PROTOCOL

Title: Characterizing orthodontic tooth movement in real time using Dental Monitoring scans: a pilot study

Introduction:

Telemedicine was first introduced into healthcare industries over 60 years ago. It is defined broadly by the World Health Organization as "the delivery of health care services, where patients and providers are separated by distance."[1] The use of electronic means allows exchange of information for the diagnosis and treatment of diseases and injuries, research and evaluation, and continuing education of health professionals.[1] Due to its great success in the medical field, the concept of teledentistry was introduced in the field of oral healthcare, but is still in its rudimentary stages. Teledentistry is not a specific service, but rather a collection of means to enhance care and delivery of education[2]; it combines telecommunications and dentistry, involving the exchange of clinical information and images for dental consultation and treatment planning. The utility of teledentistry in accessing distant and rural areas, where there is lack of availability of specialist consultation, cannot be emphasized enough. Teledentistry has also been demonstrated to reduce total patient care costs.[3] In a feasibility study done by the Chin-Shan Group Health Center and National Taiwan University Hospital in 2000, a single resident, equipped with an intraoral camera, a digital radiographic system, and a software application to transfer all images to the hospital, was sent to the Chin-Shan Township of 17,000 people.[4] This pilot project demonstrated the effectiveness of teledentistry in providing dental care to individuals living in a remote area and the viability of remote specialty consultations.[4] In 2006, the Eastman Department of Dentistry at the University of Rochester employed a teledentistry project in six inner-city elementary schools and seven child-care centers. They successfully screened 173 children, revealing that almost 40% of the children aged 12-48 months had active dental caries.[5] In Northern Ireland in 2010, a prototype teledentistry system was set up by the Community Dental Service of the Homefirst Legacy Trust in partnership with the Oral Medicine Department at the School of Dentistry, Belfast Trust and the feasibility of teledentistry as an alternative approach to the management of oral medicine referrals was positively established.[6]

According to Berndt et al., interceptive orthodontic treatments provided by sufficiently prepared general dentists and supervised remotely by orthodontic specialists through teledentistry are a viable approach to reducing the severity of malocclusions in disadvantaged children when referral to an orthodontist is not feasible.[7] A study by Stephens and Cook shows that a majority of orthodontic consultants in the UK support the concept of using teledentistry to make their advice more accessible to dentists and patients.[8] A survey by Mandall et al. revealed that most general dental practitioners supported a teledentistry system to screen new patient orthodontic referrals.[9] While there is an overall negative perception among healthcare professionals associated with the direct-to-consumer business model in orthodontics, there are some benefits of remote monitoring that orthodontists can take advantage of. One of the most valuable advantages – for both provider and patient – is the reduction in number of office visits, without eliminating the necessary professional supervision. Orthodontists can utilize their chairside time more efficiently, while patients can avoid the cost of travel to the office for frequent appointments.[10,11] Remote dental monitoring is particularly beneficial in locations and during situations such as the current COVID

pandemic where regular orthodontic visits are not feasible.[7,8] Furthermore, detection of developing problems such as poor oral hygiene, non-tracking aligners, broken appliances, or poor compliance at earlier stages may help reduce overall treatment time.[12,13]

A recently invented technology, Dental Monitoring (DM), allows orthodontists to monitor their patients remotely, using photographs or video scans taken by patients via smartphone. From this data, it can construct three-dimensional (3D) digital models.[14,15] With continuing advances in 3D digital imaging technology, conventional impression materials and dental stone casts are being replaced by digital impressions captured by intraoral scanners.[16,17] Digital models do not require disinfection and can be readily modified through computer software for more in-depth examinations of individual teeth and intra/interarch relationships. 3D mapping of tooth movement is achievable by superimposing digital models on stable structures with 3D software systems.[18-20] With the trend toward digital impressions, recent studies have focused on evaluating the accuracy of digital scanners.[20-24] Digital impressions captured by intraoral scanners have been shown to be as accurate, in both trueness and precision, as conventional elastomeric impressions, and thusare acceptable for clinical use.[22-24] Numerous studies have tested the accuracy of full-arch iTero (Align Technology, SanJose, Calif) generated digital models and demonstrated good results.

DM consists of three integrated platforms: a mobile app for the patient, a patented movement-tracking algorithm, and a web-based Doctor Dashboard through which the orthodontist receives updates on the patient's progress[14]. Using Dental Monitoring's Doctor Dashboard technology, it is possible to quantify and qualify the types of tooth movement occurring during active orthodontic treatment. Crown movements can be traced and analyzed in three axes of translation and three axes of rotation, resulting in nearly 168 measurements for each photo examination, including mesial/distal translation, extrusion/intrusion, buccal/lingual translation, angulation, mesial/distal rotation, and vestibular/lingual torque[25]. This information can improve the provider's understanding of how teeth move from week to week between adjustments. Using this knowledge, the orthodontist can determine the appropriate time needed between appointments to maximize efficiency in carrying out the treatment plan. Data on how each tooth moves also allows the orthodontist to better plan the mechanics required at subsequent appointments. A thorough understanding of tooth movement can reduce treatment time and optimize the number of office visits, greatly reducing cost to both patient and provider.

A study by Moylan et al. [26] examined the accuracy of photos taken by the patient as compared to those taken by a provider and determined that there is no statistically significant difference in the quality of scans taken by patients versus providers. It also found that the accuracy of DM's measurements was sufficient for use in clinical practice with average absolute differences of less than 1mm when comparing DM scans to plaster models. Morris et al.[27] examined the accuracy of DM scans as compared to iTero Element scans using typodonts and determined the 3D digital models generated by DM to be accurate enough for clinical application.

The study by Moylan et al. [26] evaluated the accuracy of the DM system in a model of rapid maxillary expansion. The study tried to evaluate if the tooth movement magnitudes captured with the DM videos and photographs were accurate when measured against intraoral scans taken with the iTero scanner. Another tooth movement model to be tested is the canine retraction model. DM has not been evaluated on the accuracy of measuring canine tooth movement during space closure.

Canine retraction for space closure after premolar extraction is an excellent model to evaluate rate of tooth movement. Clinical trials with surgical and non-surgical methods of tooth movement acceleration have relied on this tooth movement model to test the efficiency of the different approaches. However, a detailed understanding of the rate of canine retraction and the overall nature of tooth movement is missing in the orthodontic literature. In fact, recently Nickel et al. [28] found that canine retraction did not follow the conventional tooth movement phases that have been reported in the literature. Specifically, they reported that a majority of subjects in their study appeared not to have a lag phase and tooth movement appeared to be a continuous process. DM offers a unique opportunity to track the type of tooth movement and magnitude of tooth movement at intervals much shorter than a monthly visit, without the patient needing to visit the provider.

The objective of this study is to test the accuracy of the DM software in determining the precise tooth movements during 5-6 weeks of canine retraction. Furthermore, a description of the magnitude of tooth movement on a biweekly basis will start to provide better information on the nature of the biology of tooth movement. Determining which periods of tooth movement are more significant during the 5-6 weeks of evaluation may help elucidate what the ideal time interval is for patient visits and maximize treatment efficiency. Furthermore, the data could help determine, at an early stage, which patients will be fast and slow movers during orthodontic treatment.

Hypothesis, Aims and Objectives:

- **Null Hypothesis**: There is no significant difference in accuracy of digital scans between the Dental Monitoring and iTero groups in a maxillary canine retraction model.

- **Aims/Objectives**

    - Primary Objective: To evaluate the accuracy and reliability of Dental Monitoring scans to that of iTero digital scans during maxillary canine retraction.

    - Secondary Objective: To quantify the magnitude and type of tooth movement occurring in a 5-6 weeks period in patients undergoing maxillary canine retraction.

Study Design:

- **Study design:** Prospective clinical trial, pilot study

- **Sample size:** 40 patients

- **Sample size justification**: There has been no study evaluating the accuracy of canine retraction with this software. This will be a pilot study from which preliminary data will be obtained for a larger study.

- **Method of data gathering:** Patients undergoing orthodontic treatment in the Center for Orthodontic Care at UConn Health will be evaluated for the inclusion criteria. A total of twenty patients whose orthodontic treatment plan required extraction of at least one premolar in the maxillary arch will be recruited. The patient will be required to take photographs and video scans as dictated by Dental Monitoring (DM) on the first and final days of the study period (five weeks), while iTero scans are taken by the provider in clinic on these same days. The patients will also be asked to take photograph and video DM scans every 4 days during the 5-6 weeks period. DM will provide cheek retractors and scan boxes, which are FDA approved, and the patient will be instructed on how to use the devices to procure photographs and videos.

- **Method of measuring accuracy:** Compare the DM scans taken by the patient to iTero digital scans taken by the provider. This can be done by superimposing the stereolithographic (STL) files created from each scan and assessing the amount of deviation between the 3D models.

- **Method of measuring tooth movement:** Quantify the types of tooth movement occurring during canine retraction in buccolingual, mesiodistal, and incisogingival planes using Doctor Dashboard software available in DM. DM's 3D matching technology allows superimposition of teeth from each 3D model created per scan. Each tooth and its movements are graphed in a detailed manner to provide precise information about its type of movement.

- **Confidentiality of data/privacy of subjects:** Each subject will be assigned a code; the correlation will be denoted in a master list, which will be kept in a locked file cabinet, only accessible to the study coordinator and principal investigator.

- **Data Safety Monitoring:** The investigator and study coordinators will perform safety monitoring to ensure that risks to subjects are minimal. Serious adverse events associated with routine orthodontic treatment are rare. If any such unanticipated events occur, their provider(s) will provide any necessary clinical/palliative treatment to subjects. An assigned orthodontic resident is always on-call and available to provide such treatment and the study team will be available for consultation. Report of the event will be made to the IRB within 5 days of becoming aware of the occurrence.

- **Additional protections for vulnerable populations:** This study will likely include minorsas subjects. As detailed in Form D, additional protections will be taken for this population, including obtaining assent from the subject and permission from a parent/guardian. This study does not involve greater than minimal risk.

- **Outcome Variables**

    - **Primary Outcome**: There is no significant difference in accuracy or reliability between patient-taken DM scans and provider-taken iTero scans at the maxillary canine.

- **Secondary Outcome**: DM scans allow for precise tracking of tooth movement, which can help optimize treatment. Knowledge gained from this study and future treatment studies regarding the quantity and type of tooth movement occurring in canine retraction cases will allow the provider to be better able to customize subsequent appointments. This will allow for more efficient treatment and potentially reduced treatment time and cost in future patients.

Subject Characteristics: All subjects will have permanent dentition; Ethnicity: N/A; Gender: male and female; Other characteristics: undergoing fixed orthodontic treatment with extraction plan.

- Inclusion Criteria
  - Male and female
  - Patients with fixed orthodontic appliances, in 19x25 SS, using NiTi coil for canine retraction
  - Treatment plan requiring extraction of at least one maxillary premolar
  - Permanent dentition from first molar to first molar in the maxilla
  - Teeth with normal crown morphology
  - Fully erupted canines
  - Above 11 years of age
  - Patients with any cellular phone with a camera
- Exclusion Criteria
  - Lack of extraction in orthodontic treatment plan
  - Previous canine retraction
  - Syndromic patients
  - Cleft lip/palate patients
  - Removable appliances

Recruitment

- **Recruitment Methods and Materials**: Subjects will be identified from the Division of Orthodontics at the University of Connecticut Health Center patient pool as possibly eligible for the study by upcoming appointments. Patients (or parents of minors) will be told of the study by clinical staff or by their provider. If they are willing, they will be sequentially approached by the study coordinator and recruited if inclusion/exclusion criteria are met and consent is given.

Study Procedures

- **Screening Procedure**: Screening of patients will occur from the Division of Orthodontics at the University of Connecticut patient pool. Patients in fixed orthodontic treatment with permanent dentition undergoing space closure per a premolar extraction treatment plan will be recruited. They will be approached for consent and examined for all inclusion/exclusion criteria, utilizing the Screening Form. If the patient does not qualify for the study, the screening form will be shredded. If the patient does qualify, once verified and consented, the patient will be included in the study. The patient will be deidentified and assigned a code which will be denoted in a master list; the correlation will only be accessible in this master list kept apart from the IRB binder, in a locked file cabinet.

- **Consent Procedures**: The process of consent and inclusion/exclusion criteria will be recorded in the data collection form. Consent will be obtained by the study coordinator or co-investigator. The patient and/or parent/guardian will be informed of the procedures of the study, the possible risks/benefits of participating, and the fact that the patient's care will not be affected whether or not he/she chooses to participate in the study. If he/she chooses to participate, an informed consent form approved by the IRB will be reviewed with the patient and/or parent/guardian and all questions may be answered by the PI or study coordinator. The patient and/or parent/guardian will have sufficient time to fill out the consent forms and ask any necessary questions. In the event that the patient does not provide consent, he/she will not be included in the study. Patients over the age of 18 will sign the consent form. Patients under the age of 18, between the ages of 13 and 17, will not have a separate consent form, but will co-sign the consent form along with their parent/guardian. If the patient is under the age of 13, he/she will sign an assent form and a parent/guardian will sign the consent form. Participation will only occur if the parent/guardian and the child sign the informed consent form (ICF), indicating consent to participation. Permission from at least one parent is required for minors participating in the study. Once obtained, the Consent/Assent Forms will be stored in the subject's research file, apart from the coded data collection forms and kept in a locked file cabinet only accessible to the PI and study coordinator for study purposes. The subject and parent will also be given a HIPAA authorization form for the study to review and sign. They will be given copies of the signed documents for personal records.

  Only after Consent and HIPAA Forms have been signed, the PI, co-investigator and/or study coordinator will confirm eligibility and complete the Screening Form. Once eligibility criteria have been met, the patient and/or parent will be informed. If the patient meets the inclusion criteria and would like to participate in the study, they will sign the HIPAA form and willbe protected under HIPAA. If the patient meets the inclusion criteria and does not want toparticipate, electronic identifiers will be deleted and paper identifiers will be shredded as soon as patient decides not to participate. If the patient does not meet the inclusion criteria, electronic identifiers will be deleted and paper identifiers will be shredded as soon as the patient is deemed not a candidate for the study.

- **Study Procedure**: The study coordinator will approach patients undergoing space closure as per their premolar extraction treatment plan at the Division of Orthodontics at the

University of Connecticut. If the patient fulfills inclusion/exclusion criteria and consents to participate in the study, the study coordinator will take a digital scan using iTero Element 2 in the clinic the same day if possible, marking day 1 of the study. Then, the patient will be instructed to download the Dental Monitoring app on his/her smartphone and will be provided with all accompanying tools and education to successfully take photo and video scans themselves the same day in the orthodontic clinic. The DM cheek retractor and scan box will be provided to the patient to take home for data procurement. The cheek retractor and scan box are similar to the devices/instruments used at regular orthodontic appointments and are of minimal risk to the patient. They are used to separate the patient's soft tissue to allow good visual access of the patient's intraoral structures. At the patient's subsequent 5-6 weeks follow up appointment, another in-office iTero digital scan will be taken, marking the final day of the study. Another DM scan will be completed by the patient on the final day of the study as well. Both DM scans taken by the patient on the initial and final days will be accessed by the study coordinator and converted into STL files. The patient will also be asked to take intraoral DM photographs and video scans every 4 days to be uploadedto the DM software.

- **Subject's participation in study:** Patient will present for regular orthodontic appointments including bonding and adjustments. Upon consenting to participation in thestudy, an initial iTero scan will be taken in office on day 1. The patient will also take DMscans at home on days 1 and last day (after 5-6 weeks) of the study. The patient will present to the clinic again 5-6 weeks later for a final iTero digital scan taken by the provider, in addition to their regular 5-6 weeks adjustment appointment. A total of two DM scans and two iTero scans will be accumulated for analysis. For the second objective of the study, the patient will take DM scans every 4 days at home for a period this same 5-6 weeks period.
- **Timeline**:
  - IRB approval completed: November 2020
  - Data collection: November 2020 – July 2024
  - Data Analysis and Final Report/Manuscript: July 2024-December 2024

- **Budget:** Patients will not be billed for any additional procedures performed as part of this study. The cost of the orthodontic treatment will be billed to the patient or the patient's insurer, depending on insurance coverage. The same orthodontic procedures will be used for all subjects enrolled in thestudy and will be equivalent to the standard orthodontic treatment for any orthodontic patient requiring space closure.

- **Dissemination:** The results of this research will be published in a peer-reviewed dental journal. In addition, this work is likely to be presented at national/international meetings.

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