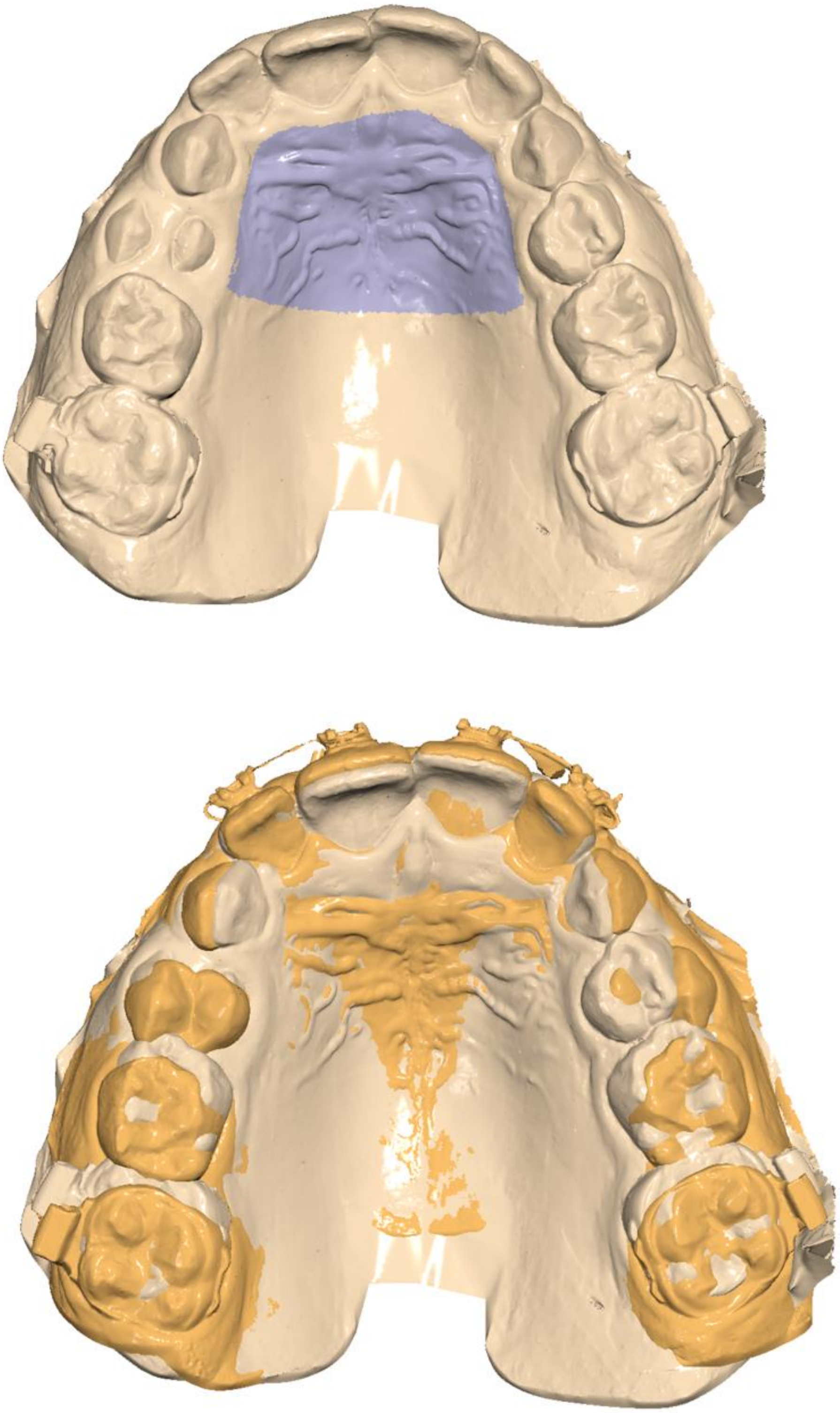
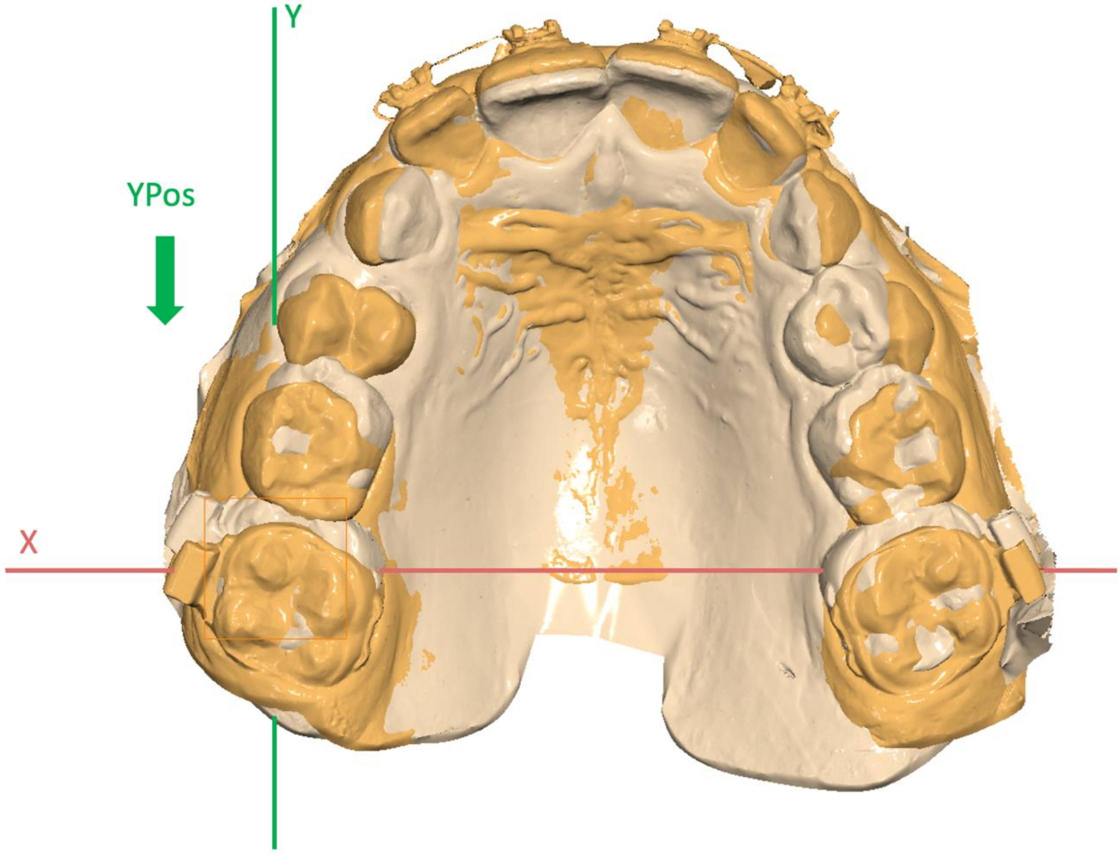
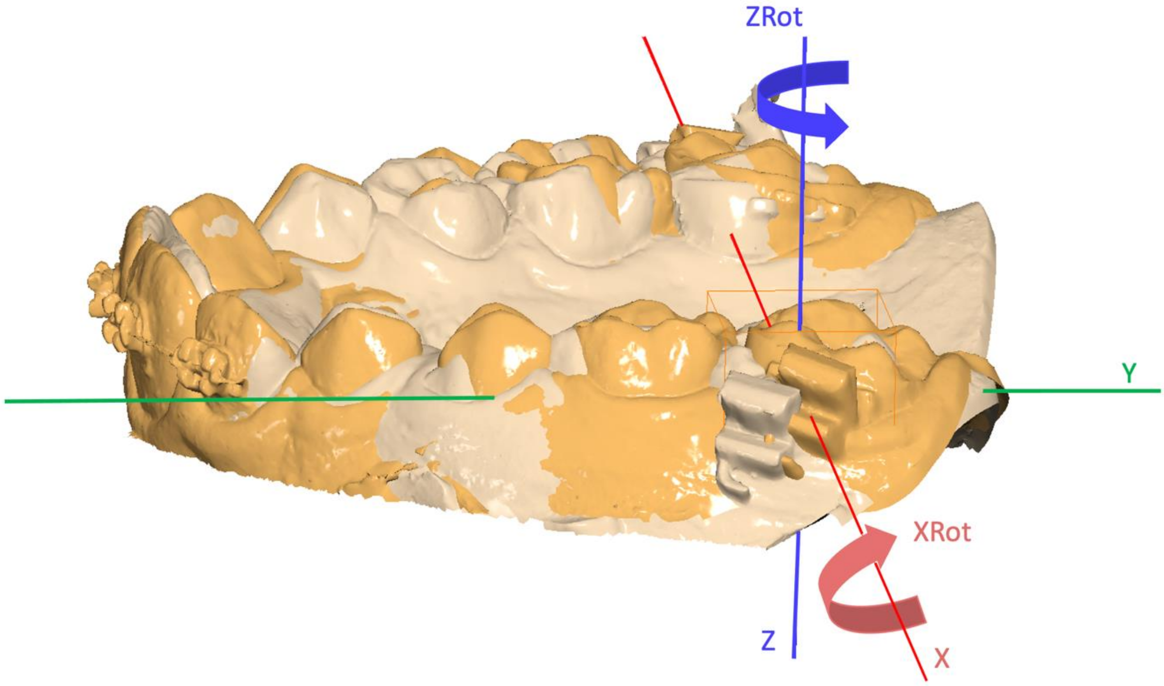
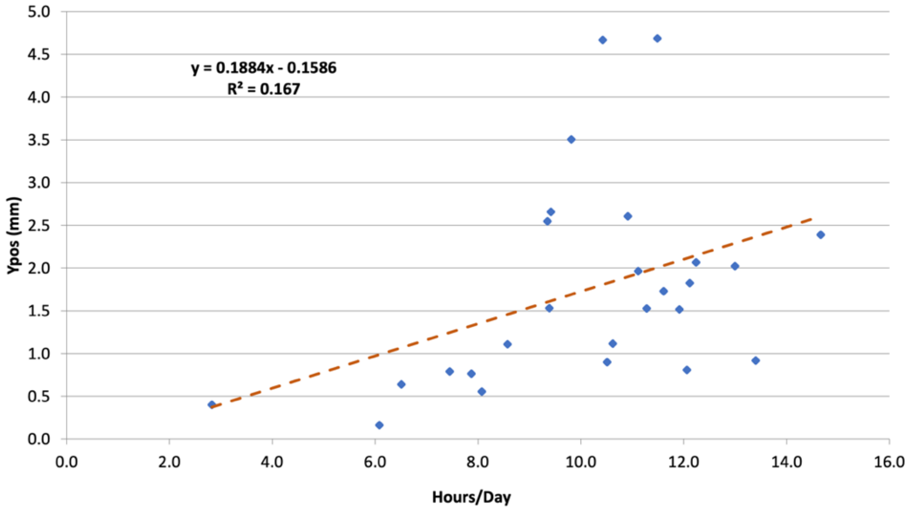


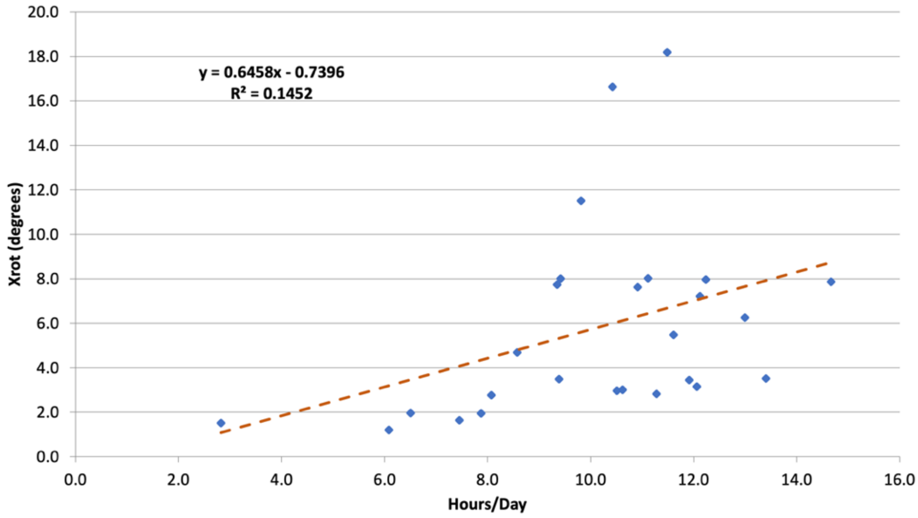
Figure 4,5: The movement of the molar to the final position was calculated for translation and rotation along the 3 axes.

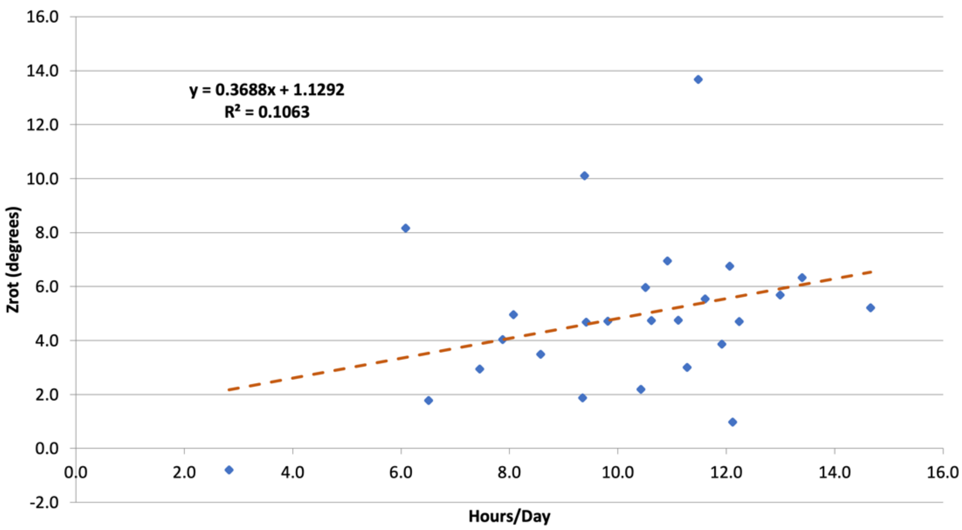


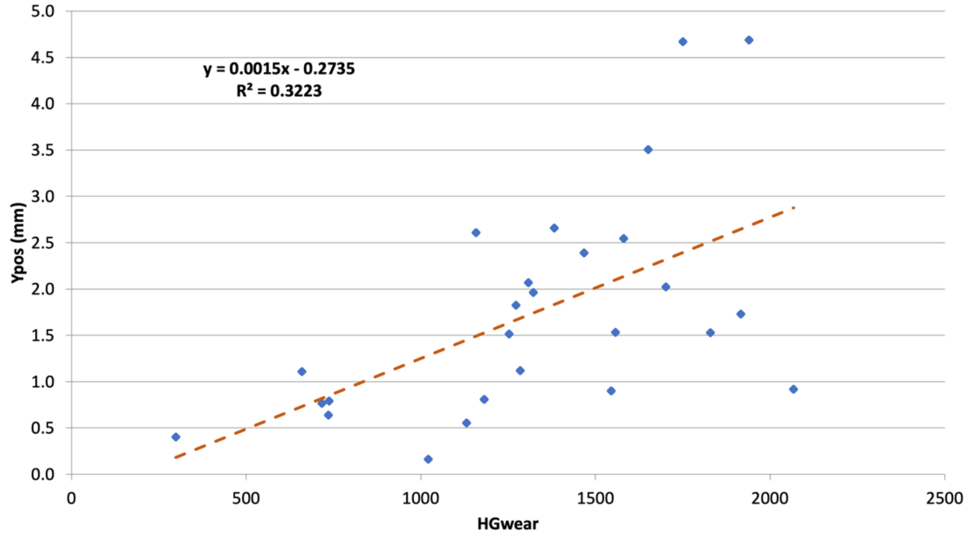


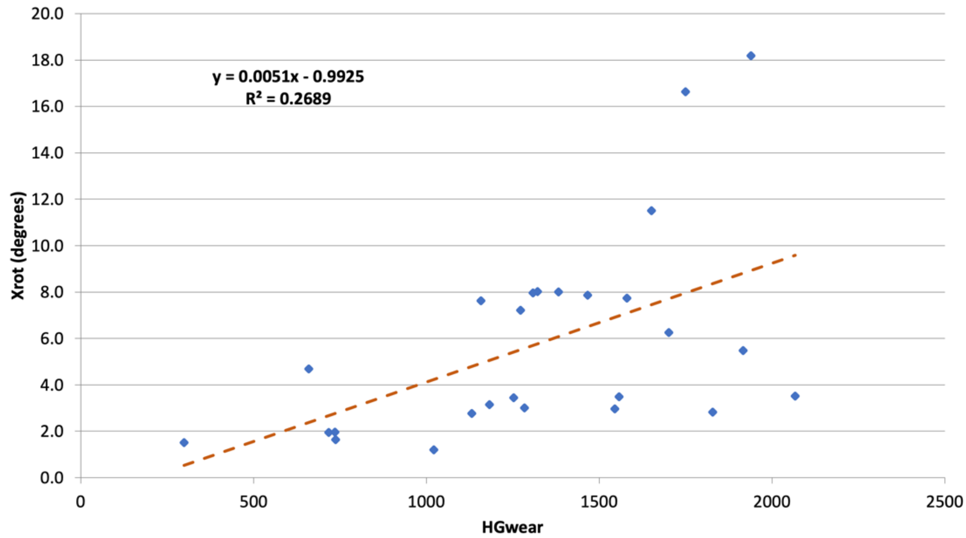
Figures 6-11: Regression plots of Hours/day and HGwear (hours) against the dependent variables.

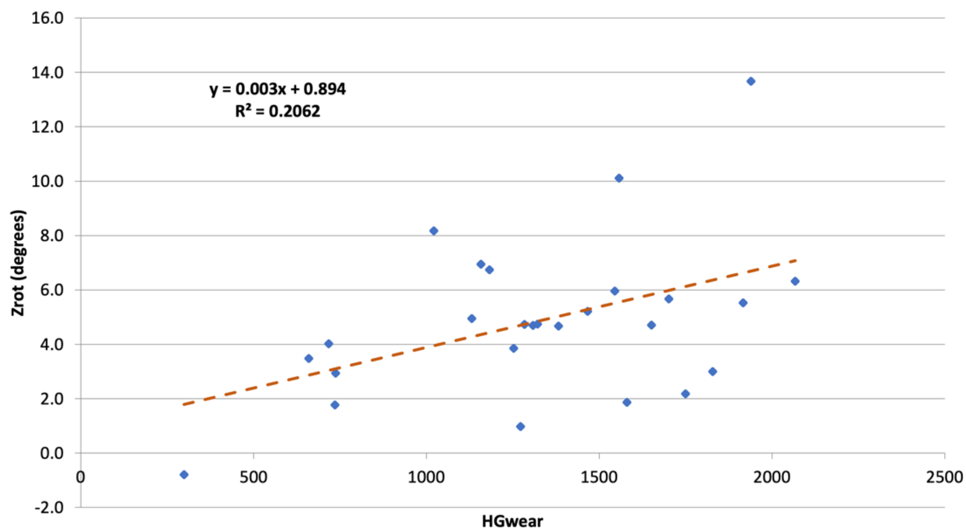







y = 0.0015x - 0.2735
R² = 0.3223
Ypos (mm)
HGwear
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
0
500
1000
1500
2000
2500


y = 0.0051x - 0.9925
R² = 0.2689
Xrot (degrees)
HGwear
0.0
2.0
4.0
6.0
8.0
10.0
12.0
14.0
16.0
18.0
20.0
0
500
1000
1500
2000
2500


y = 0.003x + 0.894
R² = 0.2062
Zrot (degrees)
HGwear
-2.0
0.0
2.0
4.0
6.0
8.0
10.0
12.0
14.0
16.0
0
500
1000
1500
2000
2500

Tables

Table 1: Variables of the study

Variable name	Description
Y axis	Sagittal axis – mesiodistal direction.
X axis	Transverse axis – buccolingual direction.
Z axis	Vertical axis – cervico-occlusal direction.
Ypos (mm)	Translation of molar crown in the mesiodistal direction. Positive values signify distal movement.
Xpos (mm)	Translation of molar crown in the buccolingual direction. Positive values signify buccal movement.
Zpos (mm)	Translation of molar crown in the cervico-occlusal direction. Positive values signify extrusion.
Yrot (degrees)	Rotation of molar crown around Y axis. Positive values signify buccal rotation of the crown.
Xrot (degrees)	Rotation of molar crown around X axis. Positive values signify distal tipping of the crown.
Zrot (degrees)	Rotation of molar crown around Z axis. Positive values signify distal rotation of the crown.
TotalTime (hours)	The total observational period for each patient.
HGwear (hours)	Cumulative hours of headgear wear.
Hours/Day	Hours of appliance use per day.
Nolla Stage	Nolla stage of second molar development.

Table 2: Results of Bland-Altman analysis for inter- and intra-observer agreement. Values in mm and degrees.

Variable	Mean of Differences	SD of Differences	t value	P	95% LoA
Intra-observer agreement, observer 1					
Ypos Right	0.027	0.109	1.265	0.2175	-0.187 to 0.242
Xrot Right	0.070	0.252	1.404	0.1725	-0.425 to 0.564
Zrot Right	-0.025	0.268	-0.471	0.6416	-0.551 to 0.501
Ypos Left	-0.032	0.131	-1.236	0.2278	-0.290 to 0.226
Xrot Left	-0.036	0.248	-0.736	0.4683	-0.521 to 0.450
Zrot Left	-0.000	0.186	-0.008	0.9933	-0.365 to 0.364
Intra-observer agreement, observer 2					
Ypos Right	0.041	0.080	2.601	*0.0154	-0.115 to 0.196
Xrot Right	-0.014	0.164	-0.443	0.6619	-0.337 to 0.308
Zrot Right	0.030	0.138	1.097	0.2832	-0.241 to 0.301
Ypos Left	-0.005	0.084	-0.293	0.7719	-0.170 to 0.160
Xrot Left	0.032	0.147	1.115	0.2755	-0.257 to 0.321
Zrot Left	0.027	0.097	1.408	0.1714	-0.163 to 0.217
Inter-observer agreement					
Ypos Right	-0.002	0.046	-0.236	0.8154	-0.093 to 0.089
Xrot Right	0.044	0.161	1.394	0.1756	-0.271 to 0.359
Zrot Right	-0.010	0.141	-0.367	0.7165	-0.286 to 0.266
Ypos Left	-0.011	0.068	-0.840	0.4090	-0.144 to 0.122
Xrot Left	-0.019	0.131	-0.724	0.4761	-0.275 to 0.238
Zrot Left	0.004	0.081	0.229	0.8208	-0.154 to 0.161

SD: Standard Deviation. LoA: Limits of Agreement. *P<0.05

Table 3: Results of Bland-Altman analysis for agreement between left and right sides. Values are in mm and degrees.

Variable	Mean of Differences	SD of Differences	t value	P	95% LoA
Ypos (mm)	0.328	0.961	1.742	0.0937	-1.555 to 2.212
Xrot (mm)	0.804	3.236	1.267	0.2169	-5.539 to 7.147
Zrot (mm)	0.344	3.844	0.456	0.6523	-7.191 to 7.879

SD: Standard Deviation. LoA: Limits of Agreement. *P<0.05

Table 4. Descriptive statistics for Ypos, Xrot, Zrot, HG-wear, total time, hours/day, age, and Nolla stage.

	Mean	SD	Median	Minimum	Maximum
Ypos (mm)	1.75	1.19	1.53	0.16	4.69
Xrot (mm)	5.79	4.36	4.10	1.20	18.18
Zrot (mm)	4.86	2.91	4.72	-0.79	13.68
HGwear (hours)	1325.6	442.6	1315.1	299.0	2067.0
TotalTime (hours)	3139.4	724.9	3022.6	1846.0	4056.0
Hours/Day	10.1	2.6	10.6	2.8	14.7
Age (years)	12.6	1.9	12.2	8.8	16.8
Nolla Stage (2nd molar)	8.4	1.0	8.8	6.5	10.0

Table 5. Bivariate Pearson correlation coefficients between all variables.

	Ypos	Xrot	Zrot	Age	Sex	Nolla	Mstatus	HGwear	TotalTime
Ypos									
Xrot	0.970**								
Zrot	0.255	0.282							
Age	-0.230	-0.305	-0.356						
Sex	0.005	0.050	-0.112	-0.035					
Nolla	-0.198	-0.294	-0.312	0.391*	-0.332				
Mstatus	-0.238	-0.330	-0.165	0.364	-0.352	0.837**			
HGwear	0.568**	0.519**	0.454*	-0.078	-0.224	-0.037	-0.077		
TotalTime	0.402*	0.360	0.368	-0.031	-0.267	0.264	0.098	0.710**	
Hours/Day	0.407*	0.379	0.328	-0.079	-0.142	-0.339	-0.184	0.725**	0.052

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table 6. Results of the General Linear Models for each of the 3 dependent variables.

Independent Variable: HGWear					
	Intercept	**Coefficient**	**F**	**P**	**R**
Ypos	-0.2554	0.0015	11.058	0.0028**	0.562
Xrot	-1.0014	0.0051	8.858	0.0066**	0.519
Zrot	0.8915	0.0030	6.225	0.0199*	0.454
Independent Variable: Hours/Day					
Ypos	-0.1337	0.1860	4.634	0.0416*	0.402
Xrot	-0.7162	0.6435	4.035	0.0560	0.379
Zrot	1.0988	0.3719	2.894	0.1018	0.328

* P<0.05, ** P<0.01

Raw Data

Regression analysis

Using SPSS 26.

Results of the General Linear Models for each of the 3 dependent variables.

Dependent Variable: YPos

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	Partial Eta Squared
Intercept	1.065	2.959	.360	.723	-5.107	7.237	.006
Age	-.090	.122	-.737	.470	-.345	.165	.026
HGwear	.002	.000	3.099	.006	.000	.003	.324
Nolla	.002	.372	.005	.996	-.775	.778	.000
[Sex=0]	-.217	.481	-.451	.657	-1.220	.786	.010
[Sex=1]	0[a]	.	.	.	.	.	.
Mstatus	-.285	.831	-.343	.735	-2.017	1.448	.006

a. This parameter is set to zero because it is redundant.

Dependent Variable: XRot

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	Partial Eta Squared
Intercept	7.094	10.803	.657	.519	-15.442	29.629	.021
Age	-.439	.447	-.983	.338	-1.371	.493	.046
HGwear	.005	.002	2.803	.011	.001	.009	.282
Nolla	-.171	1.359	-.126	.901	-3.006	2.664	.001
[Sex=0]	-.801	1.756	-.456	.653	-4.464	2.862	.010
[Sex=1]	0[a]	.	.	.	.	.	.
Mstatus	-1.461	3.033	-.482	.635	-7.787	4.865	.011

a. This parameter is set to zero because it is redundant.

Dependent Variable: ZRot

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	Partial Eta Squared
Intercept	17.620	7.156	2.462	.023	2.693	32.547	.233
Age	-.394	.296	-1.332	.198	-1.012	.223	.081
HGwear	.003	.001	2.377	.028	.000	.005	.220
Nolla	-1.545	.900	-1.716	.102	-3.422	.333	.128
[Sex=0]	.410	1.163	.353	.728	-2.016	2.836	.006
[Sex=1]	0[a]	.	.	.	.	.	.
Mstatus	2.484	2.009	1.236	.231	-1.707	6.674	.071

a. This parameter is set to zero because it is redundant.

Tables 1-4: Measurements of the two researchers (1st and 2nd time).

	1st researcher-1st time											
	LEFT						RIGHT					
CASE	XPos	YPos	ZPos	XRot	YRot	ZRot	XPos	YPos	ZPos	XRot	YRot	ZRot
1	-0.20	1.61	0.64	4.63	-1.56	6.45	-0.30	0.02	0.92	1.58	-3.89	7.15
2	-0.21	0.65	-0.06	2.25	-0.91	1.84	-0.10	0.66	-0.23	1.64	0.27	1.83
3	-0.18	1.09	0.07	5.24	-1.66	2.61	-0.04	1.11	-0.22	4.31	0.68	4.36
4	1.65	2.69	-0.91	8.89	7.40	5.81	1.24	2.41	0.69	6.62	4.00	8.07
5	-0.04	0.92	-0.02	1.89	-1.64	3.73	-0.23	0.67	0.21	1.43	-1.27	2.13
6	-0.32	2.51	-0.23	7.15	0.75	7.40	0.49	1.64	-0.43	8.62	1.17	2.17
7	0.44	0.41	0.06	2.63	-1.43	0.50	-0.37	1.81	-0.11	3.33	-0.68	8.81
8	1.32	1.61	-0.20	6.33	3.59	3.49	0.94	3.16	0.48	9.17	2.76	6.85
9	-0.40	0.88	0.16	2.84	-1.88	6.23	-0.58	0.92	0.55	3.12	-3.54	5.63
10	0.53	1.51	0.32	7.51	-0.25	2.30	-0.30	2.42	0.79	8.71	-2.54	7.04
11	-0.74	0.79	0.62	1.61	-4.21	3.18	0.02	0.71	-0.13	2.21	-0.67	4.78
12	-0.55	1.43	-0.22	2.26	-3.17	4.09	-0.38	1.58	0.54	4.52	-3.92	3.65
13	0.13	0.23	0.66	1.49	-0.09	-1.48	-0.05	0.54	0.36	1.62	0.42	-0.12
14	-0.73	1.82	0.73	5.30	-5.99	7.95	-0.10	2.19	0.30	7.37	-1.57	3.46
15	-0.06	2.37	0.72	10.85	-0.70	2.43	-1.00	1.26	0.70	3.62	-4.31	-0.42
16	-0.17	0.26	0.18	-0.64	-2.33	6.84	-0.56	0.07	0.38	3.02	-4.76	9.47
17	-0.95	1.54	0.06	1.03	-7.66	4.57	-0.72	1.57	0.46	4.62	-8.33	1.43
18	-1.26	2.19	0.14	7.10	-6.78	9.59	-1.68	0.86	0.48	-0.11	-9.44	10.64
19	-0.47	0.90	0.49	3.56	-3.36	3.34	0.19	0.96	-0.44	3.86	2.75	9.34
20	-0.85	4.88	1.15	16.28	-4.76	2.86	0.77	4.59	1.21	16.83	0.07	1.71
21	1.11	3.94	0.57	12.38	-0.39	4.89	0.86	2.96	0.42	10.46	0.90	4.66
22	-0.57	3.48	-0.14	11.22	-2.67	6.18	0.38	1.64	-0.56	4.20	-1.31	-2.42
23	-0.83	5.87	0.32	19.88	2.31	15.69	0.41	3.60	0.15	16.43	-3.01	11.66
24	1.08	1.63	-0.38	5.38	2.08	5.74	-0.32	1.81	0.26	5.90	-1.56	5.28
25	0.21	3.68	0.85	8.29	-0.71	6.72	1.15	1.65	-0.04	7.62	0.85	2.62
26	-0.70	1.18	0.42	6.46	-6.21	7.67	-1.30	-0.05	0.31	-0.93	-11.19	2.23
AVG	-0.11	1.93	0.23	6.22	-1.62	5.02	-0.06	1.57	0.27	5.37	-1.85	4.69
SD	0.74	1.43	0.45	4.86	3.34	3.33	0.72	1.13	0.44	4.42	3.68	3.62
MIN	-1.26	0.23	-0.91	-0.64	-7.66	-1.48	-1.68	-0.05	-0.56	-0.93	-11.19	-2.42
MAX	1.65	5.87	1.15	19.88	7.40	15.69	1.24	4.59	1.21	16.83	4.00	11.66
MD	-0.20	1.57	0.17	5.34	-1.60	4.73	-0.10	1.57	0.34	4.25	-1.29	4.51

	1st researcher-2nd time											
	LEFT						RIGHT					
CASE	XPos	YPos	ZPos	XRot	YRot	ZRot	XPos	YPos	ZPos	XRot	YRot	ZRot
1	-0.15	1.62	0.64	5.01	-1.28	6.19	-0.35	0.02	0.92	1.46	-4.08	7.09
2	-0.22	0.58	-0.09	2.31	-0.88	1.68	-0.10	-0.67	-0.23	1.55	0.29	1.77
3	-0.20	1.01	0.16	4.96	-1.84	2.64	-0.02	-1.16	-0.22	4.19	0.98	4.41
4	1.86	2.51	-1.10	8.38	7.93	5.87	1.12	-2.82	0.76	6.69	4.35	8.11
5	-0.08	0.91	-0.02	1.65	-1.72	3.76	-0.20	-0.68	0.21	1.37	-1.19	2.13
6	-0.40	2.32	-0.41	7.58	0.62	6.84	0.52	-1.69	-0.45	8.60	1.20	2.41
7	0.43	0.47	0.02	2.72	-1.44	0.52	-0.40	-1.88	-0.26	3.41	-0.59	9.27
8	1.17	1.77	-0.17	6.55	3.31	3.87	1.03	-3.05	0.47	9.64	3.15	6.78
9	-0.42	0.89	0.10	2.79	-1.73	6.37	-0.59	-0.93	0.56	3.15	-3.56	5.57
10	0.41	1.58	0.29	7.25	-0.40	2.63	-0.22	-2.38	0.66	8.46	-2.01	7.08
11	-0.69	0.84	0.59	1.50	-3.94	3.52	0.00	-0.78	-0.19	2.46	-0.57	4.77
12	-0.59	1.46	-0.18	2.38	-3.19	4.18	-0.32	-1.53	0.55	4.67	-3.79	3.63
13	0.12	0.25	0.65	1.22	0.04	-1.40	-0.03	-0.58	0.36	1.67	0.55	-0.18
14	-0.75	1.81	0.72	5.15	-6.09	8.06	-0.13	-2.28	0.21	7.09	-1.60	3.27
15	-0.08	2.37	0.77	10.52	-0.80	2.57	-0.97	-1.28	0.63	3.91	-4.13	-0.63
16	-0.22	0.27	0.19	-0.82	-2.30	6.93	-0.54	-0.06	0.38	3.30	-4.36	9.56
17	-0.90	1.43	0.07	1.04	-7.59	4.46	-0.80	-1.58	0.50	4.62	-8.30	1.63
18	-1.16	2.18	0.21	6.76	-6.86	9.62	-1.59	-0.88	0.49	0.14	-9.68	10.70
19	-0.47	0.81	0.59	3.18	-3.60	3.21	0.22	-1.00	-0.39	3.40	2.94	9.33
20	-0.68	4.68	1.48	16.52	-4.68	2.28	0.68	-4.47	1.42	16.93	-0.18	1.77
21	1.30	3.81	0.48	12.61	-0.17	4.44	0.71	-3.41	0.40	10.66	0.73	4.93
22	-0.56	3.55	-0.22	11.27	-2.36	6.56	0.39	-1.52	-0.66	4.31	-1.29	-2.81
23	-0.89	5.60	0.57	19.74	1.14	16.15	0.46	-3.62	0.08	16.77	-2.82	11.20
24	0.96	1.66	-0.25	5.07	2.00	5.90	-0.23	-1.80	0.36	5.31	-1.26	5.33
25	0.06	3.86	0.76	8.49	-0.85	6.75	1.27	-1.54	-0.12	7.55	0.99	2.68
26	-0.75	1.14	0.62	6.18	-6.70	7.68	-1.45	-0.01	0.16	-0.66	-10.48	2.23
AVG	-0.11	1.90	0.25	6.15	-1.67	5.05	-0.06	-1.60	0.25	5.41	-1.72	4.69
SD	0.74	1.39	0.51	4.90	3.35	3.38	0.72	1.15	0.47	4.44	3.67	3.65
MIN	-1.16	0.25	-1.10	-0.82	-7.59	-1.40	-1.59	-4.47	-0.66	-0.66	-10.48	-2.81
MAX	1.86	5.60	1.48	19.74	7.93	16.15	1.27	0.02	1.42	16.93	4.35	11.20
MD	-0.22	1.60	0.20	5.11	-1.58	4.45	-0.11	-1.52	0.36	4.25	-1.22	4.59

	2nd researcher-1st time											
	LEFT						RIGHT					
CASE	XPos	YPos	ZPos	XRot	YRot	ZRot	XPos	YPos	ZPos	XRot	YRot	ZRot
1	-0.16	1.61	0.64	4.83	-1.36	6.34	-0.32	0.00	0.93	1.51	-4.00	7.13
2	-0.22	0.62	-0.08	2.28	-0.86	1.74	-0.11	0.65	-0.23	1.60	0.28	1.80
3	-0.19	1.17	0.17	5.04	-1.75	2.60	-0.03	1.13	-0.22	4.20	0.78	4.38
4	1.71	2.69	-0.12	8.58	7.70	5.85	1.21	2.62	0.71	6.61	4.15	8.09
5	-0.07	0.92	-0.02	1.89	-1.69	3.76	-0.20	0.66	0.21	1.40	-1.21	2.13
6	-0.39	2.51	-0.36	7.45	0.75	7.11	0.49	1.66	-0.44	8.60	1.19	2.27
7	0.45	0.41	0.04	2.70	-1.43	0.51	-0.38	1.85	-0.16	3.35	-0.63	9.01
8	1.18	1.60	-0.18	6.33	3.39	3.68	0.97	3.10	0.47	9.46	2.96	6.80
9	-0.43	0.90	0.13	2.81	-1.80	6.30	-0.57	0.93	0.56	3.12	-3.53	5.60
10	0.46	1.59	0.31	7.33	-0.35	2.45	-0.30	2.32	0.71	8.64	-2.32	7.06
11	-0.68	0.82	0.60	1.61	-4.10	3.38	0.01	0.76	-0.15	2.31	-0.65	4.78
12	-0.59	1.49	-0.20	2.30	-3.16	4.09	-0.36	1.55	0.54	4.58	-3.90	3.65
13	0.12	0.25	0.66	1.31	-0.06	-1.42	-0.04	0.55	0.36	1.64	0.49	-0.14
14	-0.74	1.82	0.73	5.21	-6.00	7.99	-0.09	2.22	0.26	7.27	-1.58	3.36
15	-0.07	2.38	0.76	10.66	-0.75	2.49	-0.98	1.27	0.70	3.82	-4.30	-0.52
16	-0.20	0.27	0.18	-0.75	-2.31	6.89	-0.56	0.07	0.38	3.21	-4.50	9.46
17	-0.96	1.49	0.06	1.03	-7.63	4.51	-0.77	1.57	0.48	4.62	-8.30	1.53
18	-1.19	2.17	0.18	6.91	-6.78	9.60	-1.63	0.86	0.48	-0.01	-9.50	10.66
19	-0.48	0.89	0.51	3.26	-3.46	3.31	0.19	0.98	-0.43	3.55	2.85	9.34
20	-0.71	4.73	1.25	16.48	-4.71	2.56	0.77	4.50	1.32	16.82	0.00	1.74
21	1.24	3.89	0.57	12.56	-0.28	4.63	0.85	3.16	0.42	10.55	0.80	4.76
22	-0.58	3.52	-0.19	11.25	-2.46	6.30	0.38	1.60	-0.59	4.19	-1.32	-2.58
23	-0.86	5.87	0.44	19.78	1.90	16.00	0.42	3.61	0.10	16.59	-3.00	11.46
24	1.09	1.64	-0.35	5.18	2.01	5.80	-0.30	1.81	0.30	5.69	-1.49	5.26
25	0.51	3.72	0.81	8.40	-0.76	6.72	1.19	1.60	-0.09	7.62	0.89	2.64
26	-0.70	1.15	0.52	6.26	-6.41	7.68	-1.39	-0.02	0.20	-0.73	-10.98	2.24
AVG	-0.09	1.93	0.27	6.18	-1.63	5.03	-0.06	1.58	0.26	5.39	-1.80	4.69
SD	0.75	1.42	0.41	4.88	3.34	3.36	0.72	1.13	0.46	4.43	3.68	3.63
MIN	-1.19	0.25	-0.36	-0.75	-7.63	-1.42	-1.63	-0.02	-0.59	-0.73	-10.98	-2.58
MAX	1.71	5.87	1.25	19.78	7.70	16.00	1.21	4.50	1.32	16.82	4.15	11.46
MD	-0.21	1.60	0.18	5.19	-1.56	4.57	-0.10	1.56	0.33	4.20	-1.27	4.57

	2nd researcher-2nd time											
	LEFT						RIGHT					
CASE	XPos	YPos	ZPos	XRot	YRot	ZRot	XPos	YPos	ZPos	XRot	YRot	ZRot
1	-0.20	1.60	0.69	4.53	-1.58	6.45	-0.30	0.02	0.92	1.61	-3.75	7.22
2	-0.22	0.63	-0.07	2.27	-0.89	1.80	-0.12	0.65	-0.27	1.70	0.30	1.70
3	-0.20	1.06	0.08	5.25	-1.63	2.61	-0.05	1.12	-0.30	4.26	0.58	4.31
4	1.61	2.63	-0.98	8.78	7.30	5.80	1.26	2.49	0.58	6.45	4.11	8.00
5	-0.06	0.89	-0.05	1.91	-1.60	3.70	-0.28	0.68	0.25	1.50	-1.25	2.19
6	-0.30	2.50	-0.29	7.09	0.75	7.35	0.50	1.70	-0.48	8.58	1.14	2.10
7	0.40	0.39	0.08	2.59	-1.48	0.50	-0.41	1.71	-0.12	3.28	-0.62	8.79
8	1.39	1.60	-0.20	6.30	3.60	3.40	0.97	3.20	0.50	9.15	2.63	6.83
9	-0.36	0.87	0.20	2.80	-1.88	6.35	-0.59	0.90	0.60	3.10	-3.48	5.66
10	0.59	1.40	0.40	7.49	-0.24	2.40	-0.28	2.50	0.73	8.71	-2.59	7.00
11	-0.75	0.70	0.71	1.60	-4.20	3.13	0.02	0.71	-0.13	2.23	-0.60	4.72
12	-0.51	1.47	-0.20	2.26	-3.17	4.08	-0.31	1.61	0.60	4.49	-3.87	3.52
13	0.17	0.27	0.48	1.47	-0.11	-1.44	-0.05	0.54	0.38	1.60	0.43	-0.12
14	-0.70	1.83	0.81	5.29	-6.10	7.90	-0.07	2.21	0.36	7.36	-1.52	3.44
15	-0.09	2.36	0.83	10.78	-0.69	2.43	-1.01	1.30	0.75	3.54	-4.33	-0.48
16	-0.20	0.20	0.20	-0.60	-2.37	6.70	-0.59	0.09	0.36	2.87	-4.80	9.47
17	-0.81	1.49	0.07	1.03	-7.59	4.50	-0.73	1.55	0.51	4.56	-8.30	1.39
18	-1.15	2.19	0.14	7.10	-6.79	9.48	-1.63	0.91	0.55	-0.10	-9.35	10.58
19	-0.35	0.91	0.49	3.45	-3.31	3.38	0.21	0.90	-0.46	3.83	2.64	9.34
20	-0.79	4.91	1.14	16.28	-4.75	2.80	0.80	4.60	1.25	16.85	0.07	1.80
21	1.01	3.89	0.56	12.27	-0.36	4.78	0.90	2.97	0.47	10.50	0.90	4.58
22	-0.50	3.40	-0.14	11.26	-2.69	6.20	0.43	1.66	-0.60	4.19	-1.35	-2.46
23	-0.82	5.67	0.32	19.80	2.01	15.66	0.41	3.68	0.21	16.45	-3.01	11.60
24	1.01	1.59	-0.34	5.38	2.10	5.76	-0.32	1.90	0.26	5.88	-1.50	5.23
25	0.20	3.54	0.82	8.30	-0.71	6.70	1.15	1.68	-0.09	7.70	0.75	2.59
26	-0.69	1.10	0.47	6.38	-6.23	7.68	-1.32	-0.10	0.40	-0.90	-11.01	2.19
AVG	-0.09	1.89	0.24	6.19	-1.64	5.00	-0.05	1.58	0.28	5.36	-1.84	4.66
SD	0.71	1.41	0.47	4.85	3.31	3.31	0.73	1.15	0.46	4.42	3.64	3.62
MIN	-1.15	0.20	-0.98	-0.60	-7.59	-1.44	-1.63	-0.10	-0.60	-0.90	-11.01	-2.46
MAX	1.61	5.67	1.14	19.80	7.30	15.66	1.26	4.60	1.25	16.85	4.11	11.60
MD	-0.21	1.54	0.20	5.33	-1.59	4.64	-0.09	1.58	0.37	4.22	-1.30	4.44

Table 5: Average of 2 observers, 2 measurements each, 2 sides.

CASE	YPos	XRot	ZRot
1	0.807	3.145	6.754
2	0.638	1.953	1.770
3	1.106	4.680	3.490
4	2.607	7.624	6.951
5	0.790	1.629	2.939
6	2.067	7.960	4.705
7	1.116	3.000	4.740
8	2.387	7.864	5.214
9	0.900	2.965	5.964
10	1.962	8.011	4.746
11	0.763	1.941	4.032
12	1.514	3.433	3.859
13	0.400	1.501	-0.787
14	2.022	6.253	5.678
15	1.823	7.211	0.983
16	0.161	1.199	8.165
17	1.527	2.817	3.005
18	1.529	3.475	10.108
19	0.918	3.511	6.323
20	4.669	16.625	2.191
21	3.504	11.499	4.708
22	2.545	7.737	1.872
23	4.688	18.178	13.677
24	1.729	5.472	5.537
25	2.658	7.995	4.676
26	0.552	2.757	4.949
AVG	1.75	5.79	4.86
SD	1.19	4.36	2.91
MIN	0.16	1.20	-0.79
MAX	4.69	18.18	13.68
MD	1.53	4.10	4.72

Table 6: Theramon Data, Demographics, and second Molars' stage of development.

	THERAMON DATA				DEMOGRAPHICS	
CASE	HG-wear (hrs)	Total (hrs)	Total (days)	Hour/day	SEX	AGE
1	1182.0	2351.8	98.0	12.1	**M**	**12.8**
2	735.5	2712.8	113.0	6.5	**F**	**16.3**
3	659.5	1846.0	76.9	8.6	**F**	**11.4**
4	1157.8	2545.5	106.1	10.9	**F**	**11.5**
5	737.8	2376.5	99.0	7.5	**F**	**16.8**
6	1308.3	2565.0	106.9	12.2	**F**	**11.0**
7	1284.3	2903.0	121.0	10.6	**F**	**8.8**
8	1467.0	2400.8	100.0	14.7	**F**	**14.5**
9	1545.0	3528.0	147.0	10.5	**F**	**12.9**
10	1322.0	2855.0	119.0	11.1	**F**	**11.1**
11	717.0	2185.8	91.1	7.9	**F**	**13.0**
12	1253.0	2523.8	105.2	11.9	**M**	**12.2**
13	299.0	2540.8	105.9	2.8	**F**	**11.3**
14	1701.3	3142.3	130.9	13.0	**M**	**11.8**
15	1272.0	2519.0	105.0	12.1	**M**	**13.6**
16	1021.3	4029.5	167.9	6.1	**M**	**12.6**
17	1828.8	3891.5	162.1	11.3	**F**	**15.9**
18	1557.5	3983.0	166.0	9.4	**M**	**12.2**
19	2067.0	3701.8	154.2	13.4	**F**	**13.1**
20	1750.3	4030.5	167.9	10.4	**F**	**12.1**
21	1651.0	4038.0	168.3	9.8	**M**	**11.3**
22	1580.3	4056.0	169.0	9.4	**M**	**15.3**
23	1939.5	4052.8	168.9	11.5	**F**	**10.4**
24	1916.3	3960.8	165.0	11.6	**M**	**12.5**
25	1382.3	3523.5	146.8	9.4	**F**	**12.1**
26	1131.3	3362.5	140.1	8.1	**F**	**11.4**
AVG	1325.6	3139.4	130.8	10.1		12.6
SD	442.6	724.9	30.2	2.6		1.9
MIN	299.0	1846.0	76.9	2.8		8.8
MAX	2067.0	4056.0	169.0	14.7		16.8
MD	1315.1	3022.6	125.9	10.6		12.2

	2nd MOLARS		NOLLA STAGE		
CASE	Status L	Status R	L	R	AVG
1	NO	NO	7	7	7
2	YES	NO	9	9	9
3	NO	NO	7	7	7
4	YES	YES	9	9	9
5	YES	YES	9	9	9
6	YES	NO	8	8	8
7	NO	NO	7	7	7
8	NO	NO	7	6	6.5
9	YES	YES	10	10	10
10	NO	NO	7	7	7
11	NO	NO	8	8	8
12	YES	YES	9	9	9
13	YES	YES	10	10	10
14	YES	YES	9	9	9
15	YES	YES	9	9	9
16	YES	YES	9	9	9
17	YES	YES	9	9	9
18	YES	YES	9	9	9
19	NO	YES	8	9	8.5
20	NO	NO	8	8	8
21	NO	YES	8	9	8.5
22	YES	YES	10	10	10
23	NO	NO	7	7	7
24	NO	NO	9	9	9
25	NO	NO	8	8	8
26	NO	NO	7	7	7
AVG			8.3	8.4	8.4
SD			1.0	1.1	1.0
MIN			7.0	6.0	6.5
MAX			10.0	10.0	10.0
MD			8.5	9.0	8.8