THREE-DIMENSIONAL CHARACTERIZATION OF MAXILLARY MOLAR DISPLACEMENT SUBSEQUENT TO HEADGEAR TREATMENT WITH RESPECT TO TIME AND FORCE OF APPLICATION – DEVELOPMENT AND PILOT TEST OF A NOVEL STUDY METHOD

By

YOSSI BAR-ZION

A THESIS PRESENTED TO THE GRADUATE SCHOOL
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Orthodontic headgear for the correction of class II malocclusions has been used in orthodontics since the 1800s. Although the headgear is quite popular in the orthodontic community, the literature is rather contradictory and ambiguous with respect to the amount of time and force necessary for optimal treatment results.

A potential source of error leading to the large inconsistencies involving the orthodontic headgear research may be due to the complexity and difficulty of measuring the outcome results objectively, as well as accurately monitoring the time and force of applications. Discrepancies involving inaccurate data collection as well as outcome analysis could potentially lead to misinterpreted findings and contradictory conclusions.

The purpose of this study was to develop and pilot test a research methodology to objectively study, measure, and analyze orthodontic treatment outcome subsequent to headgear therapy with respect to time and force of application.

To effectively evaluate the therapeutic effect of the headgear, a novel orthodontic time/force recording (OTFR) headgear was developed, capable of monitoring and recording compliance as well as force levels in realtime. The second component of this study involved the development of a digital three-dimensional measurement system for the quantitative and qualitative analysis of the treatment effects.

Data collected on a pilot sample of patients treated with our newly developed OTFR headgear were analyzed in order to establish the validity of this device in clinical research, and was compared with the currently used compliance monitoring method – the self reported diary. Study models taken on this group of patients at monthly intervals were digitally analyzed using the three-dimensional measurement system for the characterization of molar displacement and the pilot testing of the technique.

The testing of the three-dimensional analysis system has been shown to provide qualitative as well as quantitative results with respect to the molar's spatial displacement subsequent to headgear use. The OTFR headgear appeared to be valid for the monitoring of compliance. The use of patients' self-reported logbook did not correlate with the true compliance as measured using two separate digital timing devices. The future use of such logbooks for the monitoring of compliance does not appear to be warranted.

Future implementation of this novel research design in clinical studies would provide invaluable insight into the treatment effects of orthodontic headgear therapy by facilitating intensive real-time data collection and objective three-dimensional tooth movement analysis.

CHAPTER 1
INTRODUCTION

Extra-oral force applications to distalize molars for the correction of class II malocclusions have been used in orthodontics since the 1800s. Historically, extra-oral maxillary traction appliances were used to improve the dental relationship between the maxilla and the mandible, as well as the skeletal relationship between the two jaws (Firouz et al., 1992). Perhaps the most popular of all orthodontic extra-oral maxillary traction appliances is the orthodontic headgear (Proffit, 1986). The appliance, simplistic in its concept and design, consists of three basic components: a facebow, strap, and force module. The facebow is made up of two parts, the inner bow that is designed to engage the maxillary molars via special attachments placed on orthodontic bands, and the outer bow to which an extra oral vector of force is applied. The strap, commonly made of flexible material to conform to the back of the patient's neck or head, is used to reciprocate the tension produced by the force module. The force module, the link between the strap and the facebow, may be composed of various materials ranging from elastic to nickel titanium, and is capable of transferring a range of forces to maxillary molars via the facebow. There are several types of headgears available for the orthodontist's use, and the choice is often dictated by the skeletal and dental diagnosis as well as clinician's preference (Ucem & Yüksel, 1998; Chaconas, 1976).

Although the use of headgear is quite popular by the orthodontic community, the literature is ambiguous with respect to the amount of force necessary for effective and predictable outcome, namely molar distalization. The forces reported vary from 300gm (Weislander, 1974) to as much as 1000gm (Watson, 1972) per side. There is also ambiguity on the amount of time the appliance is to be worn to achieve molar distalization. Armstrong (1971) and Badell (1976) suggest continuous headgear wear (24 hours a day) to achieve optimal orthodontic results, while others advocate intermittent wear. Furthermore, there is a broad inconsistency in the treatment duration which varies from several months (Firouz et al., 1992; Watson, 1972) to several years (Weislander, 1974). Ironically, the amount of reported distalization has been rather similar, about 2-3mm, regardless of the force level and time of wear (Weislander, 1974; Baumrind et al., 1981; Watson, 1972; Firouz et al., 1992). Generally, most studies report about a 2.5mm distalization in about 6 months, using an average force of 500gm per side (Ucem & Yüksel, 1998; Firouz et al., 1992; Badell, 1976).

This widely reported variability on both force and duration of wear required for optimal maxillary molar movement, creates confusion and forces the orthodontist to ultimately rely on anecdotal experiences. Knowledge of the ideal force and time of wear required for optimal orthodontic outcome would minimize treatment time, patient discomfort and costs as well as maximize treatment results and outcome. Furthermore, the efficacy of headgear treatment could be objectively compared to alternative treatment approaches, such as intra-oral appliances, with respect to cost effectiveness and outcome results.

Purpose of Study

The purposes of this study were to develop and test a study model, design and methodology to objectively study, measure, and document not only orthodontic treatment outcome subsequent to headgear therapy, but also the mode of the obtained correction. Only by accurately measuring the time appliance wear and force of application, as well as the subsequent outcomes, can the mechanism of the observed treatment results be interpreted. Insight into the mechanism and mode of the treatment outcome, could potentially lead to a more efficient use of present orthodontic appliances, as well as help in the development of future orthodontic therapy. Furthermore, results of such a study, as well as future use of the study design and methodology, may provide invaluable data for the understanding of optimal orthodontic forces and physiologic tooth movement, a subject under great deal of controversy and uncertainty (Lee, 1996; Nicolai, 1975).

Objectives

The objectives of this study include:

1. To develop a system for precise and accurate measurement tooth movement in three dimensions of space – capable of characterizing the precise tooth movement in terms of finite elements such as mesial-distal movement, buccal-lingual movement, intrusion-extrusion, torque, tip, and rotation.
2. To pilot test the reliability and validity of a newly developed force/time recording headgear with respect to time measurements.

3. To test the validity of patients' self-reported compliance logbook.
4. To pilot test the reliability and validity of a newly developed force/time recording headgear with respect to force measurements.
5. To characterize, using descriptive statistics maxillary molar displacement, subsequent to headgear wear with respect to force level and wear duration in a pilot sample of patients.

CHAPTER 2
REVIEW OF THE LITERATURE

As previously discussed, there is much controversy and conflicting reports on the optimal use and expected results with orthodontic headgear. Such conflicting reports exist with respect to outcome (Weislander, 1974; Baumrind et al., 1981; Watson, 1972; Firouz et al., 1992), force of application (Ucem & Yüksel, 1998; Tanne & Matsubara, 1996), and optimum time of wear (Armstrong, 1971; Badell, 1976; Weislander, 1974; Watson, 1972).

Historical Overview

Monitoring of Time

One possible explanation for the uncertainty and disagreement with regards to the force and duration of wear required to achieve effective molar distalization in various studies, may be due to tooth movement measurement error, as well as the patient's wear compliance and lack of effective active force estimation. Many such studies are retrospective and estimation of patient wear compliance is therefore not applicable. Prospective studies, for the most part, have generally relied on total patient cooperation and did not specifically attempt to measure the amount of appliance wear time. The few studies, which have made and attempt to record and quantify patients' compliance, have done so through the use of a self-reported diary (Kirjavainen et al., 1997; Firouz et al., 1992). While many researchers consider the self-reported patient diary as the gold standard for compliance monitoring in orthodontic study design, there is no published data supporting its reliability and validity.

There have been several attempts to combine a timing device into an orthodontic headgear reported in the literature (Guray, 1997; Banks, 1987; Northcutt,1976), as well as one such device commercially available for headgear compliance monitoring (Affirm, Ortho-Kinetics, Vista, CA). All of these timing devices, although varying in complexity of design, operate on the same basic premise. When the force module exceeds a certain preset destination the internal clock starts or resumes counting time, when the force module is below the preset distention, the counting stops. In its simplest form, these timing devices are basically modified stopwatches. Thus these devices lack the ability to characterize the compliance pattern, such as time of day headgear is worn, days of week, length of different wear periods, and other related parameters. Such parameters may prove crucial in the interpretation of the data, particularly in a study set to correlate treatment with treatment effects and outcomes. Furthermore, while few reports of a timing device incorporated into an orthodontic headgear exist, no device which is capable of monitoring the force of appliance application as well as monitoring of compliance has yet to be reported on.

Monitoring of Force

The second component, which may have contributed to the large variations in the results of different clinical studies, includes the monitoring of force of application in real time.

The relationship between magnitude of orthodontic force application and rate of tooth movement is a subject of controversy (Quinn & Yashikawa, 1985). Several investigators have attempted to study the relationship between tooth movement and force application in animal (Pilon et al., 1996; King et al., 1991) as well as human models (Lee, 1995; Andreasen & Zwanziger, 1980; Andreasen & Johnson, 1967; Boester & Johnston, 1974; Hixon et al., 1970, Hixon et al., 1969). While it is generally accepted that teeth subjected to orthodontic forces will respond, the magnitude of optimal forces is unclear. Optimal forces reported in the literature, vary from 140 grams (Boester & Johnston, 1974) to as much as 500 grams (Anreasen & Zwanziger, 1980). All the aforementioned studies were conducted on teeth subjected to continuous forces. The study of optimal forces required for maximal tooth movement using the orthodontic headgear would be considerably more complex.

Studies measuring the forces produced by the headgear have been attempted both in vitro (Tabash et al., 1984) as well as in vivo (Bratcher et al., 1985). These studies were able to gauge the force of application only in static situations, a method that is of little use in longitudinal clinical studies, due to the highly variable nature of the force of application generated by the orthodontic headgear (Johnson et al., 1999).

Previous clinical studies involving the headgear have assumed constant force of application, measured at time of appliance adjustment. The actual forces, however, may be quite different then that anticipated by the clinicians and researchers, due to force level variation. This potential error in force estimation during headgear wear, along with compliance issues previously discussed, may have lead to misinterpretation of previously reported data.

The required dynamic, real-time, monitoring of force of application in clinical headgear studies has not yet been developed and addressed.

Measurement of Tooth Displacement

The final component of previous clinical studies involving the orthodontic headgear, which may potentially have contributed to the wide variability in outcome results, involves potential errors in the measurement of tooth displacement. Such errors in measurement could lead to misinterpretation of the actual treatment effects by under- or over-estimating the true molar displacement. There are several methods of measurement of maxillary molar displacement. The three most popular techniques include: radiographic measurements, photographic assessment, and molar cusp classification.

Radiographic measurements

This technique is by far the most popular method of measurement. This technique utilizes digitized lateral cephalograms, and uses one of multiple available analysis (Johnston, 1986; Baumrind et al., 1983; Riola et al., 1974). Using cephalometric radiographs is probably the simplest and most convenient technique as these types of radiographs are obtained as a standard part of regular orthodontic treatment. This methodology is used extensively in both retrospective studies (Baumrind et al., 1983; Derringer, 1990) as well as prospective clinical trials (Keeling et al., 1998). Briefly, the lateral cephalometric radiographs are obtained before and after treatment. Predetermined landmarks are then digitized, and, using one of several analyses, the maxillary molar position is calculated with respect to stable craniofacial structures. The pre- and post-treatment measurements are then compared to calculate the maxillary molar movement. An alternative method of evaluating molar movement from radiographs involves superimposing the pre- and post-treatment radiographs and directly measuring molar movement (Isaacson et al., 1976).

There are several problems and difficulties associated with the radiographic measurement technique:

1. The cephalometric radiographs are taken at 6 monthly intervals, in order to minimize patient radiographic exposure. Consequently, short time observations of molar movement are impossible.
2. Radiographs introduce artifacts and distortion. It is very difficult, if not impossible, to position the patient's head exactly in the same orientation 6 months after the initial radiograph. Even small deviations would result in erroneous measurements. Furthermore, any changes in the distance between the patient's head and the film would cause magnification changes which, compounded with any angular position differences add variability between the radiographs. These variations are especially critical when small differences in measurements are anticipated.
3. Measurement errors and variability are introduced during the tracing and digitizing process (Keeling, 1993). Once again, these errors are critical when small increments of movement are to be detected.
4. The cephalometric assessment only captures the craniofacial structures in a two-dimensional plane: horizontal (anterior-posterior) and vertical. Any changes in the transverse plane are overlooked and consequently lost. This eliminates very important information on maxillary molar movement with respect to expansion, constriction, rotation, and torque.

Photographic assessment

This technique obtains a photographic picture of the study model, by utilizing a camera or a photocopy machine (Singh & Savara, 1971). In short, the pre- and post-treatment study models are taken of the patient using routine alginate impressions. The models are then trimmed and the occlusal surface is either photographed using a camera placed perpendicular to the occlusal plane or by 'photocopying' the occlusal surface. The photograph is then digitized, and, using the palatal rugae as a stable structure, tooth displacement is measured from serial casts. Problems involved with this technique are the following:

1. The technique relies on the occlusal plane, which would be changing subsequent to orthodontic treatment.
2. The photograph of a three-dimensional study model converts the model into a two-dimensional record.
3. Any changes in the vertical plane are undetectable due to the two-dimensional transformation and are consequently lost. This eliminates important information on maxillary molar movement with respect to extrusion, intrusion, tip, and torque.
4. This technique relies on the structural stability of the palatal rugae for tooth movement measurement. The palatal rugae, however, have been shown to undergo significant changes in orthodontically treated cases (van der Linden, 1978).

Molar cusp classification

This particular technique is potentially the least reliable of all maxillary molar displacement measurement techniques. This method evaluates the maxillary molar displacement with respect to the lower first molar. For this method, maxillary and mandibular study models are obtained and intercuspated, and the change of maxillary molar position is observed, over time, by measuring points on the upper first molar with respect to the lower first molar (Bondemark & Kurol, 1992). This method operates under the premise that despite the documented imprecision in the research utilization of the technique (Keeling et al., 1996), if appliances are not placed on the mandibular arch, no appreciable changes should occur and so the mandibular molars could be used as a stable point of reference. Such assumptions, however, are far reaching at best as significant changes in the mandibular arch growth and development, using a headgear in the absence of any mandibular arch appliances have been reported on (Tulloch et al., 1998; Keeling et al., 1998; Kirjavainen et al., 1997).

Three-Dimensional Cast Analysis

Although this technique has been used in limited capacity in tooth movement studies (Richmond 1987; Bhatia & Harrison, 1986), this system of measurements has the potential, in theory, to be the most accurate (Jones, 1991). The analysis is achieved by obtaining the three coordinates of several points on the model and then mathematically orienting them in space (Bar-Zion et al., 1998). There are several approaches to obtaining the spatial coordinates of the object surveyed including:

1. Reflex Metrograph (Swessi & Stephens, 1993; Richmond 1987; Bhatia & Harrison, 1986). This instrument basically consists of a semi-reflecting

mirror; therefore, an object standing in front of the mirror has its image at an equal distance behind the mirror. Working on this principle, a moving light source connected to a three dimensional (X,Y,Z) slide system behind the mirror can be used to record points corresponding to the image of the object. The accuracy of the Reflex Metrograph has been tested by Richmond (1984, 1987) and the error found to be less then 0.27 mm. For linear distances, however, Richmond (1987) reported mean errors as high as 1.06 mm.

2. <u>Electronic Surveyor</u> (Bar-Zion et al., 1998). This instrument is comprised of a sliding table that measures linear displacement on the 'X' and 'Y' axis. A vertical telescopic arm obtains the 'Z' axis. In a small sample study this instrument proved to be accurate and reproducible in surveying dental casts to about a 0.2mm error.

3. <u>3-D Digitizers</u>. This technology is rather new and allows the three-dimensional coordinates of an object to be imported directly into a personal computer for further analysis. The computer program could then render the object in virtual dimensions, allowing complex manipulations and measurements, otherwise deemed impossible. There are three basic types of 3-D digitizers, and they are classified according to their object capturing and digital conversion approach. The different types include ultrasonic, magnetic, and mechanical digitizers. <u>Ultrasonic:</u> Ultrasonic digitizers transmit sound waves and triangulate coordinates in 3D space using transmitters mounted to the wall or ceiling. Ultrasonic systems are deemed the least accurate and are the most susceptible to geometric distortions. Under the best conditions,

ultrasonic systems do not typically provide accuracy better than 2mm (manufacturer specifications, Artma, Utah, USA). Magnetic: Magnetic 3D digitizers work on the same principle as ultrasonic systems, using a magnetic field as the signal medium to triangulate spatial locations. These types of digitizers are very sensitive to distortions resulting from nearby metal or magnetic fields, and can generally produce resolution up to 1.5mm (manufacturer specifications, Artma, Utah, USA). Mechanical: The mechanical 3-D digitizer relates the stylus's position in space via a series of mechanical arms which tracks its movement utilizing digital optical sensors at each joint. Since this type of data capturing is strictly mechanical, it is virtually unsusceptible to external interference and distortion, producing digitizing data with accuracy of 0.25mm (manufacturer specifications, Immersion Corporation, San Jose, CA).

The various studies which have utilized this type of three-dimensional surveying, used either various teeth (Swessi & Stephens, 1993) or the palatal rugae (Bhatia & Harrison, 1986) as the reference point for calculating dental displacement. This approach may introduce much error and distortion for a tooth movement study as both the teeth and the palatal rugae change their three dimensional conformation during orthodontic tooth movement (van der Linden, 1978). Despite the fact that implementation of such three dimensional cast analysis utilizing the palatal rugae, a structure with questionable stability during tooth movement, may lead to some distortion of measurements, it still may potentially offer a more accurate and reliable measurement of true displacement.

This technique has not yet been fully developed, tested, or implemented in a study of dental changes subsequent to orthodontic headgear therapy.

Summary

When critically reviewing the present literature involving the orthodontic headgear outcome effects, it is apparent that previous studies contain basic flaws that could significantly affect the data and the interpretations of the results. Since the headgear is indeed a popular appliance that has been used by orthodontists for over a century, a close and careful evaluation of the treatment outcomes is warranted.

Addressing the potential confounding factors present in the previous studies, namely the monitoring of compliance, force of application, and precise tooth displacement measurement may provide a more objective insight into the therapeutic potential of the orthodontic headgear. Furthermore, the development of methods and protocols to accurately measure and record appliance compliance, force application, and tooth displacement, could impact future studies by providing more effective and reliable alternatives to the current methodology.

CHAPTER 3
MATERIALS AND METHODS

Orthodontic Time/Force Recording (OTFR) Headgear

To effectively evaluate the therapeutic effects of the orthodontic headgear utilizing a clinical study, a dynamic system of accurately measuring compliance as well as force of application in real-time is required.

Such novel timing headgear, capable of measuring compliance as well as force of application (OTFR Headgear) has been recently developed in our laboratory (Figure 3-1).

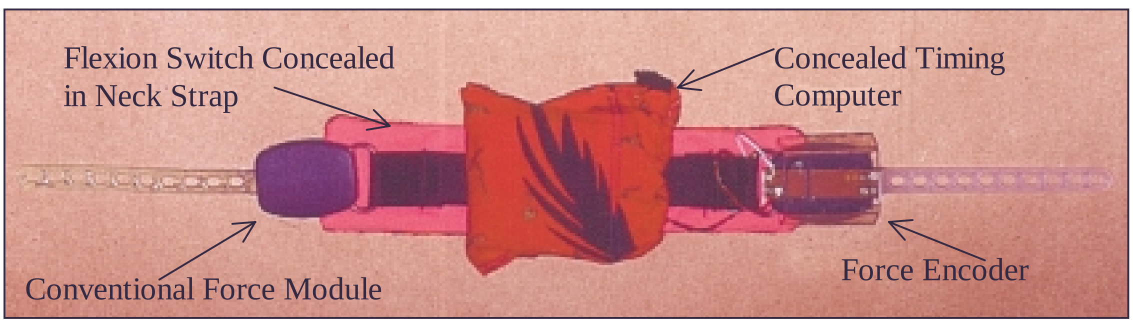


Figure 3-1. Orthodontic Time / Force Recording Headgear.

The OTFR headgear is equipped with three unique components that not only allow accurate data recording of force and time, but also innovative implements to circumvent false data collection. The three basic components include the data capturing microcomputer (Figure 3-1), a force encoder-probe that also doubles as a force module, and a flexion switch concealed in the neck-strap.

The data capturing microcomputer, utilizes a compact (measures 1.8 in x 1.9 in x 0.6 in) commercially available data logger (StowAway-Volt) by Onset Computer Corporation (Pocasset, MA). The data logger has on-board a 2.5 volt lithium cell (battery has a two year life) to power a miniature reduced instruction set computing (RISC) processor as a controller. Input to the logger is via an analog-to-digital converter, which measures voltages and converts them to 8-bit results. The data is then stored in a 32 Kbytes EEPROM (non-volatile memory), allowing up to 32,000 samples measuring voltages for different user determined monitoring periods (6 seconds to 24 minutes between observations).

The OTFR headgear's force encoder-probe is attached to a custom-made force module and uses a 100Kohm variable resistance linear potentiometer connected in parallel with the headgear's spring mechanism (Figure 3-1). This potentiometer is momentarily powered with voltage from the data logger during each of the 32,000 samples. The logger measures and stores the voltage existing across the potentiometer at each sample time (Figure 3-2). As the headgear facebow is engaged on a patient, the headgear spring will distend and the value of the voltage recorded will depend on this distension. Since the resistance of the potentiometer varies linearly with the stretch of the headgear spring, it is possible to calibrate the voltages measured by the data capturing microcomputer with the force being exerted by the headgear spring.

The final component vital to the OFTR headgear's operation is the flexion switch, concealed within the neck-strap (Figures 3-1, 3-2). The switch is activated when the neck strap is bent or flexed signaling that the headgear is in fact being worn. The flexion switch is integrated into the electronic circuitry to circumvent any potential false reading when the headgear is not being worn. Such interceptive measure is necessary due to the complexity of the force probe-encoder that may, due to hysteresis, mode of transport and storage, or inadvertent as well as intentional manipulation of the headgear by the study patient, encode a force measurement in the absence of wear. The flexion switch completes the circuit (Figure 3-2) only when the OTFR headgear is being worn by the patient, and therefore essentially eliminates all false positive force readings.

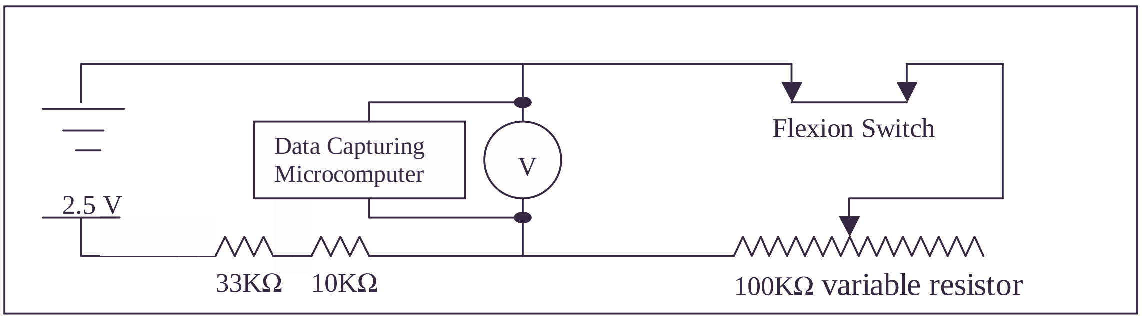


Figure 3-2. Schematics of electronic circuitry of the OFTR headgear.

The data recording microcomputer is capable of data capturing at different preset time intervals. Typically the time interval is set at two minutes, which allows sufficient memory for 45 days of active data recording. At each appointment the data is downloaded to a Pentium based personal computer, using a special program designed to read the encoded data in terms of voltage, time, and date. The data capturing microcomputer is then re-set and is thereafter ready for another 45-day session of data recording. The data is initially reported as a series of values of voltage over date and time recorded (Figure 3-3). Due to the linear fashion force-encoder potentiometer, the values are readily converted into force units such as grams or ounces. The interpolation conversion is facilitated by a data calibration set, performed by loading the force-recording module with known weights at each appointment. These measurements of force calibration can then be used to evaluate the reliability and consistency of the headgear's force encoder. A recently developed algorithm, written specifically to calculate the total wear-time as well as average force values then further interprets the data.

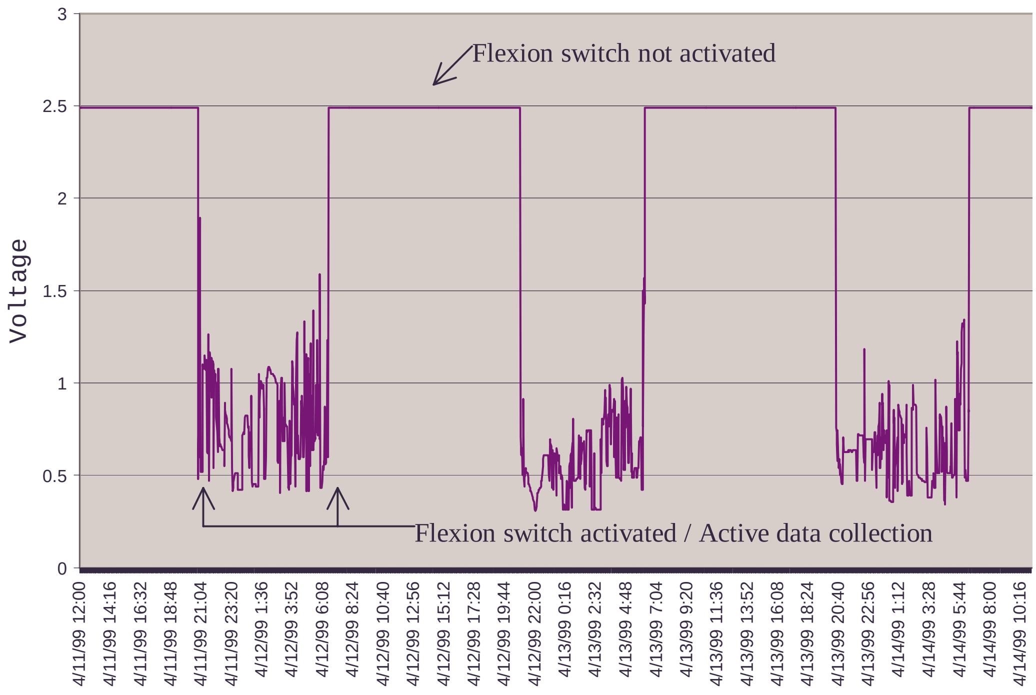


Figure 3-3. Three-day data capture of sample patient.

Development of Tooth Displacement Measurement

The second critical part of a study set to measure orthodontic headgear therapy outcomes involves the physical measurements of change produced from treatment. As previously discussed one main parameter of successful treatment is dental movement and specifically maxillary molar distalization. Much of the body of literature reported on headgear effects has measured this anticipated molar displacement in methods that, as described in chapter 2, are inaccurate, potentially distorting, difficult to measure, and not practical or feasible in the measurement of very small dental movements.

Stable Reference Point

In order to characterize and measure an object's movement in space, a stable landmark for three-dimensional superimposition is necessary. In this particular study, characterizing the maxillary molar's movement would be feasible if a stable landmark could be found or determined. Basically the landmark would have to be limited to the maxilla, and be acquired via maxillary study model impressions.

A study reported by Almeida et al. (1995), set to determine the stability and suitability of the palatal rugae as a stable landmark, has found significant dimensional changes to occur at the lateral points of the rugae, particularly following headgear treatment. The medial points of the second and third rugae, Almeida had suggested, were an appropriate landmark for serial study-model longitudinal study, despite some dimensional changes. Baily et al. (1996) repeated Almeida's protocol studying the stability of the palatal rugae in a series of orthodontically treated patients. Baily's findings showed that all rugae landmarks were statistically significantly different and have altered during the course of treatment. Despite her findings, Baily has suggested that perhaps due to the small changes in the rugae pattern, the changes may be too small for clinical significance and could potentially be used as a stable landmark pending further studies. Baily's findings were consistent with those of other investigators (Van der Linden, 1978) who also reported significant changes in the palatal rugae' configuration after orthodontic treatment. Although Almeida and Baily have suggested that small changes in the rugae dimensional pattern may be acceptable, their suggestion could prove quite contrary for the study of molar movement. Since the rugae would serve as a landmark for superimposition, so that objects further away such as the maxillary molars could be re-oriented in space, very small changes in the rugae could lead to very large and significant errors in molar measurements when the rugae are superimposed.

Since all structures in the maxillary arch, soft as well as hard tissues, are likely to undergo some dimensional change due to treatment or growth, an extra-dental stable landmark needs to be defined. This stable extra-dental structure was accomplished through the use of a Nance button by stabilizing several structures together minimizing their overall individual displacement, and maximizing the differential displacement of the objects of interest, the maxillary molars (Figures 3-4 and 3-5).

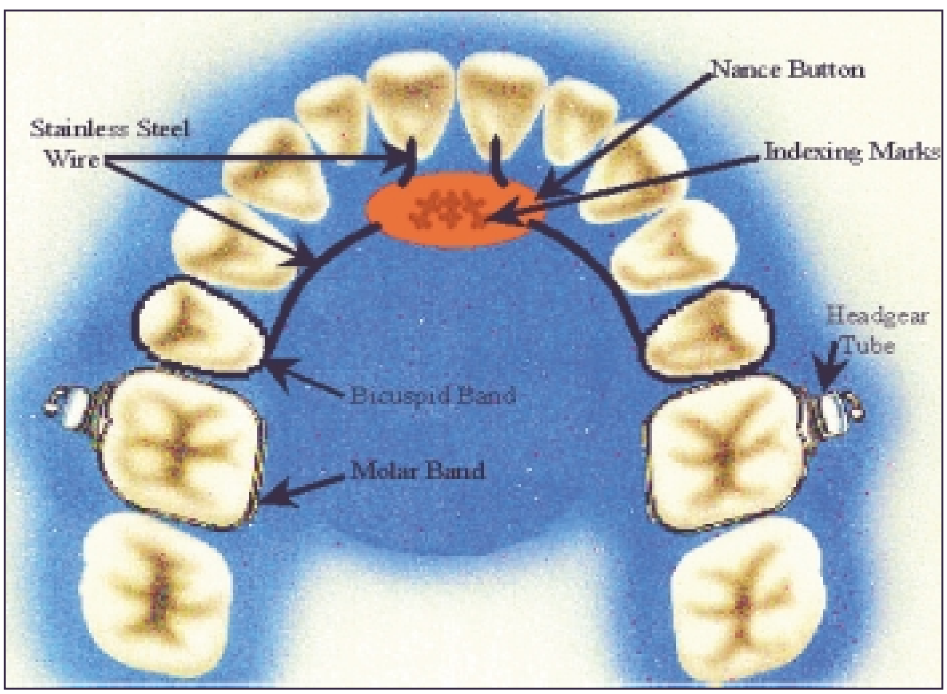


Figure 3-4. Custom Nance appliance.

Figure 3-5. Study model of Nance cemented in place.

Three-Dimensional Digitizing

Once the stable landmark is established, it, along with the object investigated needs to be digitized; in this particular case, the Nance button and the maxillary molars. The digitization process will render the selected landmarks, molars and Nance, in terms of their three-dimensional coordinates for computational manipulations and spatial digital reorientation. It is this digital reorientation that will allow the computer software to superimpose all the stable landmarks in the series, and consequently calculate molar movement, from several, serial superimpositions.

In order to mathematically compute movements of one object with respect to another object in space, the location, and plane of each object is required. The minimal amount of points that define a plane is three. Therefore, three points are needed for the stable landmark's orientation, and three points are needed for the molar orientation (Figures 3-6 and 3-7).

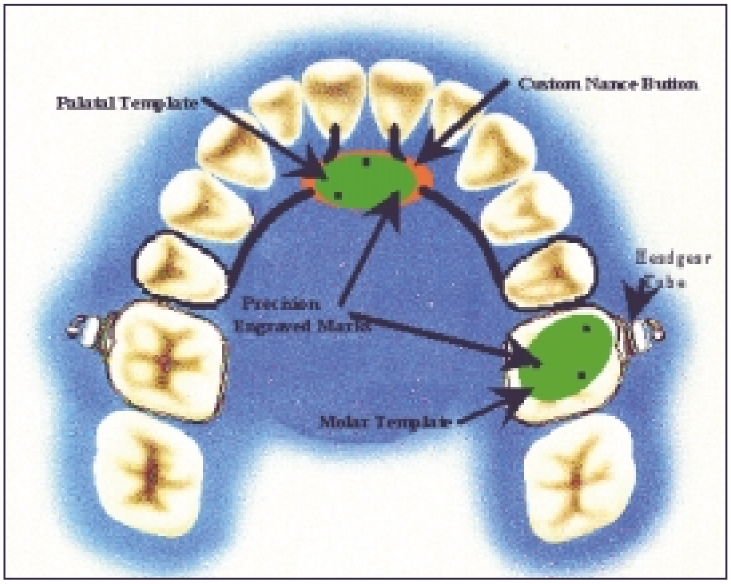


Figure 3-6. Templates placed on study model.

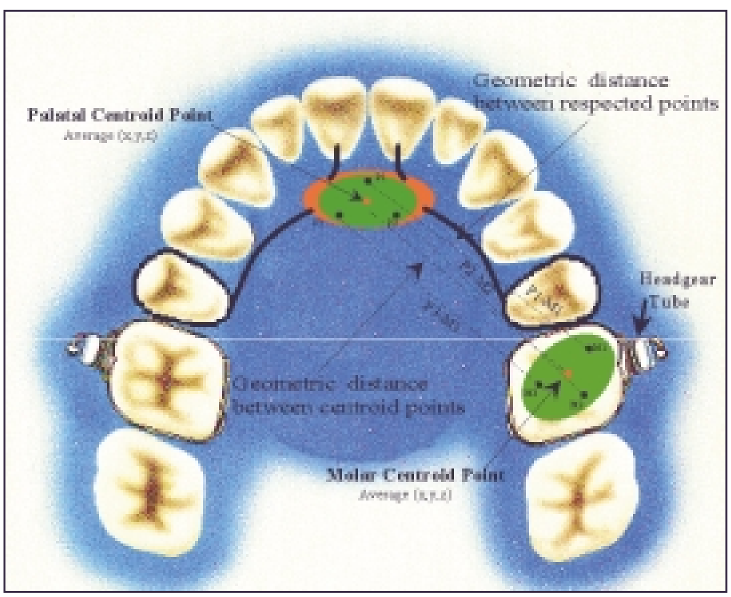


Figure 3-7. Centroid displacement and spatial analysis.

A reproducible and accurate system of designating the three points for both the molar and the stable structure, was developed and shown to be a reliable method of data point assignment (Bar-Zion et al., 1998). The system basically consists of well fitting templates, one for the stable structure and one for the maxillary molar (Figure 3-6). These templates are outfitted with three precision engraved marks, designating the three points for data acquisition. The templates are transferred from each serial cast to the next, and have proved to be rather stable due to their intimate adaptation to the maxillary molar's occlusal table and the indexing marks on the stable structure (Figure 3-4).

Figure 3-8. MicroScribe 3DX.

Once the templates are made, the study models are secured in place utilizing a modified vice grip. The templates are then placed on their perspective landmarks, and the points on the templates are digitized using a mechanical 3-D scanner, MicroScribe-3DX©

(Immersion Corporation, San Jose, CA). The MicroScribe-3DX (Figure 3-8) is connected via a serial port to a Pentium based personal computer, and the data is uploaded directly into an automated spreadsheet. The data points are stored in the spreadsheet as a series of three-dimensional coordinates (Table 3-1). Once data is collection is complete, it is interpreted using specially designed software.

Table 3-1. Sample of data captured spreadsheet.

Patient Name: Sample Patient			
	x(mm)	y(mm)	z(mm)
palate 1	268.495	-158.613	80.9095
palate 2	273.771	-165.122	81.597
palate 3	265.8814	-168.257	81.1651
molar 1-R	255.8717	-140.716	87.1222
molar 2-R	261.5681	-142.661	86.1361
molar 3-R	263.3255	-137.8	85.9757
molar 1-L	246.468	-183.142	88.7872
molar 2-L	250.1633	-179.785	89.4596
molar 3-L	252.9333	-185.782	88.4936

Three-Dimensional Analysis

The final component in the characterization of dental displacement is the three dimensional analysis of the data. As previously discussed, once the coordinates of the stable landmark as well as the coordinates of the objects of interest in a complete series of serial study models are obtained, the data is ready to be analyzed. To illustrate and measure the object's movement in space over time, all different time points need to be superimposed on the stable landmark (Figure 3-9). This will allow both qualitative and quantitative characterization of the spatial displacement of the object of interest, in this particular study the maxillary molar.

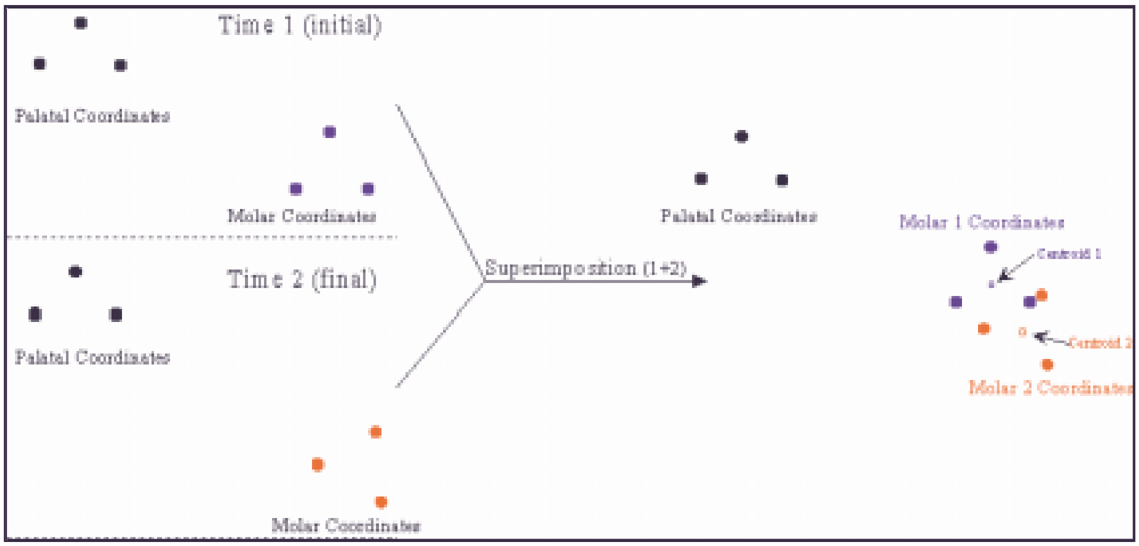


Figure 3-9. Finite element analysis.

To detect the overall molar displacement, changes in the centroid distance between the stable landmark and the maxillary molar can be calculated and compared (Figure 3-10). Changes in the geometric ratios between the corresponding coordinates could be deciphered as three-dimensional spatial changes and could be resolved to calculate the magnitude and vectors of displacement (Figure 3-10).

In order to discern and measure small spatial changes, the investigated object's movement can be reduced to its finite elements of movement (Figure 3-11). These finite elements are used to individually look at the various components of the overall spatial displacement (Figure 3-11). The movement of any object in space is made up of travel in the three planes: Sagittal <*Y-axis*> (mesio-distal), transverse <*X-axis*> (bucco-lingual), and vertical <*Z-axis*> (intrusion-extrusion) (Figure 3-11). Any two of the three vector resultants could then be used to calculate the angular change of the surveyed object: Transverse and sagittal vector combination will render rotational changes; transverse and vertical vectors combination will render tip and torque angular changes; sagittal and vertical vectors combination will render tilt angular changes.

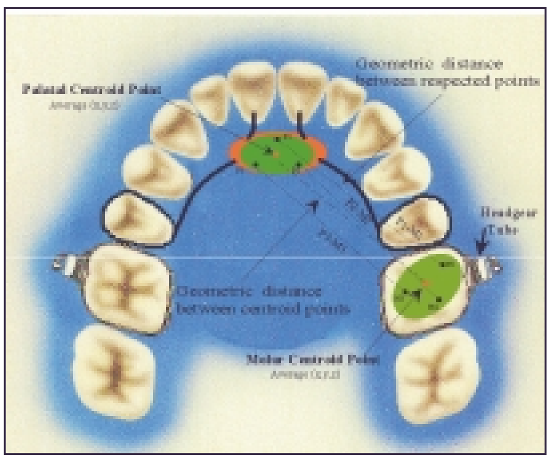


Figure 3-10. Centroid displacement and spatial analysis.

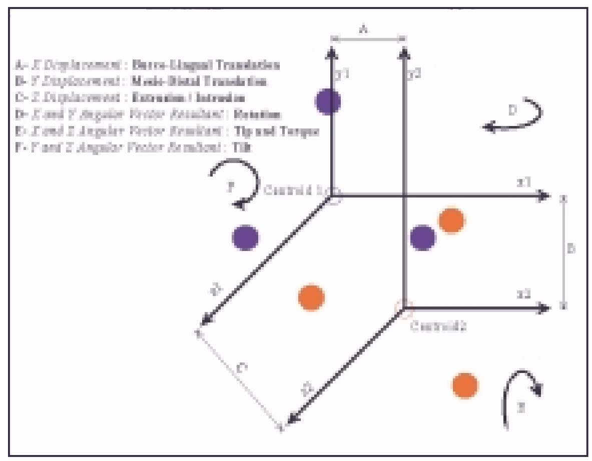


Figure 3-11. Finite element analysis.

Figure 3-10. Centroid displacement and spatial analysis.

Figure 3-11. Finite element analysis.

The maxillary molar's movement can also be evaluated qualitatively using three-dimensional rendering software. This software can be specifically programmed to digitally superimpose the data on the stable landmark, and subsequently render a graphical representation of the displaced object. The rendered graphical illustration could then be viewed from any position and angle in space, adding a new dimension to the data interpretation. This represented data will be displayed in terms of triangular objects in space each representing its respected object (Figure 3-12). Each digitized point is represented as a point forming the vertex of a triangle. When a series of data points are visualized in this manner, the graphical representation illustrates the spatial displacement of the molar, over time, with respect to the Nance button (figure 3-13). Using specially developed graphical software, the spatial displacement can potentially be viewed from any angle.

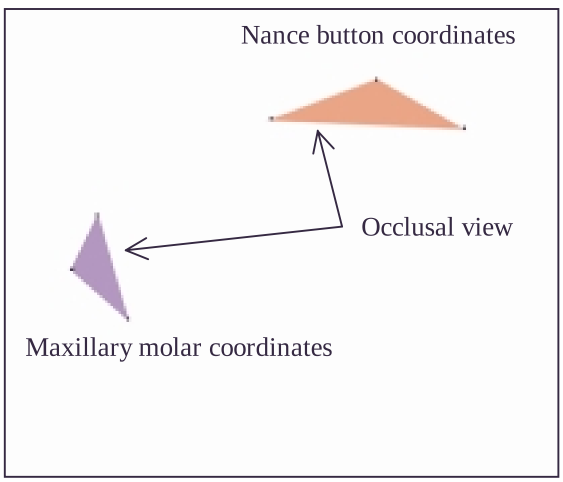


Figure 3-12. Sample object rendering (simulation).

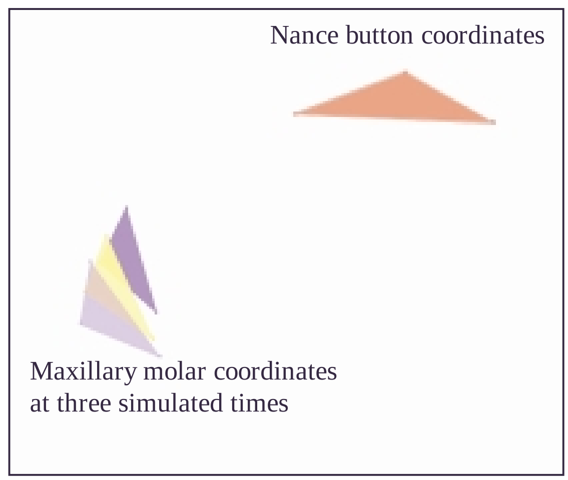


Figure 3-13. Sample of serial superimposition object rendering (simulation).

Once the three dimensional calculations are obtained, the software is able to provide quantitative results in terms of angular and absolute displacement from the perspective point of view. Furthermore, the computer can utilize substitutional emulation to generate preset views along with a molar figure substitution to provide a more familiar view of the molar's spatial displacement (Figure 3-14).

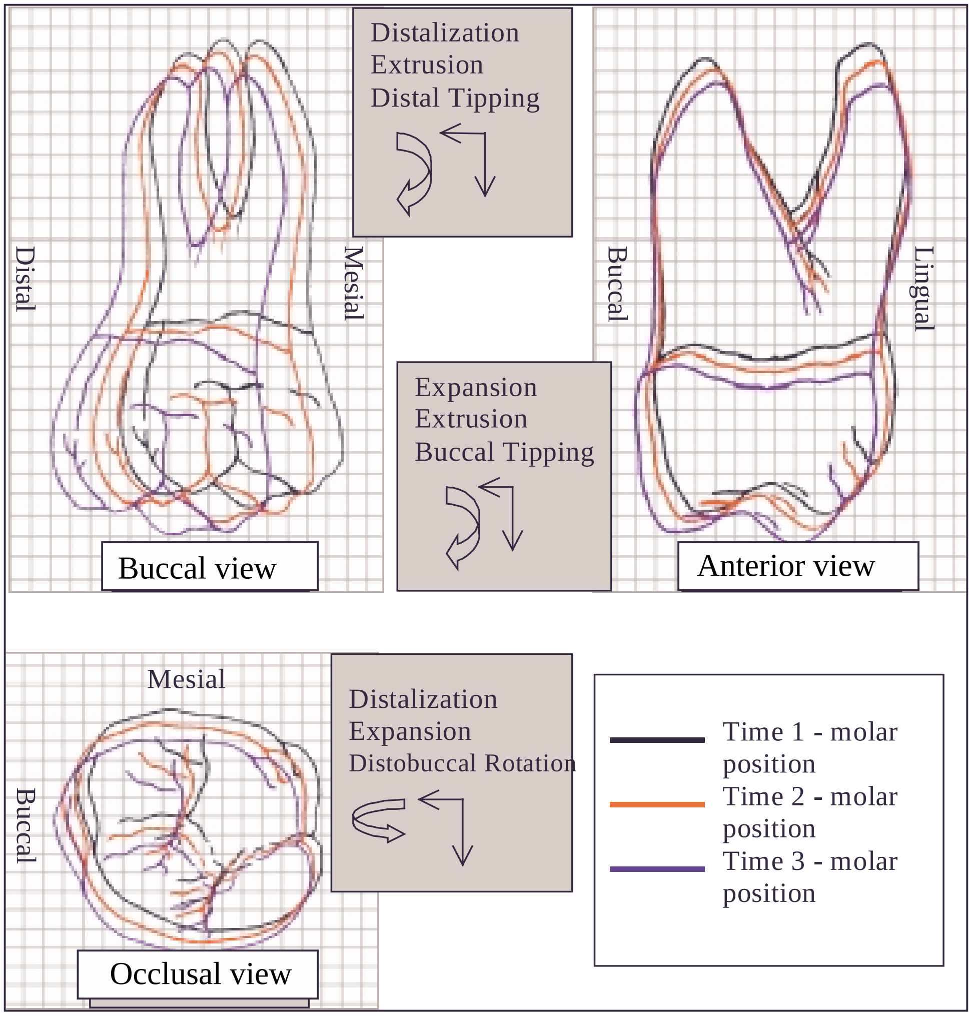


Figure 3-14. Computer generated emulation of three-dimensional displacement.

Clinical Data Collection

Subject Selection

To pilot test the study model developed, a sample size of five patients was selected to participate in the study.

Inclusion criteria

1. Patient requires headgear therapy as part of orthodontic treatment.
2. At least ¼ cusp class II dental relationship.
3. First maxillary molars as well as first or second maxillary bicuspids fully erupted (for the placement of the Nance button).
4. Patient agrees to wear special timing headgear for 6 month
5. Patient is able to present to the clinic for records at monthly intervals
6. Patient is in good health and free of dental disease

Exclusion criteria

Patients not fitting inclusion criteria

Study Design

A flow chart representing the study protocol is depicted in figure 3-15.

In order to test the validity of the timing devices, one of the patients' mothers was asked to personally place and remove her daughter's headgear as well as record the time of wear episodes in the assigned log-book. With the single exception of the compliance diary entries recorded by her mother, this patient followed the same protocol as the other subjects.

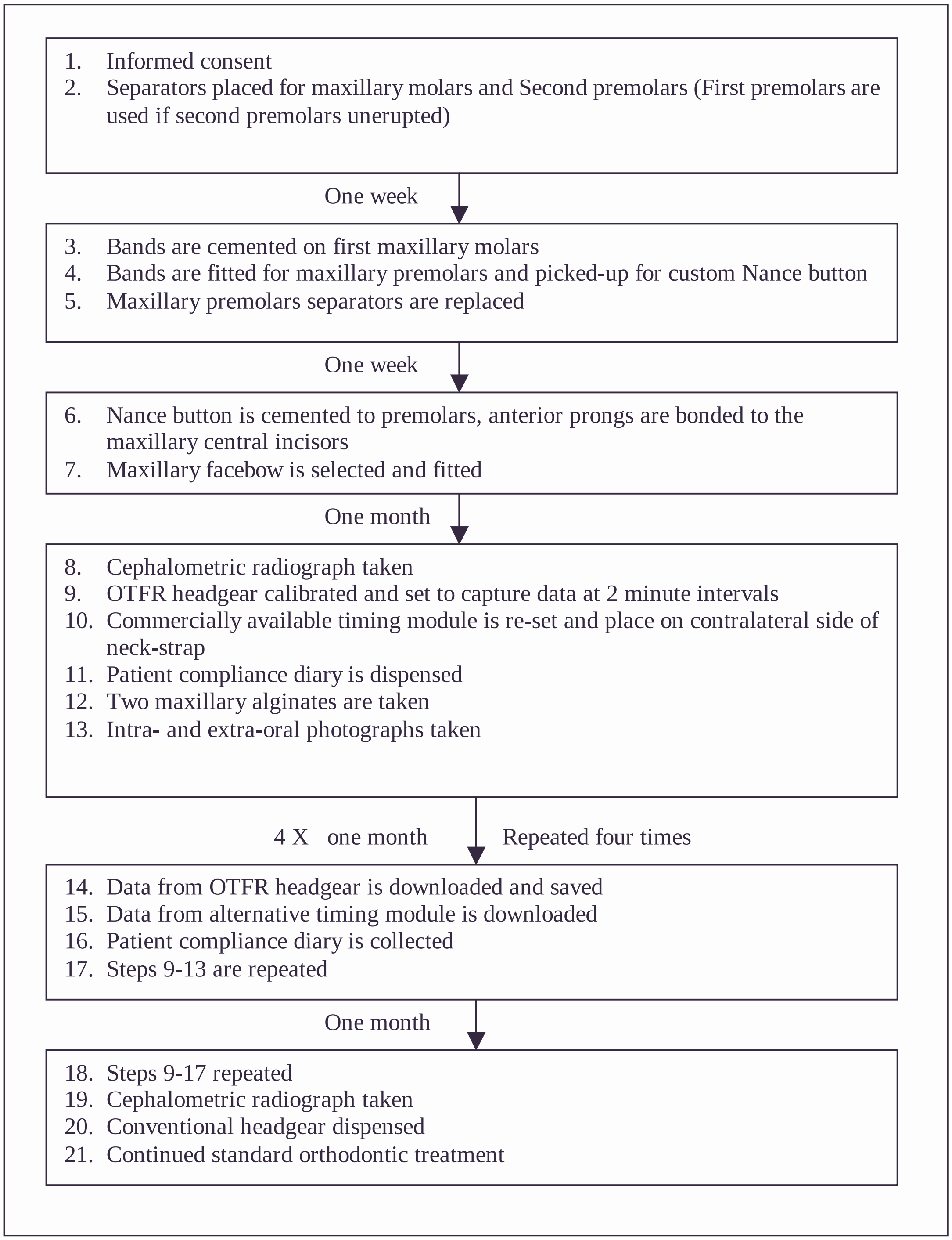


Figure 3-15. Study design flow chart.

Initial appointment: After obtaining an Institutional Review Board approved informed consent from the patient, orthodontic separators were placed in preparation for banding of the maxillary first molars as well as the banding of the second premolars. In cases where the second premolars had not yet erupted, the first premolars were used.

Second appointment: Bands were fitted for the maxillary first molars as well as the selected premolars. The premolar bands were then picked-up utilizing an alginate impression, poured up, and a modified Nance button was later fabricated (Figure 3-5). The maxillary bands were cemented at this appointment, and the premolars orthodontic separators are re-placed in preparation for the Nance button delivery in one-weeks time.

Third appointment: The Nance appliance is cemented in place, and the anterior stabilizing wires are bonded to the maxillary central incisors for added stabilization of the Nance (Figures 3-4, 3-5), which will serve as the stable landmark in the tooth movement part of the study. Maxillary facebow is selected and is passively fitted into the maxillary molars' headgear tubes. A cephalometric radiograph is taken of the patient. The patient returns to the clinic in one month, allowing any inadvertent forces applied to the premolars due to the Nance appliance cementation to be expressed. This step is taken to avoid any potential tooth movement due to the Nance button. Such initial tooth movement artifact could potentially distort the findings.

Fourth to tenth appointments: At each monthly appointment, for the next six months, data collection records are taken. Upon patient arrival the data form the OTFR and the commercially available timer (Affirm, Ortho-Kinetics, Vista, CA) are downloaded and stored, The patient's self reported compliance diary is retrieved and filed, The OTFR headgear is calibrated using known weights ranging from 100 to 800 grams. The calibration data is then downloaded and stored, and the OTFR timing microcomputer is set to record at two-minute intervals. The commercially available timer is reset and placed on the contra-lateral side of the OTFR headgear's force probe. Two maxillary alginate impressions are taken and are later poured in lab stone. Intra- as well as extra-oral pictures are taken. The patient's diary is collected and a new diary is given to the patient for self-reported compliance. The headgear is adjusted and set clinically to 16 ounces per side using a Dontrix gauge (ETM Corp, Glendora, CA). The patient is reminded to wear the headgear for 12 hours per day, and is to return to the clinic in one month for the next appointment.

Eleventh appointment: Following the final record appointment, the patient was given a conventional headgear, the Nance button was removed (if necessary) and orthodontic treatment was continued.

Data Analysis

Testing of the Three-Dimensional Molar Measurement System (objective 1)

Before the tooth displacement measurement methodology is used to analyze the collected study models, the developed analysis system needs to be implemented on a set of study models that had undergone visible dental change. This is necessary to determine the feasibility of the system to analyze data when change is obviously apparent. Should none of the study patients experience any measurable dental changes, it could be ascertained that the system is in fact capable of characterizing molar displacement when such displacement is present, and an estimate of the technique sensitivity could be established.

A set of study models, obtained from a patient undergoing headgear therapy who exhibited significant apparent dental change, was selected from our dental clinic. Since this set of models was selected retrospectively, it lacks the stable landmark created by the Nance button. We felt that for this preliminary examination of the molar displacement measurements system, the palatal rugae could be used. This determination was based on the facts that the amount of apparent dental movement was so large, that the sensitivity of the technique of measurement would overwhelm distortion arising from the palatal rugae deformation, and the technique feasibility could therefore be examined.

The initial and final maxillary models of this selected patient would be digitized and analyzed according to the methods described above. The results of this section of the study would be reported and illustrated both as qualitative visual representation of the gross movement, and also as quantitative linear and angular changes.

Analysis of Timing Data (objectives 2 and 3)

The timing data can be separated into four parts:

1. OTFR headgear data
2. Affirm (commercially available timer) data
3. Actual time of appliance recorded by patient's mother in assigned logbook
4. Patients' self reported compliance recorded in assigned diary

This data will be correlated to answer the various objectives. In order to test the validity of the OTFR the total time of wear recorded using the OTFR will be correlated with the known total time of wear recorded by the mother. The data from the Affirm timer would be correlated with the known time of wear as well as the OTFR. If three sets of time recordings exhibit statistically significant correlation and their values are similar in magnitude, we can assume with reasonable certainty that the OTFR headgear microcomputer along with its interpolating algorithm is valid in the estimation of wear time and evaluation of compliance.

Should the OTFR and the Affirm timing data prove valid, the total time of wear will be correlated with the patients' self reported compliance diary. This will provide an insight into the reliability of such compliance monitoring method previously utilized in published clinical headgear studies yet never validated. If the self reported diary does in fact correlate with statistical significance with the OTFR and Affirm timing data, it would provide support for the continued use of this popular method in future clinical studies.

Analysis of Force Data (objective 4)

The force data will be used to evaluate the reliability of the OTFR in force recording measurement utilizing the calibration data, as well as calculating the average force of application during each period of wear.

Intra-reliability: The calibration data obtained at each monthly visit from each OTFR headgear would be statistically evaluated to ascertain the ability of the headgears' force probe to record the same known force levels over time. This particular analysis will provide insight into the longevity of the OTFR headgears' components, and will influence future designs. Furthermore, this data will be used to convert the voltage reading captured by the ORFR microcomputer into the clinically relevant force values.

Inter-reliability: The calibration data from each headgear set will then be averaged and correlated across all other OTFR headgears in this study. This analysis will determine if each individual headgear requires its own calibration data-set or if a single calibration set will suffice for all manufactured headgear, saving time and resources when the OTFR headgear is implemented in a large clinical study.

Analysis of Tooth Displacement (objective 5)

All collected study models would be scanned and analyzed for three-dimensional molar displacement using the newly developed methodology described above. The results would be evaluated both qualitatively and quantitatively.

Qualitative results would provide insight into the general pattern of maxillary molar displacement following headgear therapy, should such a pattern in fact exist. Quantitative results would be described in terms of overall displacement in each plane of space, as well as respected angular changes. The results will be further reported in terms of displacement from time-point to time-point, as well as overall changes, further assisting in detecting a possible pattern of displacement, should one in fact exist.

Should a pattern of maxillary molar spatial displacement be detected, it will be correlated and related to the time and force of application. Such findings will suggest the significance that force and time of application bear on tooth movement, as well as provide insight into the potential of future investigations to determine the ideal force levels and time of applications necessary for optimal outcomes.

CHAPTER 4
RESULTS AND DISCUSSION

Tooth Displacement Characterization of a Selected Study Model

Study models of a nine-year old orthodontic patient undergoing headgear therapy were selected to test the tooth displacement model. The patient's pretreatment (Figure 4-1) and post-treatment (Figure 4-2) models had exhibited an apparent large maxillary molar displacement. This could be visibly noted by the space apparently created between the first molars and the maxillary second primary molars. These study models were selected retrospectively, and so they lacked the fabricated stable landmark developed for the subjects enrolled in the prospective study. It was determined to use the palatal rugae as the stable landmark for the analysis of these study models. This was done with two considerations:

1. The stability of the palatal rugae could be evaluated using the three-dimensional analysis software for their suggested stability (Baily, 1997; Almeida, 1995).
2. It was determined that despite potential deformation in the palatal rugae secondary to treatment, the apparent large magnitude of maxillary molar displacement could still be detected.

Figure 4-1. Pretreatment models.

Figure 4-2. Post-treatment models.

Figure 4-1. Pretreatment models.

Figure 4-2. Post-treatment models.

The models were digitized and analyzed as described in chapter three. Each model was digitized five consecutive times, and the means were used with three-dimensional analysis software to produce quantitative and qualitative results of maxillary molar displacement (Tables 4-1 and 4-2).

Table 4-1. Pretreatment averaged digitized values.

Table 4-2. Post-treatment averaged digitized values.

Table 4-1. Pretreatment averaged digitized values.

Time 1	X (mm)	Y (mm)	Z (mm)
palate 1	264.7176	-148.7966	92.54328
palate 2	268.1068	-140.5322	88.9753
palate 3	261.1059	-131.3662	93.40006
molar 1-R	242.099	-123.398	100.9215
molar 2-R	244.7412	-117.8221	100.382
molar 3-R	249.381	-118.8547	99.96186

Table 4-2. Post-treatment averaged digitized values.

Time 2	X (mm)	Y (mm)	Z (mm)
palate 1	260.7638	-152.242	88.82768
palate 2	264.8879	-143.3413	85.91742
palate 3	256.9131	-133.9568	89.893
molar 1-R	234.9356	-126.9538	95.98292
molar 2-R	237.2209	-120.5735	95.86216
molar 3-R	241.7571	-121.1681	96.4798

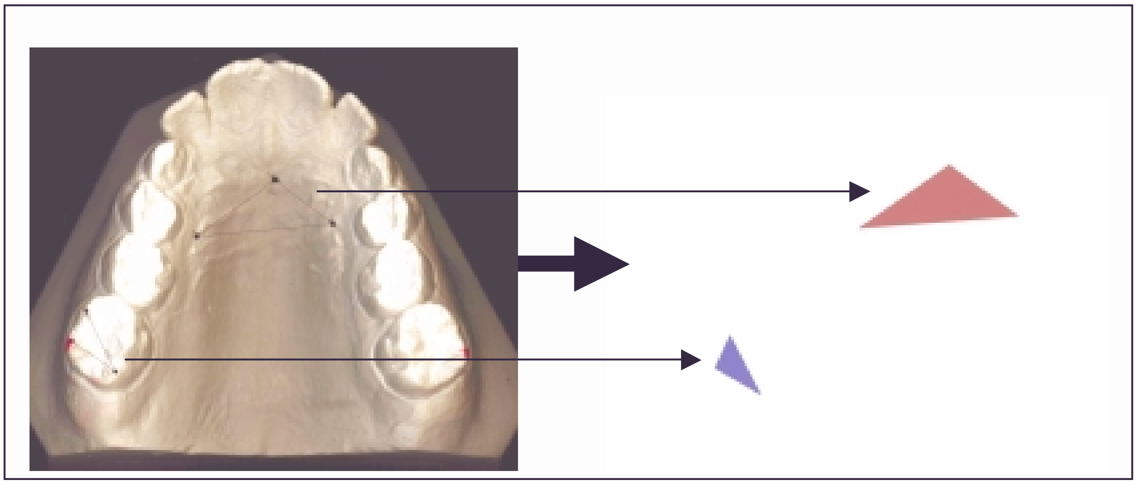


Figure 4-3. Digital conversion of pre-treatment structures into three-dimensional graphics.

Figure 4-3. Digital conversion of pre-treatment structures into three-dimensional graphics.

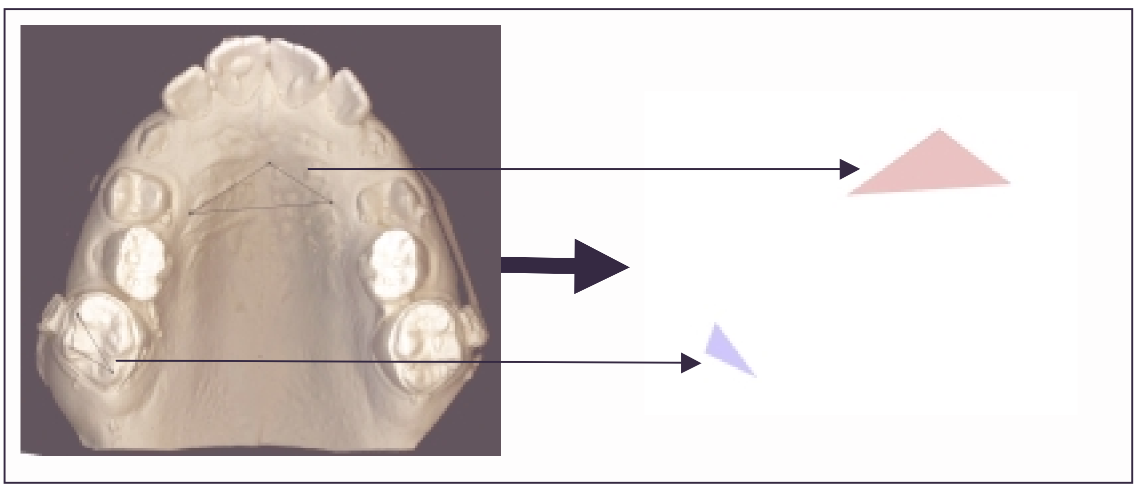


Figure 4-4. Digital conversion of post-treatment structures into three-dimensional graphics.

Figure 4-4. Digital conversion of post-treatment structures into three-dimensional graphics.

Values were entered into the digital graphic rendering software, which used the three-dimensional coordinates to generate two triangles, each positioned in space at its digitized spatial location. One triangle represented the palatal rugae triangle, and the other represented the molar occlusal table triangle (Figure 4-3).

Both models were digitally converted into a three-dimensional graphical representation in the manner described above. Post-treatment models (Figure 4-2) digital conversion is illustrated in figure 4-4. Once both models were in digital form, the software identifies each set of palatal and molar triangles (Figures 4-3, 4-4), and mathematically grouped them together in space. The computer then treated each set of triangles as a separate object, such that when each object was manipulated in space, its related structures and their spatial relationships remained static. This procedure was crucial in preparation for the next step of palatal superimposition (Figure 4-5).

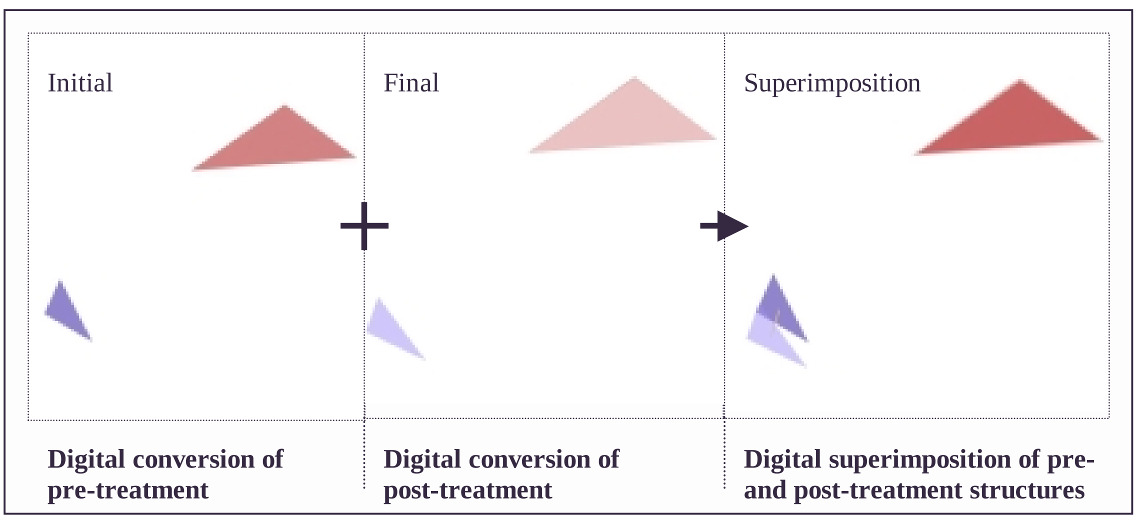


Figure 4-5. Digital superimposition of digitized structures on palatal rugae.

Figure 4-5. Digital superimposition of digitized structures on palatal rugae.

The palatal triangle of each set of related structures was then identified, and the analysis software mathematically found the best-fit spatial capture for the palatal triangles. The best-fit algorithm was designed to place both palatal triangles on the same spatial plane, simultaneously altering their corresponding molar triangle to its interpolated spatial position, and then rotate the triangles until geometrical best fit was achieved.

The resolved molar triangles were then graphically rotated to obtain the desired views (Figures 4-6, 4-7, and 4-8). Both qualitative and quantitative evaluations were performed in this manner. To aid in the measurement and visualization of the spatial displacement the software was programmed to calculate the geometric centroid of each molar triangle and place a vertical line perpendicular to each molar's occlusal table through its geometric centroid. Magnitude of spatial displacement as well as angular changes were then calculated and reported in orthodontic terms, to provide clinically useful information (Figures 4-6, 4-7, and 4-8).

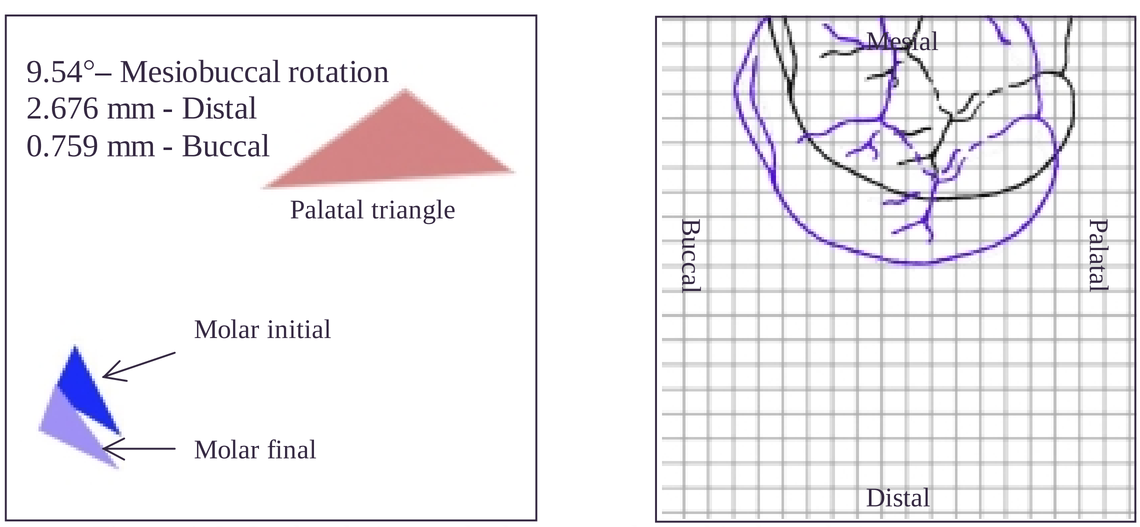


Figure 4-6. Occlusal view, calculations and graphical emulation.

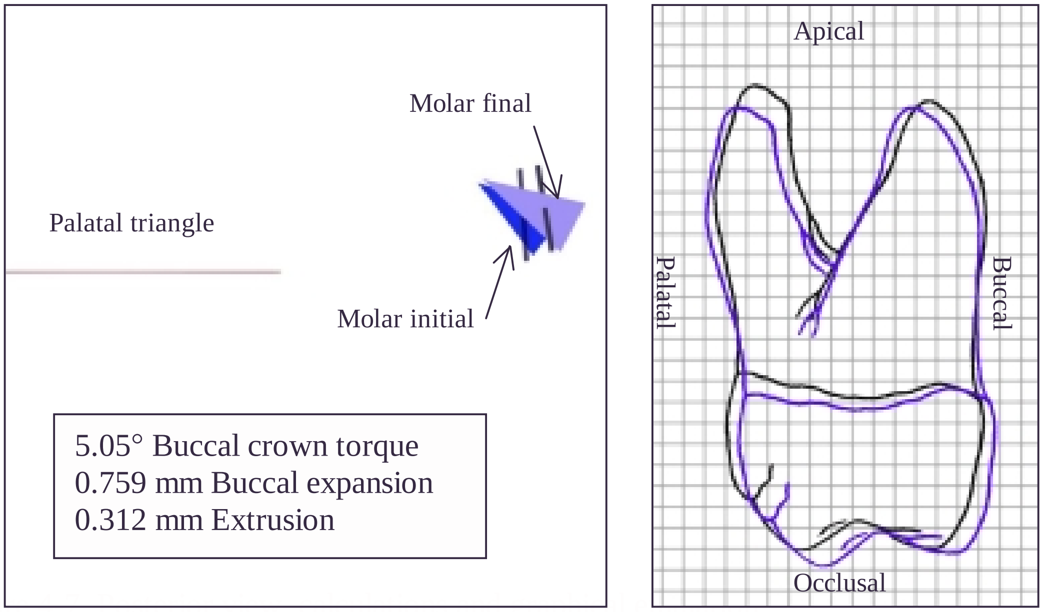


Figure 4-7. Posterior view, calculations and graphical emulation.

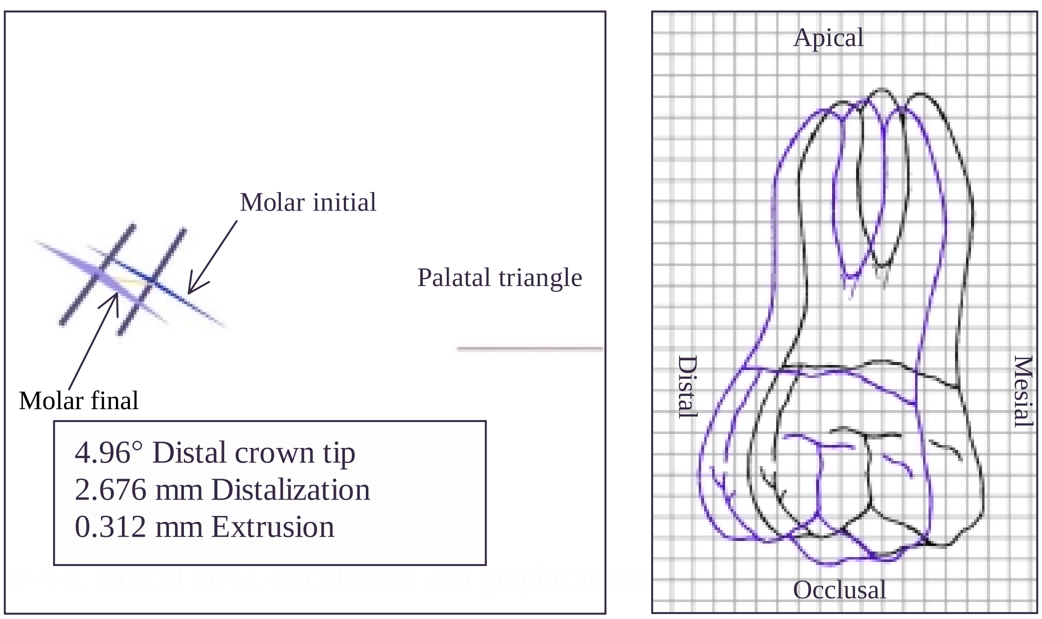


Figure 4-8. Buccal view, calculations and graphical emulation.

The newly developed analysis system was capable of providing both quantitative as well as qualitative measurements of the spatial molar displacement. This analysis system, though employed utilizing the palatal rugae, was still capable of producing results with reasonable resolution. The palatal rugae, as anticipated, underwent some dimensional deformation evident by the slight differences in the palatal triangles representation (Figure 4-5). The use of the Nance button as the stable landmark would have afforded more accurate superimposition for even greater resolution in detecting yet smaller spatial displacements. The ability of this system of analysis to successfully utilize the palatal rugae as a stable landmark further suggests the future potential of this system in retrospective studies as well as prospective studies. Though the resolution may have been compromised due to the somewhat dimensionally unstable nature of the palatal rugae, the time points of interest were spaced far enough apart, allowing a larger displacement to be detected using less resolution. By utilizing the palatal rugae in future clinical studies, the study design could be simplified, eliminating the Nance button fabrication and all related steps.

The data output of this system was unique and provided clinically relevant and applicable information. The quantitative results were described in orthodontically relevant planes of space, as well as applicable angular and linear dimensions. The data could then be exported into a spreadsheet, allowing for further analysis when related to time and magnitude of force application, as well as statistical modeling of the pattern and rate of molar movement. The qualitative results available through the use of this system provided virtually unlimited views of the treatment effects, from all planes of space. This visualization potential could allow researchers as well as clinicians an insight into the true three-dimensional changes that occur during treatment. Changes in the various planes that were previously undetectable and went unnoticed could now be visualized from a different plane of space, and their significance could further be explored.

This three-dimensional analysis system is not limited for the detection of molar movements from study models, but for spatial analysis of virtually any tooth following small modifications to the data capture protocol. Such application may include the study of canine retraction, space closure, incisor intrusion, growth and development, or any such study in which the spatial displacement of one object with respect to another is of interest.

Timing Data

Timing data collected during this study can be separated into four groups, OTFR, Affirm, third-person logbook, and patients' diary. Each set of data collected was imported into a spreadsheet, the third-person logbook and the compliance diaries were manually entered into a database, the total time of wear was calculated, and results were imported into the main spreadsheet (Table 4-3). Due to some OTFR malfunctions some data for several time points were not available. The same held true for some of the diary data, in which the patient did attempted to record the length of wear or had lost the diary, and for the Affirm time recorder that experienced some software failure later revised by the manufacturer.

OTFR malfunctions included situations in which some of the wiring solder joints came loose during routine headgear wear, force-probe module failure, and some cases of unintentional breakage due to improper headgear storage and handling.

In performing the correlation estimates, both the Pearson correlation and the Spearman rank correlation tests were performed. The Pearson correlation test assumes normal distribution of the actual values and is therefore influenced by extreme values. The Spearman rank correlation test is a non-parametric test that does not assume a normal distribution of the data values. Each value is assigned a rank and therefore, the estimation of the correlation coefficient is not influenced by extreme values. The Spearman rank test for non-parametric values was determined to be the more appropriate test for analysis of this data due to the nature of the data set. For the sake of completeness both correlation coefficients were reported.

Table 4-3. Timing data – spreadsheet summary.

Patient ID	Start Date	End Date	Hrs-comp	Hrs-affirm	Hrs-diary
1	1/28/99	3/3/99		273.3	305.5
1	3/4/99	4/1/99	125.9	126.1	125.25
1	4/1/99	5/13/99	148.6	149.1	149
1	5/20/99	6/8/99		90.7	90.6
1	6/8/99	7/1/99		102.9	103.3
1	5/20/99	5/26/99	39.6		39.5
1	6/12/99	6/13/99	5.9		6.1
2	10/1/98	10/29/98	324.7		285.4
2	10/29/98	12/15/98			428.25
2	12/15/98	1/14/99	258.5		261
2	1/14/99	2/17/99		160.8	191.1
2	2/18/99	3/18/99	87.56	86.7	197
2	3/21/99	5/2/99	122.1	123.6	316
3	12/17/98	1/19/99	112.1		117.5
3	1/28/99	3/4/99	252.1	241.4	302
3	3/4/99	4/1/99		102.3	190.2
3	4/1/99	4/20/99	148	146.5	52.5
3	4/20/99	5/27/99	215.1	217.4	73.6
3	6/1/99	6/30/99	161.1		137.1
4	10/17/98	10/28/98			12.4
4	12/30/98	1/20/99			0.25
5	3/18/99	4/14/99		178.4	192
5	4/15/99	6/13/99		190.8	176.5
5	6/14/99	7/22/99		123.1	
5	7/27/99	8/19/99		87	95.2

Correlation of the OTFR Headgear with Third-Person Log Book

To evaluate the validity of the OTFR headgear's ability to record and report the correct time of appliance wear, the timing data recorded by the OTFR needed to be evaluated against the actual time of wear. The actual time of appliance wear is difficult to determine in this type of studies due to the inability of the investigator to physically observe and record compliance over the study period. In order to acquire this data, we asked one of the patients' mothers to place the headgear on her daughter and personally record the wear period in a logbook (third-person logbook). The data from this third-person logbook was then entered into a database, total time of wear per period was calculated, and then correlated with the OTFR total time data (Table 4-4).

Table 4-4. OTFR and third party logbook correlation.

Start Date	End Date	Hrs-diary	Hrs-comp	
3/4/99	4/1/99	125.25	125.9	Correlation
4/1/99	5/13/99	149	148.6	r(s)=1.00 p=0.0001
5/20/99	5/26/99	39.5	39.6	r(p)=1.00 p=0.0001
6/12/99	6/13/99	6.1	5.9	

The highly significant correlation r=1.00, p=0.0001 using both the Spearman and the Pearson correlation test, suggested that the OTFR headgear was in fact accurate in estimating true time of wear. This was based on the assumption that the patient's mother actually recorded the true time of wear in the third party logbook. Three factors could support the validity of the third-person logbook. The first factor involves the pattern of the entry points. The third-person logbook was very detailed in its recordings of the wear periods. Some entries were as short as a few minutes, detailing removal of appliance for tooth brushing, eating, and various other such episodes. The logbook also revealed placement and removal of headgear at various times which appeared to correlate with the careful interview of the patient and the mother with respect to wear patterns. The second factor supporting the third-party logbook validity was its high statistical correlation with the OTFR headgear. Although such correlation could potentially be due to chance, in reality the total time value of both were so close that it seems unlikely. Finally, the third-party logbook was also correlated with the total time of wear recorded by the Affirm timing device (Table 4-5). The reliability of the Affirm timing device has not previously been reported on in the literature, however the manufacturer's independent evaluation estimates the device tolerance at ± 2%. The Affirm total time recorded was highly correlated with the third-party logbook r=1.00, p=0.0001 for both the Pearson and the Spearman rank correlation tests further supporting the validity and reliability of the OTFR headgear in measuring and estimating appliance wear as well as compliance.

Table 4-5. Affirm and third party logbook correlation.

Start Date	End Date	Hrs-affirm	Hrs-diary	
3/4/99	4/1/99	126.1	125.25	Correlation
4/1/99	5/13/99	149.1	149	r(s)=1.00 p=0.0001
5/20/99	6/8/99	90.7	90.6	r(p)=1.00 p=0.0001
6/8/99	7/1/99	102.9	103.3	

Correlation of Timing Headgear with Commercial Timing Device

To further test the reliability of the newly developed OFTR headgear, the recorded time data was also correlated with the commercially available headgear time monitor – Affirm. As previously mentioned, although not reported on in the literature, the

Affirm's reliability according to the manufacturer's independent testing is high with tolerance as low as ± 2%. The correlation of the OFTR with the Affirm was important not only to help evaluate and support the OTFR's reliability and vice versa, but also to establish the two as reasonably similar in their ability to estimate time of wear. This would allow us to compensate and substitute missing data points due to appliance malfunction for establishment of a more complete timing data set. The recorded data from the two appliances were evaluated and appeared to be highly correlated r=1.00, p=0.0001 using both the Pearson and the Spearman rank correlation tests (Table 4-6).

Table 4-6. Affirm and OTFR correlation.

Start Date	End Date	Hrs-affirm	Hrs-comp	
3/4/99	4/1/99	126.1	125.9	Correlation
4/1/99	5/13/99	149.1	148.6	r(s)=1.00 p=0.0001
2/18/99	3/18/99	86.7	87.56	r(p)=1.00 p=0.0001
3/21/99	5/2/99	123.6	122.1	
1/28/99	3/4/99	241.4	252.1	
4/1/99	4/20/99	146.5	148	
4/20/99	5/27/99	217.4	215.1	

The significant correlation between the OTFR and the Affirm, further supported the validity and reliability of the newly developed appliance. In addition it also documented the reliability of the Affirm module. Being relatively inexpensive and reliable in its ability to record total time of wear, the Affirm module could potentially be used in various clinical applications of compliance monitoring. The OTFR, however, with its ability to characterize the wear pattern, as well record force levels, makes it much more suitable for research applications. The characterization of the wear time is made possible with the OTFR due to its unique data recording microcomputer, which records a date and time signature for each data point. This allows a graphical representation of the wear pattern as well as highly intensive analysis of the data for detection of different patterns of wear, such as time of day, days of week, length of each period of wear, and similar parameters.

Correlation of Timing Headgear with Commercial Timing Device and Patient Diary

Monitoring of compliance in previous clinical studies evaluating the treatment effect of orthodontic headgear was attempted using patient self-reported compliance diary (Kirjavainen et al., 1997; Firouz et al., 1992). While many researchers consider this method of compliance monitoring as the gold standard, its validity and reliability has not yet been evaluated. To evaluate the reliability of the patient's diary as a potential source for estimating headgear compliance, the diary data was entered into a database, calculated for total time of wear per period and compared with both timing devices, the OTFR and the Affirm timer (Table 4-7).

Table 4-7. Patient's diary, Affirm, and OTFR headgear data.

Start Date	End Date	Hrs-affirm	Hrs-diary	Hrs-comp	
10/1/98	10/29/98		285.4	324.7	Correlation affirm and diary ->
12/15/98	1/14/99		261	258.5	r(p)=0.12, p=0.75
1/14/99	2/17/99	160.8	191.1		r(s)=-0.04, p=0.91
2/18/99	3/18/99	86.7	197	87.56	
3/21/99	5/2/99	123.6	316	122.1	Correlation OTFR and diary ->
12/17/98	1/19/99		117.5	112.1	r(p)=0.39, p=0.30
1/28/99	3/4/99	241.4	302	252.1	r(s)=-0.27, p=0.49
3/4/99	4/1/99	102.3	190.2		
4/1/99	4/20/99	146.5	52.5	148	
4/20/99	5/27/99	217.4	73.6	215.1	
6/1/99	6/30/99		137.1	161.1	
3/18/99	4/14/99	178.4	192		
4/15/99	6/13/99	190.8	176.5		

Analysis of the data revealed no statistically significant correlation between the patients' self-reported compliance and either the OTFR $r(p)=0.39$, $p=0.30$ / $r(s)=-0.27$, $p=0.49$ or the Affirm timer $r(p)=0.12$, $p=0.75$ / $r(s)=-0.04$, $p=0.91$. This suggested that although the assumption in the literature that the daily diary is a reliable method for securing data on headgear compliance, we found no statistical correlation to support this assumption. In fact the patients' diary both over- as well as underestimated true total wear time as measured by the electronic timers, without any decipherable systematic error.

When carefully reviewing the patient's diary entries it became apparent that many of the entries for several days were entered at a single time, further supporting the noted discrepancy. When the patients' were asked about it the common reply was that they had forgotten to provide entries for a few days and entered them in bulk a few days later. Some of the patients had worn the headgear and forgot to enter the wear period in the diary causing an underestimation of true wear time. Others had reported a wear time that was in actuality interrupted by several hours of non-wear (specifically detected by the OTFR) thereby overestimating the true wear time. The errors in entries were not consistent however, such that each patient may have overestimated or underestimated the true wear-time without any particular trend.

The use of a patient's diary to record and monitor compliance has been used not only in dentistry and orthodontics (Kirjavainen et al., 1997; Firouz et al., 1992) but also in other fields of medicine including pulminology (Berg et al., 1998; Malo, 1996), cardiology (Torrisi et al., 1997), oncology (Lee et al., 1992), neurology (Neugebauer, 1989), and particularly in pharmacology (van Berge Henegouwen et al., 1999; Straka et al., 1997; Olivieri et al., 1991). While many studies have relied on the diary for compliance, only one reported study had set to study the reliability of self-reported drug regimen compliance using electronic monitoring in pharmacology (Straka et al., 1997). In his study, Straka's findings suggested poor correlation between the patients' self-reported compliance and true drug compliance.

Our findings of poor correlation between self-reported and true compliance is consistent with findings of other researchers (Straka et al., 1997) evaluating similar parameters in somewhat different fields. The use of such a method for the monitoring of compliance appears to be unjust and may in fact contribute to the large inconsistencies reported in the various headgear clinical studies. The implementation of a digital timing device, such as the OTFR headgear in future clinical studies will provide a true and reliable measure of compliance. Such data, along with force recordings will provide invaluable data for the establishment of dose-response evaluation for force, time, and tooth movement.

Force Data

The second component of the OTFR headgear data includes the recording of force measurements. The OTFR's force recording capability makes it a novel measurement device, incorporating newly developed technology for research application; this pilot study is the first long-term implementation and testing of such device in a clinical trial.

In order to utilize and interpret the force measurements recorded by the OTFR, a series of base-line force calibrations were taken at each appointment (Figure 4-8). The calibrations were accomplished by placing a series of known weights in a cradle suspended from the end of the force-probe module, such that as the weight increased, the distension was greater, altering the voltage recordings. The voltage recordings were then plotted against the known force values. Since we anticipate that the resistance across the variable resistor is linear, and that the spring force distention constant is linear, we should be able to plot the weight against voltage and attain a line with a particular slope and intercept. The slope and intercept values could then be used to interpolate the real-time force data.

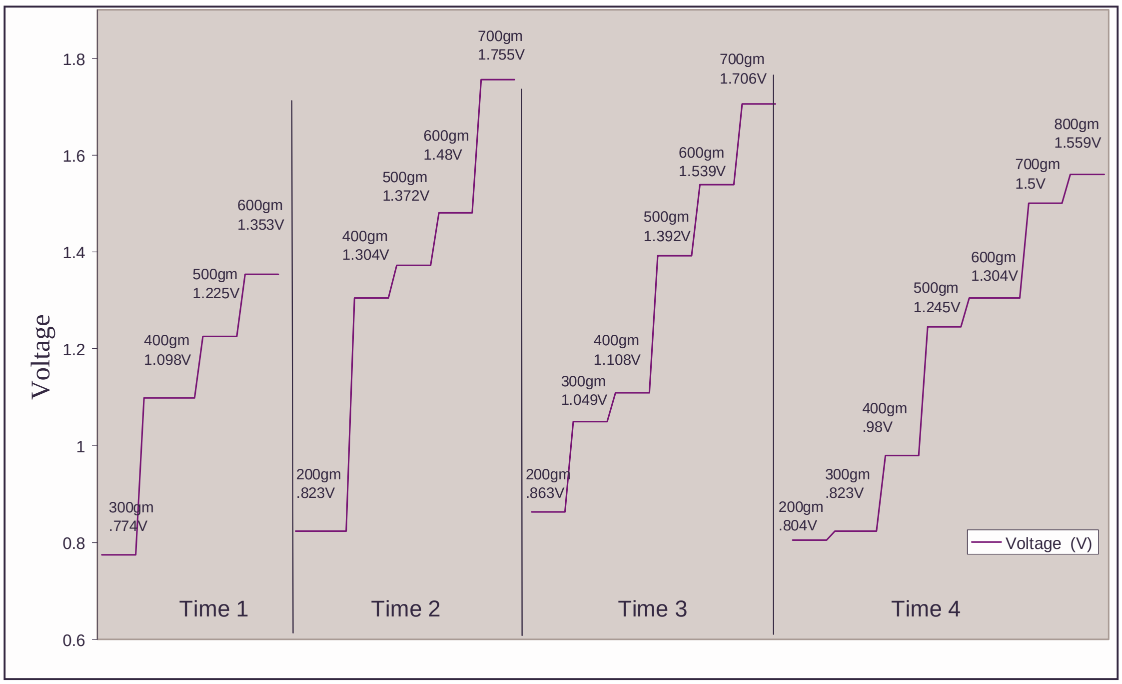


Figure 4-9. Patient RS – Force calibration recording.

The calibrations performed at each appointment served two functions: obtain data necessary to convert voltage values into force values and secondly, as part of this pilot study, evaluate the ability of the electronic force-probe encoder to provide consistent and reliable force measurements over time. To determine this reliability, the various force-voltage plots were evaluated for serial time points, and their variability was assessed. This variability was also evaluated across all force encoders to determine the inter-force encoder reliability. A sample of the force calibration recording is presented in Figure 4-9 and the force-voltage plot is illustrated in Figure 4-10. Similar plots were performed for all calibration data sets.

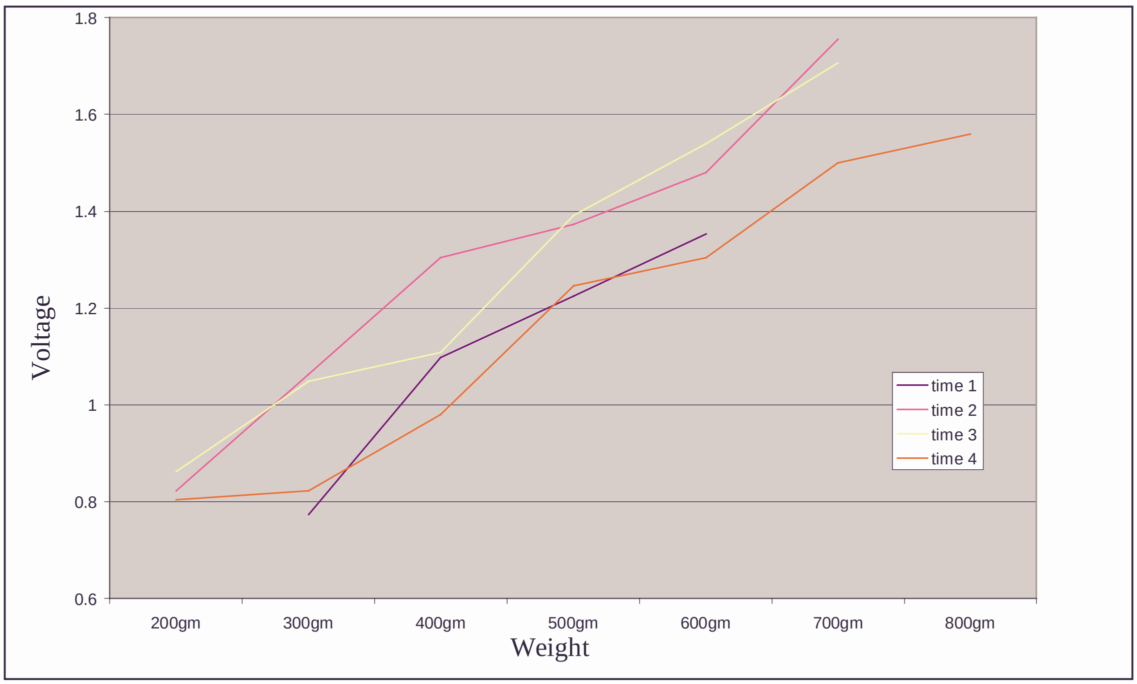


Figure 4-10. Patient RS – Force / Voltage plots.

When the various plots of the serial time points were evaluated (Figure 4-10), it became apparent that the force-voltage relationship was not consistent over time. Similar trends were noted for the other data sets as well. For better visualization of the variation in voltage recordings between times for the same calibrated weight, as well as visualization of the variability across different OTFR headgears, each patient data-set was assigned a symbol designation, and the entire data was plotted (Figure 4-11).

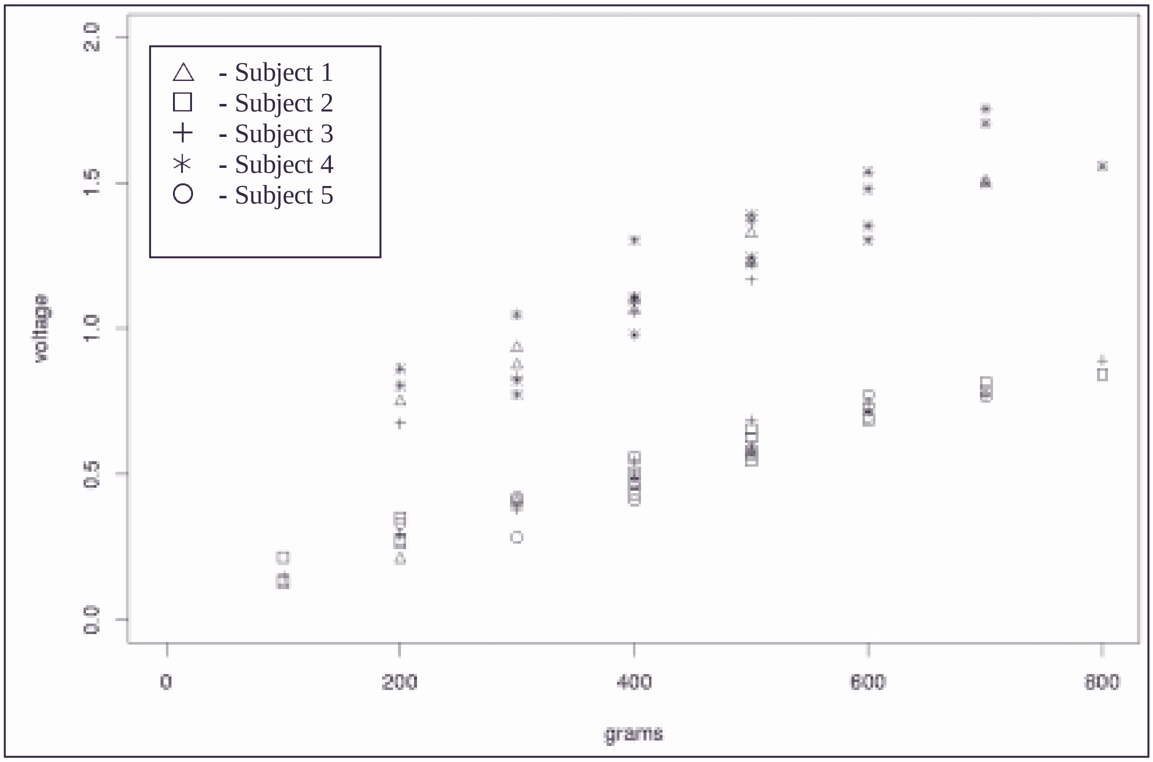


Figure 4-11. Scatter plot of force/voltage data of entire calibration set.

The scatter plot (Figure 4-11) further illustrates the force recording variability within each OTFR headgear, for example subject #4 calibration for 600gm. Figure 4-11 also points out the inter-headgear variability for force recordings. It is interesting to note that despite the intra-headgear variability, two distinct patterns of force/voltage trends became apparent; one pattern includes subjects 1 and 4, while the other pattern includes subjects 2,3, and 5. The generalized inter- and intra-headgear variability rendered the data of voltage readings exceedingly difficult to interpolate into meaningful force values, since the true conversion factor necessary to convert voltage into force values remained uncertain.

In order to determine factors contributing to the variability in an attempt to isolate its source, modeling of voltage as a function of force (weight) was performed for each of the subjects' recorded data set. Since the force-probe encodes the force data in a linear fashion, three linear models of voltage as a function of weight were developed.

Model 1: *voltage = intercept + B1 * grams*

Here, voltage is a linear function of grams, such that the intercept estimates the "baseline" voltage when grams=0

Model 2: *voltage = intercept + B1 * months + B2 * grams* Here, months is coded as 1,2, or 3; this term allows for a consistent shift over time, in a positive or negative direction.

Model 3: *voltage = intercept + B1 * month1 + B2 * month2 + B3 * month3 + B4 * grams*

Here, the model is set to allow the 'correction' to vary from month to month; month1 is coded as 0 if not month 1, or as 1 if it is month 1. Since we had observations from 4 months, we only needed the 3 month variables above. The correction for the 4^{th} month would be the intercept term, since all other month terms would be 0.

From this analysis, the coefficient for grams (B1 in model 1, B2 in model 2, B4 in model 3) should give us an idea of the consistency of the voltage / force relationship between subjects, and the months or month1 to month3 coefficients, and their significance, will indicate important departures from the basic linear model. The results of the models are presented in tables 4-8 to 4-12.

Table 4-8. Subject 1 – Modeling voltage as a function of force (weight).

Model 1:	Overall model: p=0.0001						
		intercept				grams	R^2=0.966
	estimate	0.081				0.001	
	p-value	0.0016				0.0001	
	s.e.					0.00004	
Model 2:		intercept	months			grams	R^2=0.974
	estimate	0.034	0.018			0.001	
	p-value	0.26	0.0454			0.0001	
	s.e.					0.00004	
Model 3:		intercept	month1	month2	month3	grams	R^2=0.983
	estimate	0.084	-0.044	-0.018	0.037	0.001	
	p-value	0.0018	0.08	0.46	0.1	0.0001	
	s.e.					0.00004	

The modeling results suggested a significant role for the intercept value as a contributor for the departure from the anticipated basic linear model for all subjects except subject #3. For model 2, with the exception of subject #3, and for all subjects of models 3, significant finding were detected, suggesting the months term as well as the changes from one month to the next, as important contributors to the detected variation from the anticipated linear model.

Variations between Headgears

The intercept estimate, the largest contributing factor to the apparent variability from the linear model, represents the voltage value when the force or weight is zero.

Table 4-9. Subject 2 – Modeling voltage as a function of force (weight).

Model 1:	Overall model: p=0.0001						
		intercept				grams	R^2=0.851
	estimate	0.459				0.0016	
	p-value	0.0001				0.0001	
	s.e.					0.00015	
Model 2:		intercept	months			grams	R^2=0.856
	estimate	0.504	-0.018			0.0016	
	p-value	0.0001	0.46			0.0001	
	s.e.					0.00015	
Model 3:		intercept	month1	month2	month3	grams	R^2=0.937
	estimate	0.355	0.021	0.173	0.184	0.0016	
	p-value	0.0001	0.7	0.0025	0.0011	0.0001	
	s.e.					0.00011	

Table 4-10. Subject 3 – Modeling voltage as a function of force (weight).

Model 1:	Overall model: p=0.0127						
		intercept				grams	R^2=0.478
	estimate	0.129				0.0019	
	p-value	0.63				0.0127	
	s.e.					0.0006	
Model 2:		intercept	months			grams	R^2=0.899
	estimate	-0.244	0.326			0.0012	
	p-value	0.11	0.0002			0.0042	
	s.e.					0.00032	
Model 3:		intercept	month1	month2	month3	grams	R^2=0.990
	estimate	0.553	-0.625	-0.062		0.0014	
	p-value	0.0001	0.0001	0.13		0.0001	
	s.e.					0.00011	

Variations of such sort can be contributed to inconsistencies in the fabrications of the force encoders. Since each one the OTFR headgears in this pilot study was individually manufactured, it is likely that each force probe would have a unique initial rest position and therefore some resistance would be measured across the encoder. To circumvent this problem in future OTFR headgear manufacturing, the initial resistance of each encoder could be set at zero or another predetermined resistance, making the intercepts uniform across all headgears. Establishing uniform force-encoders would allow the replacement of OTFR headgear in mid-treatment due to potential headgear loss, damage, or malfunction without significant data collection differences, an important consideration in future large clinical studies. Also, the establishment of uniformity across all force encoders, would ease the use of this device by eliminating the need for intensive calibration data collection and analysis, as well as make the isolation of inaccurate data collection to a malfunctioning headgear reasonably simple.

Table 4-11. Subject 4 – Modeling voltage as a function of force (weight).

Model 1:	Overall model: p=0.0049						
		intercept				grams	R^2=0.363
	estimate	0.262				0.0009	
	p-value	0.0485				0.0049	
	s.e.					0.00027	
Model 2:		intercept	months			grams	R^2=0.756
	estimate	0.569	-0.134			0.001	
	p-value	0.0001	0.0001			0.0001	
	s.e.					0.00017	
Model 3:		intercept	month1	month2	month3	grams	R^2=0.973
	estimate	0.04	0.503	0.036	0.006	0.0011	
	p-value	0.23	0.0001	0.23	0.83	0.0001	
	s.e.					0.00006	

Table 4-12. Subject 5 – Modeling voltage as a function of force (weight).

Model 1:	Overall model: p=0.0001						
		intercept				grams	R^2=0.906
	estimate	0.065				0.0011	
	p-value	0.188				0.0001	
	s.e.					0.0001	
Model 2:		intercept	months			grams	R^2=0.906
	estimate	0.064	0			0.0011	
	p-value	0.32	0.98			0.0001	
	s.e.					0.0001	
Model 3:		intercept	month1	month2	month3	grams	R^2=0.912
	estimate	0.059	-0.004	0.026		0.0011	
	p-value	0.28	0.91	0.49		0.0001	
	s.e.					0.0001	

Variations within Headgears over Time

The second important finding using modeling of the pilot data is the detection of variations in force to voltage conversion factors from month to month. Such intra-headgear calibration data variations occurring over time could potentially impact the data in a more significant manner then inter-headgear variations due to intercepts. Since the calibration data is used to develop the conversion factors to interpolate the voltage measurements into meaningful force values, changes in the calibrations and consequently the conversion factors would make the force recording indecipherable. This uncertainty arises since we cannot precisely determine when during the course of the recording period the changes in calibration values occurred nor can we predict the pattern of change.

Two factors may have contributed to this intra-force encoder variability, both are associated with the encoder's design and fabrication. The first factor is related to the force probe intrinsic hysterisis, resulting from binding and friction within the internal components. The described hysterisis could lead to inaccuracies in measurements since the headgear's force probe undergoes some internal bindings under function. These bindings would lead to the generation of different voltage readings under similar force levels. In our calibration data collection great care was taken to avoid artifacts due to hysterisis, by loading and unloading the force-probe's spring in a uniform and consistent fashion throughout the study. While hysterisis cannot be entirely eliminated due to the nature of the device's operation, it can be greatly reduced by modifying the force encoder to undergo less friction, and altering the force module to allow less binding during function.

The second potential component leading to intra-force encoder variability is alteration in resistance across the variable resistor over time. Such changes in resistance can be brought forth due to increased function of the resistor beyond it's designed tolerance, introduction of contamination such as sweat onto the resistor's contact surface, flexion of the sliding components, and other such time related resistance altering factors. Basically, if resistance were altered across the variable resistor over time it would make data interpolation highly inaccurate, since the rate and pattern of such change is likely to be random and unpredictable. This problem, although critical, could be corrected and circumvented with fairly minor apparatus revisions. The resistor itself could be replaced with one of higher tolerance and durability, the entire force-encoder should be encased in a protective casing, and other such implementations to increase the force-encoder's durability and consistency.

Despite the presently reported problems, the OTFR has been successful in the collection of the voltage recordings, which makes its design, for the most part, effective and functional. The main problems with this unique device stem from the durability of its components rather then its novel concept design. Following revisions of the force-probe encoder, it is likely that the OTFR headgear force recordings be relatively consistent, both within and across headgears, making the use of the OTFR in large clinical study invaluable for the collection of time and force data.

Tooth Movement Data

The final component of this pilot study involved the measurement of the maxillary molar displacement using the newly developed analysis system described in chapter 3. The serial study models were digitized, analyzed, and their centroid displacements were evaluated for the detection of tooth movement (Table 4-13).

The centroid displacement data was then mathematically analyzed with respect to time, looking at total as well as annualized displacement for the left and right maxillary molars (Table 4-14). Descriptive statistics of the data was performed and is represented in Table 4-15.

The Changes in molar displacement are presented in graphical form (Figures 4-12 to 4-16). Each line was then tested for linear trend, to detect if the distances were changing over time in a uniform linear manner; the p-values and R^2 values are listed in table 4-16).

Table 4-13. Serial study models centroid distance data.

Subject 1	Centroid results:						
date	12/17/98	01/28/99	03/04/99	04/01/99	04/20/99	05/27/99	07/01/99
p-mR	26.01375	25.8385	25.71792	25.63614	25.35939	25.40421	25.44911
p-mL	25.05825	24.97996	24.86637	24.7285	24.75937	24.48681	24.64375
Subject 2	Centroid results:						
date	10/01/98	10/29/98	12/15/98	01/14/99	02/18/99	03/18/99	05/03/99
p-mR	28.32946	28.33766	28.18476	27.88086	27.87187	27.88454	27.7989
p-mL	30.61198	30.73332	30.85037	30.47233	30.21945	30.46612	30.52185
Subject 3	Centroid results:						
date	10/15/98	11/12/98	12/17/98	02/02/99	03/18/99	04/15/99	05/27/99
p-mR	31.8815	31.64829	31.52422	31.68327	31.4617	31.59308	31.59813
p-mL	31.96796	31.78871	31.79189	31.87752	31.76298	31.65795	31.8449
Subject 4	Centroid results:						
date	03/18/99	04/15/99	06/14/99	07/22/99			
p-mR	27.73471	27.49168	27.44613	27.36195			
p-mL	29.60711	29.52234	29.21378	29.145			
Subject 5	Centroid results:						
date	01/28/99	03/04/99	04/01/99	05/20/99	07/01/99		
p-mR	25.89126	25.97744	26.06482	25.54013	25.66678		
p-mL	28.61314	28.26028	28.23787	28.2145	28.3037		

p-mR - centroid distance between palate and right maxillary molar
p-mL - centroid distance between palate and left maxillary molar

Table 4-14. Summary of total and annualized centroid change.

Subject	Days	TCh-Right	TCh-Left	ACh-Right	ACh-Left
1	196	0.56465	0.41450	0.0028809	0.0021148
2	214	0.53055	0.09012	0.0024792	0.0004211
3	224	0.28337	0.12306	0.0012650	0.0005494
4	126	0.37275	0.46211	0.0029584	0.0036675
5	154	0.22448	0.30944	0.0014577	0.0020094

TCh - Total change in centroid distance
Ach - Annualized change in centroid distance

Table 4-15. Descriptive statistics of molar displacement.

Variable	N	Mean	Std. Dev.	Minimum	Maximum
Days	5	182.8000000	42.5355270	126.0000000	224.0000000
TCh-R	5	0.3951603	0.1493228	0.2244790	0.5646470
TCh-L	5	0.2798457	0.1679301	0.0901217	0.4621081
ACh-R	5	0.0022082	0.0079710	0.0012650	0.0029584
ACh-L	5	0.0017524	0.0013308	0.0004211	0.0036675

Days - # of days from initial to final visit
TCh - Total change in centroid distance
Ach - Annualized change in centroid distance / per day

Evaluation of the descriptive statistics revealed a linear trend of molar movement for four molar teeth (subject 1 right and left, subject 2 right molar, and subject 4 left molar). While some linear trends were statistically significant, the magnitude of the total displacement was particularly small (<0.57mm) over the six months of treatment and can likely be considered not clinically significant. The small magnitude of displacement bordered on the lower extreme of the system resolution, as these values were somewhat within the error of measurement envelope. Due to the unexpectedly small displacement, three-dimensional characterization of the slight molar movement was not practical or feasible since the apparent spatial displacement was within the specified error of measurement. It is interesting to note that none of the patients exhibited any visible dental changes following the headgear trial, and all but one patient maintained the same anterior-posterior dental classification. The one patient who experienced some molar correction had lost her mandibular primary second molars, which we suspected was the source of her correction mechanism.

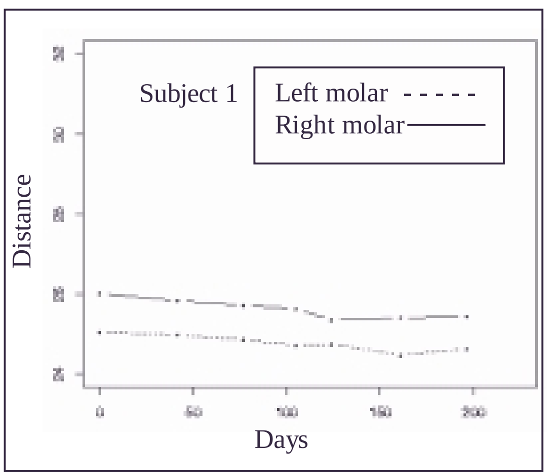


Figure 4-12. Subject 1 – Centroid graph.

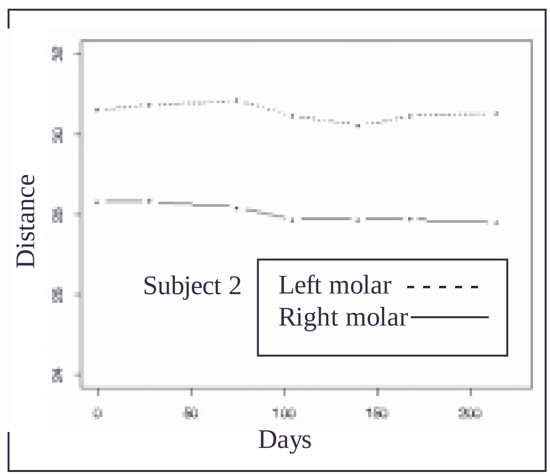


Figure 4-13. Subject 2 – Centroid graph.

Figure 4-12. Subject 1 – Centroid graph.

Figure 4-13. Subject 2 – Centroid graph.

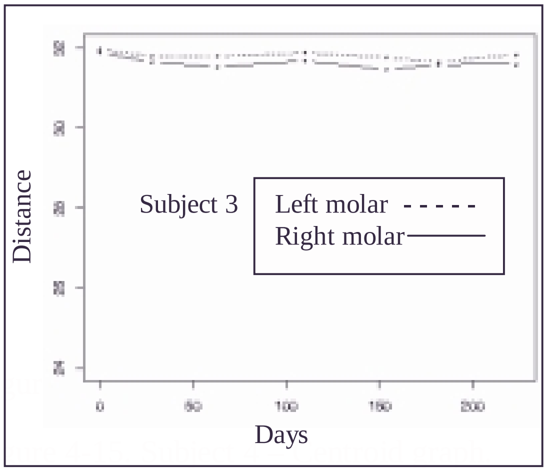


Figure 4-14. Subject 3 – Centroid graph.

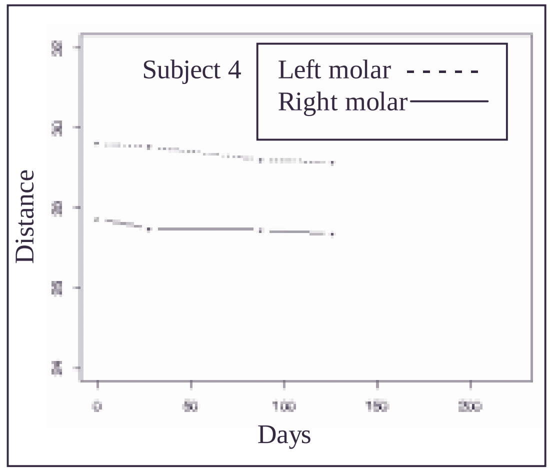


Figure 4-15. Subject 4 – Centroid graph.

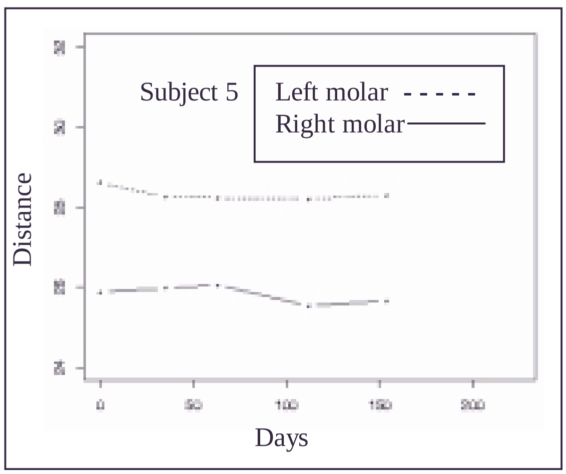


Figure 4-16. Subject 5 – Centroid graph.

Table 4-16. Linear trends of centroid graphs.

	Right		Left	
Subject	p-value	R2	p-value	R2
1	0.0041	0.83	0.0036	0.84
2	0.0025	0.86	0.22	0.28
3	0.18	0.32	0.26	0.24
4	0.11	0.80	0.0129	0.97
5	0.20	0.48	0.29	0.35

Our findings of virtually undetectable molar movement following orthodontic headgear treatment were not consistent with those of others (Ucem, 1998; Tanne, 1996; Firouz, 1992; Baumrind, 1981; Weislander, 1974; Watson, 1972). One of three potential scenarios or some combination of each could potentially explain this apparent disagreement. 1- all previously reported literature on headgear treatment effect grossly overestimated the maxillary molar displacement, which in fact does not exist. 2- the patients in our study had experienced molar movement but we were not able to detect it due to our method of measurement. 3- while the orthodontic headgear is capable of displacing maxillary molars, our patients did not experience any detectable displacement due to factors independent of appliance potential or measurement technique.

The first possible scenario is highly unlikely. Despite systematic errors in molar displacement measurement, the body of literature supporting maxillary molar displacement is highly comprehensive, and while previous studies have relied on inaccurate measurement techniques, it is reasonable to assume that some molar displacement could potentially occur following headgear therapy. This notion is further supported by our initial experiment, in which we have detected considerable molar movement subsequent to headgear wear.

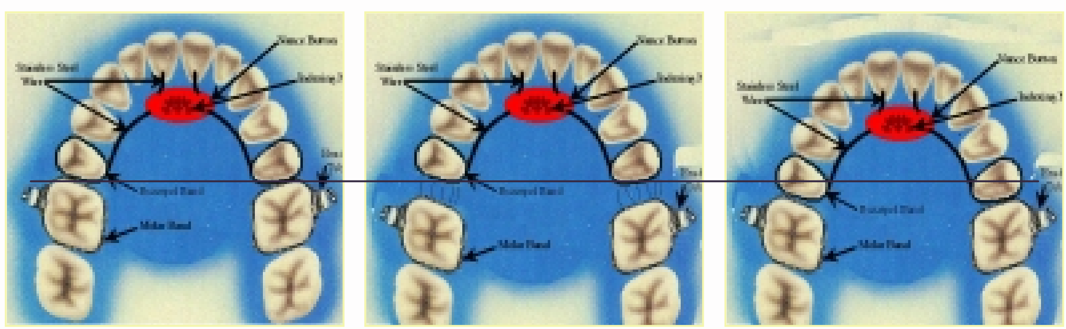
The second possible scenario that our patients did in fact experience some molar displacement subsequent to treatment yet our system of measurement was incapable of detecting the change is also somewhat unlikely. This scenario is doubtful as our newly developed system has been tested and was in fact capable of characterizing molar movement on a selected study model. Our lack of molar movement detection is consistent with our visual findings, both intra-oral and from study models, further supporting the findings or our measurement technique.

The most likely explanation for the lack of molar displacement in our patients involves several factors independent of the appliance treatment potential or the measurement technique. Factors that could have potentially contributed to the exceedingly small or otherwise undetectable molar movement in our sample include the presence of second molars as well as the use of the Nance button to the second premolars.

All of the patients in our study were either in the late mixed dentition or early permanent dentition, and all had erupted second permanent molars. The feasibility of molar distalization with the use of orthodontic headgear in the presence of erupted second molars has been shown to be less effective (Battagel & Ryan, 1998). By actively selecting patients with fully erupted permanent premolars for the utilization of the Nance button, the patients effectively also had second permanent molars, a factor which could have contributed to the lack of clinically significant molar movement.

The Nance button, the appliance specifically placed for the establishment of a stable landmark, may have inadvertently contributed to the lack of detectable molar displacement. Two potentially related problems may have been brought forth through the use of the Nance button in our patients. Both involve the fact that by essentially stabilizing the second premolars using the Nance, the interseptal and interdental periodontal fibers may have hindered the molar’s movement. Such potential mechanism is supported by the work of Gianelly et al. (1989), as well as others (Bondemark & Kurol, 1992; Muse et al., 1993), who have demonstrated the spontaneous distal migration of maxillary second premolars following maxillary molar distalization. This finding was attributed to the intersepteal and interdental periodontal fibers pulling on the second premolar as the adjacent molar was distalized. The same concept could also be applied to suggest that if the second premolars are held in place through the use of the Nance appliance, their static position could potentially hinder the maxillary molar distalization.

The second potential problem involving the Nance button's possible role in obscuring the results, involved the same periodontal fiber mechanism in an alternative manner. In a similar manner to that which could contribute to restrictive molar movement, the entire dentition, from second premolar to second premolar could be driven back along with the molars (Figure 4-17).



Inital Distalization Final

Figure 4-17. Mechanism of potential en-mass distalization.

This distal en-mass movement of the entire dentition has been previously observed following the use of appliances that hold the maxillary teeth together (Weiland , 1997;Orton, 1996). Such conceivable scenario could potentially lead to an undetectable molar movement by any intra-arch measurement technique since all objects would experience the same spatial displacement. These potential problems could be minimized by placing the Nance button on the first premolars or circumvented altogether by using the palatal rugae as presented earlier in the chapter. While the use of the Nance button is likely to increase the resolution, if the absence of it will allow for more subsequent tooth movement and more clinically relevant findings, its elimination should be evaluated in future studies pending further investigation.

In the absence of tooth movement it was not possible to draw any conclusions or correlations with respect to force and time of application, although it is conceivable that this study design would facilitate such analysis in the presence of tooth movement.

CHAPTER 5
SUMMARY AND CONCLUSIONS

This pilot study is the first of its kind with respect to data collection and analysis. It incorporates novel technology specifically designed for research implementation, and highly computer intensive graphical analysis of the data, previously unattainable.

As with every clinical study, data interpretation is highly dependent on the quality of the data collected, and the strength of the data analysis. Our newly developed materials and methods for clinical headgear studies add a new dimension to the data acquisition and outcome analysis. The OTFR headgear's ability to collect force as well as compliance data in real time allows for calculations and analysis never before possible due to data collection shortcomings.

Lessons learned from this pilot study will lead to improvement of the OTFR and allow the reliable use of such device in future clinical studies. Furthermore, this study was the first of its kind to test the validity of the patient's self-reported diary for monitoring of compliance. While such method is considered the gold standard in clinical orthodontic studies, we have shown that such assumptions are without scientific basis and do not correlate with true compliance. This is a very important finding as it not only scrutinizes results of previous studies, but also suggests the necessary use of real-time compliance monitoring device in clinical research.

The testing of the three-dimensional analysis system has been shown to provide qualitative as well as quantitative results with respect to the molar spatial displacement subsequent to headgear use. The use of this system offers the investigator the ability to view dental changes from different planes of space, and could potentially visualize important dimensional changes previously overlooked. It is encouraging to discover that the palatal rugae could potentially be used as a stable landmark for three-dimensional superimposition studies, although further investigation is warranted. Should the palatal rugae prove to be useful for such purpose in future studies, our analysis system would prove invaluable not only in prospective clinical trials but also in retrospective ones as well.

Although the tooth movement component of this pilot study has not detected any clinically significant displacement, it provides much insight into potential problems with this type of design in future studies. While the Nance button provides and excellent stable landmark for three-dimensional model analysis, it may interfere with the clinical effects potentially occurring in its absence. This finding of potential molar movement restraint due to the application of a Nance button on the adjacent premolars warrants future investigation, not only for the purpose of stable structure establishment, but also to provide further insight in to the dynamics of tooth movement.

Future studies using this novel design should be implemented following correction of the encountered problems. Only through the use of such real-time data acquisition headgear, capable of collecting force as well as compliance data, and the implementation of advanced three-dimensional analysis to accurately measure the outcomes would we be able to appreciate the true treatment effects of the orthodontic headgear. An appliance of enormous popularity and use spanning back over a century, yet still to date its effects and underling mode of action remain virtually unknown.

Conclusions:

1. The three-dimensional study model analysis system was successful in the characterization of spatial molar displacement.
2. The palatal rugae’ potential as a stable structure for spatial superimposition appears favorable pending further investigation.
3. The orthodontic time/force recording (OTFR) headgear appears valid for the monitoring of compliance.
4. The OTFR headgear’s force encoder was inconsistent in its force recording yet its data acquisition potential was shown to be successful.
5. The use of patients’ self-report logbook does not appear to correlate with true compliance as measured using two separate digital timing devices. The future use of such logbooks for the monitoring of compliance does not appear to be warranted in clinical orthodontic research.
6. Limited tooth movement (< 0.56mm) was noted for patients in our pilot study subsequent to headgear therapy. The apparent small movement may be related to the presence of erupted permanent second molars and the Nance stabilizing appliance.

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BIOGRAPHICAL SKETCH

Yossi Bar-Zion was born in Israel and raised in southern California. He attended the University of California at Irvine for his undergraduate study and then the State University of New York at Buffalo for his dental education. At Buffalo Dr. Bar-Zion was engaged in several research projects that had earned him multiple awards, including the American Association for Dental Research student fellowship award, Quintessence award for outstanding achievement in research, Omicron Kappa Upsilon research award, and the Hinman's most outstanding presentation in basic science research award. Dr. Bar-Zion was distinguished for his academic achievements as well, and received several recognitions including the Edwin C. Jauch award for the most outstanding completed comprehensive dental restoration case, the Alpha Omega scholastic achievement award, the American Academy of Orofacial Pain award, the Omicron Kappa Upsilon scholastic award, the Oral Surgery Society award, and the Barrett Foundation award for highest scholastic average for four years of dental study. Dr. Bar-Zion graduated summa cum laude from the State University of New York at Buffalo in 1997, obtaining a Doctor of Dental Surgery degree. Following graduation, Dr. Bar-Zion continued his dental education at the University of Florida to complete a degree of Master of Science with a certificate in orthodontics. At the University of Florida Dr. Bar-Zion was involved in clinical research as well as the applications of computers in the field of orthodontics.