Assessment of Two Options for Limited Treatment of Anterior Dental Misalignment

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THESIS

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This thesis is dedicated to my parents Mahmud Parsa and Soheila Abolhoda, whose love and dedication are the reasons for me being where I am today. I would also like to dedicate this thesis to my sister and brother, Sara and Arash, who have stuck with me through this crazy ride called life.

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LIST OF ABBREVIATIONS

3D	3-Dimensional
ABO	American Board of Orthodontics
CBCT	Cone-Beam Computed Tomography
DM	Dental-Monitoring™
DOF	Degrees Of Freedom
ICC	Intra-Class Correlation
MIMICS	Materialise Interactive Medical image Control System
MTM	Minor Tooth Movement
OGS	Objective Grading System
PI	Principal Investigator
STL	STereoLithography

Summary

3M™ Incognito™ Lite and Dentsply MTM® Clear Aligner are two treatment systems used for correcting misalignment of the canine to canine region often referred to as “the social six.” Both systems use appliances fabricated from a digitally designed setup of the desired outcome. There is no research on whether each system actually achieves the clinical outcome promised in tehse digital setups.

Initial malocclusion, final outcome and digital setup of 34 patients treated using Incognito™ Lite and 23 patients treated using Dentsply MTM® Clear Aligner were evaluated to determine the efficacy of these systems in achieving desired outcomes. Final outcomes with discrepancies in tooth position less than 0.5 mm or 4 degrees from the desired tooth position were considered clinically acceptable.

Both systems had on average discrepancies that were smaller than clinically acceptable limits, while some variables showed statistically significant lower means discrepancies and others showed no difference. Graphic representations of the amount of final-setup discrepancy based on amount of planned movement are presented to assist in treatment planning and case selection using these systems.

1. INTRODUCTION

1.1 Background

The advent of technology in the orthodontic world has brought about numerous custom treatment modalities that intend to automate and facilitate the orthodontic treatment process. These technologies make use of a virtual setup of the final desired position of teeth to fabricate appliances that are then supposed to move patients' teeth into that desired position. The fabricated appliances range from customized archwires (SureSmile®), customized brackets and archwires (Insignia™, Incognito™) to clear aligners (Invisalign®).[1–4] Currently, there is limited research on the accuracy and predictability with which these appliances, which often also claim faster and better results than traditional braces, achieve their promised outcomes.[5–9]

In addition, with the increased interest in limited adult orthodontic treatment, there is an increased presence of treatment modalities that will predictably and esthetically treat minor misalignments of anterior teeth. Many companies and dental laboratories provide treatment appliances that only aim at aligning the anterior teeth - the upper and lower canine-canine region often referred to as "the social six." Two of the current technologies used for esthetic alignment of anterior teeth are the 3M™ Incognito™ Lite and Dentsply MTM® Clear Aligner Systems. The Incognito™ Lite system used the same fully customized technology as the full Incognito™ system for placing brackets on the lingual surface of teeth, but with brackets only placed on the canine to canine region. Lingual pads can be added to first premolars for additional anchorage if deemed necessary by the

orthodontist.[10] The Dentsply MTM® Clear Aligner system makes use of a series of clear aligners with pressure points to align anterior misalignment. [11] Neither of these two methods have been independently studied and published in a peer-reviewed journal. This research aims to evaluate the accuracy and predictability of two such treatment systems and determine limitations of each.

1.2 Significance

Whether a treatment modality achieves the results it promises or not is an important question that affects both the orthodontist and the patient. The orthodontist should be aware of any shortcomings in the system he or she is using in order to able to achieve the outcome he or she is envisioning. Knowledge of these shortcomings may help in creating overcorrections into the digital setup that may assist the orthodontist in achieving better treatment results.[6] Virtual setups produced by these techniques may sometimes be used in the initial treatment consultation with the patient as well. Significant discrepancies between the predicted outcome and the outcome achieved by the treatment may result in patients that are unhappy for not receiving the result that was promised to them.

Results of this study would assist clinicians in providing better information to their patients, having better expectations of what may or may not work, and being able to make better clinical decisions when a specific system should be used. Currently, there are some general guidelines for the scope of cases that these systems should be used for, but these are based on clinical judgements of experts using them and not peer-reviewed data. Detailed data based on what

these systems were able to achieve in a clinical setting would be a stronger indication of their strengths and limitations.

1.3 Specific Aims

This study aims to evaluate the accuracy and predictability of tooth movement using two esthetic treatment systems for treatment of minor misalignment of anterior teeth, namely the Dentsply MTM® Clear Aligner and Incognito™ Lite systems.

A secondary aim to this study will be to determine whether both systems are appropriate for cases with similar misalignment and difficulty and if not, what is the amount of discrepancy which can be expected to be treated predictably by each system.

1.4 Hypotheses

1. There is no statistical difference between the predicted and achieved position of teeth above clinical acceptable limits of 0.5mm and 4 degrees, using the Dentsply MTM® Clear Aligner system.

2. There is no statistical difference between the predicted and achieved position of teeth above clinical acceptable limits of 0.5mm and 4 degrees, using the Incognito™ Lite system.

3. There is no statistical difference between the planned tooth movement using the Dentsply MTM® Clear Aligner and the Incognito™ Lite systems.

2. REVIEW OF LITERATURE

2.1 Digitally Assisted Orthodontics

Over the last several decades, numerous technologies have entered the orthodontic world in order to enhance the possibilities of treatment using the 3-dimensional models of the dentition. These technologies add possibilities to orthodontic treatment that were previously not possible or cost-effective due to the difficulty or time- intensive nature of the manual labor required. The 3M™ Incognito™ system is one of these technologies. It uses 3-dimensional models of the initial dentition to fabricate custom pads for brackets so that they adhere better to the lingual surfaces of teeth. In addition, it provides robotic bent arch wires and better manufacturing promises to promises a treatment outcome that is reviewed and approved by the orthodontist digitally.[12] In a similar fashion, Invisalign® has used various patents in its manufacturing processes to be able to create a series of clear aligners that are then used to move the patient's teeth from their initial position to a promised final position. Invisalign® also uses a digital setup of the final position of the teeth which is approved by the clinician before the appliances are fabricated.[13] There are numerous other companies that offer digital technologies that similarly use a 3-dimensional digital setup of the dentition approved by the clinician to provide custom-fabricated appliances.[14] The claims made by these appliances with regards to the accuracy with which they produce the promised outcome have not been widely studied. However, several studies do exist that attempt to evaluate the outcome of each system.

2.2 Evaluation of Treatment Outcomes

Evaluation of treatment outcomes in orthodontics has taken various forms over the years. Traditionally, tracings of cephalometric radiographs have been used for evaluating dental and skeletal changes occurring during treatment due to treatment mechanics or growth. There are multiple methods available for performing cephalometric superimpositions, which also have certain limitations. [15–18] The common concept between the superimpositions is to use the most stationary landmarks (implants, anterior cranial base, etc.) to evaluate the movements of other components. However, cephalometric tracings do not evaluate the final occlusal outcome. Multiple indexes exist for evaluating the occlusal outcome of treatment. The American Board of Orthodontics' (ABO) Objective Grading System (OGS) is such a system commonly referenced in the literature for evaluating treatment outcome.[19] Both these methods can be valuable in evaluating treatment outcomes, but they do not provide detailed information about movement of each specific tooth during treatment.

The digital setup of the final position of the teeth for these systems is approved by the clinician, and it may or may not be attempting to match the ABO OGS grading criteria, but rather is based on patient specific treatment goals. In addition, these systems can only effectively promise intra-arch positioning of teeth but any inter-arch discrepancies would depend on the remaining treatment plan consisting of elastics or inter-arch appliances. Therefore, it is more reasonable to look at how well these systems can achieve the promised intra-arch positioning of teeth. In addition, it would be clinically useful to know how much and what types of

movements they are able to achieve, and where they fall short of the promised outcome.

2.3 Evaluation of Individual Tooth Movement in 3 Dimensions

A cephalometric tracing allows for evaluating tooth movement in the sagittal plane. To evaluate tooth movement 3-dimensionally, a 3-dimensional (3D) model of the dentition is necessary. An additional requirement for being able to compare initial and final position of the teeth is having a stationary surface area to be used for superimposition purposes, similar to metallic implants or anterior cranial base in cephalometric superimpositions. When treating all teeth in both upper and lower arches, there are no reliably stationary surfaces within the dentition. However, research suggests that the palatal rugae in the maxilla are subject to minimal changes over the course of treatment and can serve as stationary landmarks for superimpositions, allowing for evaluation of 3D movements of teeth in the maxillary arch. [20,21] Ashmore et al. used these concepts to create 3D renditions of points on rugae and a combination of 4 points on each maxillary first molar to evaluate the effects of headgear treatment on first molars in 3 planes of space. They were able to show good reliability for measuring translational movements (mesio-distal, facio-lingual and occluso-gingival), but their method was unable to measure rotations with good reliability. [22]

Ghislanzoni et al. used manually placed points on the dentition to evaluate their tip, torque and linear measurements.[23] Although they did not measure or report any values for rotation, they showed that their technique was reproducible for tip, torque and linear measurements. The linear measurements reported in this

validation study were measurements such as intermolar or inter-canine distance and not mesio-distal, facio-lingual or occluso-gingival measurements as in the previously mentioned study. Lineberger et al., from the same group, then used these methods to evaluate the 3-dimensional treatment effected produced by a passive self-ligating bracket. [24] They used 3-dimensional models to compare the initial and final position of the teeth in the maxillary arch by evaluating the linear measurements, tip and torque in each model, and comparing the results. This allowed them to make comments about tip and torque values for each individual tooth, as well as linear measurements between multiple teeth. However, tooth-specific linear movements or rotation were not reported, likely since such measurements would not be accurate without a stationary surface to superimpose on.

Chen et al. have shown good reproducibility in evaluating movement of a single tooth in all 6 degrees of freedom (DOF) by comparing the patient's CBCT (Cone-Beam Computed Tomography) scans from 2 time-points that were 2 weeks apart. [25] They used two CBCT models of the same mandible taken two weeks apart and manually moved the position of certain teeth a predetermined amount. The bone and teeth structures were separated from each other by use of the Materialise MIMICS (Materialise Interactive Medical Image Control System) software. Chen et al. reported that human intervention to ensure the borders of teeth were selected correctly was necessary during this process. The MIMICS software also automatically determined a coordinate system for the volume of each tooth, with a centroid at the center of the volume. They then used a best-fit iterative

closest-point algorithm to superimpose the two mandible scans on each other. The comparison between the coordinate systems of each tooth between the two scans then determined the changes in the 6 DOF for that specific tooth. Using this protocol, Chen et al. Reported an error of less than 5% and 10% in their translation and rotation measurements, respectively.

2.4 Automated Evaluation of Tooth Movement in 3 Dimensions

3-Dimensional software developed over the past years have certainly added a variety of tools that has enabled 3D evaluation of tooth movement with placement of manual points. However, this processes are significantly technique sensitive and time consuming. Therefore, their use for regular evaluation of clinical outcomes is not practical. Various companies have developed software algorithms, that allow for automatic evaluation of the tooth movement without the need for users to select points.

Although most companies do not release their proprietary algorithms for doing the calculations, Beers et al. discussed the concepts behind automatic tooth movement calculations in an article in 2003. [26] Similar concepts are likely used by other software as well. Beers discussed the need for defining a local coordinate system at each tooth. To define this local coordinate system, Beers discussed the need for a closed digital surface at each tooth, which would then be used to determine a local coordinate system and center. The orientation and position of these two coordinate systems and centers can be compared between two models to evaluate the movement of each tooth in all 6 DOF. The two models would need to be superimposed on each other on some stable landmarks (stationary posterior

teeth, palatal rugae, implants) to be able to compare the absolute position of the teeth. If no stationary landmarks exist (if for example, the entire lower dentition was treated) only a relative comparison of the position of the same tooth between the two models can be made.

Miller et al. studied the error in Align Technology's digital model superimposition tool described above.[27] They used palatal rugae as stationary landmarks and by doing repeat measurements determined the average measurements to be about 0.2mm in translation and less than 1° in rotation.

2.5 Evaluation of Tooth Movement and Outcome of Treatment with Customized Appliances

To date, there are three studies that attempt to evaluate the effectiveness and accuracy of various customized appliance systems using comparisons of the digital setup with the final outcome. These three studies used to two different methods for determining the accuracy of tooth positioning according to the digital setup. Kravitz et al. carried out a prospective study that evaluated the Invisalign system while only allowing for movements in the anterior region.[6] Therefore, they were able to use the posterior teeth as stationary landmarks for superimposition. In this manner, they were able to compare both the initial and the final position of the teeth with the digital setup, which made it possible to determine a ratio between the actual tooth movement (discrepancy between initial model and final model) to predicted tooth movement (discrepancy between initial model and predicted digital setup). In this manner, it was possible to report the accuracy by calculating the percentage of the predicted tooth movement that was actually achieved.

Grauer et al and Larson et al studied retrospective cases using the 3M Incognito and SureSmile systems, respectively.[5,8] These cases involved treatment of majority of patients' teeth and thus did not have a stationary surface unaffected by treatment within the dentition to use for superimposition. Therefore, in both studies, it was only possible to compare the final outcome with the predicted digital setup. A best-fit superimposition of the final outcome on the predicted digital setup can generate discrepancy numbers in distance (mm) and degrees of rotation for each tooth, which can then be classified as clinically acceptable or not acceptable. Ideally, the discrepancy would be zero. Grauer et al. accepted discrepancies less than 1mm or 4 degrees as clinically acceptable while Larson et al. accepted discrepancies less than 0.5mm and 2 degrees as clinically acceptable.

Each method has advantages and disadvantages of its own. Looking at the percentage of predicted movement that was actually achieved, as Kravitz et al. did, can underestimate the clinical acceptability of the system in small movements. On the other hand, using the discrepancy between the final and predicted outcomes, as Grauer et al. and Larson et al. did, can overestimate the accuracy of the system. For example, if a tooth is predicted to move 1mm but only moves 0.5mm, it has moved 50% of its amount of predicted movement, a seemingly low and unacceptable number, while looking at the discrepancy of final outcome to predicted setup would put this tooth within the clinically acceptable range. In the current study, since the posterior teeth will not be moved, it will be possible to determine accuracy and predictability of each system using both methods as a means of complementing each other.

3. MATERIALS AND METHODS

3.1 Retrospective De-identified Data

3.1.1 Patient Population Studied

The subject population studied was a population of adult (18+ years old at initial records appointment) patients previously treated at Get It Straight Orthodontics in Chicago, IL using either the MTM® clear aligner or Incognito Lite systems. Consecutively treated patients in the aforementioned private practice using either the MTM® clear aligner or Incognito Lite systems were de-identified by an employee of the practice, who was not the practice owner, and provided to the principal investigator (PI) for evaluation.

All patients were treated by one of the two orthodontists at Get It Straight Orthdontics in Chicago, IL. The practice owner has been using the Incognito and Incognito Lite system at his practice since 2002. He was also involved with developing the Dentsply MTM® clear aligner therapy for 4 years from 2006 before its launch in 2011. Both him and the other orthodontist associate consistently use both systems at this practice.

The records for each patient included routine records taken for patients undergoing treatment including: pretreatment (initial) and posttreatment (final) intraoral occlusion scans, diagnostic radiographs (which may include panoramic, cephalometric or CBCT radiographs as indicated necessary by clinician at time of treatment) as well as the digital setup from either MTM® or Incognito™ Lite systems in STL (STereoLithography) format. All radiographs and digital impressions were already collected during routine orthodontic care and none were collected for

research purposes. For certain cases, the initial STL was created by digitizing PVS impressions as opposed to an intra-oral chairside scan. These scans were available through either Dentsply or 3M and were included in the study.

Additional non-identifier information collected included: sex, age at start of treatment, days in treatment from bonding or delivery of aligners to debonding of appliances, number of appointments including bonding and debonding, number of emergency or unexpected appointments, number of failed appointments, archwire sequence for the Incognito Lite group, number of aligner sets for the MTM® group, any extraction as part of treatment, amount of IPR prescribed in the setup, amount of IPR recorded in the charts, any detail bends added to the Incognito™ Lite wires and any manual activations added to the MTM aligners.

3.1.2 Inclusion Criteria

Adult (18+ years old) patients treated with Incognito™ Lite or MTM® clear aligner systems in either dental arch at Get It Straight Orthodontics between dates from 01/01/2010 to 02/10/2017.

3.1.3 Exclusion Criteria

- Surgical or skeletal anchorage treatment
- Lack of attendance compliance defined by no appointment in 3 consecutive months
- Undiagnostic records or unavailability of records
- Combination treatment with other appliances outside of MTM® or Incognito™ Lite systems including tooth positioners

3.2 Sample Baseline Evaluation

In order to better understand the patient types for whom these treatment modalities were used, we evaluated radiographic and dental diagnostic information for the samples at baseline.

3.2.1 Radiographic Evaluation

De-identified radiographs were used for evaluation of the skeletal and dental conditions of each sample at baseline. These radiographs were either taken as an initial cephalometric x-ray or reconstructed from CBCT radiographs. The following points and definitions were used for tracing:

- Sella – The center of pituitary fossa.[28]
- Nasion – The junction of the nasal and frontal bone as seen on the profile of the cephalometric roentgenogram.[28]
- Point A - The deepest midline point on the premaxilla between the anterior nasal spine and prosthion.[28]
- Point B - The deepest midline point on the mandible between infradentale and pogonion.[28]
- Menton – The lower most point of the contour of the chin.[28]
- Gonion - The midpoint mediolaterally on the posterior border of each gonial angle.[28]
- U1 Tip – The tip of the maxillary central incisor.
- U1 apex – The root apex of the maxillary central incisor.
- L1 tip – The tip of the mandibular central incisor.
- L1 apex – The root apex of the mandibular central incisor.

The above points were used to determine the following measurements for each sample using Dolphin Imaging software:

- ANB – The angulation between point A, nasion and point B.
- SNA – The angulation between sella, nasion and point A.
- SNB – The angulation between sella, nasion and point B.
- SN-MP – The angulation between the line connecting sella to nasion and the line connecting menton to gonion.
- U1-SN – The angulation between the line connecting sella to nasion and the line connect U1 tip to U1 apex.
- L1-MP – The angulation between the line connecting menton and gonion and the line connect L1 tip to L1 apex.
- Interincisal angle – The angulation between the line connect U1 tip to U1 apex and the line connecting L1 tip to L1 apex.

3.3 Evaluation of Collected Data

3.3.1 Dental Monitoring™

Dental Monitoring™ (DM) is a mobile monitoring solution in orthodontics that uses photos taken by patients of their teeth, along with the initial scan of the malocclusion, to provide the orthodontist with a current model of where the patients' teeth are. Photos need to be taken at least every two weeks but can be provided as often as one week. Before starting treatment, the treating orthodontist provides DM with a digital scan of the malocclusion in STL format. As treatment progresses, patients use the Dental Monitoring™ app on their cell phones to take photos at two week intervals. The patented DM software then determines the

amount of movement of teeth in 6 DOF using machine vision and metaheuristic algorithms. The movements can be described in terms of the center of the incisal edges or an imaginary center of resistance inside the crown (referred to by DM as crown / root measurements respectively). Crown measurements were chosen for this study to report numbers that may be more easily understood clinically. Doctors are then able to track each tooth's movement on their dashboard and determine the need for setting up appointments as they see fit.[29]

3.3.2 Data Submission to Dental Monitoring

In order to submit the anonymized data to DM, a dummy patient account was created for each patient. The anonymized sample number was used as both the first and last names. 01/01/2000 was selected as the dummy birthday, and a dummy email was inserted. For each sample, the anonymized maxillary and mandibular STL files for initial malocclusion, final result and digital setup were added to the patient attachments. A randomly selected sample of 5 cases from each group were submitted to DM a week later from their original submission to determine the reliability of the system in achieving the same results.

A DM engineer was assigned to this research project. The engineer was instructed to superimpose each of the treated arches on the presumptively stationary first premolar to second molar teeth when present. At a minimum the second premolar and first molar were to be used to achieve a superimposition between the two STLs being studied. The DM software then provides the discrepancy between the teeth position between the two STL files in all 6 DOF. For each sample, three comparisons were made: Initial-final, initial-setup, and

final-setup. The initial-setup comparisons represent the amount of planned tooth movement. The initial-final comparisons represent the amount of tooth movement achieved clinically. The final-setup comparisons represent the discrepancy between the planned and achieved position of the teeth. The output for each comparison on each sample were placed in a single Excel spreadsheet and sent back to the PI.

3.3.3 Collected Data From Dental Monitoring

The comparison data from each comparison for each single patient were provided on a separate spreadsheet by DM. The data were then combined to have the data for all the patients in each group in one excel spreadsheet, with each patient's data in one row of the spreadsheet. The columns represented the 6 DOF for each tooth analyzed in the sample. For example, if 6 teeth were analyzed for each sample, there would be 36 columns.

For purposes of this study, it was assumed that the posterior teeth were stationary. In addition, the assumption was made that the systems' capacity to achieve a desired movement would be same on the left and right sides of the dentition. Therefore, each patient would contribute two teeth to maxillary central incisor data, two teeth to the maxillary lateral incisor data, etc.

The discrepancy between the final position of the teeth after treatment and the predicted position of teeth in the digital setup was provided by the DM software for each single tooth in all 6 DOF. Ideally, this discrepancy would be exactly zero. However, some small discrepancies may be acceptable clinically. Even though the threshold at which a discrepancy may be noticed is likely different for each patient

or clinician, 0.5 mm and 4 degrees were chosen as clinically acceptable discrepancies based on previous studies and the fact that discrepancies of this magnitude would not lead to loss of any points using the ABO OGS criteria.[5,8,19] To ensure that the presence of positive and negative discrepancies surrounding zero would not lead to inaccurate results, the absolute values of all measurements were taken before testing against 0.5 mm and 4 degrees.

3.4 Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows. The intra-class correlation coefficient was used to determine reproducibility of DM measurements after resubmission of the same 10 cases. Student independent t-test was used to determine any statistical difference between the skeletal and dental cephalometric measurements between the two groups. Independent sample t-test was also used to compare the age, treatment length, number of appointments and number of activation/detail bends between the two groups. For each comparison, Leven's test for equality of variance was used to evaluate equality of variance the p-value was selected accordingly. Pearson Chi-square tests were used to determine any differences between the two systems in the categorical variables sex, number of failed appointments and number of emergency appointments.

One-sample t-tests were used to evaluate whether the absolute values of any discrepancies between planned and achieved tooth movements (the final-setup discrepancy) were larger than clinically significant values chosen as 0.5 mm and 4 degrees. Independent samples t-tests were used to compare the amount of

planned tooth movement, amount of achieved tooth movement and the discrepancy between the two values among the two systems for all 6DOF for each anterior tooth. Leven's test for equality of variance was used to evaluate equality of variance the p-value was selected accordingly.

4. RESULTS

4.1 Collected Data Demographic and Descriptive Statistics

There were a total of 34 patients treated with Incognito™ Lite and 27 patients treated with the MTM® Clear Aligner system, represented in TABLE I. In the Incognito™ Lite group, 23 patients were treated in both upper and lower arches, while 9 patients were treated only in the upper arch and 3 patients were treated only in the lower arch. In the arches that were not treated with Incognito™ Lite in this group, 1 arch was treated with an active Essix appliance, 1 arch was still in treatment at time of data collection, and the remaining 9 arches were not treated. In the MTM® Clear Aligner system group, 12 patients were treated in both upper and lower arches, while 9 patients were treated only in the upper arch and 6 patients were treated only in the lower arch. In the arches that were not treated with MTM® Clear Aligner system in this group, 5 arches were treated with an active Essix appliance, 1 arch was treated with a full Incognito appliance, 1 arch with Incognito Lite, and the remaining 8 arches were not treated. Only the arches that were treated using either Incognito™ Lite or MTM® Clear Aligner were evaluated using the DM software. The total number of arches evaluated in each system are in TABLE II.

The demographics of the patients treated in each group are shown in TABLE III. Even though on average the patients treated with MTM® Clear Aligner were 8 years younger than the patients treated with the Incognito™ Lite group, this difference was not statistically significant when compared using t-test. Pearson chi-square test showed no statistically significant difference in the distribution of

female and male patients between the two groups, but both groups had a significantly higher proportion of female patients compared to male patients, as seen in Figure 1.

TABLE I – NUMBER OF PATIENTS TREATED IN THE UPPER AND LOWER DENTITION USING EACH SYSTEM

	Patients with Both Arches Treated	Patients Treated in the Upper Arch Only	Patients Treated in the Lower Arch Only
Incognito™ Lite	23	8	3
MTM® Clear Aligner	12	9	6

TABLE II – TOTAL NUMBER OF ARCHES EVALUATE IN EACH SYSTEM

	Total Number of Upper Arches Evaluated	Total Number of Lower Arches Evaluated
Incognito™ Lite	32	26
MTM® Clear Aligner	21	18

TABLE III – DEMOGRAPHICS OF PATIENTS TREATED IN EACH GROUP

	Age at Start of Treatment [Mean(SD)]	Number of Female Patients	Number of Male Patients
Incognito™ Lite	43.9 (16.1)	28	6
MTM® Clear Aligner	36.7 (14.6)	22	5

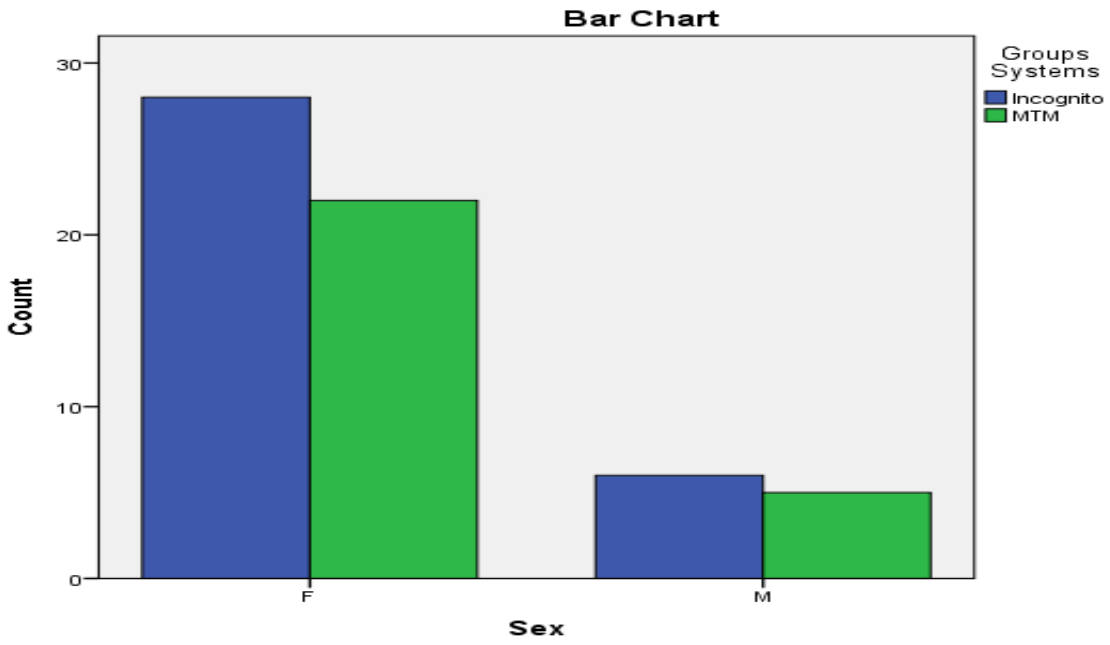


Figure 1 - Distribution of female and male patients between the two groups

32 of the 34 patients treated with Incognito™ Lite and 19 of the 27 patients treated with MTM® Clear Aligner system had either an initial cephalometric or CBCT x-ray available for tracing. The skeletal and dental cephalometric evaluation of the patients are reported in TABLE IV. There were no statistically significant differences between the skeletal or dental measurements at the initiation of treatment between the two groups. It should be noted that the differences between upper central incisor angulations were reaching statistical significance with a p-value of 0.063, suggesting that initial angulation of upper incisors may have been a factor in the clinical decision made to use one system over the other.

TABLE IV – SKELETAL AND DENTAL CEPHALOMETRIC EVALUATION AT BASELINE

	Incognito™ Lite [Mean(SD)]	MTM® Clear Aligner [Mean(SD)]	p-value
SNA	81.7 (4.8)	80.7 (3.9)	0.40
SNB	77.7 (4.7)	77.8 (4.4)	0.93
ANB	4.1 (2.2)	2.8 (2.9)	0.10
SN-MP	33.3 (5.9)	36.2 (7.9)	0.15
U1-SN	97.9 (9.1)	102.9 (9.4)	0.06
L1-MP	92.3 (5.8)	89.7 (6.9)	0.15
Interincisal Angle	136.8 (9.8)	131.7 (11.2)	0.10

4.2 Intra-reliability Evaluation of Dental-Monitoring Measurements

A sample of 10 randomly selected patients were resubmitted back to the DM for evaluation a week later than the remaining submissions. The DM representative working on the case was not made aware that these would be repeated cases, and they were numbered accordingly. The same comparisons as all the other patients were performed on these cases (initial-final, initial-setup, final-setup). These measurements were then tested for reproducibility and the intra-class correlation (ICC) coefficients were higher than 0.85 with 95% confidence interval ranging between 0.579 and 0.999. Mesio-buccal and rotation variables in the lower and tip variables in the upper showed low ICC coefficient variables. When looking at the comparisons in detail, it became obvious that the reason these 3 variables showed a low ICC were due two 2 separate individual teeth that the software was not able to match correctly in one of the two instances, showing

significantly different numbers between the two submissions. The remaining teeth showed extremely similar values in both submissions. Considering the frequency of this match error (2 in approximately 120), it was decided that the DM system can still be used for evaluating tooth movements but the extreme measurements should be taken with caution.

4.3 Incognito™ Lite Treatment and Evaluation

The following archwire sequence was used in the Incognito™ Lite treatment: 0.014 Super Elastic CuNiTi, 0.016x0.0122 Super Elastic CuNiTi, 0.018x0.025 Super Elastic CuNiTi, and 0.017x0.025 Beta III Titanium. All patients were treated with these 4 wires in the same sequence. Archwire changes were done as indicated by the clinician. If any detail bends were necessary at the end of treatment, they were placed in the 0.017x0.025 Beta III Titanium wire. No Extractions were planned as part of treatment for any patients in this group. However, interproximal reduction was used as indicated. Clinical variables related to treatment length and appointments are reported in TABLE V. Treatment length was measured in days from appliance delivery to appliance debond. Total number of appointments were counted from appliance delivery to appliance removal, including emergency appointments. Number of detail bends represent each time the wire had to be modified for a single tooth. The archwire could be modified for multiple teeth in a single appointment.

TABLE V – CLINICAL VARIABLES RELATED TO TREATMENT WITH INCOGNITO™ LITE

	Length of Treatment (Days)	Total Number of Appointments	Number of Emergency Appointments	Number of Failed Appointments.	Number of Detail Bends
Incognito™ Lite	305.8 (151.3)	12.6 (7.3)	1.4 (1.8)	0.6 (1.4)	2.0 (1.8)
- **All variables are reported as mean (standard deviation).**					

4.3.1 Initial-Setup Comparisons

The discrepancy between the initial malocclusion and the digital setup represents the amount of planned tooth movement given the needs and treatment objectives specific to each case. The means and standard deviations for each anterior tooth in 6 DOF is given in TABLE VI through TABLE IX. For the purposes of this thesis, positive translational numbers represent occlusal, buccal and mesial movements of the crown compared to the initial reference tooth (for initial-setup comparisons, the initial teeth were used as reference). Positive rotational numbers represent a mesial rotation of the crown (clinically “mesial-in”), mesial tip of the crown (distal tip of root), and buccal torque of the crown (lingual root torque) compared to the initial reference tooth (for initial-setup comparisons, the initial teeth were used as reference).

TABLE VI – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-0.15	0.72	0.10	0.97	0.00	0.69
Lateral Incisor	0.14	0.75	0.12	0.97	-0.15	0.68
Canine	-0.26	0.61	0.33	0.70	-0.01	0.69
First Premolar	0.00	0.08	0.12	0.49	-0.02	0.11

TABLE VII – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	0.05	6.52	0.07	2.62	4.33	6.08
Lateral Incisor	0.28	9.54	-0.20	4.82	2.17	6.62
Canine	0.25	10.84	0.41	6.17	4.74	4.31
First Premolar	-0.55	2.82	-0.29	1.39	0.12	1.59

TABLE VIII – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-1.09	1.16	0.77	1.12	-0.09	0.81
Lateral Incisor	-0.76	1.01	0.39	0.91	-0.16	0.83
Canine	-0.55	0.97	0.37	0.80	-0.10	0.70
First Premolar	-0.01	0.26	-0.05	0.70	0.04	0.13

TABLE IX – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-1.35	8.22	1.03	4.21	4.78	5.81
Lateral Incisor	-5.13	12.22	4.33	7.07	4.75	6.56
Canine	0.97	10.60	-0.53	6.37	5.68	5.94
First Premolar	0.72	5.62	-0.38	2.76	-0.24	7.12

Since averaging numbers that could be negative or positive could lead to the mean values being close to zero and not clinically useful, the means and standard deviations of the absolute values of the amount of planned tooth movement are shown in TABLE X through TABLE XIII.

TABLE X – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.55	0.48	0.79	0.57	0.52	0.45
Lateral Incisor	0.61	0.44	0.81	0.55	0.58	0.38
Canine	0.51	0.42	0.62	0.45	0.53	0.43
First Premolar	0.02	0.08	0.13	0.49	0.03	0.11

TABLE XI – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	4.94	4.21	1.93	1.75	5.58	4.94
Lateral Incisor	7.27	6.11	3.42	3.38	5.40	4.36
Canine	8.03	7.22	4.82	3.83	5.15	3.80
First Premolar	0.68	2.79	0.38	1.36	0.37	1.55

TABLE XII – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	1.31	0.90	0.96	0.95	0.66	0.46
Lateral Incisor	1.00	0.75	0.70	0.69	0.64	0.52
Canine	0.88	0.69	0.69	0.55	0.53	0.47
First Premolar	0.09	0.25	0.15	0.68	0.04	0.12

TABLE XIII – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	6.78	4.75	3.17	2.94	5.45	5.17
Lateral Incisor	10.14	8.23	6.14	5.42	6.33	4.87
Canine	7.83	7.13	4.89	4.07	6.57	4.93
First Premolar	1.63	5.42	0.86	2.65	1.63	6.93

4.3.2 Initial-Final Comparisons

The discrepancies between the initial malocclusion and the final result describe the amount of tooth movement that was actually achieved clinically. The means and standard deviations for each anterior tooth in 6 DOF is given in TABLE XIV through TABLE XVII. These numbers are reported considering the final

position of each tooth in reference to its initial position. As before, positive translational numbers represent occlusal, buccal and mesial movements of the crown compared to the initial reference tooth. Positive rotational numbers represent a mesial rotation of the crown (clinically “mesial-in”), mesial tip of the crown (distal tip of root), and buccal torque of the crown (lingual root torque) compared to the initial reference tooth.

TABLE XIV – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		**Bucco-Lingual**		**Mesio-Distal**	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-0.16	0.58	0.23	0.83	0.01	0.56
Lateral Incisor	0.11	0.47	0.24	0.78	0.07	0.61
Canine	-0.01	0.36	0.24	0.50	0.21	0.46
First Premolar	-0.05	0.21	0.01	0.49	0.10	0.28

TABLE XV – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		**Tip**		**Torque**	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.31	4.80	0.04	2.55	1.99	3.71
Lateral Incisor	-1.26	7.20	0.38	3.87	1.09	3.75
Canine	-2.60	8.50	1.73	3.57	1.60	2.24
First Premolar	-2.46	6.12	-0.08	1.81	-1.25	3.23

TABLE XVI – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-0.87	0.91	0.97	1.13	-0.16	0.92
Lateral Incisor	-0.44	0.73	0.51	0.96	-0.04	0.70
Canine	-0.32	0.83	0.37	0.73	-0.04	0.51
First Premolar	-0.09	0.25	0.00	0.42	-0.04	0.22

TABLE XVII – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-2.30	6.53	0.79	3.08	4.05	5.07
Lateral Incisor	-6.09	9.57	3.61	4.95	2.71	4.61
Canine	-1.88	7.69	0.24	4.02	2.27	3.85
First Premolar	-2.13	3.92	-0.49	2.00	-0.52	2.60

Since averaging numbers that could be negative or positive could lead to the mean values being close to zero and not clinically useful, the means and standard deviations of the absolute values of the amount of planned tooth movement are shown in TABLE XXXVI through TABLE XXXIX.

TABLE XVIII – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.49	0.34	0.66	0.54	0.41	0.39
Lateral Incisor	0.38	0.30	0.67	0.46	0.43	0.44
Canine	0.28	0.23	0.46	0.30	0.38	0.33
First Premolar	0.16	0.14	0.34	0.35	0.18	0.24

TABLE XIX – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	3.71	3.03	1.90	1.68	3.20	2.71
Lateral Incisor	5.42	4.85	3.01	2.43	3.10	2.36
Canine	6.46	6.06	2.97	2.61	2.16	1.70
First Premolar	3.94	5.27	1.30	1.25	2.42	2.47

TABLE XX – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	1.03	0.72	1.15	0.94	0.61	0.71
Lateral Incisor	0.68	0.50	0.83	0.68	0.50	0.48
Canine	0.67	0.58	0.66	0.48	0.38	0.33
First Premolar	0.21	0.16	0.31	0.27	0.16	0.15

TABLE XXI – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	5.64	3.96	2.51	1.92	4.92	4.22
Lateral Incisor	8.29	7.53	4.48	4.07	4.14	3.28
Canine	5.66	5.48	3.02	2.62	3.44	2.83
First Premolar	3.07	3.23	1.53	1.37	1.95	1.78

4.3.3 Final-Setup Comparisons

The discrepancies between final outcome and digital setup for the Incognito™ Lite group can be viewed in TABLE XXII through TABLE XXV. Before running statistical testing, the absolute values of these discrepancies were taken. The results of the one-sample t-tests compared to our clinically acceptable limits

for the Incognito™ Lite group can be viewed in TABLE XXVI through TABLE XXIX. No variables showed statistically significant higher discrepancy mean values compared to the clinically significant values of 0.5 mm and 4 degrees. Some values showed statistically significant lower discrepancy mean values (p-value <0.05) compared to the test values, signifying more accuracy compared to our clinically acceptable limits. These are labeled bold in TABLE XXVI through TABLE XXIX.

TABLE XXII – TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		**Bucco-Lingual**		**Mesio-Distal**	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-0.27	0.45	0.10	0.67	0.09	0.47
Lateral Incisor	-0.15	0.46	0.00	0.58	0.24	0.45
Canine	0.02	0.41	-0.20	0.53	0.23	0.36
First Premolar	-0.05	0.31	-0.15	0.69	0.14	0.30

TABLE XXIII – ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		**Tip**		**Torque**	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.34	3.18	-0.07	2.30	-2.37	4.19
Lateral Incisor	-1.50	4.61	0.52	3.19	-1.12	4.33
Canine	-2.89	4.81	0.96	4.33	-3.09	3.59
First Premolar	-2.01	4.61	0.20	2.26	-1.47	3.08

TABLE XXIV – TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.10	0.61	0.13	0.63	0.01	0.52
Lateral Incisor	0.16	0.59	-0.06	0.59	-0.01	0.55
Canine	0.03	0.62	-0.36	0.57	0.02	0.52
First Premolar	-0.12	0.38	-0.08	0.51	0.05	0.43

TABLE XXV – ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.80	3.40	-0.24	3.00	-0.25	4.44
Lateral Incisor	-1.25	4.15	-0.76	4.11	-1.52	4.83
Canine	-3.19	4.66	0.25	4.86	-3.23	4.31
First Premolar	-2.62	6.69	0.20	2.68	-1.29	3.06

TABLE XXVI – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.42	0.31	0.51	0.45	**0.35**	0.32
Lateral Incisor	**0.38**	0.30	0.43	0.39	**0.38**	0.34
Canine	**0.29**	0.29	0.41	0.39	**0.33**	0.27
First Premolar	**0.21**	0.24	0.41	0.58	**0.20**	0.26

TABLE XXVII – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	**2.22**	2.29	**1.79**	1.43	3.57	3.20
Lateral Incisor	3.23	3.59	**2.36**	2.19	3.39	2.89
Canine	4.22	3.68	**3.17**	3.08	3.50	3.18
First Premolar	3.69	3.39	**1.56**	1.62	**2.35**	2.47

TABLE XXVIII – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.44	0.42	0.49	0.40	**0.40**	0.31
Lateral Incisor	0.40	0.45	0.45	0.36	0.43	0.33
Canine	0.40	0.46	0.52	0.41	**0.40**	0.32
First Premolar	**0.27**	0.29	**0.36**	0.37	**0.24**	0.36

TABLE XXIX – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE INCOGNITO™ LITE GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	**2.66**	2.19	**2.14**	2.05	3.45	7.12
Lateral Incisor	**2.99**	3.06	**3.23**	2.54	3.81	8.05
Canine	4.25	3.62	3.69	3.06	3.93	7.90
First Premolar	4.25	5.78	**1.86**	1.91	**2.49**	5.24

4.4 MTM Clear Aligner Evaluation

The MTM® Clear Aligner Service Center uses a series of prefabricated clear aligners fabricated from a 3D setup of a desired outcome. Each tray is typically worn for 4 weeks before switching to the next step in the series. This group of treated patients had an average of 5.8 trays fabricated for the treatment, with a

minimum of 3 and maximum of 10 trays used. Statistics on number of aligners used can be found in TABLE XXX. No Extractions were planned as part of treatment for any patients in this group. However, interproximal reduction was used as indicated. Clinical variables related to treatment length and appointments are reported in TABLE XXXI. Treatment length was measured in days from appliance delivery to appliance debond. Total number of appointments were counted from appliance delivery to appliance removal, including emergency appointments. Number of detail bends represent each time the wire had to be modified for a single tooth. The archwire could be modified for multiple teeth in a single appointment.

TABLE XXX – STATISTICS ON NUMBER OF TRAYS USED IN MTM® CLEAR ALIGNER THERAPY

	MEAN	STANDARD DEVIATION	MINIMUM	MAXIMUM
MTM® Clear Aligner	5.8	2.1	3	10

TABLE XXXI – STATISTICS ON NUMBER OF TRAYS USED IN MTM® CLEAR ALIGNER THERAPY

	Length of Treatment (Days)	Total Number of Appointments	Number of Emergency Appointments	Number of Failed Appointments.	Number of Detail Bends
MTM® CLEAR ALIGNER	336.5 (214.2)	10.4 (4.2)	0.1 (0.5)	0.6 (1.3)	7.5 (3.9)
- **All variables are reported as mean (standard deviation).**					

4.4.1 Initial-Setup Comparisons

The discrepancy between the initial malocclusion and the digital setup represents the amount of planned tooth movement given the needs and treatment objectives specific to each case. The means and standard deviations of these discrepancies for each anterior tooth using the MTM® Clear Aligner system is given in TABLE XXXII through TABLE XXXV in all 6 DOF. For the purposes of this thesis, positive translational numbers represent occlusal, buccal and mesial movements of the crown compared to the initial reference tooth (for initial-setup comparisons, the initial teeth were used as reference). Positive rotational numbers represent a mesial rotation of the crown (clinically “mesial-in”), mesial tip of the crown (distal tip of root), and buccal torque of the crown (lingual root torque) compared to the initial reference tooth (for initial-setup comparisons, the initial teeth were used as reference).

TABLE XXXII – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.02	0.31	-0.04	0.90	-0.04	0.32
Lateral Incisor	0.03	0.26	0.06	0.71	-0.08	0.45
Canine	0.07	0.21	0.14	0.52	0.05	0.49
First Premolar	0.03	0.04	0.05	0.08	0.01	0.04

TABLE XXXIII – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.24	4.41	0.09	1.69	-2.03	5.00
Lateral Incisor	-0.08	6.66	-0.17	2.05	-2.79	5.34
Canine	-0.63	5.92	0.92	2.17	-0.93	3.26
First Premolar	-0.06	0.47	0.10	0.46	-0.10	0.46

TABLE XXXIV – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-0.18	0.42	0.41	1.04	-0.14	0.43
Lateral Incisor	-0.11	0.33	0.12	0.65	-0.15	0.30
Canine	-0.04	0.26	0.31	0.45	0.02	0.22
First Premolar	-0.01	0.04	0.03	0.07	0.04	0.06

TABLE XXXV – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.44	6.29	-0.15	2.63	0.06	4.92
Lateral Incisor	-2.76	5.67	1.09	2.89	-1.02	3.84
Canine	-0.52	3.82	1.20	2.18	1.02	2.56
First Premolar	-0.51	0.55	-0.27	0.72	-0.19	0.58

Since averaging numbers that could be negative or positive could lead to the mean values being close to zero and not clinically useful, the means and standard deviations of the absolute values of the amount of planned tooth movement are shown in TABLE XXXVI through TABLE XXXIX.

TABLE XXXVI – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.24	0.19	0.63	0.64	0.23	0.22
Lateral Incisor	0.20	0.16	0.50	0.50	0.32	0.32
Canine	0.17	0.14	0.41	0.34	0.35	0.34
First Premolar	0.03	0.03	0.07	0.06	0.03	0.03

TABLE XXXVII – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	2.92	3.28	1.22	1.15	3.72	3.88
Lateral Incisor	5.10	4.20	1.64	1.20	4.59	3.86
Canine	4.37	3.99	1.89	1.39	2.42	2.35
First Premolar	0.34	0.33	0.34	0.31	0.37	0.29

TABLE XXXVIII – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.33	0.32	0.83	0.75	0.33	0.31
Lateral Incisor	0.27	0.21	0.54	0.38	0.27	0.19
Canine	0.19	0.18	0.45	0.30	0.17	0.13
First Premolar	0.03	0.03	0.05	0.05	0.05	0.05

TABLE XXXIX – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	4.92	3.85	2.19	1.40	3.90	2.93
Lateral Incisor	4.50	4.38	2.02	2.32	3.27	2.19
Canine	2.56	2.85	1.76	1.73	2.02	1.84
First Premolar	0.60	0.45	0.57	0.52	0.39	0.46

4.4.2 Initial-Final Comparisons

The discrepancies between the initial malocclusion and the final result describe the amount of tooth movement that was actually achieved clinically. The means and standard deviations for each anterior tooth in 6 DOF is given in TABLE XL through TABLE XLIII. These numbers are reported considering the final position of each tooth in reference to its initial position. As before, positive translational numbers represent occlusal, buccal and mesial movements of the crown compared to the initial reference tooth. Positive rotational numbers represent a mesial rotation of the crown (clinically “mesial-in”), mesial tip of the crown (distal tip of root), and buccal torque of the crown (lingual root torque) compared to the initial reference tooth.

TABLE XL – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.10	0.30	-0.29	0.73	-0.05	0.21
Lateral Incisor	0.02	0.32	-0.17	0.61	-0.17	0.38
Canine	0.01	0.18	-0.01	0.32	-0.08	0.31
First Premolar	0.05	0.08	0.08	0.15	-0.10	0.11

TABLE XLI – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.03	1.99	-0.41	1.53	-1.31	3.23
Lateral Incisor	-0.23	4.24	-0.49	2.56	-1.15	3.12
Canine	0.19	1.90	-0.18	1.82	-0.32	1.45
First Premolar	0.63	1.10	-0.25	1.09	-0.01	1.13

TABLE XLII – TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-0.21	0.53	0.07	0.85	-0.33	1.07
Lateral Incisor	-0.08	0.27	-0.12	0.57	-0.03	1.07
Canine	-0.02	0.28	0.12	0.43	-0.21	0.30
First Premolar	-0.02	0.14	0.07	0.16	-0.22	0.22

TABLE XLIII – ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.58	4.90	-0.42	1.88	0.66	4.20
Lateral Incisor	-1.01	4.99	0.69	2.98	-0.11	2.38
Canine	-0.36	2.57	-0.32	1.56	0.45	2.38
First Premolar	0.63	1.17	-0.73	1.17	0.42	1.15

Since averaging numbers that could be negative or positive could lead to the mean values being close to zero and not clinically useful, the means and standard deviations of the absolute values of the amount of planned tooth movement are shown in TABLE XXXVI through TABLE XXXIX.

TABLE XLIV – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.22	0.23	0.58	0.53	0.18	0.12
Lateral Incisor	0.23	0.22	0.47	0.42	0.28	0.31
Canine	0.15	0.10	0.23	0.23	0.24	0.21
First Premolar	0.07	0.06	0.12	0.12	0.10	0.11

TABLE XLV – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	1.31	1.48	1.11	1.12	2.44	2.47
Lateral Incisor	2.88	3.08	1.72	1.94	2.51	2.15
Canine	1.33	1.35	1.16	1.40	1.15	0.93
First Premolar	0.99	0.79	0.87	0.69	0.73	0.85

TABLE XLVI – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.41	0.40	0.67	0.52	0.53	0.98
Lateral Incisor	0.22	0.17	0.39	0.42	0.49	0.94
Canine	0.21	0.18	0.33	0.30	0.28	0.24
First Premolar	0.11	0.10	0.13	0.12	0.22	0.21

TABLE XLVII – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN INITIAL MALOCCLUSION AND THE FINAL RESULT OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	3.43	3.50	1.44	1.26	3.00	2.97
Lateral Incisor	3.35	3.80	1.65	2.56	1.87	1.43
Canine	1.82	1.83	1.16	1.07	1.78	1.61
First Premolar	0.97	0.89	1.02	0.91	0.90	0.82

4.4.3 Final-Setup Comparisons

The discrepancies between final outcome and digital setup for the MTM® Clear Aligner group can be viewed in TABLE XLVIII through TABLE LI. Before running statistical testing, the absolute values of these discrepancies were taken. The results of the one-sample t-tests compared to our clinically acceptable limits

for the MTM® Clear Aligner group can be viewed in TABLE LII through TABLE LV. No variables showed statistically significant higher discrepancy mean values compared to the clinically significant values of 0.5 mm and 4 degrees. Some values showed statistically significant lower discrepancy mean values (p-value <0.05) compared to the test values, signifying more accuracy compared to our clinically acceptable limits. These values are labeled bold TABLE LII through TABLE LV.

TABLE XLVIII – TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		**Bucco-Lingual**		**Mesio-Distal**	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	-0.02	0.23	-0.18	0.52	0.01	0.36
Lateral Incisor	-0.09	0.37	-0.16	0.46	-0.07	0.45
Canine	-0.06	0.26	-0.13	0.42	-0.13	0.39
First Premolar	0.04	0.11	0.04	0.23	-0.07	0.14

TABLE XLIX – ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		**Tip**		**Torque**	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	0.19	3.53	-0.26	1.98	0.67	3.19
Lateral Incisor	0.01	4.97	-0.41	2.58	1.43	3.74
Canine	0.44	5.52	-1.30	2.32	0.64	2.85
First Premolar	0.83	1.17	-0.34	1.06	0.13	1.09

TABLE L – TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	0.01	0.34	-0.28	0.38	-0.20	1.16
Lateral Incisor	0.05	0.28	-0.24	0.49	0.17	1.05
Canine	0.10	0.23	-0.18	0.25	-0.18	0.35
First Premolar	0.03	0.14	0.05	0.17	-0.22	0.27

TABLE LI – ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	-0.24	5.41	-0.04	2.19	0.68	2.91
Lateral Incisor	1.59	4.45	-0.54	1.92	0.98	2.47
Canine	0.15	3.60	-1.38	2.00	-0.44	1.92
First Premolar	1.10	1.43	-0.91	1.39	0.62	1.21

TABLE LII – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	**0.18**	0.13	0.42	0.36	**0.26**	0.25
Lateral Incisor	**0.28**	0.25	**0.35**	0.34	**0.32**	0.32
Canine	**0.19**	0.18	**0.37**	0.23	**0.31**	0.26
First Premolar	**0.07**	0.08	**0.15**	0.18	**0.10**	0.12

TABLE LIII – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF UPPER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	**2.25**	2.70	**1.40**	1.40	**2.23**	2.35
Lateral Incisor	3.82	3.13	**1.91**	1.75	**3.04**	2.58
Canine	4.19	3.56	**2.08**	1.63	**2.17**	1.92
First Premolar	**1.11**	0.90	**0.81**	0.76	**0.80**	0.74

TABLE LIV – ABSOLUTE VALUE OF TRANSLATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Occluso-Gingival		Bucco-Lingual		Mesio-Distal	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Central Incisor	**0.23**	0.25	**0.36**	0.31	0.42	1.10
Lateral Incisor	**0.20**	0.19	**0.33**	0.43	0.40	0.98
Canine	**0.19**	0.16	**0.25**	0.18	**0.27**	0.29
First Premolar	**0.11**	0.09	**0.13**	0.12	**0.22**	0.27

TABLE LV – ABSOLUTE VALUE OF ROTATIONAL DISCREPANCIES BETWEEN FINAL OUTCOME AND DIGITAL SETUP OF LOWER ANTERIOR TEETH IN THE MTM® CLEAR ALIGNER GROUP

	Rotation		Tip		Torque	
	Mean (°)	SD (°)	Mean (°)	SD (°)	Mean (°)	SD (°)
Central Incisor	3.48	4.11	**1.70**	1.34	**2.38**	1.77
Lateral Incisor	3.14	3.50	**1.57**	1.20	**2.12**	1.55
Canine	**2.78**	2.25	**1.87**	1.54	**1.52**	1.23
First Premolar	**1.43**	1.08	**1.23**	1.11	**1.08**	0.81

4.5 Comparative Statistics Between the Two Treatment Modalities

4.5.1 Comparison of Treatment Timing and Other Clinical Variables

An independent sample test was used to compare treatment length and total number of appointments between the two groups. No statistically significant difference was noted between the two groups in these two variables (p-value >

0.05). Number of failed appointments and number of emergency appointments were compared using Pearson Chi-square tests. Number of failed appointments showed no statistically significant difference between the two groups (p-value > 0.05) while the patients in the Incognito™ Lite group had a statistically significant higher number of emergency appointments (p-value < 0.05). The frequency of failed appointments and emergency appointments can be seen in Figure 2 and Figure 3 respectively.

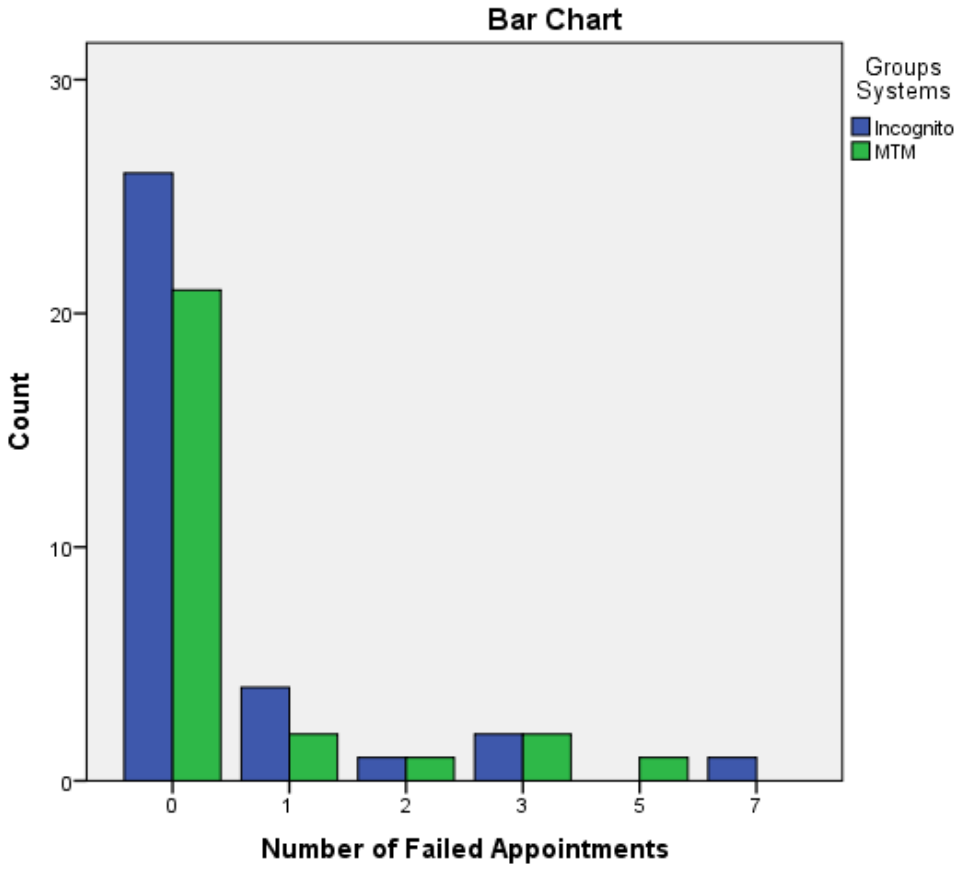


Figure 2 - Frequency failed appointments in Incognito Lite vs MTM Clear Aligner

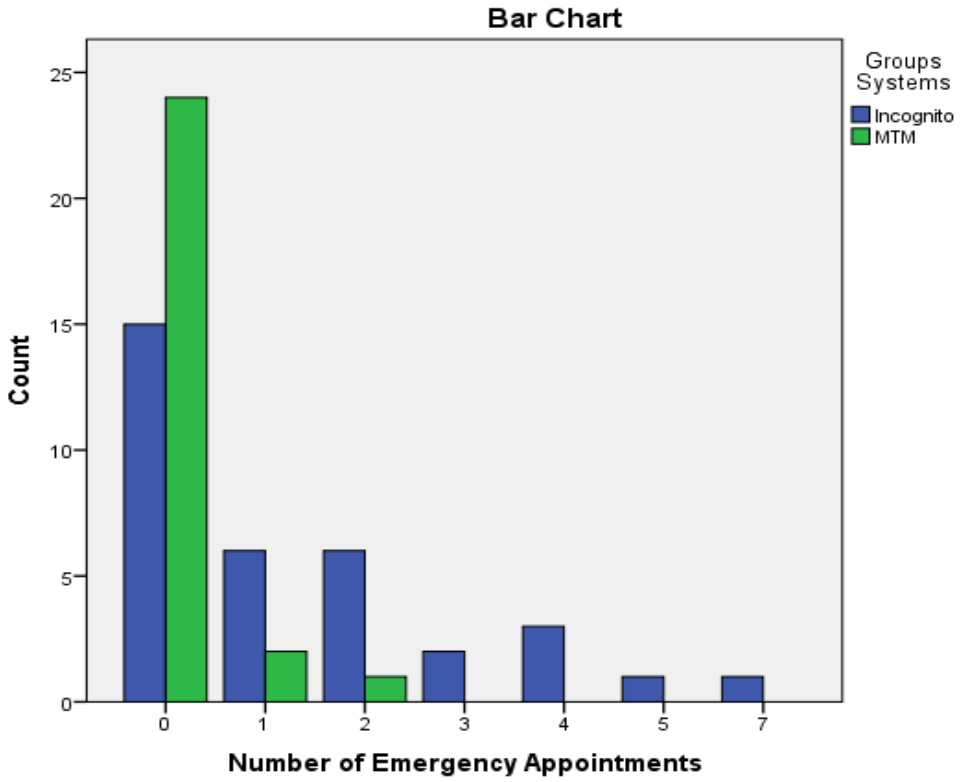


Figure 3 - Frequency emergency appointments in Incognito Lite vs MTM Clear Aligner

In clinical practice, the number of detail bends in the Incognito™ Lite group and the number of manual activations in the MTM® Clear Aligner were recorded per instance per tooth. Therefore, these two variables were compared with each other to determine whether the number of times a clinician would need to intervene in the system were different between the two systems. This variable was termed the number of manual adjustments and showed a statistically significant higher value in the MTM® Clear Aligner group. The results of comparisons for all these groups can be seen in TABLE LVI.

TABLE LVI - COMPARISON OF TREATMENT TIMING AND OTHER CLINICAL VARIABLES

	Incognito™ Lite	MTM® CLEAR ALIGNER	Statistical Significance
Length of Treatment (Days)	305.8 (151.3)	336.5 (214.2)	N.S.
Total Number of Appointments	12.6 (7.3)	10.4 (4.2)	N.S.
Number of Emergency Appointments	1.4 (1.8)	0.1 (0.5)	p-value < 0.05
Number of Failed Appointments.	0.6 (1.4)	0.6 (1.3)	N.S.
Number of Manual Adjustments	2.0 (1.8)	7.5 (3.9)	p-value < 0.05

4.5.2 Comparison of Planned Tooth Movement Between the Two Systems

The discrepancy between the initial position of the teeth and their position in the digital setup represents the amount of planned tooth movement as reported in sections 4.3.1 and 4.4.1. The absolute values of these discrepancies were compared between the two systems using independent t-tests, and the results are reported in TABLE LVII through

TABLE ***LXII***.

TABLE LVII - COMPARISON OF PLANNED OCCLUSO-GINGIVAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Occluso-gingival Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.55	0.48	**
	MTM	0.24	0.19	
Upper Lateral Incisor	Incognito Lite	0.61	0.44	**
	MTM	0.20	0.16	
Upper Canine	Incognito Lite	0.51	0.42	**
	MTM	0.17	0.14	
Lower Central Incisor	Incognito Lite	1.31	0.90	**
	MTM	0.33	0.32	
Lower Lateral Incisor	Incognito Lite	1.00	0.75	**
	MTM	0.27	0.21	
Lower Canine	Incognito Lite	0.88	0.69	**
	MTM	0.19	0.18	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LVIII - COMPARISON OF PLANNED BUCCO-LINGUAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Bucco-lingual Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.79	0.57	N.S.
	MTM	0.63	0.64	
Upper Lateral Incisor	Incognito Lite	0.81	0.55	**
	MTM	0.50	0.50	
Upper Canine	Incognito Lite	0.62	0.45	*
	MTM	0.41	0.34	
Lower Central Incisor	Incognito Lite	0.96	0.95	N.S.
	MTM	0.83	0.75	
Lower Lateral Incisor	Incognito Lite	0.70	0.69	N.S.
	MTM	0.54	0.38	
Lower Canine	Incognito Lite	0.69	0.55	*
	MTM	0.45	0.30	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LIX - COMPARISON OF PLANNED MESIO-BUCCAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Mesio-buccal Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.52	0.45	**
	MTM	0.23	0.22	
Upper Lateral Incisor	Incognito Lite	0.58	0.38	**
	MTM	0.32	0.32	
Upper Canine	Incognito Lite	0.53	0.43	*
	MTM	0.35	0.34	
Lower Central Incisor	Incognito Lite	0.66	0.46	**
	MTM	0.33	0.31	
Lower Lateral Incisor	Incognito Lite	0.64	0.52	**
	MTM	0.27	0.19	
Lower Canine	Incognito Lite	0.53	0.47	**
	MTM	0.17	0.13	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LX - COMPARISON OF PLANNED ROTATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Rotation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	4.94	4.21	*
	MTM	2.92	3.28	
Upper Lateral Incisor	Incognito Lite	7.27	6.11	*
	MTM	5.10	4.20	
Upper Canine	Incognito Lite	8.03	7.22	**
	MTM	4.37	3.99	
Lower Central Incisor	Incognito Lite	6.78	4.75	N.S.
	MTM	4.92	3.85	
Lower Lateral Incisor	Incognito Lite	10.14	8.23	**
	MTM	4.50	4.38	
Lower Canine	Incognito Lite	7.83	7.13	**
	MTM	2.56	2.85	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXI - COMPARISON OF PLANNED TIP BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Tip	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	1.93	1.75	*
	MTM	1.22	1.15	
Upper Lateral Incisor	Incognito Lite	3.42	3.38	**
	MTM	1.64	1.20	
Upper Canine	Incognito Lite	4.82	3.83	**
	MTM	1.89	1.39	
Lower Central Incisor	Incognito Lite	3.17	2.94	N.S.
	MTM	2.19	1.40	
Lower Lateral Incisor	Incognito Lite	6.14	5.42	**
	MTM	2.02	2.32	
Lower Canine	Incognito Lite	4.89	4.07	**
	MTM	1.76	1.73	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXII - COMPARISON OF PLANNED TORQUE BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

TORQUE	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	5.58	4.94	*
	MTM	3.72	3.88	
Upper Lateral Incisor	Incognito Lite	5.40	4.36	N.S.
	MTM	4.59	3.86	
Upper Canine	Incognito Lite	5.15	3.80	**
	MTM	2.42	2.35	
Lower Central Incisor	Incognito Lite	5.45	5.17	N.S.
	MTM	3.90	2.93	
Lower Lateral Incisor	Incognito Lite	6.33	4.87	**
	MTM	3.27	2.19	
Lower Canine	Incognito Lite	6.57	4.93	**
	MTM	2.02	1.84	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

4.5.3 Comparison of Achieved Tooth Movement Between the Two Systems

The discrepancy between the initial position of the teeth and their final position after treatment represents the amount of achieved tooth movement as reported in sections 4.3.2 and 4.4.2. It should be kept in mind that the amount of achieved tooth movement depends on the amount of planned tooth movement and should be looked at with that context in mind. The absolute values of these

discrepancies were compared between the two systems using independent t-tests, and the results are reported in TABLE LXIII through

TABLE ***LXVIII***.

TABLE LXIII - COMPARISON OF ACHIEVED OCCLUSO-GINGIVAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Occluso-gingival Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.49	0.34	**
	MTM	0.22	0.23	
Upper Lateral Incisor	Incognito Lite	0.38	0.30	**
	MTM	0.23	0.22	
Upper Canine	Incognito Lite	0.28	0.23	**
	MTM	0.15	0.10	
Lower Central Incisor	Incognito Lite	1.03	0.72	**
	MTM	0.41	0.40	
Lower Lateral Incisor	Incognito Lite	0.68	0.50	**
	MTM	0.22	0.17	
Lower Canine	Incognito Lite	0.67	0.58	**
	MTM	0.21	0.18	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXIV - COMPARISON OF ACHIEVED BUCCO-LINGUAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Bucco-lingual Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.66	0.54	N.S.
	MTM	0.58	0.53	
Upper Lateral Incisor	Incognito Lite	0.67	0.46	*
	MTM	0.47	0.42	
Upper Canine	Incognito Lite	0.46	0.30	**
	MTM	0.23	0.23	
Lower Central Incisor	Incognito Lite	1.15	0.94	**
	MTM	0.67	0.52	
Lower Lateral Incisor	Incognito Lite	0.83	0.68	**
	MTM	0.39	0.42	
Lower Canine	Incognito Lite	0.66	0.48	**
	MTM	0.33	0.30	

N.S. No Statistically Significant Difference
*** p-value < 0.05**
**** p-value <0.01**

TABLE LXV - COMPARISON OF ACHIEVED MESIO-BUCCAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Mesio-buccal Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.41	0.39	**
	MTM	0.18	0.12	
Upper Lateral Incisor	Incognito Lite	0.43	0.44	N.S.
	MTM	0.28	0.31	
Upper Canine	Incognito Lite	0.38	0.33	*
	MTM	0.24	0.21	
Lower Central Incisor	Incognito Lite	0.61	0.71	N.S.
	MTM	0.53	0.98	
Lower Lateral Incisor	Incognito Lite	0.50	0.48	N.S.
	MTM	0.49	0.94	
Lower Canine	Incognito Lite	0.38	0.33	N.S.
	MTM	0.28	0.24	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXVI - COMPARISON OF ACHIEVED ROTATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Rotation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	3.71	3.03	**
	MTM	1.31	1.48	
Upper Lateral Incisor	Incognito Lite	5.42	4.85	**
	MTM	2.88	3.08	
Upper Canine	Incognito Lite	6.46	6.06	**
	MTM	1.33	1.35	
Lower Central Incisor	Incognito Lite	5.64	3.96	**
	MTM	3.43	3.50	
Lower Lateral Incisor	Incognito Lite	8.29	7.53	**
	MTM	3.35	3.80	
Lower Canine	Incognito Lite	5.66	5.48	**
	MTM	1.82	1.83	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXVII - COMPARISON OF ACHIEVED TIP BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Tip	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	1.90	1.68	N.S.
	MTM	1.11	1.12	
Upper Lateral Incisor	Incognito Lite	3.01	2.43	**
	MTM	1.72	1.94	
Upper Canine	Incognito Lite	2.97	2.61	**
	MTM	1.16	1.40	
Lower Central Incisor	Incognito Lite	2.51	1.92	**
	MTM	1.44	1.26	
Lower Lateral Incisor	Incognito Lite	4.48	4.07	**
	MTM	1.65	2.56	
Lower Canine	Incognito Lite	3.02	2.62	**
	MTM	1.16	1.07	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXVIII - COMPARISON OF ACHIEVED TORQUE BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

TORQUE	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	3.20	2.71	N.S.
	MTM	2.44	2.47	
Upper Lateral Incisor	Incognito Lite	3.10	2.36	**
	MTM	2.51	2.15	
Upper Canine	Incognito Lite	2.16	1.70	**
	MTM	1.15	0.93	
Lower Central Incisor	Incognito Lite	4.92	4.22	*
	MTM	3.00	2.97	
Lower Lateral Incisor	Incognito Lite	4.14	3.28	**
	MTM	1.87	1.43	
Lower Canine	Incognito Lite	3.44	2.83	**
	MTM	1.78	1.61	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

4.5.4 Comparison of Planned and Achieved Tooth Movement Between the Two Systems

The discrepancy between the final position of the teeth and the planned digital setup treatment represents the error in each treatment system as reported in sections 4.3.3 and 4.4.3. It should be kept in mind that the amount of discrepancy likely depends on the amount of planned tooth movement and should be looked at with that context in mind. The absolute values of these discrepancies were

compared between the two systems using independent t-tests, and the results are reported in TABLE LXIX through **Error! Reference source not found.**.

TABLE LXIX - DISCREPANCY OF ACHIEVED AND PLANNED OCCLUSO-GINGIVAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Occluso-gingival Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.42	0.31	**
	MTM	0.18	0.13	
Upper Lateral Incisor	Incognito Lite	0.38	0.30	N.S.
	MTM	0.28	0.25	
Upper Canine	Incognito Lite	0.29	0.29	*
	MTM	0.19	0.18	
Lower Central Incisor	Incognito Lite	0.44	0.42	**
	MTM	0.23	0.25	
Lower Lateral Incisor	Incognito Lite	0.40	0.45	**
	MTM	0.20	0.19	
Lower Canine	Incognito Lite	0.40	0.46	**
	MTM	0.19	0.16	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXX - DISCREPANCY OF ACHIEVED AND PLANNED BUCCO-LINGUAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Bucco-lingual Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.51	0.45	N.S.
	MTM	0.42	0.36	
Upper Lateral Incisor	Incognito Lite	0.43	0.39	N.S.
	MTM	0.35	0.34	
Upper Canine	Incognito Lite	0.41	0.39	N.S.
	MTM	0.37	0.23	
Lower Central Incisor	Incognito Lite	0.49	0.40	N.S.
	MTM	0.36	0.31	
Lower Lateral Incisor	Incognito Lite	0.45	0.36	N.S.
	MTM	0.33	0.43	
Lower Canine	Incognito Lite	0.53	0.41	**
	MTM	0.25	0.18	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXXI - DISCREPANCY OF ACHIEVED AND PLANNED MESIO-BUCCAL TRANSLATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Mesio-buccal Translation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	0.35	0.32	N.S.
	MTM	0.26	0.25	
Upper Lateral Incisor	Incognito Lite	0.38	0.34	N.S.
	MTM	0.32	0.32	
Upper Canine	Incognito Lite	0.33	0.27	N.S.
	MTM	0.31	0.26	
Lower Central Incisor	Incognito Lite	0.40	0.31	N.S.
	MTM	0.42	1.10	
Lower Lateral Incisor	Incognito Lite	0.43	0.33	N.S.
	MTM	0.40	0.98	
Lower Canine	Incognito Lite	0.41	0.32	*
	MTM	0.27	0.29	

N.S. No Statistically Significant Difference
*** p-value < 0.05**
**** p-value <0.01**

TABLE LXXII - DISCREPANCY OF ACHIEVED AND PLANNED ROTATION BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Rotation	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	2.22	2.29	N.S.
	MTM	2.25	2.70	
Upper Lateral Incisor	Incognito Lite	3.23	3.59	N.S.
	MTM	3.89	3.13	
Upper Canine	Incognito Lite	4.22	3.68	N.S.
	MTM	4.19	3.56	
Lower Central Incisor	Incognito Lite	2.66	2.19	N.S.
	MTM	3.48	4.11	
Lower Lateral Incisor	Incognito Lite	2.99	3.06	N.S.
	MTM	3.14	3.50	
Lower Canine	Incognito Lite	4.33	3.61	*
	MTM	2.78	2.25	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TABLE LXXIII - DISCREPANCY OF ACHIEVED AND PLANNED TIP BETWEEN INCOGNITO LITE AND MTM CLEAR ALIGNER

Tip	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	1.79	1.43	N.S.
	MTM	1.40	1.40	
Upper Lateral Incisor	Incognito Lite	2.36	2.19	N.S.
	MTM	1.96	1.75	
Upper Canine	Incognito Lite	3.17	3.08	*
	MTM	2.08	1.63	
Lower Central Incisor	Incognito Lite	2.14	2.05	N.S.
	MTM	1.70	1.34	
Lower Lateral Incisor	Incognito Lite	3.23	2.54	**
	MTM	1.57	1.20	
Lower Canine	Incognito Lite	3.76	3.05	**
	MTM	1.87	1.54	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

TORQUE	Groups	Mean	Std. Deviation	
Upper Central Incisor	Incognito Lite	3.57	3.20	*
	MTM	2.23	2.35	
Upper Lateral Incisor	Incognito Lite	3.39	2.89	N.S.
	MTM	2.96	2.55	
Upper Canine	Incognito Lite	3.50	3.18	**
	MTM	2.17	1.92	
Lower Central Incisor	Incognito Lite	3.45	2.68	*
	MTM	2.38	1.77	
Lower Lateral Incisor	Incognito Lite	3.81	3.22	**
	MTM	2.12	1.55	
Lower Canine	Incognito Lite	3.44	2.83	**
	MTM	1.78	1.61	
N.S. No Statistically Significant Difference *** p-value < 0.05** **** p-value <0.01**				

5. DISCUSSION

5.1. Dental-Monitoring Evaluation

The DM software is used clinically for evaluating tooth movements when taking photos every 1-2 weeks. This short time interval between photos is important to ensure that accurate STL files can be reconstructed from the initial STL as treatment progresses. During this study, there was no need for DM to reconstruct any STL files since they initial, final and setup STL files were all available. The reproducibility of the measurements was evaluated using ICC coefficients, which was significantly affected by 2 single teeth mismatched by the best-fit algorithms in one of two submissions. The incidence was low (2 in ~120) and did not affect the results significantly, but the more extreme measurements should be taken with caution because they may represent a mismatch in the best-fit algorithm. However, the amount of movements that the software was asked to calculate were larger in our study than usually occurs in 1-2 week intervals during treatment. Therefore, this incidence of mismatching may be less when evaluating tooth movement that is occurring at much smaller increments. Another component of the DM software is the ability to reconstruct in-treatment STL files from a specific set of photographs and the initial STL malocclusion. This reconstruction could also represent a source of error when calculating tooth movement and would need be evaluated in a separate study. Finally, the reproducibility of measurements doesn't necessarily represent accuracy. Defining tooth movement in 3D is a difficult task and any movement can only be expressed based on the definitions used for the center of the local coordinate system at each tooth and the definitions used for

determining the 3 axes. Therefore, the amount of movement would be different based on the definitions used for center and axes of the local and global coordinate system. Since there is no gold standard definition for how tooth movement should be defined, determining accuracy is not possible. Numbers can only be reported in the context of how they were measured and interpreted accordingly to that definition only.

5.2. Evaluation of Incognito Lite and MTM Clear Aligner Systems

When evaluating Incognito Lite and MTM Clear Aligner Systems, it's important to keep in mind the patient population and the treatment objectives the systems aim to achieve. As reported in section 4.1, the average patient at the start of treatment was in his or her 30s and 40s. In addition, a much higher proportion of the patients treated were female (50 females vs 11 males), which aligns well with the esthetic offerings of both systems. Both systems aim at treating the "social six" canine to canine region and therefore no skeletal or antero-posterior correction can be planned nor achieved. The results of this study should be interpreted with that consideration in mind.

5.2.1. Evaluation of Treatment Difficulty

Since this study evaluated retrospective cases that were not assigned to one method or the other randomly, it is certainly possible that there were differences in the initial malocclusions present. Besides the differences in the cost of each treatment method, one system may have been offered to the patient over the other based on the amount of misalignment presented and the types of tooth movement desired. To evaluate the differences between the initial malocclusion

between the two groups, the skeletal and dental cephalometric measurements were compared as reported in TABLE IV. There were no statistically different cephalometric measurements although the upper incisors were on average more retroclined in the Incognito Lite group. This may have been a deciding factor when treatment planning in that cases in need of more proclination of upper incisors could have selectively been treated with Incognito Lite instead of MTM. However, lack of any difference in the cephalometric measurements between the two groups does not necessarily indicate that both groups had equal difficulty in terms of the movements needed. Considering the patient population and the appliances used, it is likely that no correction of skeletal or antero-posterior discrepancies were part of the patient-specific treatment objectives. Therefore, the amount of planned tooth movement in each system was compared to better understand that differences in the cases treated with each system.

Sections 4.3.1 and 4.4.1 report the amount of planned tooth movement for each system.The comparison of the amount of tooth movement planned using each system is reported in section 4.5.2. There are significant differences in many of the measured variables for the planned tooth movement. This signifies a difference between the initial malocclusion between the two groups since the amount of movement necessary to get them to ideal alignment was significantly different. Most notably, the amount of rotation planned for the Incognito Lite group was significantly higher than the MTM group for all teeth except for the lower central incisors. Incognito Lite cases had on average of 2-5 degrees more rotation planned. Also, the range of planned rotation was much higher in the Incognito Lite

group when considering standard deviations, indicating that Incognito Lite may have been used preferentially when higher rotations were necessary. This would be likely considering the reported difficulties of correcting significant rotations with clear aligner therapy in the literature.[6] The planned occluso-gingival translator movements were also higher in the Incognito Lite group for all teeth. However, it should be noted that the means compared were for absolute values and therefore do not indicate whether the occluso-gingival movements planned were extrusive or intrusive. The bucco-lingual planned movements showed some statistically significant and some statistically insignificant differences between the two groups. However, even when statistical significance was present, the difference is likely not clinically significant (~0.2-0.3mm). The mesio-distal differences between the two groups were statistically significant for all teeth. However, it should be noted that the mesio-distal measurements, as well as all other variables, are only reported within the arch. Therefore, any mesio-distal movement measured does not reflect antero-posterior movement. Changes in mesio-distal position of the teeth when measured at crown tips can result from IPR, resolving of crowding or resolving of spacing. Therefore, increased planned mesio-distal movements in the Incognito Lite group likely represent a higher presence of crowding, spacing or IPR. The amount of planned tip and torque movement were generally higher for the Incognito Lite sample even though not statistically significant for lower central incisor tip and torque as well as upper lateral incisor torque. The planned movements for the Incognito Lite patients also had a higher range, indicating that

patients with high discrepancy for tip and torque may have been preferentially treated with the Incognito Lite Group.

5.2.2. Clinical Timing and Other Variables

When comparing clinical treatment time and other variables, it should be kept in mind that the cases treated with Incognito Lite and MTM were not identical at the beginning of treatment. Therefore, any difference or lack thereof, should be interpreted with that in mind. For the patients treated in this sample, there was not statistically significant difference between number of appointments and treatment time. However, this does not indicate that both systems would lead to similar number of appointments or treatment time since the cases treated with Incognito Lite were more severe. Therefore, it is likely that for similarly difficult cases, Incognito Lite may have a shorter treatment time. On the contrary, it is likely that treatment of very light malocclusions may be more time-efficient and less costly since there would be no need for fabrication of customized bracket pads and going through multiple wire changes before arriving at the final result. Since the total treatment time and number of appointments were similar between the two groups, number of emergency and failed appointments can be compared between the two groups in that context. For the same average treatment length, patients treated in the Incognito Lite group had more emergency appointments compared to the patients in the MTM group. This can be expected when considering that the MTM clear aligners are removable and are unlikely to lead to any patient-perceived emergencies while the brackets and wires on the lingual surfaces in the Incognito Lite group can certainly lead to patients feeling “wire-pokes” or other emergencies.

Finally, both systems allow for the clinician to make modifications to the appliances by either placing dimples in the clear aligners or adjustment bends in the pre-fabricated wires. The need for doing these adjustments represents an inherent imperfection in both systems in achieving the final outcome necessary. However, it's likely that any such system will need minimal modifications. In our study, the MTM group had a statistically significant higher amount of manual adjustments needed by the clinician to be able to achieve the desired digital setup. Therefore, clinicians may expect to need to make manual adjustments more commonly when using the MTM Clear Aligner treatment compared to Incognito Lite treatment.

5.2.3. Clinical Success for Incognito Lite and MTM

As reported in 4.3.3 and 4.4.3, both systems had discrepancies between the final result and the digital setup that were on average not higher than our clinically acceptable limits of 0.5mm and 4 degrees. These results indicate that when used for appropriate cases both systems lead to final results that are within a clinically acceptable range of the planned digital setup. It should be noted however that these were average discrepancy values and do not indicate what the success rate for each movement was when significant movement is planned. Looking at the range of the discrepancies present indicates that there were certainly movements that were not fully expressed clinically. It is likely that these were the teeth that were planned for larger movements.

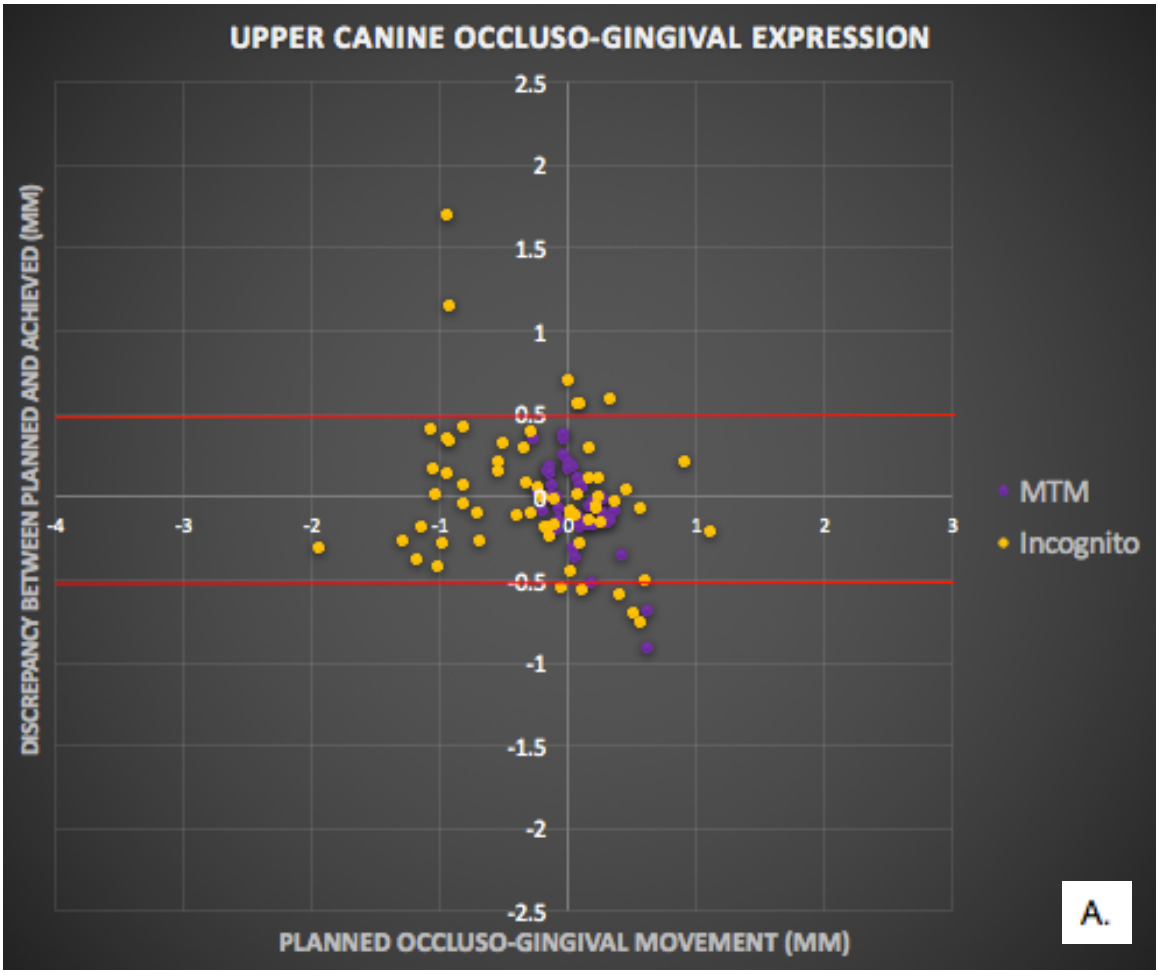
Comparisons between the achieved tooth movements using each system were reported in section 4.5.3. The amount of achieved movement using the Incognito Lite system was higher in most variables as expected since these cases

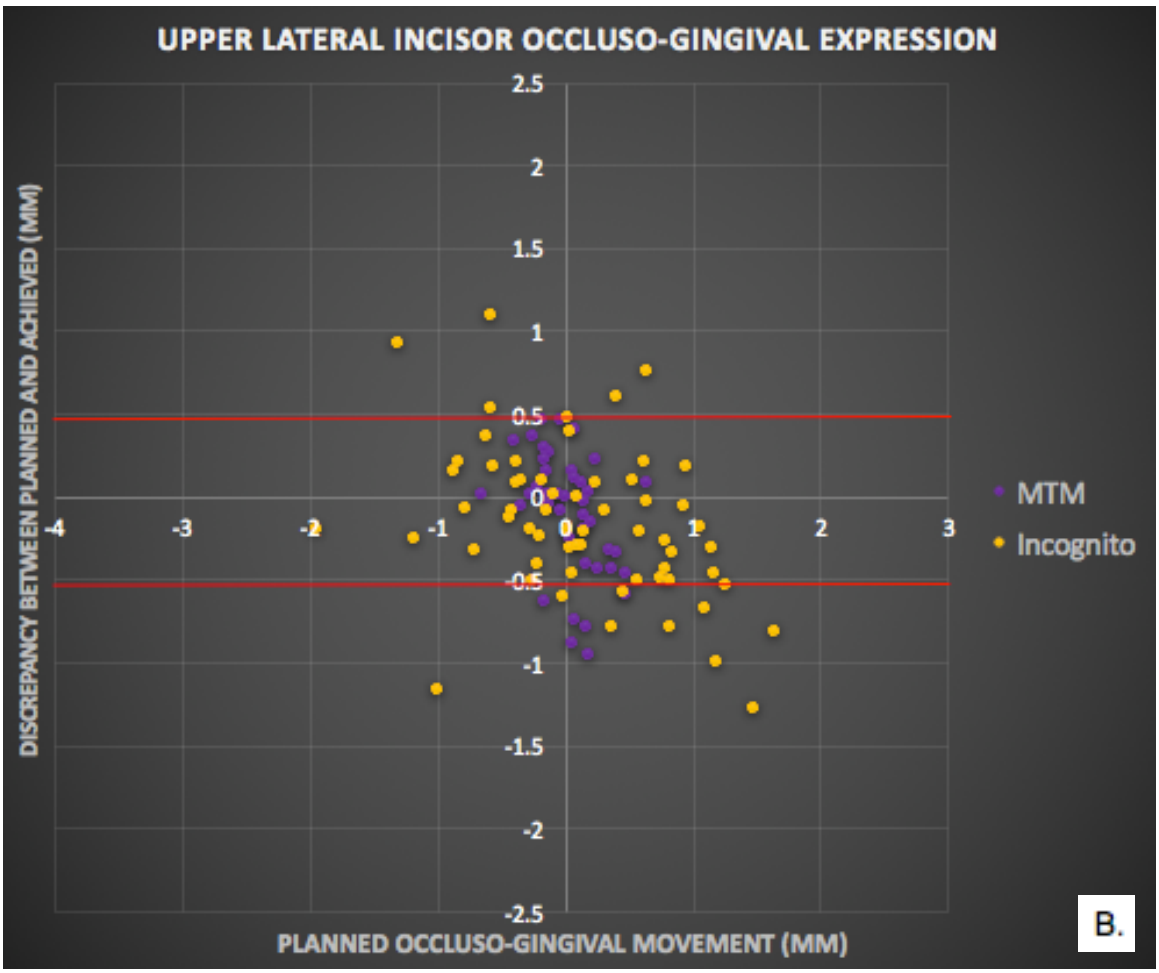
had a higher amount of planned tooth movement. Comparisons between the amount of discrepancy between the planned and achieved among the two systems is reported in section 4.5.4. These results show no statistically significant difference between the two systems for most variables. However, some variables (mainly torque variables) show less discrepancy between the planned and achieved treatment outcomes in the MTM group compared to the Incognito Lite group. While some of these differences are statistically significant, it is likely that these differences are clinically insignificant since all of them are less than 2 degrees. In addition, even though the amount of final-setup discrepancies were smaller for some MTM variables, Incognito Lite had higher planned tooth movement for most variables. Therefore, it cannot be concluded that the MTM system would have smaller discrepancies compared to Incognito Lite for the same case.

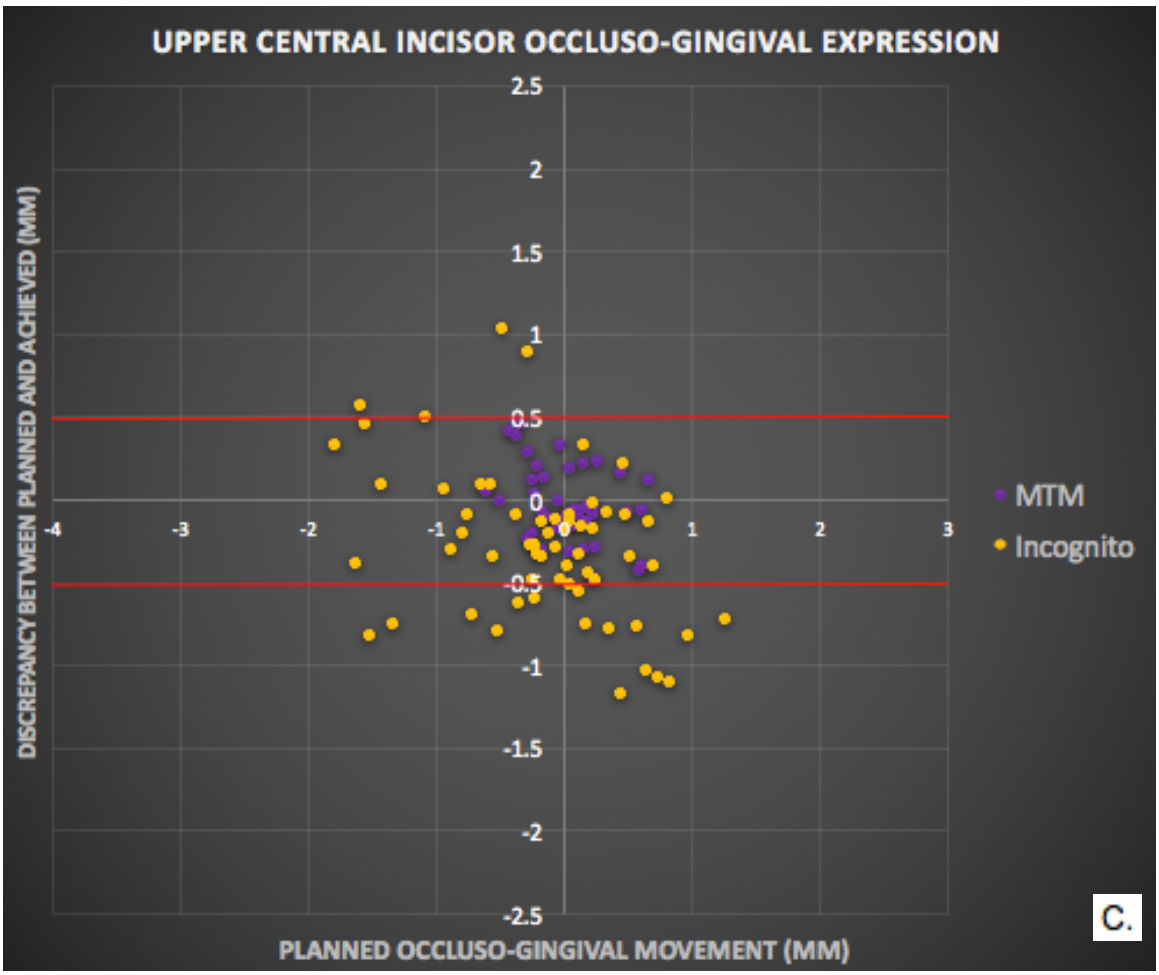
5.2.4. Clinical Success as a Function of Planned Tooth Movement

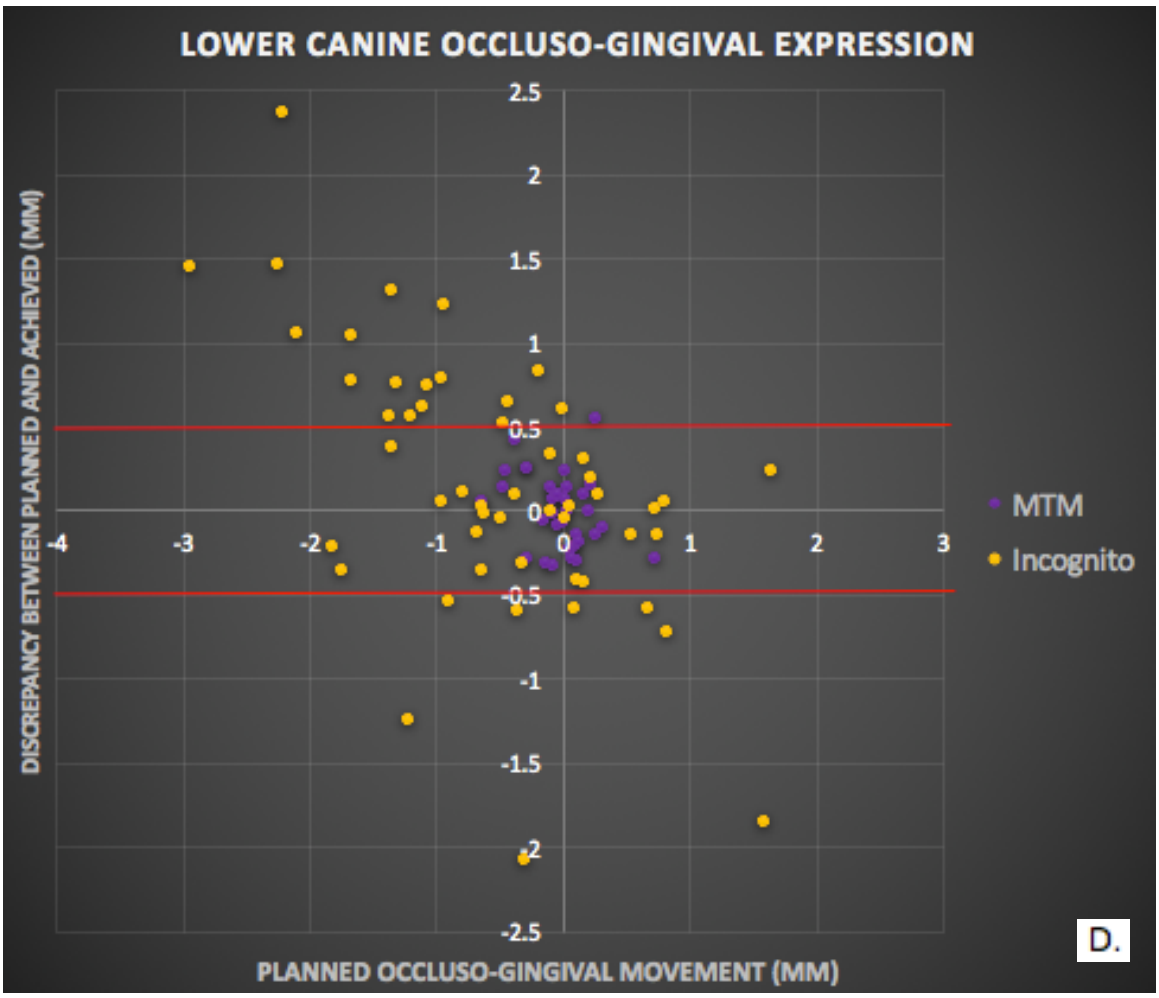
It is possible to create graphs that depict the amount of the discrepancy between the planned and achieved position of teeth as a function of the amount of planned tooth movement. These graphs could be used to determine how the amount of planned tooth movement could affect the amount of final discrepancy. The results are showing in Figure 4 for occluso-gingival movements, Figure 5 for bucco-lingual movements, Figure 6 for rotation movements, Figure 7 for tip movements and Figure 8 for torque movements. It is important to note that that as can be seen from the graphs, it is possible to have a final outcome that is clinically acceptable or not with the same amount of planned tooth movement. There are

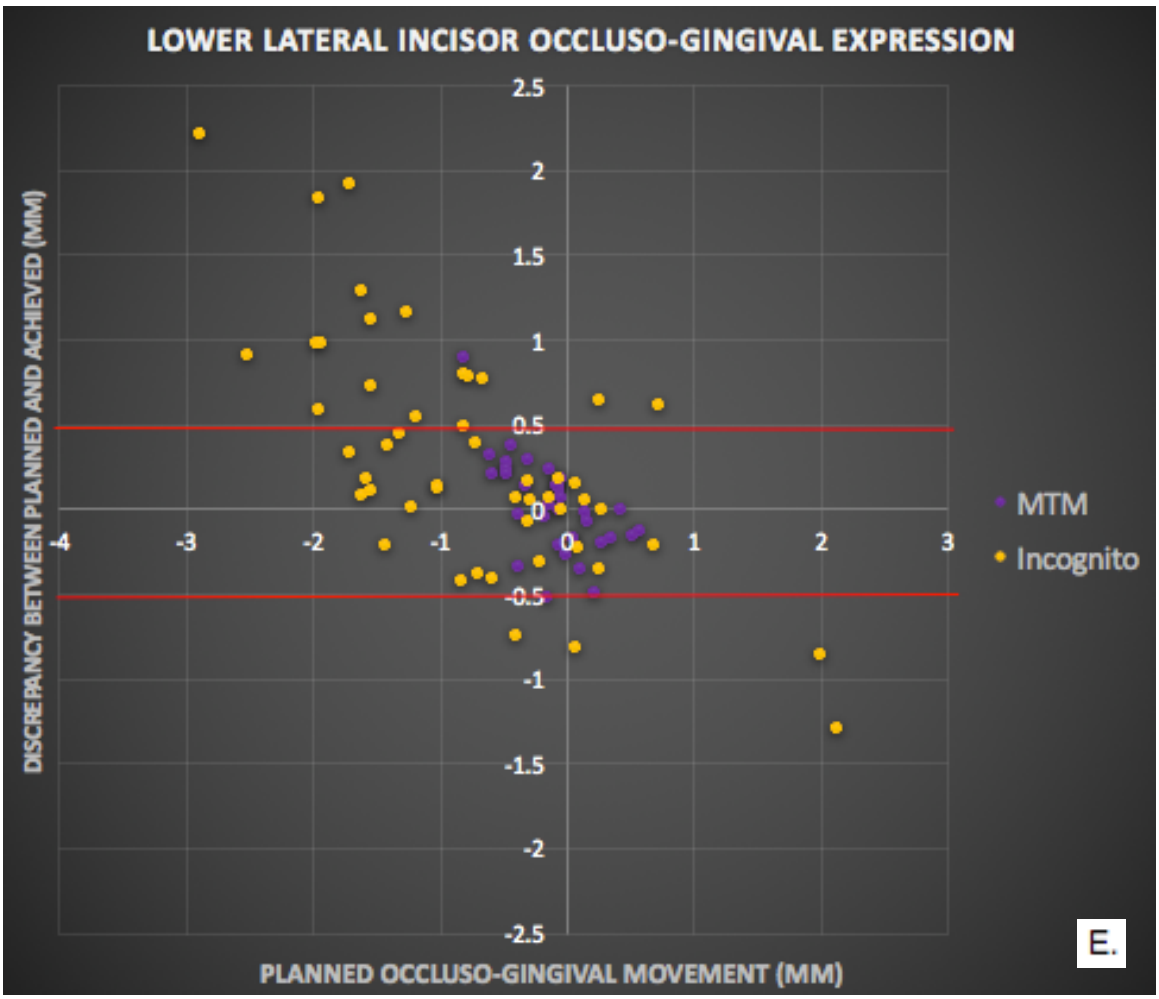
many factors that can affect the success of a particular tooth movement besides the amount of planned movement including crowding, overjet available, amount of planned movement for adjacent teeth and biological factors. Therefore, it is not possible to simply predict the success of a tooth movement based on the amount of planned movement, but graphs like these can give ideas for the range of values that may be more likely to be successful.




UPPER LATERAL INCISOR OCCLUSO-GINGIVAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED OCCLUSO-GINGIVAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-2.5
-4
-3
-2
-1
0
1
2
3
MTM
Incognito
B.


UPPER CENTRAL INCISOR OCCLUSO-GINGIVAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED OCCLUSO-GINGIVAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-2.5
-4
-3
-2
-1
0
1
2
3
MTM
Incognito
C.


LOWER CANINE OCCLUSO-GINGIVAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED OCCLUSO-GINGIVAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-2.5
-4
-3
-2
-1
0
1
2
3
MTM
Incognito
D.


LOWER LATERAL INCISOR OCCLUSO-GINGIVAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED OCCLUSO-GINGIVAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-2.5
-4
-3
-2
-1
0
1
2
3
MTM
Incognito
E.

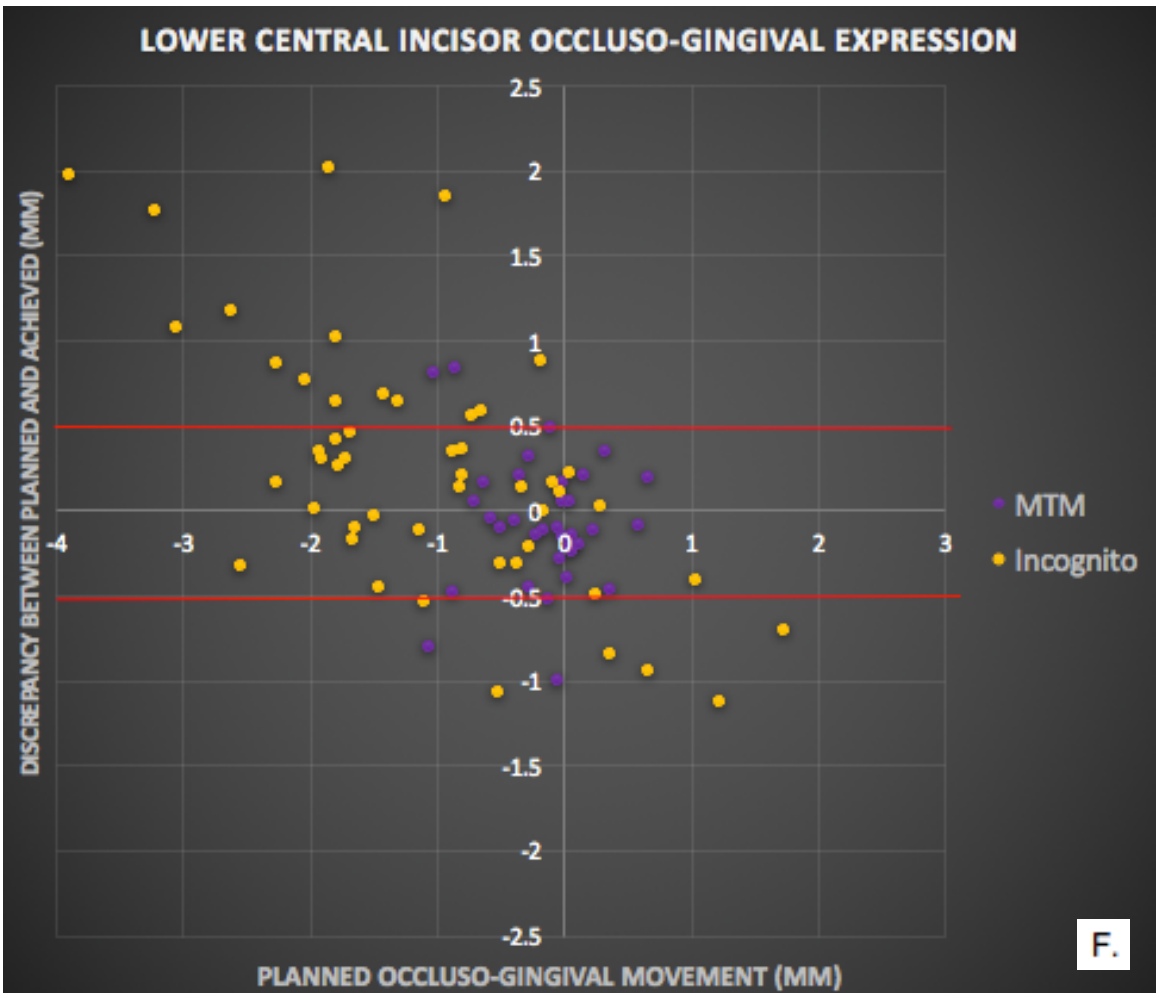
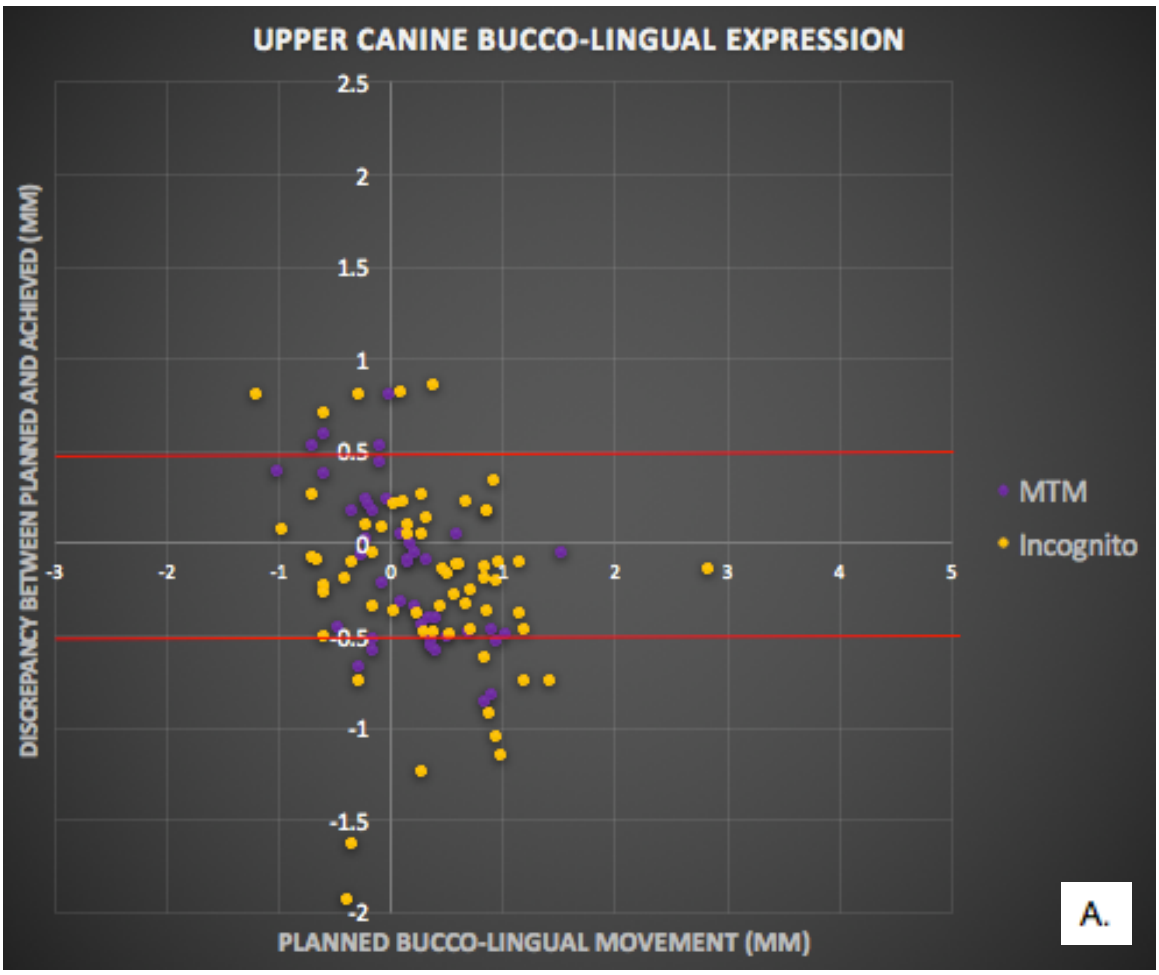
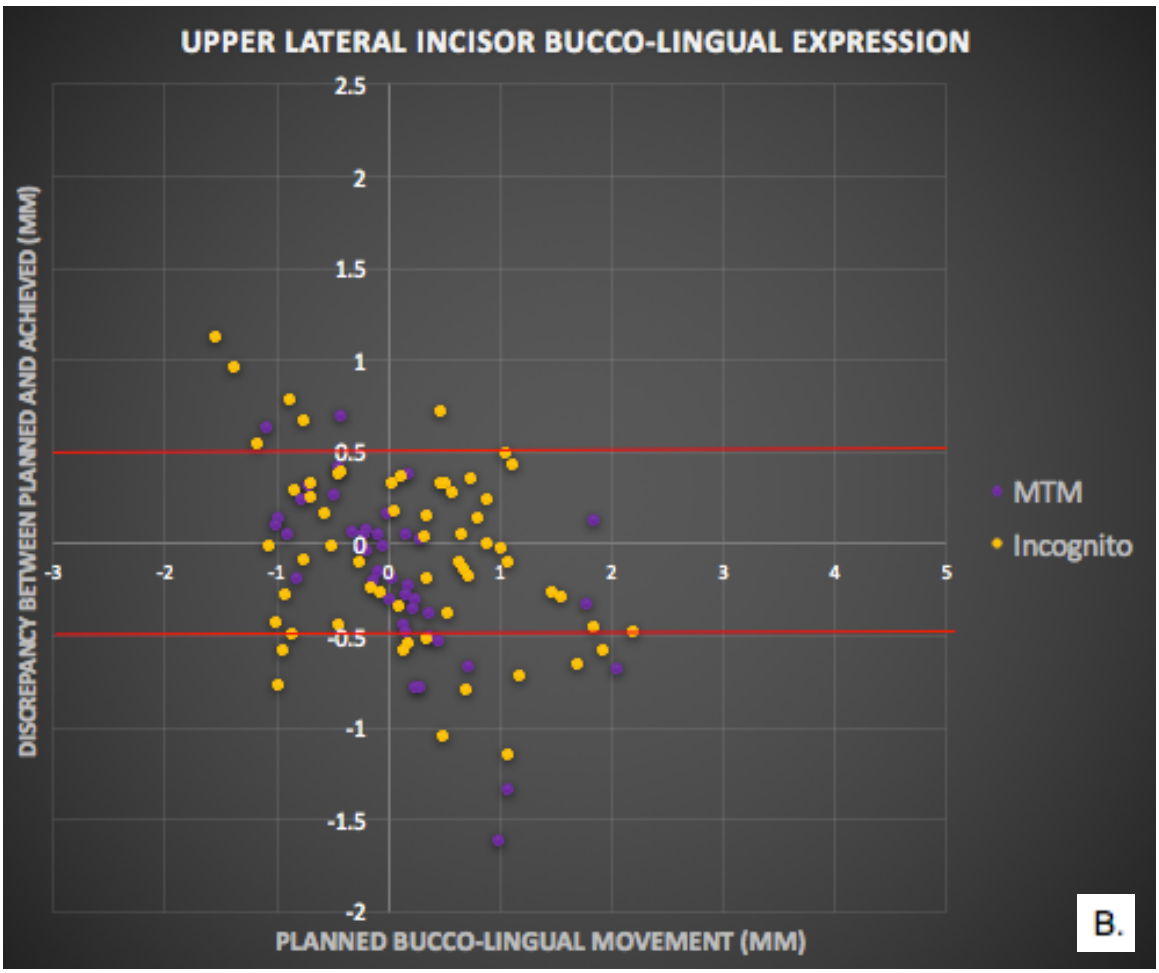
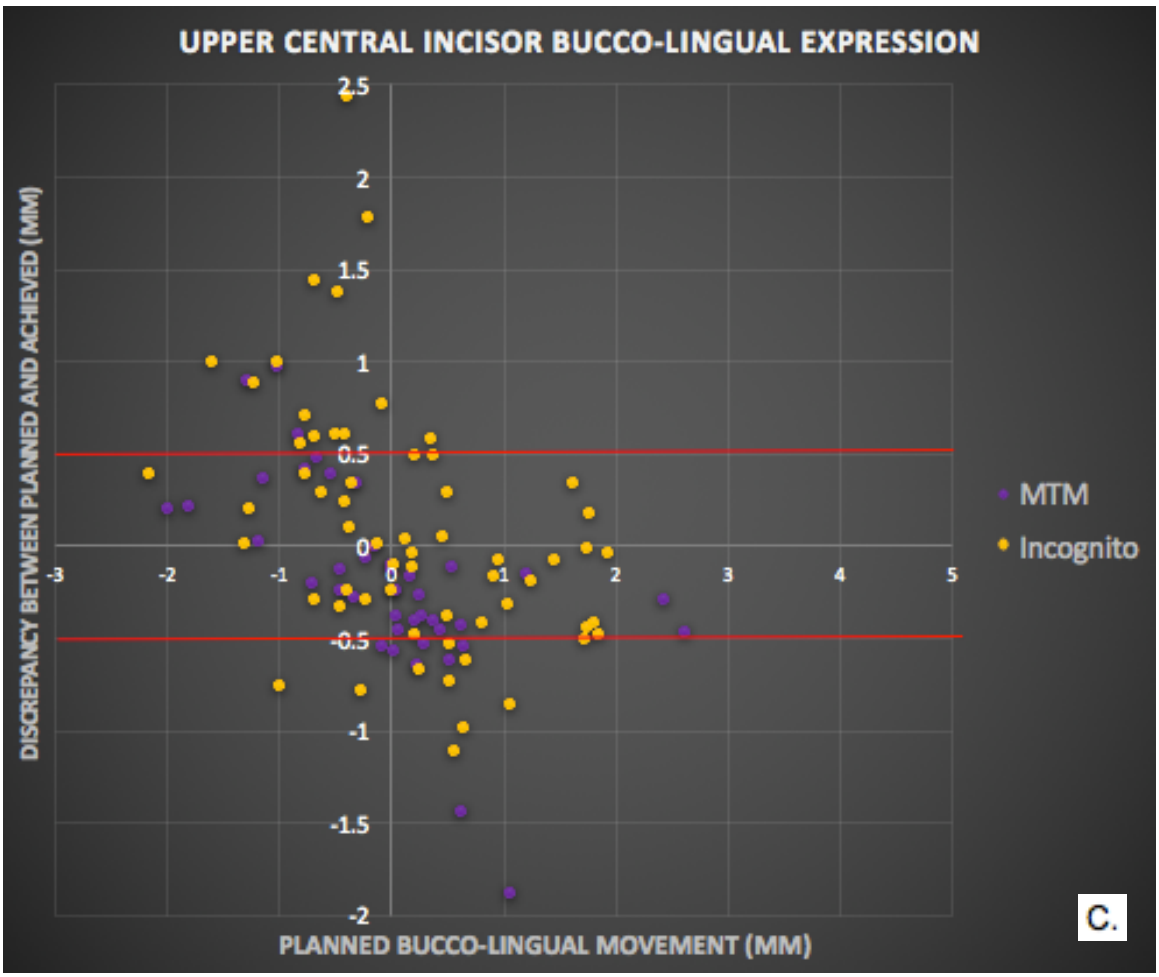
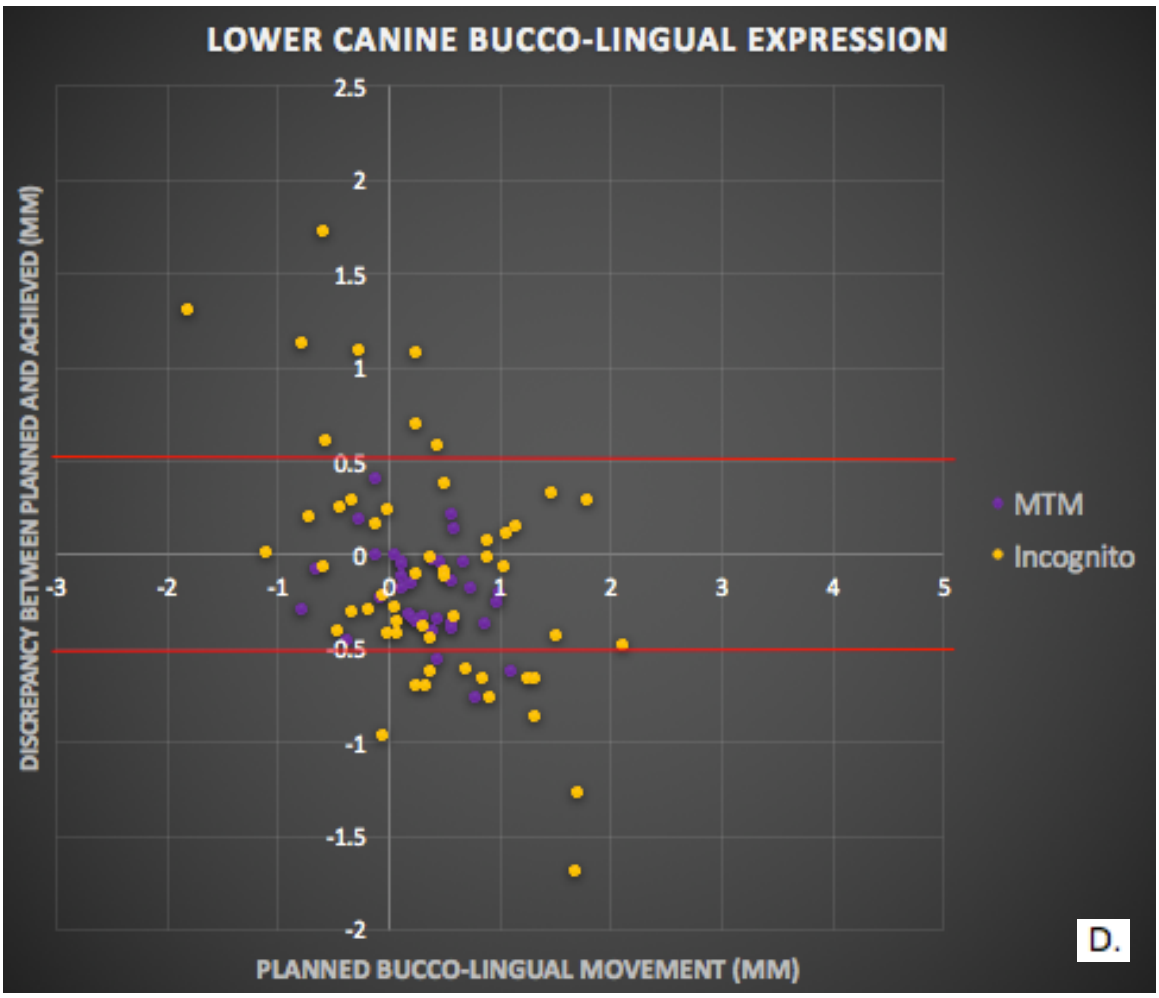


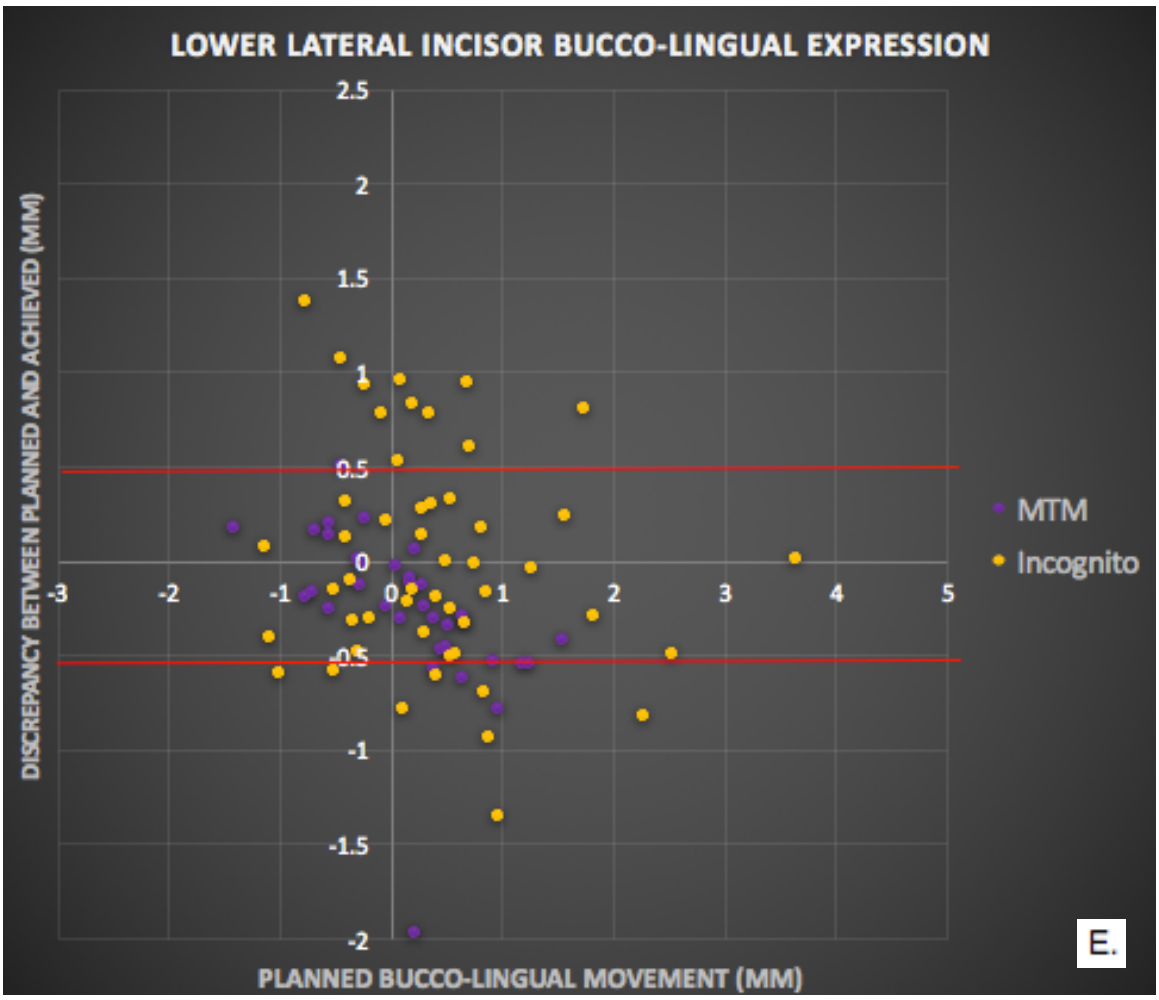
Figure 4 - Amount of discrepancy between final outcome and digital setup plotted against amount of planned occlusso-gingival movement for A) upper canines B) upper later incisors C) upper central incisors D) lower canines E) lower lateral incisors F) lower central incisors.


UPPER CANINE BUCCO-LINGUAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED BUCCO-LINGUAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-3
-2
-1
0
1
2
3
4
5
MTM
Incognito
A.


UPPER LATERAL INCISOR BUCCO-LINGUAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED BUCCO-LINGUAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-3
-2
-1
0
1
2
3
4
5
MTM
Incognito
B.


UPPER CENTRAL INCISOR BUCCO-LINGUAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED BUCCO-LINGUAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-3
-2
-1
0
1
2
3
4
5
MTM
Incognito
C.


LOWER CANINE BUCCO-LINGUAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED BUCCO-LINGUAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-3
-2
-1
0
1
2
3
4
5
MTM
Incognito
D.


LOWER LATERAL INCISOR BUCCO-LINGUAL EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (MM)
PLANNED BUCCO-LINGUAL MOVEMENT (MM)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-3
-2
-1
0
1
2
3
4
5
MTM
Incognito
E.

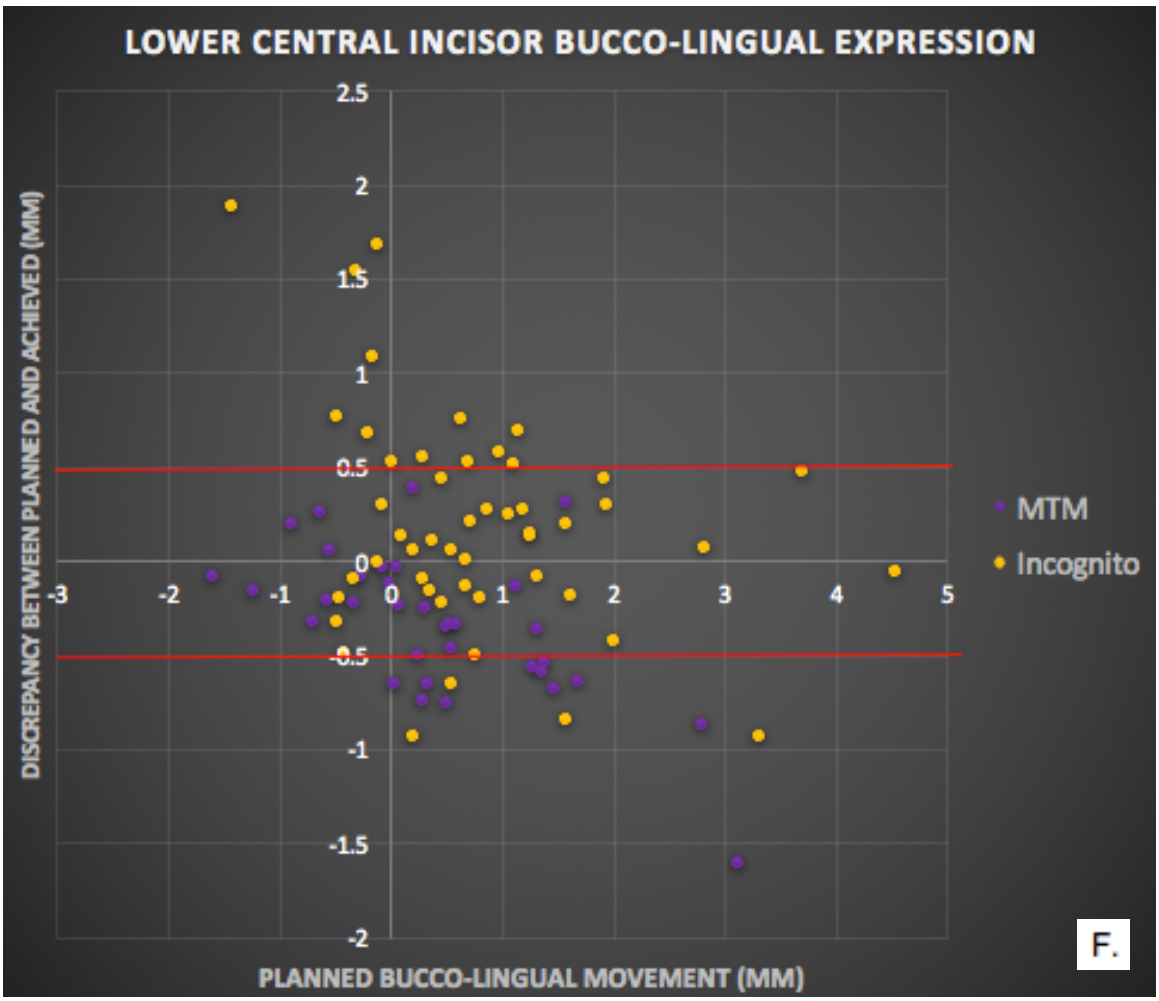
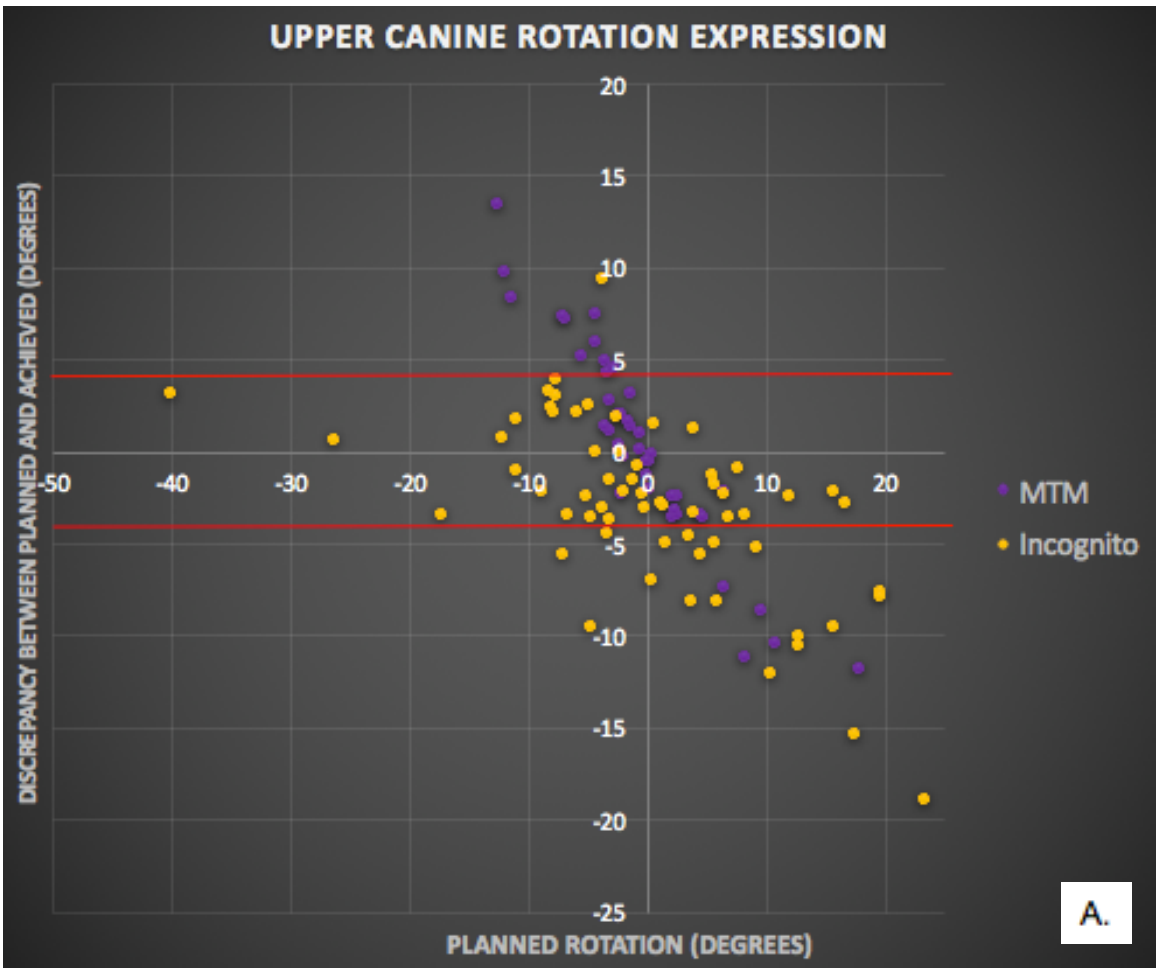
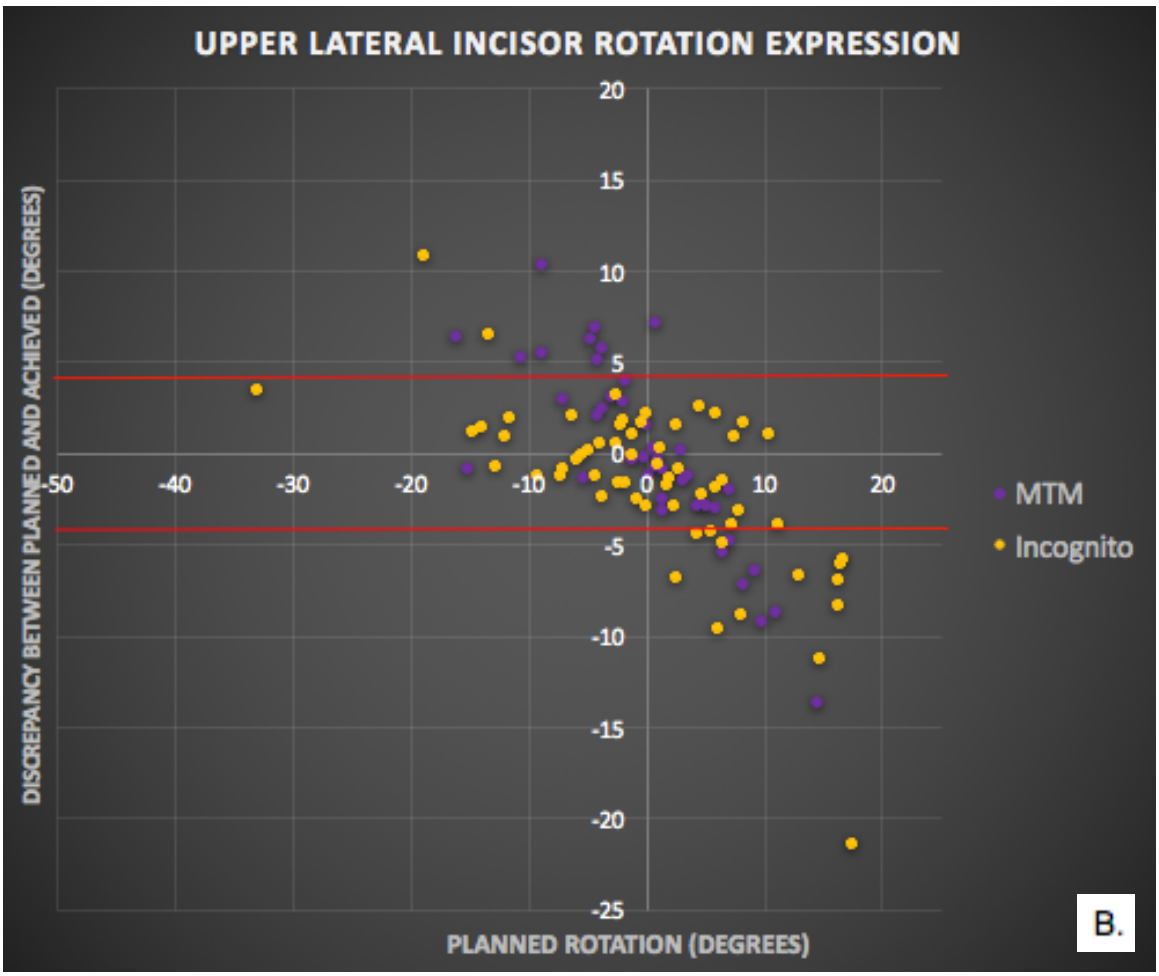
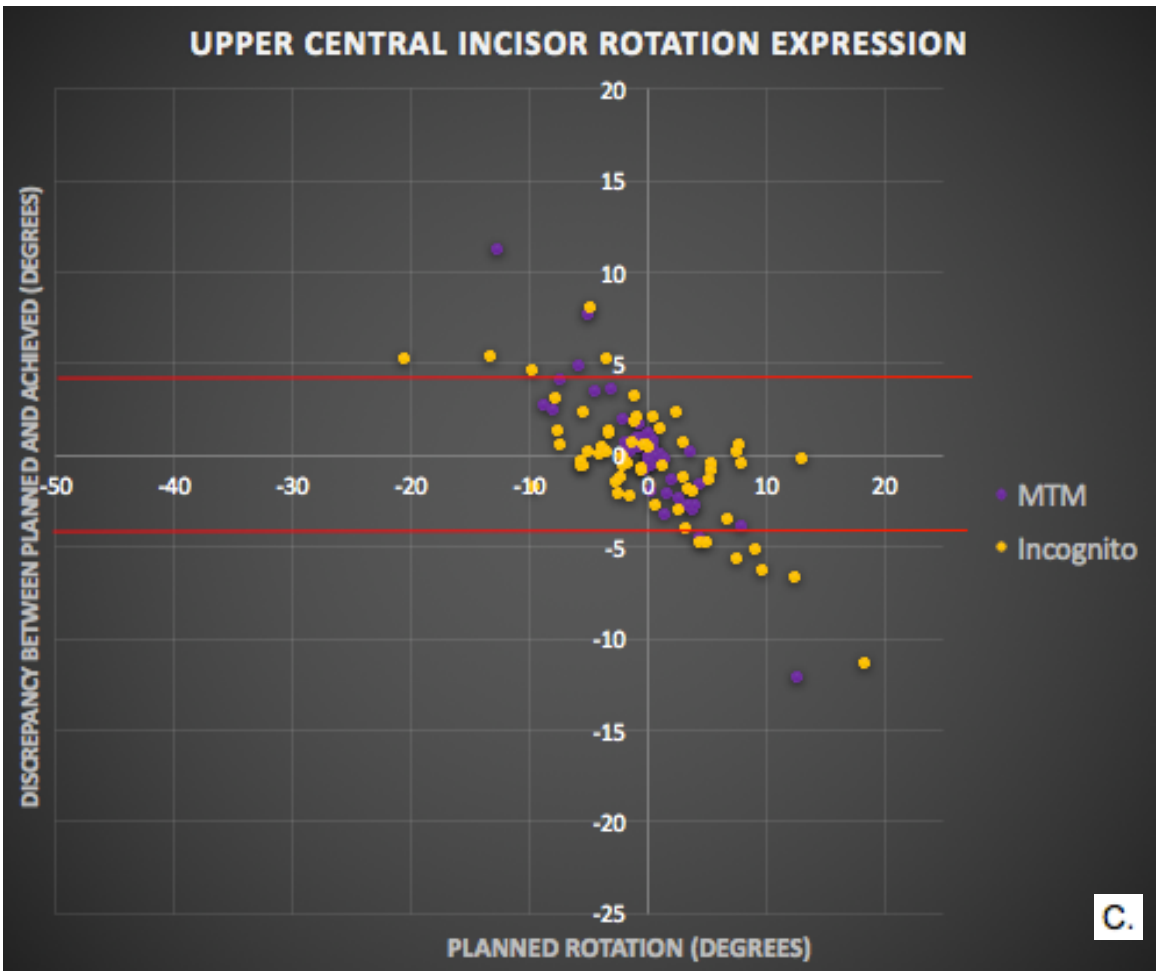
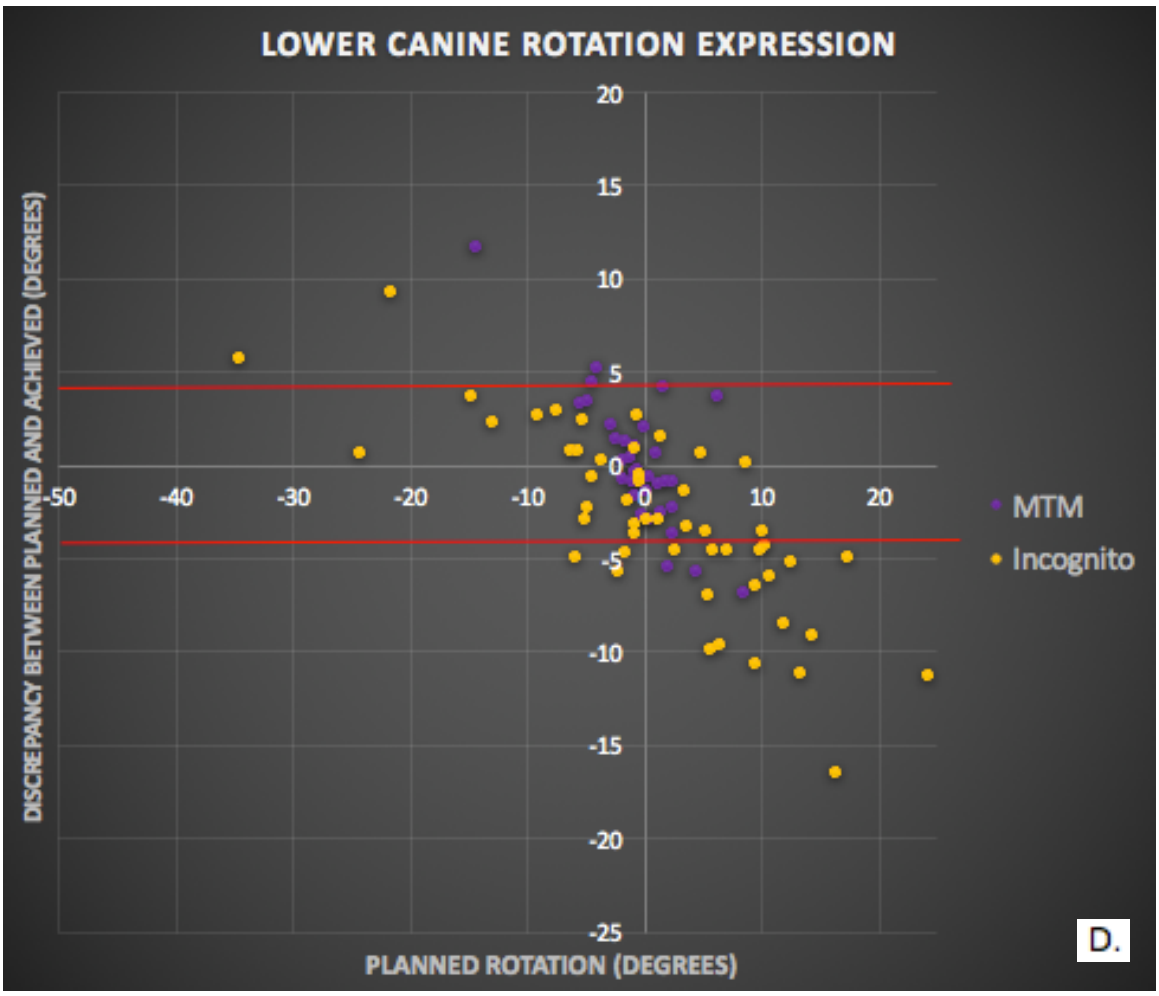


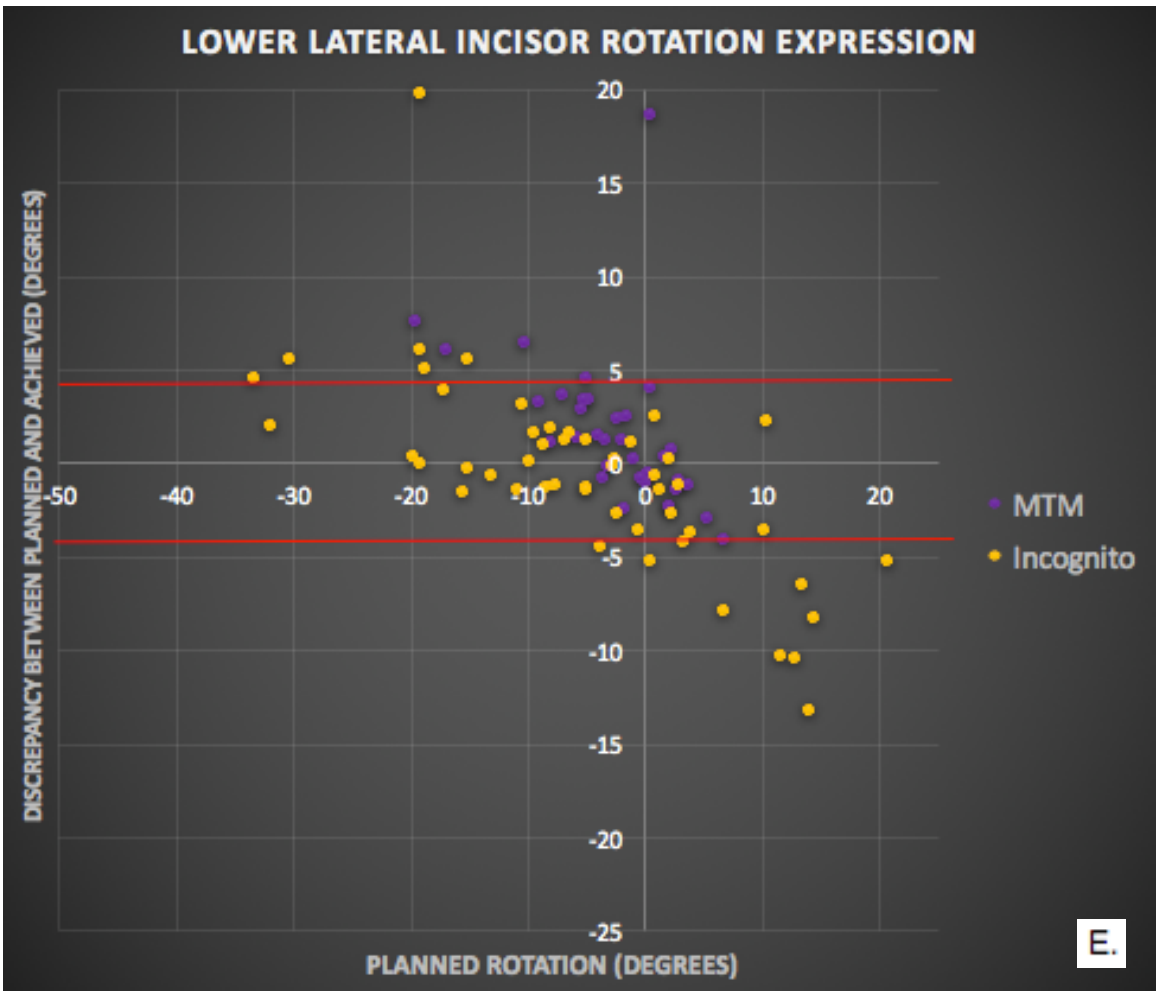
Figure 5 - Amount of discrepancy between final outcome and digital setup plotted against amount of planned bucco-lingual movement for A) upper canines B) upper later incisors C) upper central incisors D) lower canines E) lower lateral incisors F) lower central incisors.


UPPER CANINE ROTATION EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED ROTATION (DEGREES)
20
15
10
5
0
-5
-10
-15
-20
-25
-50
-40
-30
-20
-10
0
10
20
MTM
Incognito
A.


UPPER LATERAL INCISOR ROTATION EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED ROTATION (DEGREES)
20
15
10
5
0
-5
-10
-15
-20
-25
-50
-40
-30
-20
-10
0
10
20
MTM
Incognito
B.


UPPER CENTRAL INCISOR ROTATION EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED ROTATION (DEGREES)
20
15
10
5
0
-5
-10
-15
-20
-25
-50
-40
-30
-20
-10
0
10
20
MTM
Incognito
C.


LOWER CANINE ROTATION EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED ROTATION (DEGREES)
20
15
10
5
0
-5
-10
-15
-20
-25
-50
-40
-30
-20
-10
0
10
20
MTM
Incognito
D.


LOWER LATERAL INCISOR ROTATION EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED ROTATION (DEGREES)
20
15
10
5
0
-5
-10
-15
-20
-25
-50
-40
-30
-20
-10
0
10
20
MTM
Incognito
E.

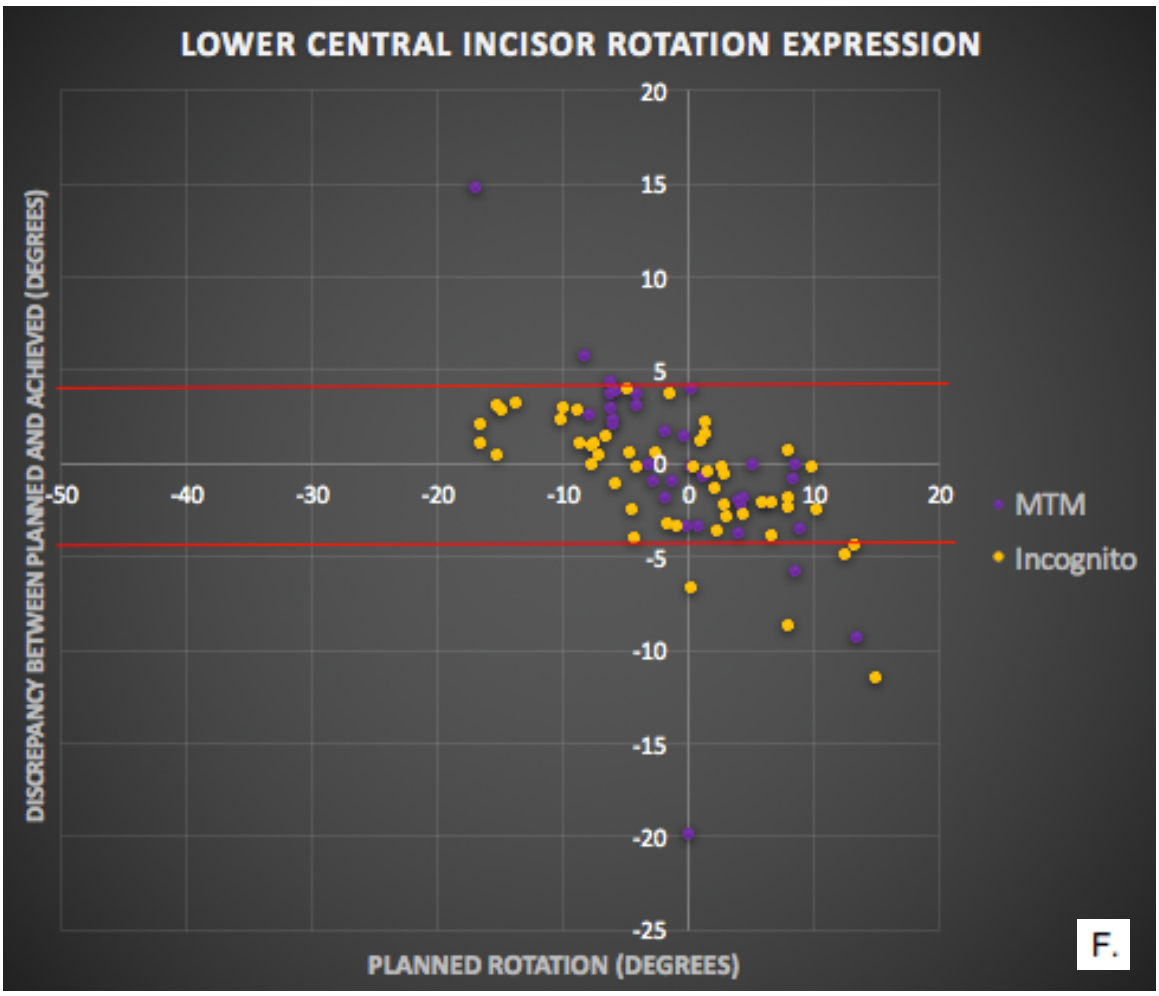
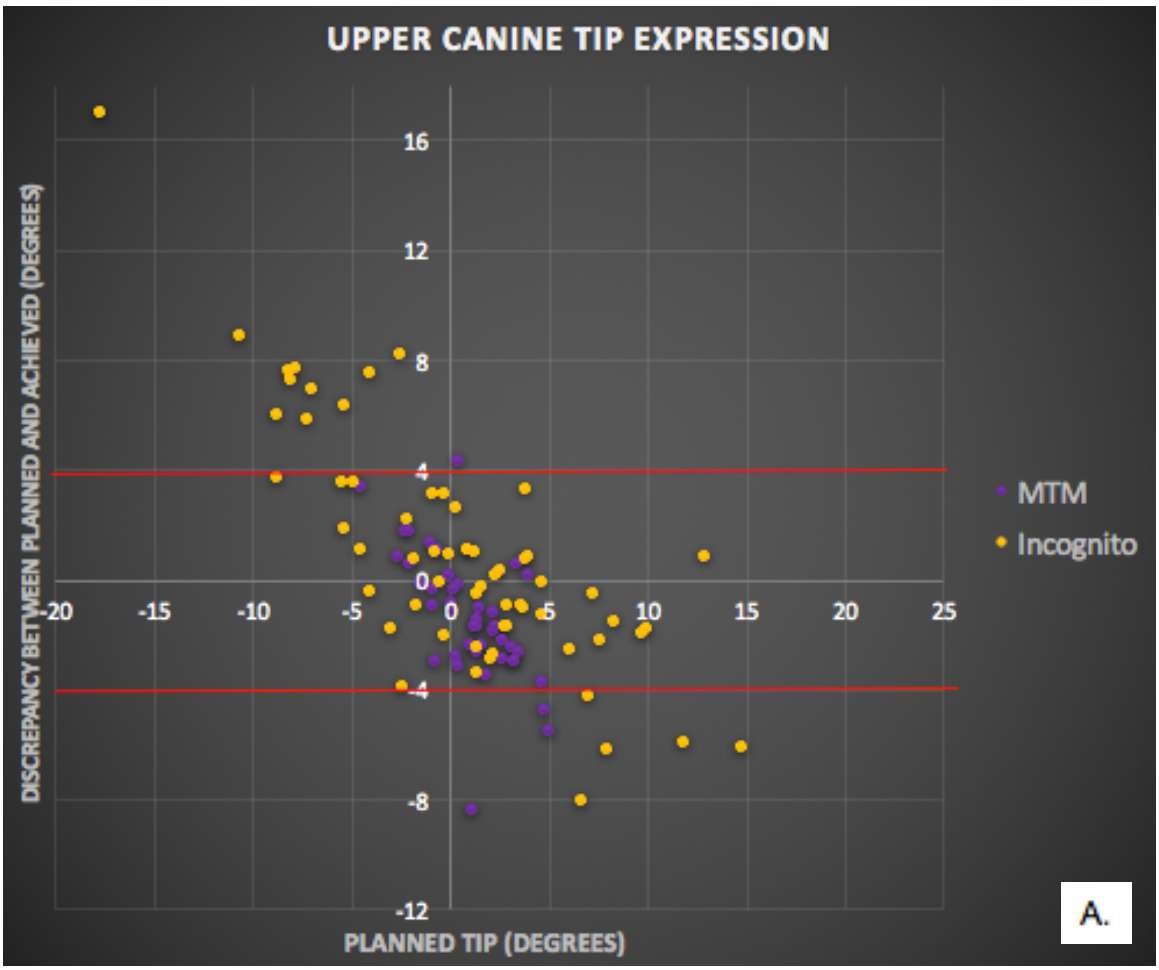
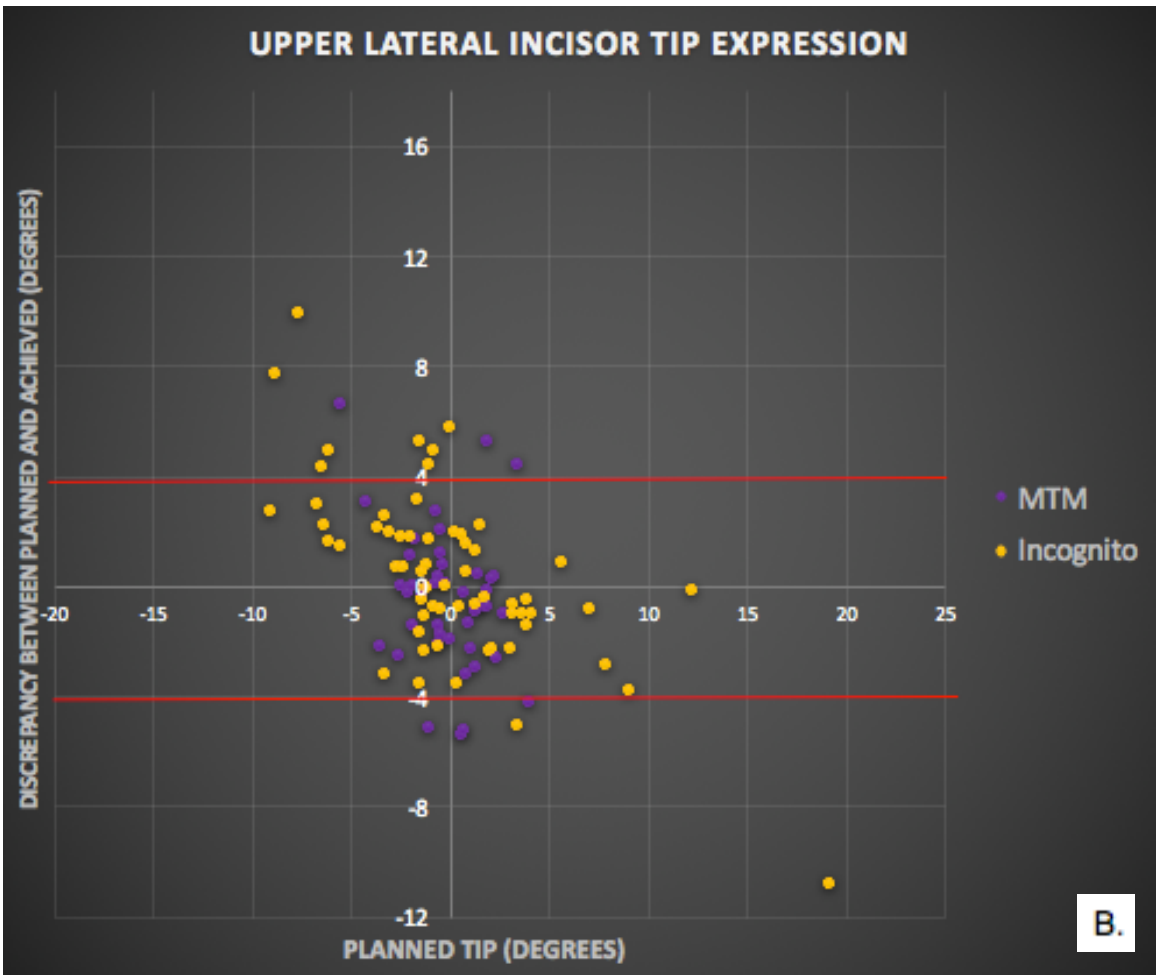
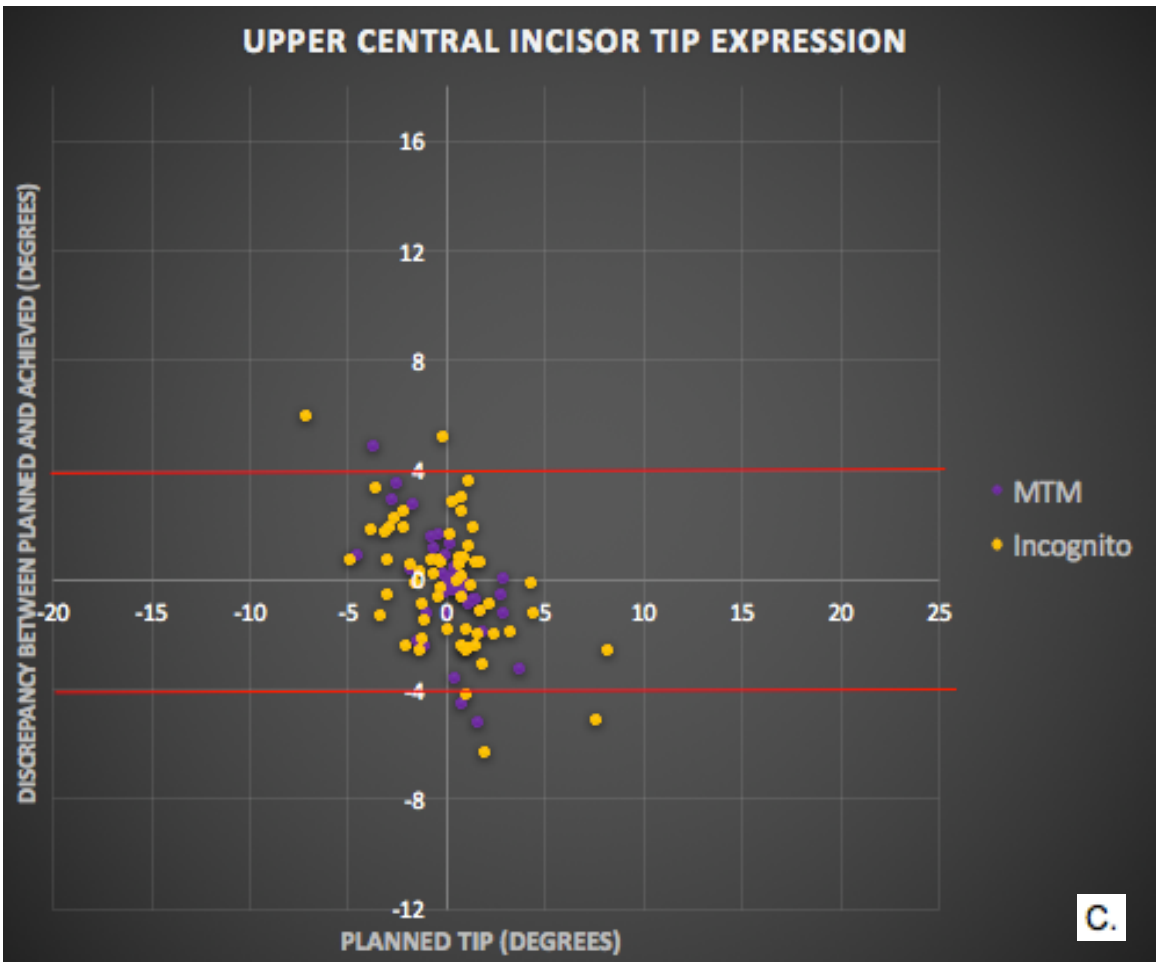
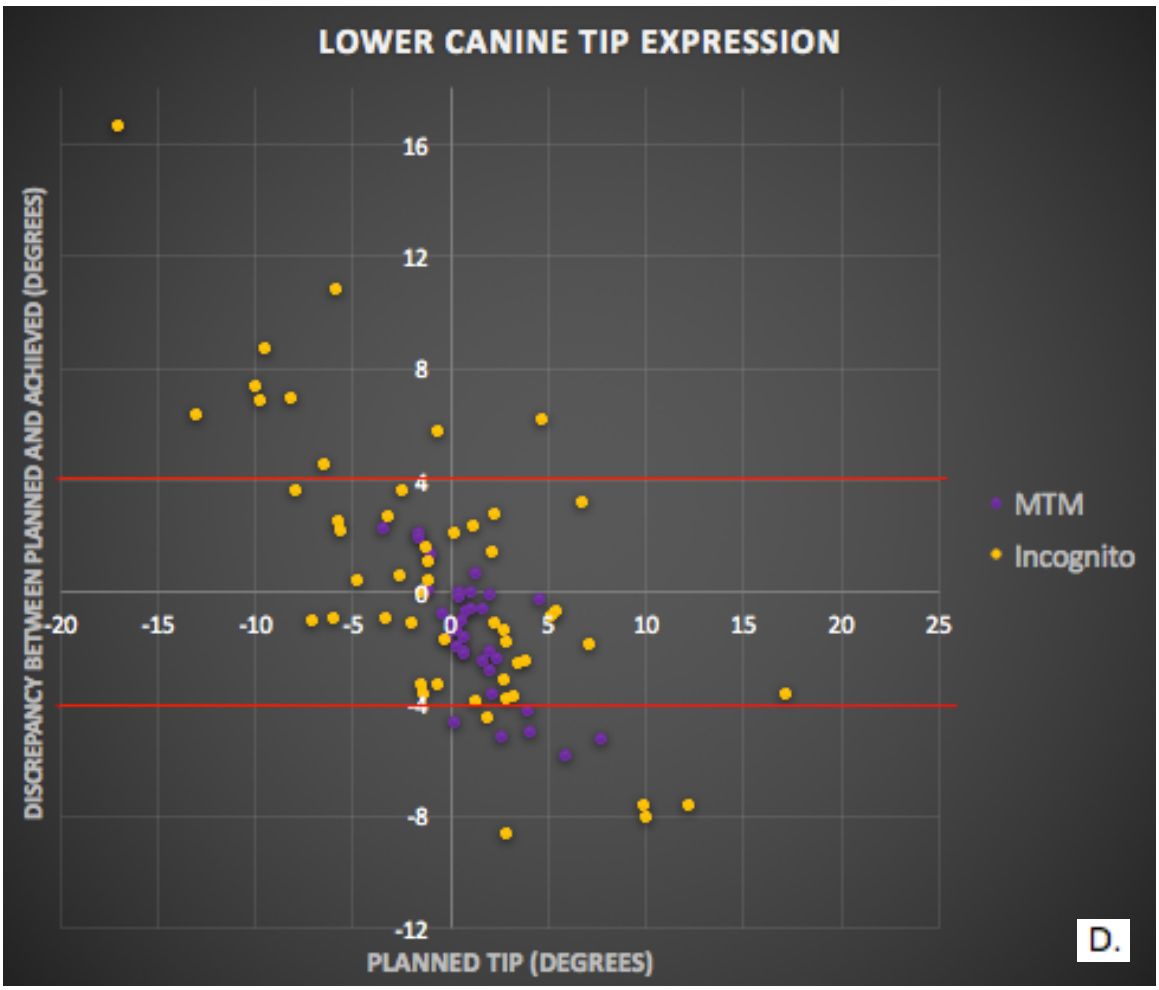


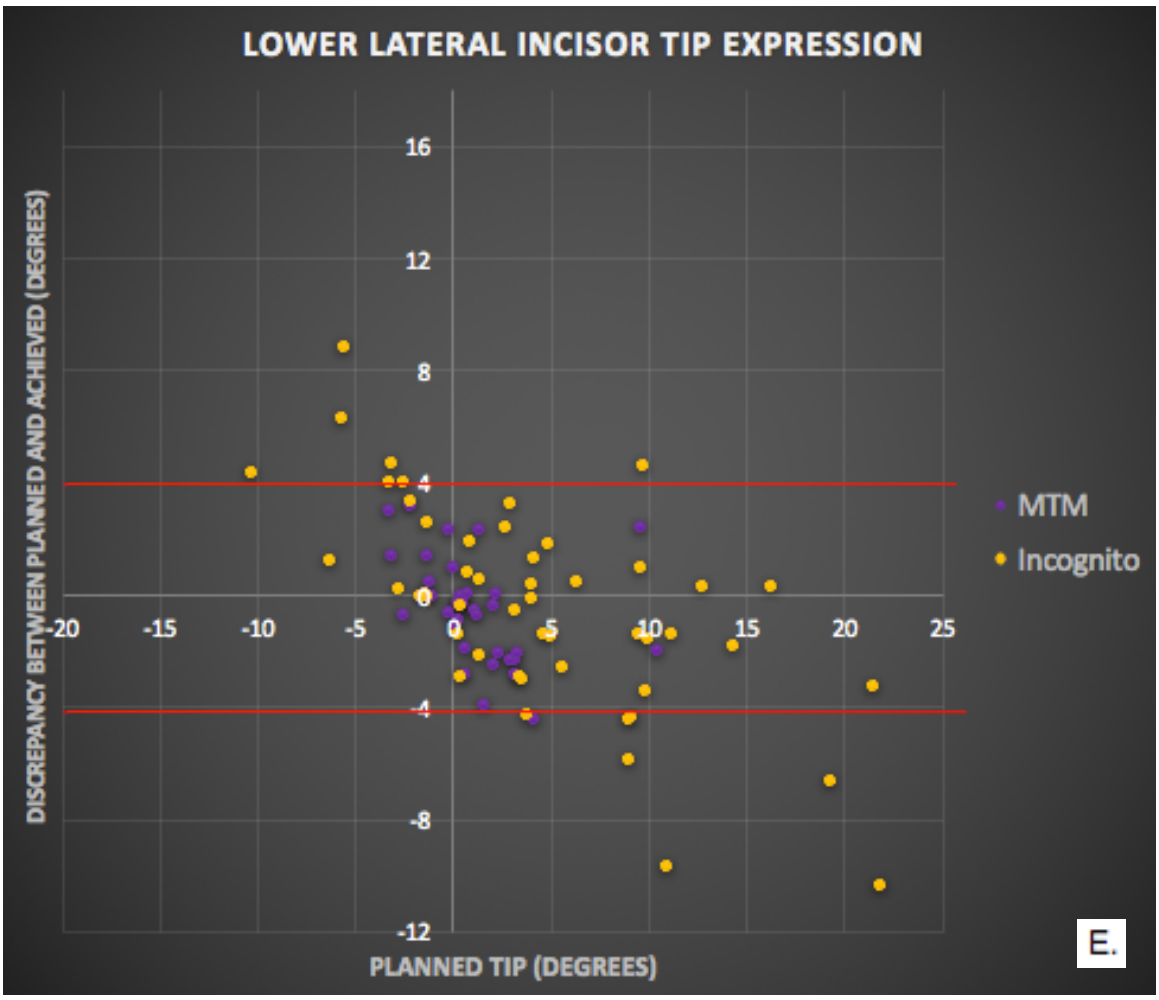
Figure 6 - Amount of discrepancy between final outcome and digital setup plotted against amount of planned rotation movement for A) upper canines B) upper later incisors C) upper central incisors D) lower canines E) lower lateral incisors F) lower central incisors.


UPPER CANINE TIP EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED TIP (DEGREES)
16
12
8
4
0
-4
-8
-12
-20
-15
-10
-5
0
5
10
15
20
25
MTM
Incognito
A.


UPPER LATERAL INCISOR TIP EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
16
12
8
4
0
-4
-8
-12
-20
-15
-10
-5
0
5
10
15
20
25
PLANNED TIP (DEGREES)
MTM
Incognito
B.


UPPER CENTRAL INCISOR TIP EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
16
12
8
4
0
-4
-8
-12
-20
-15
-10
-5
0
5
10
15
20
25
PLANNED TIP (DEGREES)
MTM
Incognito
C.


LOWER CANINE TIP EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED TIP (DEGREES)
16
12
8
4
0
-4
-8
-12
-20
-15
-10
-5
0
5
10
15
20
25
MTM
Incognito
D.


LOWER LATERAL INCISOR TIP EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
16
12
8
4
0
-4
-8
-12
-20
-15
-10
-5
0
5
10
15
20
25
PLANNED TIP (DEGREES)
MTM
Incognito
E.

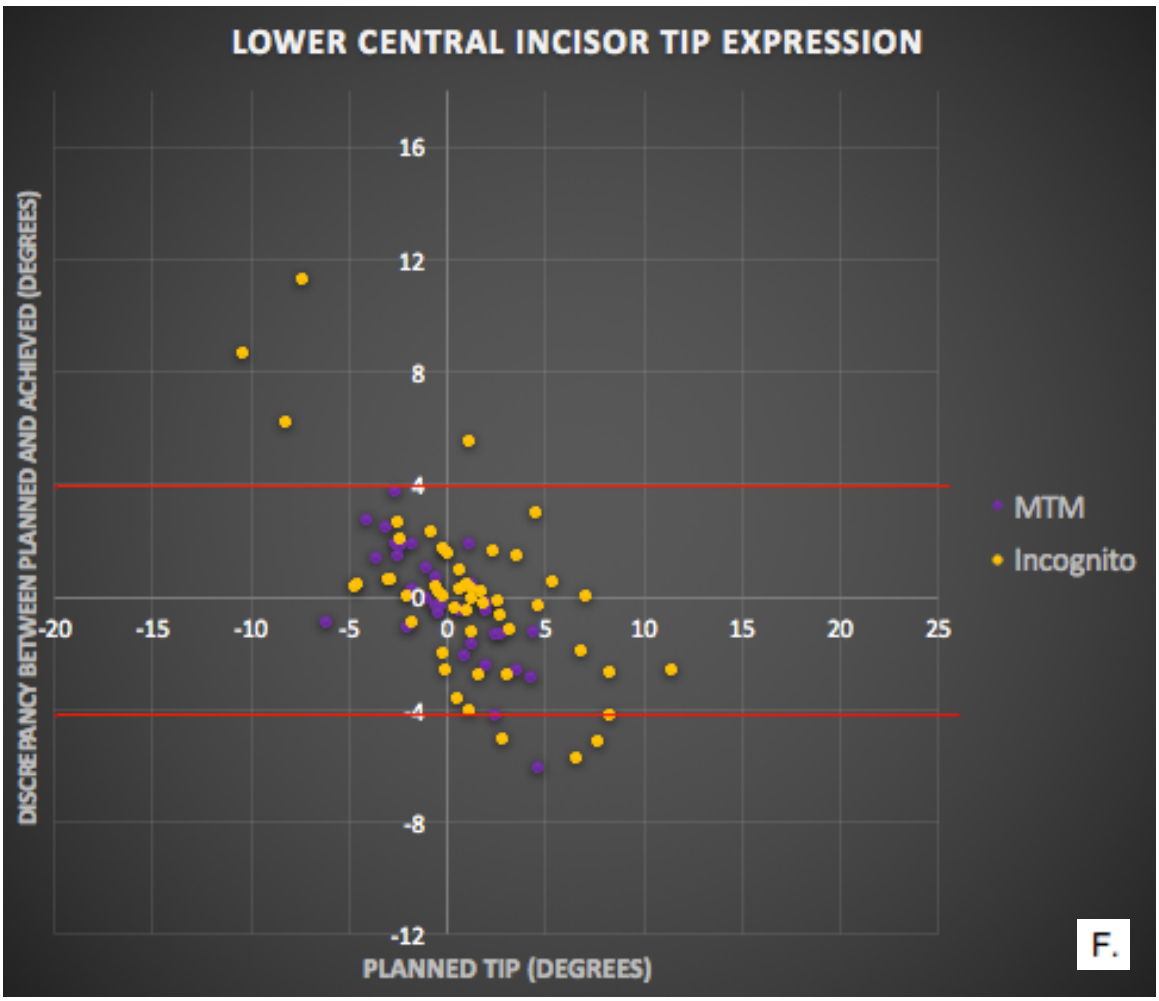
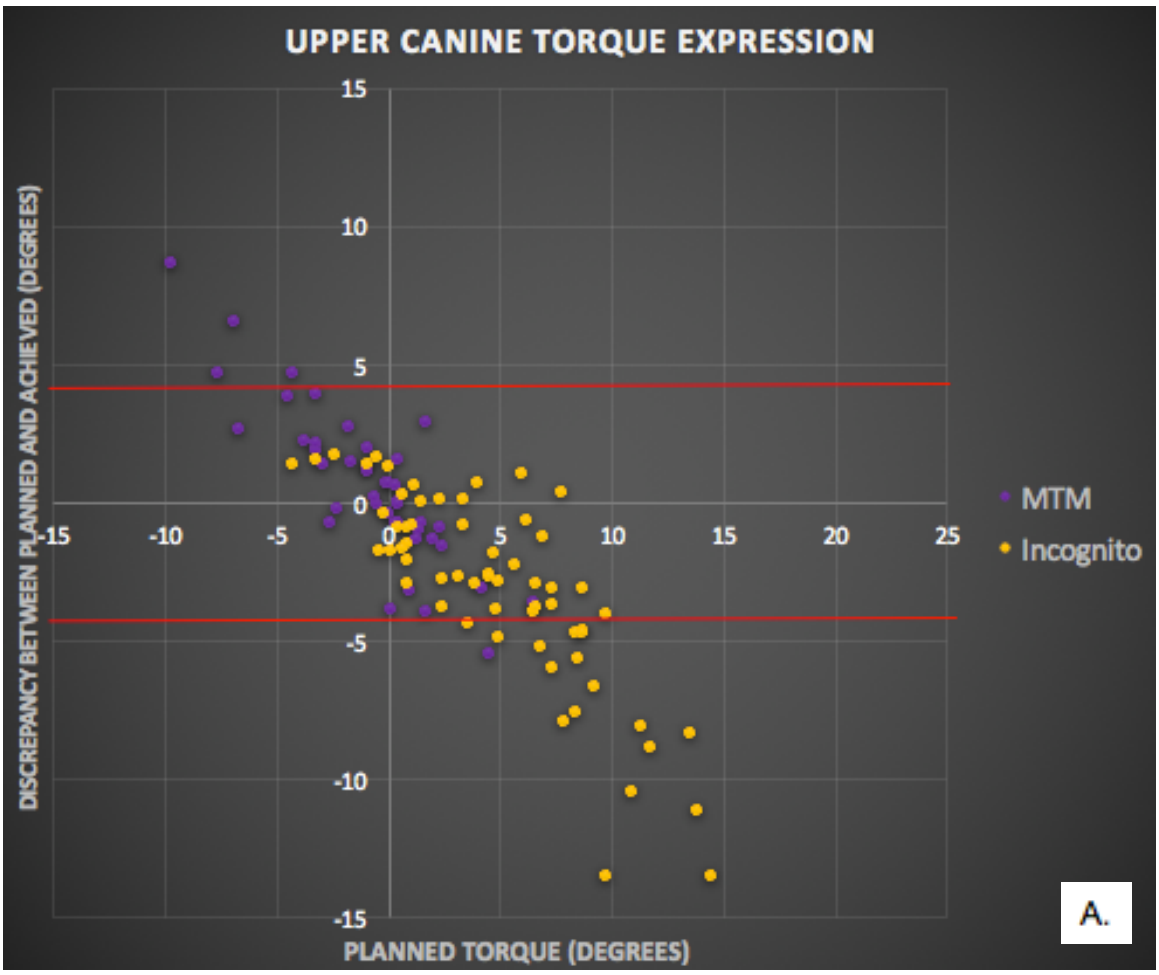
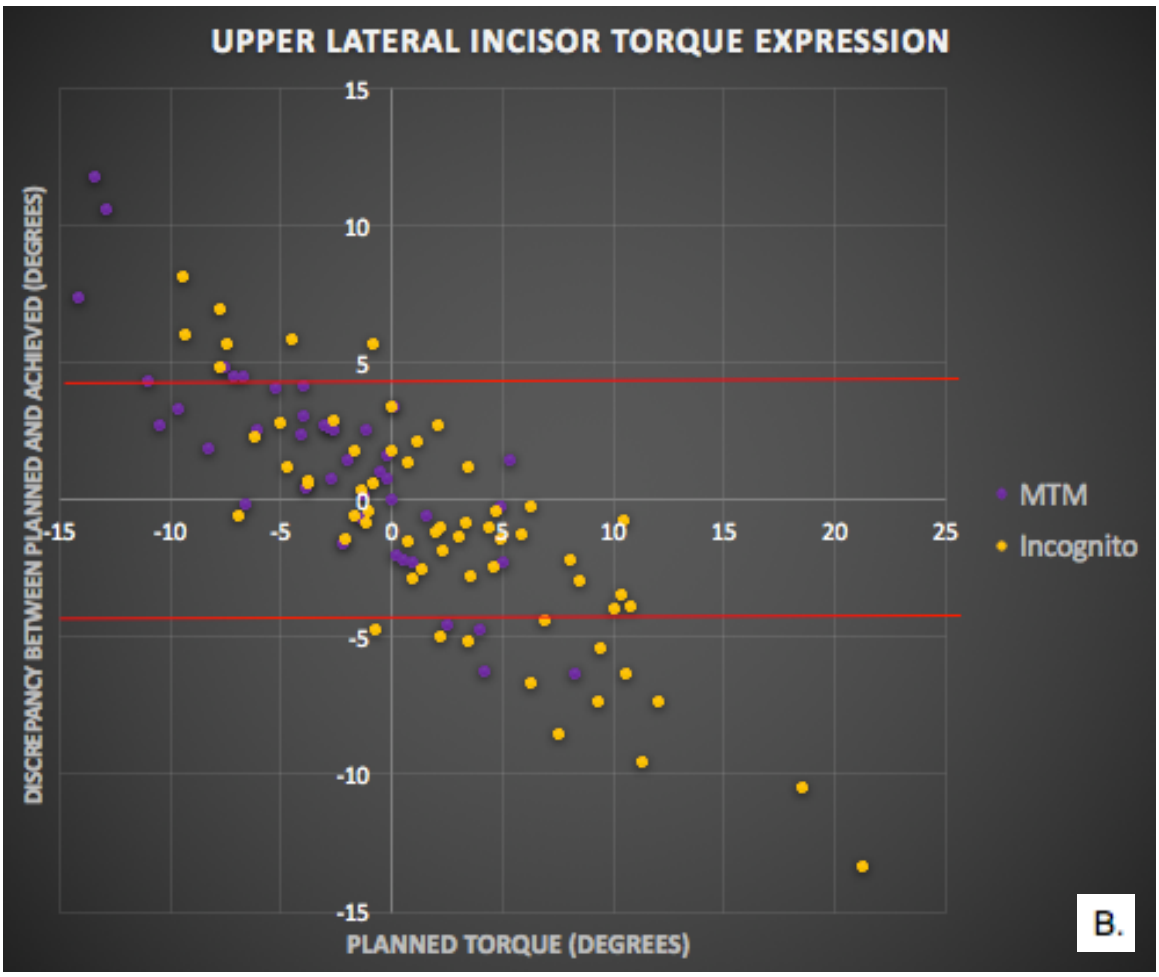
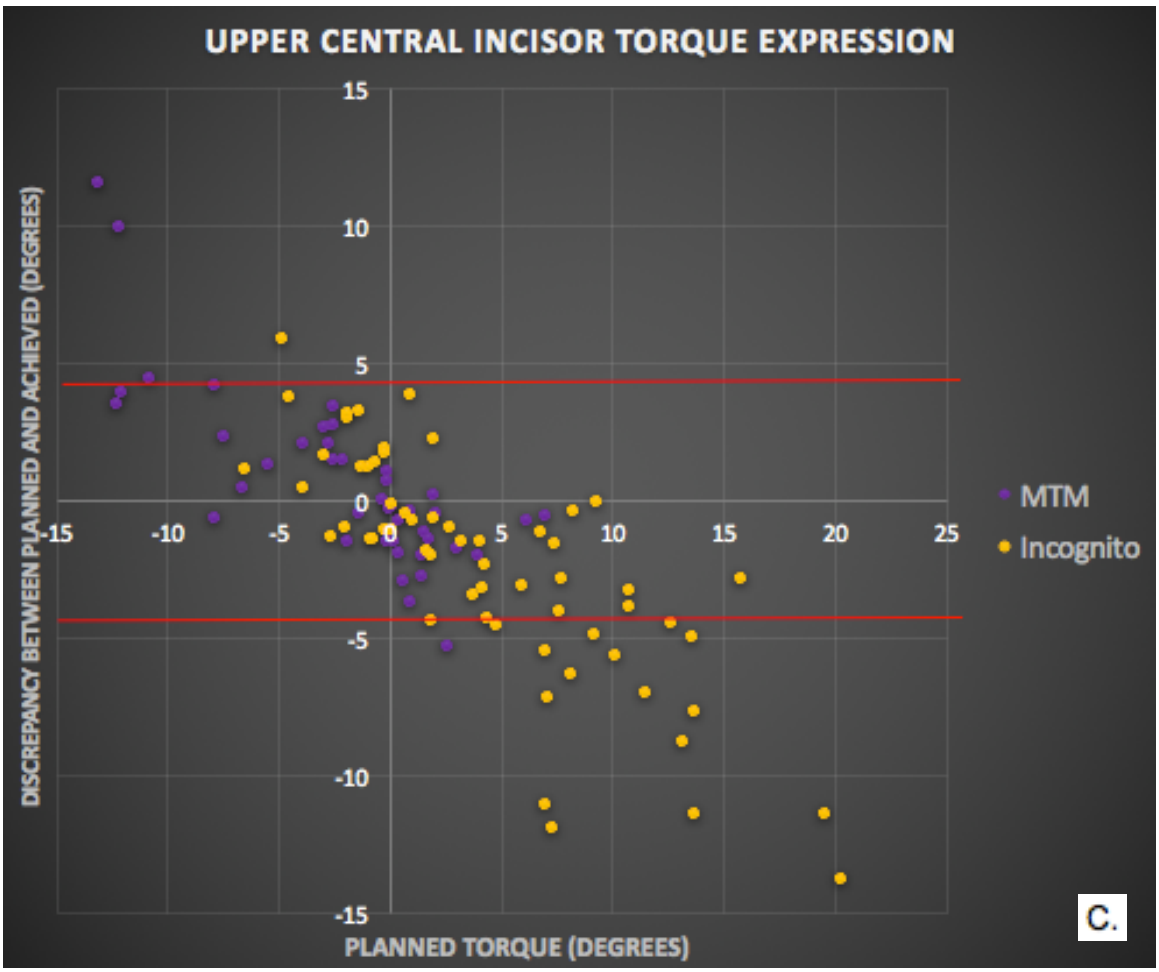
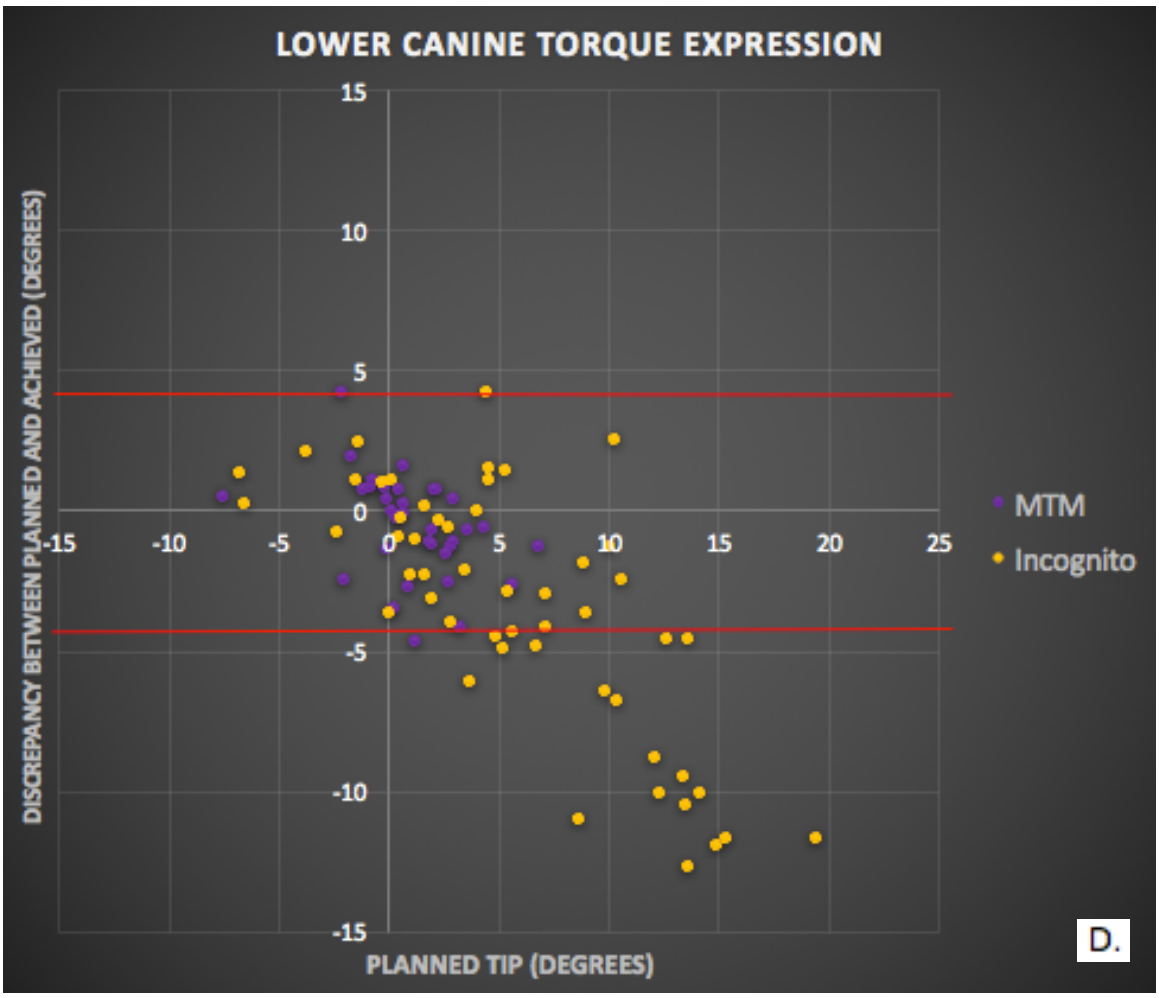


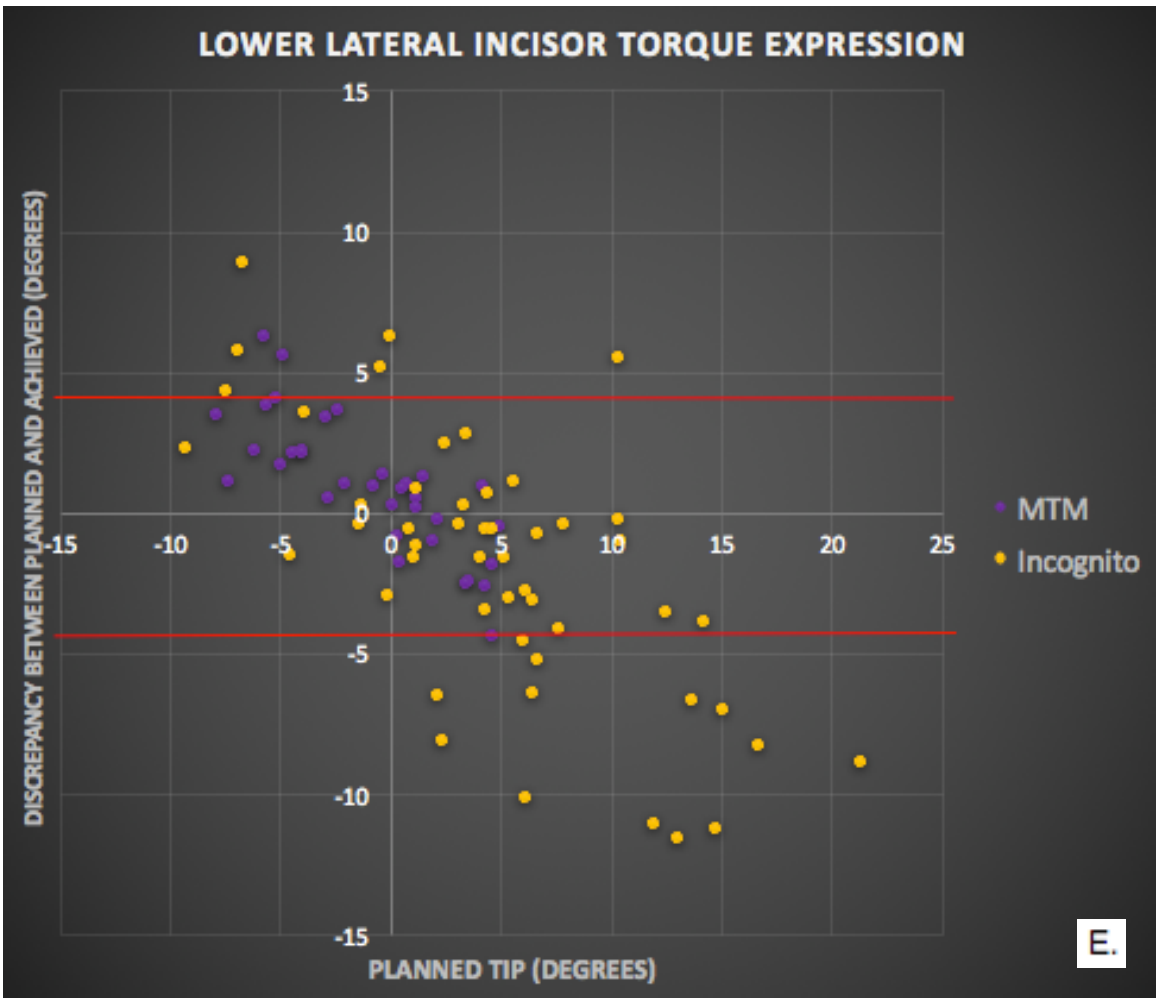
Figure 7 - Amount of discrepancy between final outcome and digital setup plotted against amount of planned tip movement for A) upper canines B) upper later incisors C) upper central incisors D) lower canines E) lower lateral incisors F) lower central incisors.


UPPER CANINE TORQUE EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED TORQUE (DEGREES)
15
10
5
0
-5
-10
-15
-15
-10
-5
0
5
10
15
20
25
MTM
Incognito
A.


UPPER LATERAL INCISOR TORQUE EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED TORQUE (DEGREES)
15
10
5
0
-5
-10
-15
-15
-10
-5
0
5
10
15
20
25
MTM
Incognito
B.


UPPER CENTRAL INCISOR TORQUE EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED TORQUE (DEGREES)
15
10
5
0
-5
-10
-15
-15
-10
-5
0
5
10
15
20
25
MTM
Incognito
C.


LOWER CANINE TORQUE EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED TIP (DEGREES)
15
10
5
0
-5
-10
-15
-15
-10
-5
0
5
10
15
20
25
MTM
Incognito
D.


LOWER LATERAL INCISOR TORQUE EXPRESSION
DISCREPANCY BETWEEN PLANNED AND ACHIEVED (DEGREES)
PLANNED TIP (DEGREES)
15
10
5
0
-5
-10
-15
-15
-10
-5
0
5
10
15
20
25
MTM
Incognito
E.

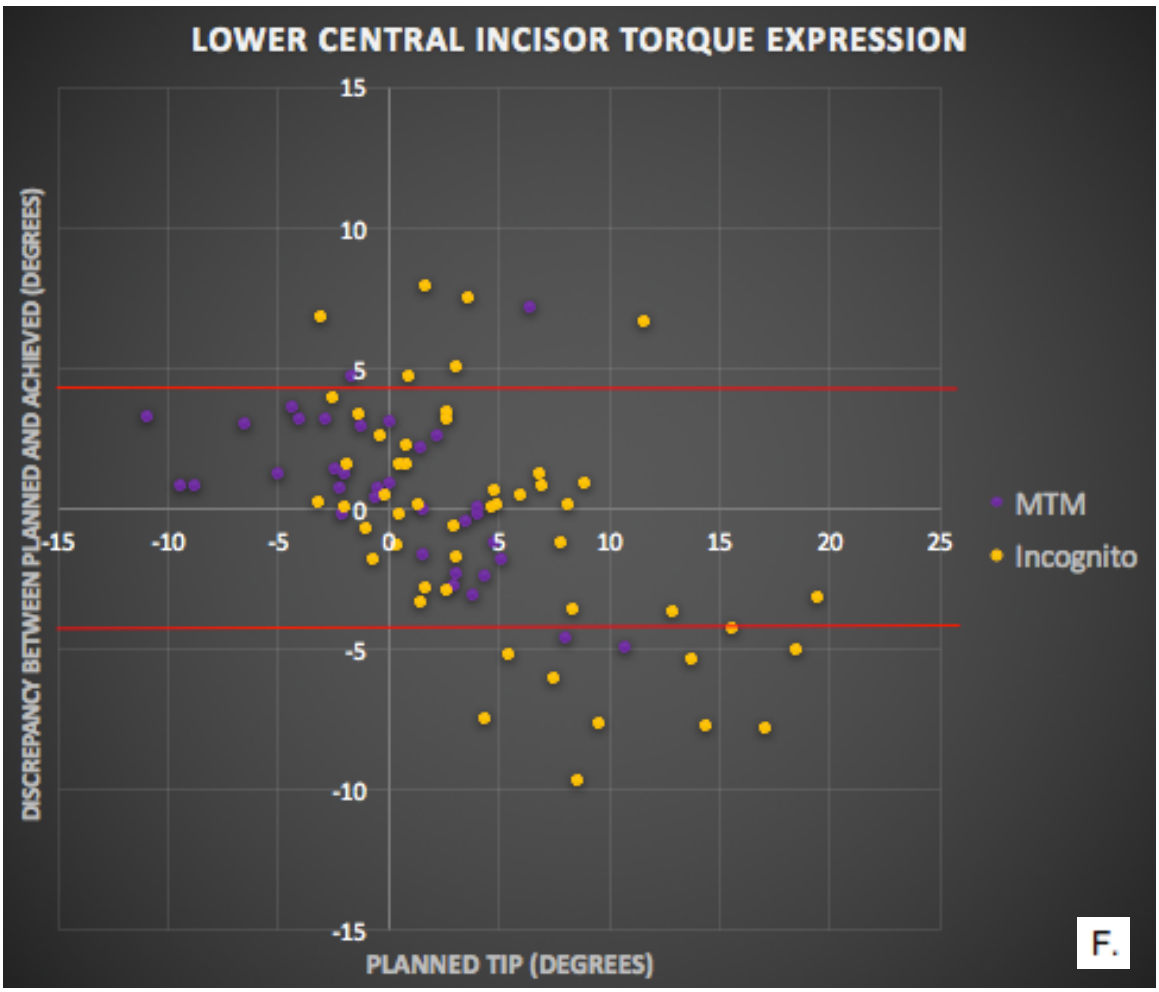


Figure 8 - Amount of discrepancy between final outcome and digital setup plotted against amount of planned torque movement for A) upper canines B) upper later incisors C) upper central incisors D) lower canines E) lower lateral incisors F) lower central incisors.

6. CONCLUSION

- Both Incognito Lite and MTM Clear Aligner, when used for appropriate cases, showed differences between the planned and achieved movement that were on average smaller than clinically acceptable limits of 0.5 mm and 4 degrees.
- For cases that would have a similar length of treatment, the Incognito Lite treatment is likely to result in more emergency appointments while the MTM Clear Aligner treatment is likely to need more manual modifications for achieving final results.
- In the sample studied, Incognito Lite system was used in cases that had significantly higher amounts of occluso-gingival translation, rotation, tip and torque planned compared to the MTM Clear Aligner system.

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APPENDIX

Determination Notice
Research Activity Does Not Involve "Human Subjects"

October 21, 2016

Shahab Parsa, DDS
Orthodontics
801 S. Paulina Street
Room 131, M/C 841
Chicago, IL 60607
Phone: (312) 996-7505 / Fax: (312) 996-0873

RE: Research Protocol # 2016-0445
"Efficacy of Two Options for Limited Treatment of Anterior Dental Misalignment"

Sponsor: None

Dear Dr. Parsa:

The above proposal was reviewed on October 21, 2016 by OPRS staff/members of IRB #7. From the information you have provided, the proposal does not appear to involve "human subjects" as defined in 45 CFR 46. 102(f).

The specific definition of human subject under 45 CFR 46.102(f) is:

> *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains
>
> (1) data through intervention or interaction with the individual, or
> (2) identifiable private information.
>
> *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

All the documents associated with this proposal will be kept on file in the OPRS and an electronic copy of this letter is being provided to your Department Head for the department's research files.

If you have any questions or need further help, please contact the OPRS office at (312) 996-1711 or me at (312) 355-2908.

Sincerely,

Charles W. Hoehne, B.S., C.I.P.
Assistant Director, IRB #7
Office for the Protection of Research Subjects

VITA

Name: Shahab Parsa

EDUCATION: B.S., Bioengineering, University of California San Diego, La Jolla, 2009

M.S., Bioengineering, University of California San Diego, La Jolla, 2010

D.D.S., Doctorate of Dental Surgery, University of California San Francisco, San Francisco, 2014

M.S., Oral Biology, University of Illinois at Chicago, Chicago, 2017

TEACHING: AADR Academic Dental Careers Fellowship, Lecturer, UCSF Biomedical Sciences Anatomy Laboratory – Teaching Assistant, UCSF

HONORS: UCSF Community Dental Clinic Certificate of Appreciation as the most committed volunteer assistant in class - 2011

UCSD department of Bioengineering Outstanding Academic Achievement Award – 2009

CalIT2 Summer Research Scholarship - 2009

PROFESSIONAL MEMBERSHIP: American Association of Orthodontics
American Dental Association
Chicago Dental Society

ABSTRACTS: **A Combined Double-tweezers and Wavelength-tunable Laser Nanosurgery Microscope.** Annual SPIE Conference proceedings - 2009