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A Randomized Clinical Trial Comparing Outcomes of Open-versus Closed-Surgical Exposure of Palatally Impacted Maxillary Canines: A Pilot Study

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A Randomized Clinical Trial Comparing Outcomes of Open- versus Closed-Surgical Exposure of Palatally Impacted Maxillary Canines: A Pilot Study

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Chapter I: Introduction

A- Background

1- Canine Impaction

Maxillary canine impaction is a frequent clinical problem affecting approximately 2% of the population [1]. Seen twice as commonly in females than in males, nearly 8% of those affected show bilateral impaction of the canines [2]. Impactions can occur buccally or palatally. Previously, palatal impactions were believed to occur three times more frequently than buccal impactions [3]; however, recent studies suggest that the prevalence of buccal to palatal impactions is closer to 1:1 [4, 5]. The etiology of canine impaction is not fully understood, although the lateral incisor has been considered to be a critical factor in guiding the proper eruption of the canine [6]. Disturbance in the eruption path of the canine due to malformed or absent lateral incisors may play a role in the development of their impaction [4, 7]. Other factors that have been implicated in canine impaction include tooth size-arch length discrepancies, abnormal tooth bud formation, prolonged retention, or early loss of the deciduous canine [6, 8].

2- Clinical Treatment

Uncovering and guiding the eruption of impacted maxillary canines involves a multidisciplinary approach, with the surgical exposure of the tooth involving a surgeon [periodontist or oral surgeon] and the orthodontic traction to align the tooth into the arch by an orthodontist. The surgical methods can vary based on the location of the impaction-either buccal or palatal, and/or the vertical position of the canine relative to the mucogingival junction [1]. The different approaches to the surgical exposure aim to minimize detrimental periodontal outcomes that may occur once the tooth

is orthodontically extruded through the overlying tissue. Buccally impacted canines may be covered by either non-keratinized or keratinized tissue (depending on the vertical position), but palatally impacted canines are always covered by keratinized tissue. Therefore, regardless of the surgical exposure method, the periodontal attachment may be compromised simply because of the initial location of the canine tooth [9].

The standard surgical methods can be divided into two primary categories: open and closed exposure methods:

In the open exposure method, the soft and bony tissue overlying the canine is removed and a periodontal pack is placed over the site for 7-10 days to allow for healing to occur [9]. After the periodontal pack is removed, the canine is either given time to passively erupt into the arch [10] or it is erupted actively soon after the exposure surgery. Active eruption occurs by the application of an orthodontic force from an attachment bonded to the canine during the exposure surgery [2].

For the closed exposure method, a flap is raised to expose the tooth and a bonded attachment with a chain is placed on the exposed tooth surface [11]. The flap is then sutured back into position with the chain threaded through the border of the flap. This allows for the immediate application of an orthodontic force from the chain to facilitate the eruption of the canine through the closed periodontium, a process termed orthodontic traction [12].

3- Treatment Methods and Outcomes

For the open eruption of buccally impacted canines, the vertical position of the canine relative to the mucogingival junction (MGJ) has been used to dictate the type of surgical approach in order to ensure optimal long-term periodontal outcomes. For example, if the canine is coronal to the MGJ, it is believed that no flap is necessary and a simple excision or gingivectomy with open eruption will suffice to maintain the periodontal attachment on the canine. However, if the canine is apical to the MGJ, either an apically positioned flap must be sutured in place or a closed-exposure approach should be used [10]. Currently, no randomized, prospective studies exist in the literature to suggest that one method is superior to the other in preserving the periodontal attachment.

The decision as to which surgical method is performed in clinical practice is centered on the convenience of a surgical method, the need for additional surgeries, overall treatment time, and/or long-term periodontal health. Previous studies have reported shorter surgical times with the open exposure method, with the closed exposure method taking up to three times longer [13]. However, another study compared the closed exposure method to the open exposure method and found no difference in treatment duration between the two methods [14]. Eruption of impacted canines has also been implicated as one of the major causes of increased orthodontic treatment time [15]. Based on the current literature, it is unclear as to which surgical method (open or closed exposure) is most efficient for erupting the impacted canine to the arch [13, 16]. An added problem associated with impacted canines is the need for re-exposure if the first surgical intervention fails, specifically due to breakage of bonded attachments in the closed exposure approach or regrowth of overlying

tissue in the open exposure approach. In an examination of a series of 72 patients, Ferguson et al. found that open exposure and free eruption of the canine was successful in a majority of cases without the need for a bonded attachment and with no patients requiring re-exposure [17]. Furthermore, Pearson and colleagues found that approximately 30% of closed exposure cases required a second surgical intervention, in comparison to 15% of cases treated with the open exposure approach [13].

Another primary concern with impacted canines is the long-term periodontal health of the adjacent teeth in the arch. Previous studies have shown that extensive removal of bone surrounding the impacted tooth at the time of the exposure can negatively impact the bony support of the tooth once it is guided into the arch [18]. Wisth et al. reported a reduction in periodontal support and loss of alveolar bone height in orthodontically corrected canines compared to untreated canines [16, 19]. However, other studies have shown no significant differences in the periodontal status between treated and untreated canines when evaluating pocket depth, level of attached gingiva, bleeding score, occlusal function and/or gingival recession [20-22].

Recently, there have been a number of systematic reviews and meta-analyses conducted by various research groups trying to assess whether a significant difference exists in the outcome of the open versus closed surgical exposure of palatally impacted canines. Cassina et al., Sampaziotis et al., and Parkin et al. are the three aforementioned research teams that have published on the topic in the last year [23-25]. The findings of systematic reviews on the outcomes of open versus closed surgical exposure of impacted canines have not always been consistent. Cassina et al. concluded

that open surgical exposure is superior in treatment duration and ankylosis risk over the closed technique; however, Cassina et al. did not only include palatally impacted canines [23]. On the other hand, Parkin et al. concluded that both techniques may be equally successful [24]. However, all the reviews agree that there is a need for further research on the topic due to the limited number of existing trials.

4- Pre-Operative Diagnostic Imaging

Diagnosis and localization of impacted maxillary canines on radiographs is an important tool for determining if a surgical approach is required and where to gain access to the impacted tooth during surgery. Numerous radiographic methods have been described in the literature using a combination of panoramic, periapical, and occlusal radiographs. Consecutive periapical x-rays with an incorporated mesial shift are widely used to determine the buccal or palatal position of impacted canines by the application of Clark's SLOB rule [26]. On panoramic x-rays, Ericson and Kurol have described the position of the impacted canine relative to the midline of the lateral incisor for predicting the likelihood of self-correction of the canine's eruption path following extraction of the deciduous canine [28]. Angulation of the canine relative to the lateral incisor and sector localization on panoramic x-rays are also well-described methods for determining the severity of the impaction [29-30]. The primary limitation of traditional radiographs is that they are 2-dimensional representations and the localization of the canine can be confounded by overlapping structures and distortion. Nearly 80% of clinicians need to use two or more supplemental radiographs to localize the impacted tooth [30].

For accurate diagnosis and localization, there are numerous benefits to utilizing 3D imaging modalities. Historically, multi-slice medical CT scans have been the only form of 3D imaging that were available. Limitations include high radiation dose, expense, and lack of access for dentists. Recently, the Cone Beam CT (CBCT), which delivers a significantly lower dose of radiation compared to conventional CT, has gained popularity for imaging the craniofacial region. While CBCT images can be used in lieu of other 2D images such as panoramic radiographic projection and lateral cephalogram to minimize radiation dose, studies have shown great variability in the amount of radiation exposure to patients between different CBCT machines, and therefore caution should be exercised [31-33]. Use of CBCT should be prescribed on a case-by-case basis. The literature indicates that cases with impacted teeth are ideal for CBCT imaging due to the orthogonal 1:1 representation, which produces images free of distortion and overlapping structures [32, 34].

In addition, in cases where the impacted canine is impinging on the lateral incisor roots, root resorption can occur and may be difficult to diagnose in both panoramic and intraoral images [5, 35]. Lateral incisor root resorption is the primary adverse effect of impacted maxillary canines and, if severe, can impact the long-term prognosis of the affected tooth. CBCT has been found to be significantly more sensitive for the detection of external root resorption of the lateral incisor in impacted canine cases [36]. Oberoi and Kneuppel found that CBCT facilitated accurate localization of impacted canines and evaluation of the lateral incisor root resorption, which was moderate to severe in 18% of cases [37]. In an evaluation of 6 different CBCT systems, Alqerban et al. showed that all systems had high diagnostic accuracy in assessing the severity of lateral incisor root resorption in cases of impacted canines [38].

While CBCT imaging has been found to be valuable in localizing impacted canines and for visualizing adjacent structures, radiation concerns still exist. The small-volume CBCT is now available, which further reduces the radiation dose from the traditional CBCT, focusing on a small and focused field of view. A comparison of 14 CBCT devices showed significantly lower radiation exposure with small volume CBCT compared to traditional full field of view CBCTs [39]. The Kodak 9000 3D CBCT had the lowest overall dose of radiation, with an effective dose of 19μSv in the anterior maxillary region. Conventional intraoral radiographs for detecting impacted canines include 2 periapical or an occlusal x-ray, which have effective doses of 10μSv and 7μSv, respectively [40, 41].

B- Study Rationale

Currently, there are few prospective, randomized studies comparing the closed versus open surgical exposure methods for palatally impacted maxillary canines. In addition, there are no studies showing the diagnostic ability of small volume CBCT in maxillary canine impaction cases or the clinical utility of CBCT to assess root resorption. Using the small volume CBCT, the position of the impacted canines will be localized and precise data measurements of the changes in bone height, width, and root resorption that occurred during the orthodontic treatment will be determined. While both the open and closed surgical exposure methods are used in the clinical setting for the management of palatally impacted canines, the dental literature lacks evidence whether one method for surgical exposure is better than the other.

A recent meta-analysis by the Cochrane Collaboration comparing open to closed surgical exposure methods found insufficient evidence to support one method over the other and cited a need for high quality clinical trials to further understand the impact of these surgical methods on dental health, esthetics, economics and other patient factors [42-43]. Therefore, the purpose of this prospective, randomized clinical study outlined in this protocol is to determine if there is a difference in the dental health and treatment outcomes of those with impacted maxillary canines exposed by the closed versus open surgical exposure method.

C- Outcome Assessment

- **Primary Outcome**: Determine the amount of gingival recession, clinical attachment level (CAL), keratinized gingiva, and attached gingiva between open and closed surgical exposures

- **Secondary Outcomes**:
  - Determine the bone thickness and height, pre- and post- surgery between open and closed surgical exposure groups
  - Compare the length of treatment between open and closed surgical exposures

Chapter II: Hypotheses and Aims

A- Hypotheses and General Objectives

1- Hypotheses

1. There is no significant difference in the amount of gingival recession, clinical attachment level, or the amount of keratinized gingiva between palatally impacted maxillary canines that are exposed by the open versus the closed surgical exposure methods.

2. There is no significant difference in the bone width and the bone height between open versus the closed surgical exposure methods.

3. There is no significant difference in the treatment length between open and closed surgical exposure methods.

2- General Objectives

To date, there are very few high quality randomized clinical trials comparing the outcomes between closed and open surgical exposure methods for the treatment of palatally impacted maxillary canines. The primary aim of this study is to elucidate if the type of surgical exposure (closed versus open exposure method) impacts the periodontal outcome for palatally impacted maxillary canines after orthodontic traction has aligned them in the arch.

B- Specific Aims and Objectives

This study will determine if the type of surgical exposure method (closed versus open) impacts:

1- Periodontal outcomes, specifically regarding the amount of gingival recession, width of keratinized gingiva, and clinical attachment level

2- Bone thickness and height, pre- and post- surgery

3- Length of treatment

Chapter III: Materials and Methods

A- Study Design and Screening Procedure:

1- Study Design

This study was approved by the Institutional Review Board (IRB) of University of Connecticut (IRB # 16-169-1). The aim of this study was to perform a randomized clinical trial recruiting a total of 46 patients randomly divided in two groups: (1) 23 subjects undergoing the closed surgical exposure; (2) 23 subjects undergoing the open surgical exposure.

The sample size was computed based on identifying a 0.5 mm (effect size) difference in periodontal attachment level between the two treatment groups. The population means and variances of the primary outcome variable (periodontal attachment level) for the two different techniques of canine exposure were obtained from prior studies (mean of 0.3 mm for open technique and 0.8 mm for closed technique) examining periodontal attachment levels following canine exposure techniques. A sample of 46 subjects (23 per group) will be required to identify a difference of 0.50mm in attachment level, with a power of 80%, an alpha of 5%, and two-sided statistical tests [44, 45, 46].

2- Screening & Recruitment Procedures

All new patients who present for initial screening at the University of Connecticut Orthodontic Clinic and pursue orthodontic treatment are assigned to a primary orthodontic provider, who will

provide all orthodontic treatment to that patient. New patients who might qualify for enrollment in this study will undergo the same initial screening appointment and primary orthodontic provider assignment as patients who are not enrolled in the study. Subjects will be further examined for potential inclusion in the study during this Screening Visit (Visit 1) with their primary orthodontic provider based on specific screening qualifications. The initial clinical indicators of canine impaction are a healthy patient who is 12 years or older at the start of treatment, with unerupted permanent maxillary canines with the absence of a "canine bulge" in the buccal vestibule or the presence of a "canine bulge" on the palate, and an inclination of the unerupted canine towards the lateral incisor as visualized on the panoramic x-ray in the patient's clinical record.

3- Enrollment

If the patient's primary orthodontic provider determines during the Screening Visit (Visit 1) that the patient might be eligible for inclusion in the study, the PI or Study Coordinator were contacted. Eligible patients should meet the following initial inclusion/exclusion criteria:

Inclusion Criteria

1. Healthy patient, non-smoker
2. Full complement of dentition (central incisor to 1st molar) in the quadrant with the impacted maxillary canine
3. Unerupted permanent maxillary canine[s] determined to be impacted by clinical exam and panoramic film at screening based on the criteria of impaction described by Bishara [2]:
    a) Retention of primary canines past 12 years of age

b) Presence of palatal bulge indicating palatal impaction

c) Splaying, migration or distal tipping of the adjacent lateral incisor

d) Mesial angulation of unerupted canine as noted on a panoramic x-ray in relation to the lateral incisor

Exclusion Criteria

1. Fully erupted canine
2. Evidence of extremely poor oral hygiene
3. Missing permanent central or lateral incisor, 1st or 2nd premolar, or 1st molar in the quadrant with the canine impaction
4. Medical issues that affect tooth movement or ability to use the required mechanics
5. Failure to provide oral and written consent to participation

Final eligibility will be determined by reviewing the inclusion/exclusion criteria and the CBCT radiograph, which will be taken during the Records Visit (Visit 2).

Subjects enrolled in the study may be withdrawn from the study by the investigator in the event of surgical failure (meaning that the bracket bonded to the impacted canine falls off before the canine is actively erupted through the gingiva). These subjects, under clinical care standards, return for a second exposure procedure; however, they would be eliminated from the study, even though they may have completed previous visits. In addition, if the CBCT indicates significant damage to the adjacent teeth requiring extraction of other teeth, the patient will no longer be eligible for the study

and the PI/ Study Coordinator will discontinue the subject's participation. Lastly, subjects who are not compliant with appointments will also be eliminated from the study.

We will be following the subjects enrolled in this study for the duration of their orthodontic treatment, with a total of 5 visits included as trial timepoints. After orthodontic treatment is completed, the patient is given retainers and will be re-evaluated for the retention of their orthodontic treatment for up to 2 years, as is standard for all patients treated at the UCONN orthodontic clinic.

B- Study Procedure

1- <u>Standardized Orthodontic Treatment Protocol</u>

The timing of the study visits is planned to coincide with subjects' scheduled orthodontic appointments as determined by their primary orthodontic provider. Comprehensive treatment for orthodontic cases such as those with impacted canines typically lasts an average of 24-36 months. The researchers will not provide any direction of care to the subject's primary orthodontic provider in regards to the subject's orthodontic treatment. The treatment plan is dictated and carried out by the subject's primary orthodontic provider.

Subjects will be bonded with 0.022-inch slot twin brackets with MBT prescription. At the same appointment, the initial phase of orthodontic treatment: leveling and alignment will begin. Once the leveling and alignment phase is complete and the subject is in a 0.019" x 0.025" stainless steel wire, they will be referred to the UCONN Periodontics Clinic for surgical exposure of the impacted

maxillary canine. To ensure consistency among surgeons, Dr. Takanori Sobue will supervise all surgical procedures.

2- Randomization Procedure

Once the three-dimensional position of the impacted canine is determined and verified to be palatally impacted by our calibrated oral and maxillofacial radiologist, the patient will then be randomized to either the "open" or "closed" surgical exposure group using block randomization. The principle investigator will be blinded to the patients' assigned study group. Randomization will occur with 46 opaque envelopes (23 for closed exposure, 23 for open exposures) one day before the surgery. This sealed envelope with the coded number indicating the surgical group will be given to the doctor/provider performing the surgery and the subject will officially be designated to that group.

3- Data Collection Procedure

The periodontal measurements obtained at Visit 3- the day of surgery include: plaque score, gingival index, bleeding on probing, and attachment level on adjacent teeth. The same periodontal assessments will also be recorded once the canine is aligned in the arch (Visit 5). The periodontal measurements will be recorded as follows:

- **Gingival Index**

A modified version of the Gingival Index developed by Loe and Silness [47] will be used. Grades of the severity of gingivitis will be scored by clinical inspection based on the size, color, and

texture of the gingival margin adjacent to the bracket and bleeding on probing. 6 surfaces will be examined per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and distolingual) on the adjacent teeth (premolar and lateral incisor). The scoring criteria will be as follows:

Score 0: Normal gingival

Score 1: Mild inflammation, slight change in color and edema. No bleeding on probing

Score 2: Moderate inflammation, redness, edema, and glazing. Bleeding on probing

Score 3: Severe inflammation, marked redness and edema. Ulceration and tendency toward spontaneous bleeding

- **Bleeding Index**

Bleeding Index is a dichotomous measurement. If bleeding is present (Gingival Index score of 2 or 3) at specific sites within 30 seconds of periodontal probing, it will be recorded on the data collection form.

- **Plaque Index**

A modified version of the Plaque Index developed by O'Leary [48] will be used. The operator, using an explorer or the tip of a probe, will examine each surface for soft plaque accumulations at the dentogingival junction. When found, they are recorded on the data collection form by shading in the surface with plaque present. After the adjacent teeth are examined and scored, an index can be derived by dividing the number of plaque containing surfaces by the total number of available surfaces. The plaque index will be recorded at 6 tooth surfaces (mesiobuccal(MB), buccal (B), distobuccal (DB), mesiolingual (ML), lingual (L), and distolingual (DL)). This is a dichotomous

measurement; therefore, plaque will be noted only on those sites where it is present. After all teeth have been scored, the index will be calculated by dividing the number of surfaces with plaque by the total number of surfaces scored and then multiplied by 100 to determine a percentage of surfaces with plaque present [48].

- **Keratinized Gingiva**

The amount of clinical attachment will be measured as the distance from the free gingival margin to the mucogingival junction using a periodontal probe as done in previous studies [12, 18, 21, 46, 49]. Measurements will be taken from the midline of the adjacent lateral incisors and premolars. Also, a midpoint measurement will be made in the space created for the unerupted canine. Once erupted, the measurements will be taken on the midline of erupted canine.

- **Gingival Recession**

Gingival recession will be measured with a periodontal probe as the distance between the CEJ and the free gingival margin at the midpoint of the crowns on the adjacent lateral incisors and premolars [12]. Once the canine has erupted, gingival recession measurements will be taken at the time of complete alignment to the arch and at the time of debonding of orthodontic appliances.

- **Clinical Attachment Level**

Clinical attachment will be determined from the 6-point probing depths on the mesial, midline, and distal aspects of both the buccal and palatal tooth surfaces. Clinical attachment level is the

distance between the CEJ to the base of the periodontal pocket. In another words, it can be described as the amount of recession plus the probing depth.

- **Oral Hygiene Assessment**

Two weeks after the canine exposure surgery (Visit 4), the orthodontic provider will report the subjects' oral hygiene as "Excellent" or "Good" or "Fair" or "Poor." The study coordinator will record this assessment.

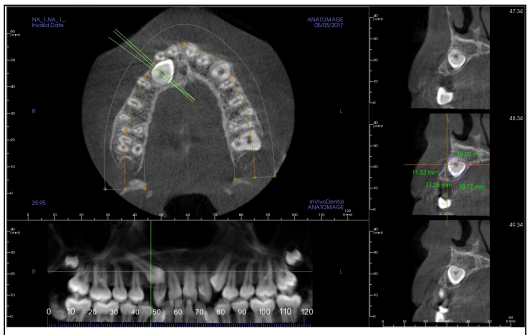
- **Patient Satisfaction Survey**

At Visit 4 (2 weeks after the canine exposure surgery), subjects will be asked verbally by the study coordinator about their comfort level immediately after surgery; recorded answers will be either "Excellent" or "Good" or "Fair" or "Poor." At the same visit, subjects will be asked to report their General Satisfaction with the surgical procedure, again answered as either "Excellent" or "Good" or "Fair" or "Poor."

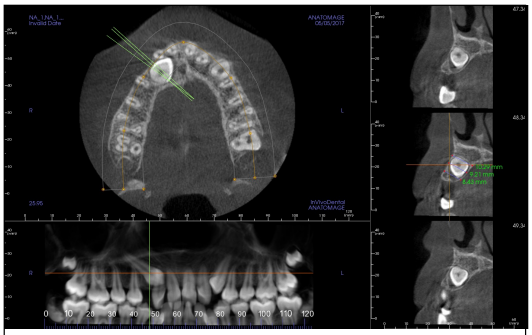
- **Small Volume CBCT**

Two small volume CBCT images will be acquired for each subject during the study through the use of the Kodak 9000© 3D Extraoral Imaging System. The localized field of view (38mm x 50mm) will capture the canine region, including the adjacent lateral incisor and premolar. The first image will be acquired within 12 weeks of the surgical exposure and will be used in lieu of the traditional 2-3 periapical (PA) radiographs to minimize radiation exposure. As mentioned above, the small volume CBCT is equivalent to 2 periapical radiographs, and typically at least 2-

3 PA films using a mesial film shift technique are taken prior to this surgical procedure to assess the location of the impacted canine in the arch. The first small volume CBCT will be used to localize the impacted canine (buccal, palatal, or midalveolar) and to determine the mechanics plan. A second small volume CBCT will be taken on the day that the canine is aligned in the dental arch, typically at least 10-12 months after the first small-volume CBCT was obtained. The purpose of the final CBCT will be to assess the degree of root resorption, if any, on the adjacent lateral incisor and premolar and to make measurements of the alveolar bone of the aligned canine and the vertical bone height of the adjacent teeth. These measurements will be compared to the initial CBCT taken prior to the time of surgery. Specifically, we will evaluate the correlation, if any, between the severity of impaction with the resorption of the canine root itself as well as on the adjacent lateral incisor and premolar. We will also examine the thickness of the buccal cortex overlying the canine and its relation to the amount of recession on the canine and attempt to correlate the buccal ridge height and the thickness of the ridge before and after bringing the tooth into alignment. Interpretation of CBCT images will be done in collaboration with an UCONN Health Oral and Maxillofacial Radiologist, who will be blinded to patient allocation. Measurements will be recorded according the technique described by Tadinada, et al. [50], as shown on an actual subject's CBCT images below:



Bone height will be measured from a standardized point to the bone crest.



This height will be assessed on the sagittal section and the corresponding axial image at that particular height will be used to measure the bone width.

- **Treatment Duration**

Treatment duration will be calculated from the day that canine traction is initiated until the day that the canine is aligned and engaged in a 16x22 stainless steel archwire. Treatment duration will not be evaluated by total treatment time because treatment time required for different malocclusions (which were not controlled for in the Inclusion criteria) can confound these results.

C. Statistics

Simple descriptive statistics will be used to summarize the data. The primary outcome variable of interest is periodontal attachment level and the primary independent variable is the type of canine exposure technique (open versus closed methods). The distribution of periodontal attachment levels will be examined by one sample Kolmigorov-Smirnov test. The differences in outcome between the two treatment groups will be examined by multivariable linear regression analysis. The effects of potential confounders such as age, gender, race, and other patient/treatment level co-variates will be adjusted in the regression model. Interaction terms will also be included. Ordinary Least Squares methods will be used for fitting the regression model. Multiple imputation strategies will be used in cases with missing values. In the imputation strategy, we will examine all patient level covariates and build a multivariable regression model to compute the predicted probability of a patient having the missing characteristic based on the distribution of all other covariates. This predicted probability value will be used wherever there is missing data for a particular variable/case. We will also conduct sensitivity analyses, wherein we will use other imputation strategies such as Markov Chain Monte Carlo Sampling and "hot deck imputation" strategies to account for missing data. All analyses will be conducted on an intention to treat basis.

All statistical tests will be two-sided a p-value of <0.05 will be deemed to be statistically significant.

Chapter IV: Results

Sixteen patients were enrolled since the start of the project, 10 females and 6 males; of these, 5 (1 male, 4 females) were assigned to the Closed exposure group and 2 (0 males, 2 females) were assigned to the Open exposure group. Enrollment was initiated in March 2017. We are currently in the active phase of subject recruitment. Out of the 16 patients recruited, 6 patients were determined to be ineligible after initial screening: 1 female patient decided to have the canine exposure surgery in another clinic, 1 female patient failed to get parental consent, 2 (1 female, 1 male) patients had an unfavorable position of the canine, and two (1 female, 1 male) patients had poor oral hygiene which could confound the periodontal measurements. See **Figure 1** for a diagram of patient flow.

The mean age of the participants allocated to the Open and Closed groups at the beginning of the trial was 14.0 and 14.2 years old, respectively. On the day of recruitment, 7 patients out of the 16 had a retained primary canine in the position of the impacted canine.

In terms of the Gingival Index, scores were recorded 1 week before the exposure surgery. For the 2 subjects in the Open exposure group, the mode for both the lateral incisor and the premolar was 1, which means that the patients most frequently had mild inflammation. For the 5 subjects in the

Closed exposure group, the mode for the lateral incisors and the premolar was 0, which means that the patients most frequently had normal gingiva. See **Table 1.**

For the Gingival Bleeding Index (BI), where a tooth surface is scored if bleeding is present on probing, readings were recorded 1 week prior to the exposure surgery. In the Open exposure group (n=2), bleeding was present on 21%± 31.7% of the surfaces. In the Closed exposure group (n=5), bleeding was present on 28%± 26.18% of the surfaces. See **Table 2.**

For the Plaque Index (PI), where a tooth surface is scored if plaque is present, readings were recorded 1 week prior to the exposure surgery. In the Open exposure group (n=2), plaque was present on 33% ± 47.14% of the surfaces. In the Closed exposure group (n=5), plaque was present on 37% ± 22.01% of the surfaces. See **Table 3.**

In terms of gingival recession, at the appointment 1 week prior to the exposure surgery, no subjects in either the Closed or Open exposure groups had recession on their lateral incisor or premolar.

For the Clinical Attachment Level (CAL) measurements, the following average measurements were recorded 1 week before the exposure surgery. For the 2 subjects in the Open group, the average lateral incisor measurement was 1.6mm ±0.6mm. For the premolar, the average measurement was 2.0mm ±0.9mm. For the 5 subjects in the Closed group, the average lateral incisor measurement was 1.9mm ±0.9mm. For the premolar, the average measurement was 1.9mm ±0.7mm. See **Table 4.**

In terms of Keratinized Gingiva (KG) measurements, the following average measurements were recorded 1 week before the exposure surgery. For the 2 subjects in the Open group, the average lateral incisor measurement was 5.8mm ±1.2mm. For the premolar, the average measurement was 6.3mm ±1.0mm. For the 5 subjects in the Closed exposure group, the average lateral incisor measurement was 5mm ±0.9mm. For the premolar, the average measurement was 4.6mm ±0.8mm. See **Table 5.**

When asked about their post-surgical comfort and satisfaction, the responses were similar between the Open and Closed groups. Both patients enrolled in the Open group reported that their level of comfort was "Good" whereas two patients in the Closed group reported that their level of comfort was "Good" and three patients in the Closed group reported that their level of comfort was "Excellent." See **Figure 2.** For the post-surgical satisfaction level, 1 patient in the Open group reported "Good" and the other patient reported "Excellent." Likewise, in the Closed group, 2 patients reported "Good" and 3 patients reported "Excellent" when asked about their post-surgical satisfaction level. See **Figure 3.**

Oral hygiene was also assessed two weeks post-surgically. 3/5 patients in the Closed group had "Excellent" oral hygiene compared with 0/2 subjects in the Open group. 2/5 subjects in the Closed group had "Fair" oral hygiene compared with 2/2 subjects in the Open group. No subjects had "Good" or "Poor" oral hygiene. See **Figure 4.**

Due to the fact that recruitment began in March 2017 and 10 patients have been enrolled and are at various timepoints within the trial, only the descriptive statistics detailed above could be reported. The trial will continue, and after all 46 patients have completed all trial timepoints, statistics to compare treatment outcomes will be completed as discussed in the Statistics section.

Chapter V: Discussion

Current trial recruitment includes sixteen patients with palatally impacted canines, 10 females and 6 males. This is a ratio of female: male patients of 1.67:1. Previous literature has cited the incidence of palatally impacted canines as 2 times more prevalent in females than males [2]. Although currently a small sample size, our patient population has similar gender ratio.

To add, in terms of our subject population, 7/16 recruited patients had a retained primary canine at the start of the trial. It is anecdotally accepted that many patients with palatally (not labially) impacted canines have a retained primary canine. Future research could investigate this true percentage, as perhaps it could be a clinical indicator for dentists or pedodontists that the permanent canine is palatally impacted.

Furthermore, it is well-accepted that after teeth are extracted, there is higher rate of bone turnover, due to the Regional Acceleratory Phenomenon (RAP) [51]. A prospective clinical trial by Fischer, in 2007, investigated whether surgical exposure of palatally impacted canines in conjunction with corticotomy of the surrounding bone (which is said to induce RAP) would increase the rate of traction of the impacted canine. They found a 28-33% reduction in treatment time for the canines

receiving the adjunctive corticotomy procedure [52]. It is possible that for patients with retained primary canines, who have these teeth extracted at the same time that the impacted canine is exposed and bonded, could have faster orthodontic traction into the arch, due to the RAP. However, literature also describes this phenomenon only lasting around 2-4 months [51]. Future research could examine whether extraction of primary canines immediately before orthodontic traction of impacted teeth is impactful.

In 2008, the Cochrane Collaboration published a systematic review evaluating the outcomes of open versus closed exposure technique for palatally impacted canines. As all of the included studies were retrospective in nature, the conclusion called for the need for future randomized, prospective studies [42]. This was the impetus to undertake this randomized clinical trial, titled *A Randomized Clinical Trial Comparing Outcomes of Open-versus Closed-Surgical Exposure of Palatally Impacted Maxillary Canines: A Pilot Study.*

Since then, 3 randomized clinical trials and 3 quasi-randomized clinical trials have been published to assess whether a significant difference exists in the outcome of the open versus closed surgical exposure of palatally impacted canines [46, 53, 54, 55, 56, 57]. Some or all of these trials have been included in 3 recent systematic reviews/meta-analyses [23, 24, 25]. However, the findings of these aforementioned systematic reviews on the outcomes of open versus closed surgical exposure of impacted canines have not always been consistent. Cassina et al. concluded that open surgical exposure is superior in treatment duration and ankylosis risk over the closed technique. However, a flaw of Cassina's study was that not only palatally impacted canines were included for analysis

[23]. On the other hand, Parkin et al. concluded that both techniques may be equally successful [24]. Lastly, Sampaziotis also concluded that the open and closed techniques are equivalent in terms of periodontal outcomes and aesthetic appearance. In addition, they reported that pain on the first day after the surgery was similar for patients who received the closed or open exposure surgical technique [25].

All of the systematic reviews concluded that there is still a need for further research on the topic due to the limited number of existing trials. High quality randomized trials comparing the outcomes of open versus closed surgical exposure of palatally impacted canines—such as our trial— are especially important as they will yield generalizable knowledge about the outcomes of the two techniques of surgical exposure.

Chapter VI: Conclusions

This randomized clinical trial investigating the outcomes of closed versus open surgical exposure for palatally impacted canines is ongoing. Due to our current small sample size of recruited patients at various trial timpoints, no conclusions can be drawn at this time.

Figures

Figure 1. Diagram of Current Subject Flow

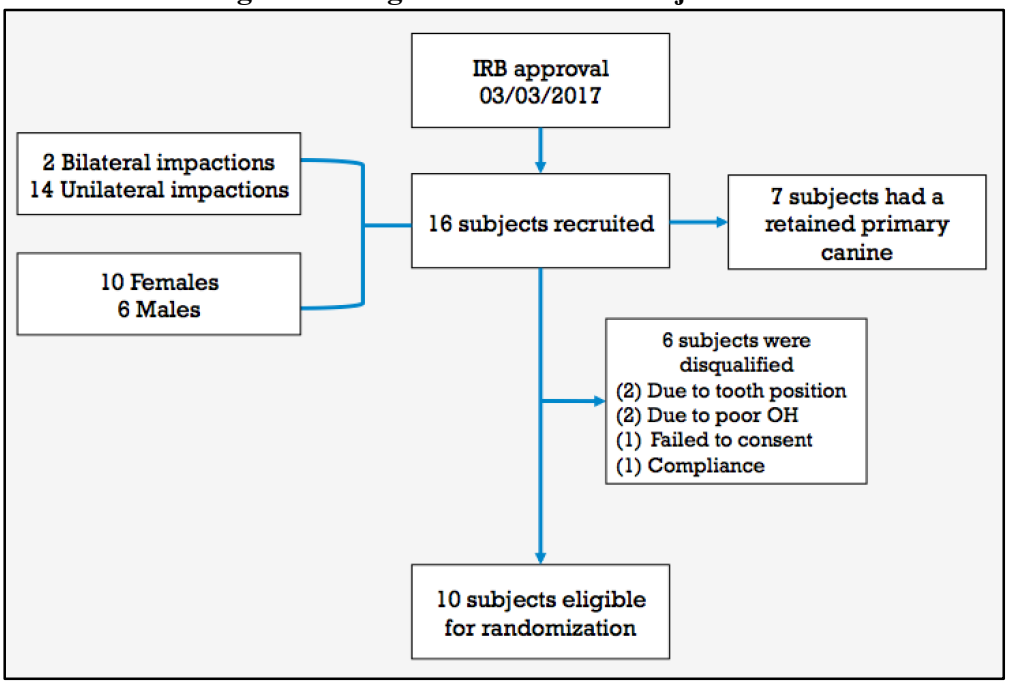


Figure 2. Post-Surgical Comfort Level

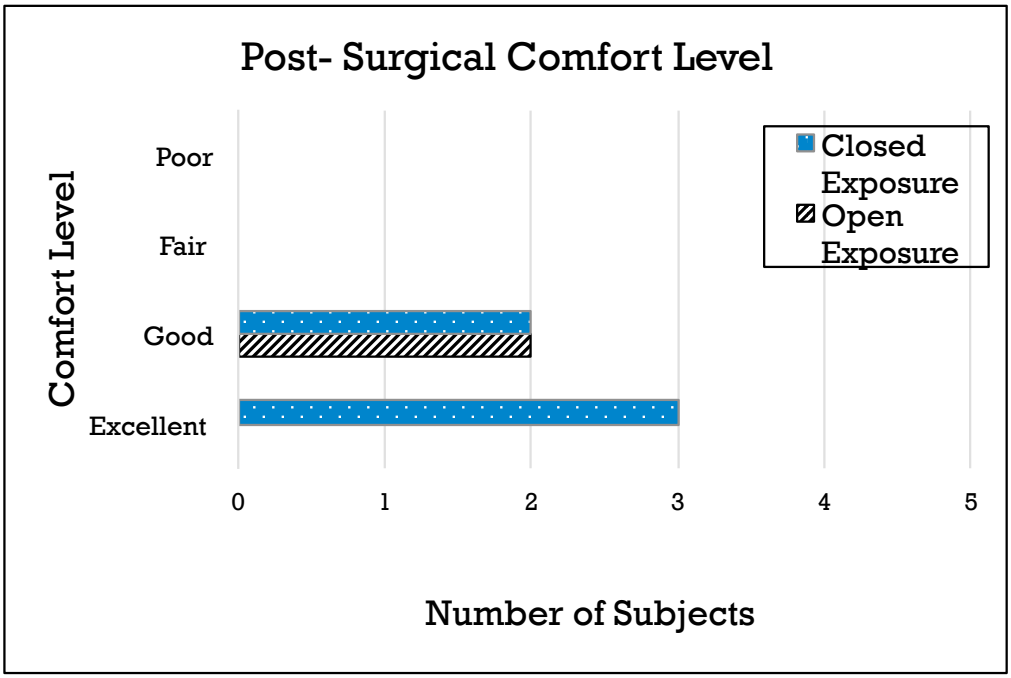


Figure 3. Post-Surgical Patient Satisfaction

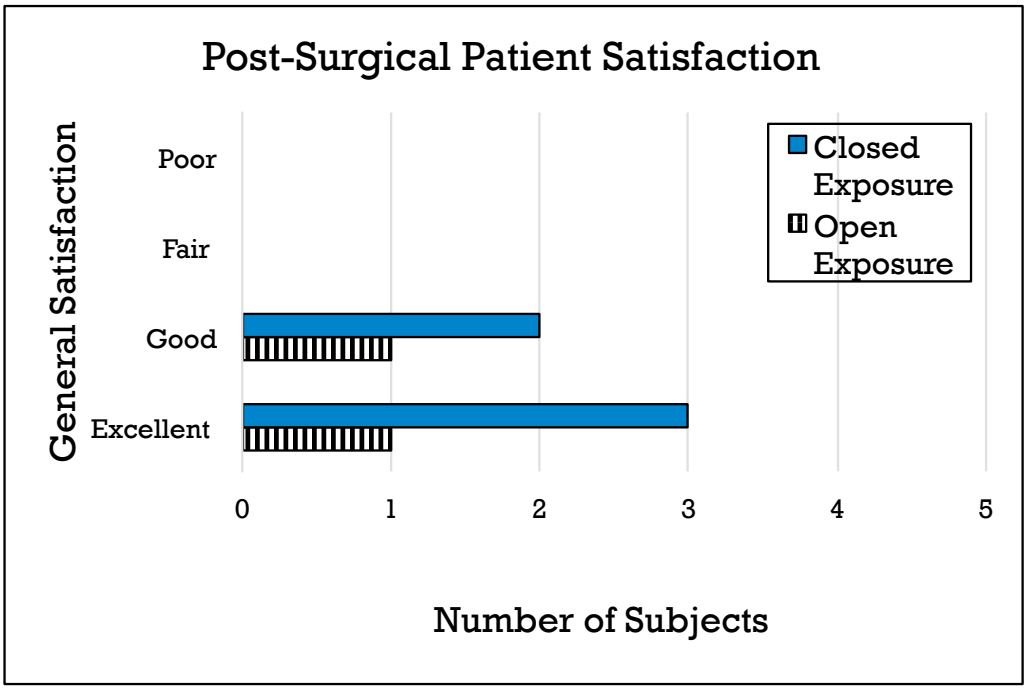
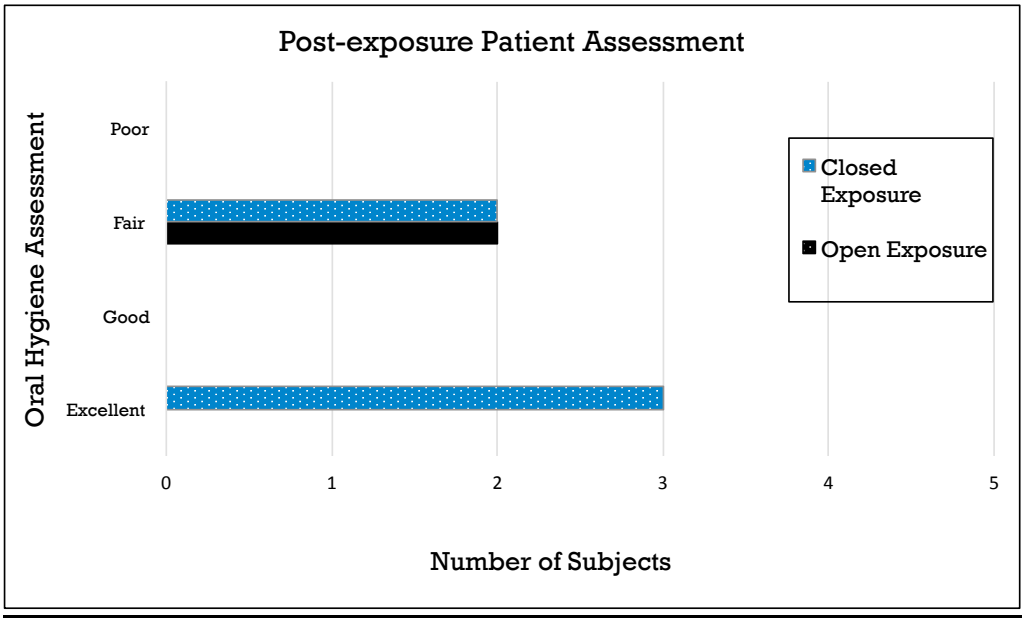


Figure 4. Post-Exposure Oral Hygiene Assessment



Tables

Table 1. Gingival Index

Gingival Index (GI)		
Exposure Group	Open (2)	Closed (5)
Mode	1	0
Median	1	0.5

Table 2. Gingival Bleeding Index

Gingival Bleeding Index (GBI)		
Exposure Group	Open (2)	Closed (5)
Average	21% ±31.70%	28% ±26.18%

Table 3. Plaque Score

Plaque Score (PS)		
Exposure Group	Open (2)	Closed (5)
Average	33% ±47.14%	37% ±22.01%

Table 4. Clinical Attachment Level

Clinical Attachment Level (CAL)		
Exposure Group	Open (2)	Closed (5)
Lateral incisor	1.6mm ±0.6mm	1.9mm ±0.9mm
Premolar	2.0mm ±0.9mm	1.9mm ±0.7mm

Table 5. Keratinzed Gingiva

Keratinized Gingiva (KG)		
Exposure Group	Open (2)	Closed (5)
Lateral incisor	5.8mm ±1.2mm	5mm ±0.9mm
Premolar	6.3mm ±1.0mm	4.6mm ±.8mm

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