

RETREATMENT FOLLOWING IN-PERSON CLEAR ALIGNER THERAPY, DIRECT-TO-
CONSUMER CLEAR ALIGNER THERAPY, AND CONVENTIONAL FIXED
ORTHODONTIC APPLIANCES

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University of Missouri-Kansas City, 2020

ABSTRACT

This study examined the effect of original orthodontic treatment modality, in particular, in-person clear aligner therapy (CAT), direct-to-consumer clear aligner therapy (DTC CAT), and conventional fixed appliances, on patients seeking orthodontic retreatment. This investigation also studied the effect of original treatment modality on treatment concerns including anterior tooth crowding, anterior tooth spacing, periodontal concerns, and occlusal discrepancies. A survey was sent to 66 U.S. accredited Advanced Education Orthodontic Residency Programs in Oct. 2019. We received 11 fully completed surveys for a 17% response rate for the retreatment analyses.

Based on analysis of variance, ($\alpha=0.05$), the reported proportion of patients seeking orthodontic retreatment following treatment by conventional fixed appliances was significantly higher than that of both in-person and DTC CAT. There were no significant differences between original treatment modality and any treatment concerns. With increased numbers of patients completing treatment with new orthodontic treatment modalities such as DTC CAT, additional investigations will be necessary to fully comprehend the long-term patient satisfaction after orthodontic treatment.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Dentistry have examined a thesis titled “Retreatment Following In-Person Clear Aligner Therapy, Direct-to-Consumer Clear Aligner Therapy, and Conventional Fixed Orthodontic Appliances,” presented by Kendall Tada, candidate for the Master of Science degree, and certify that in their opinion it is worthy of acceptance.

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CHAPTER 1

INTRODUCTION

Orthodontic Appliances

Currently, there are a multitude of treatment modalities for patients seeking comprehensive orthodontic treatment. These treatment options include conventional fixed orthodontic appliances directly supervised during in-person office visits with an orthodontist or dentist, in-person clear aligner therapy (CAT) also directly supervised by an orthodontist or dentist, or direct-to-consumer CAT (DTC CAT) remotely supervised through electronic communication by an orthodontist or dentist. While there are numerous brands and prescriptions of fixed appliances, CAT is available in the U.S. through a limited number of brands. As of September 2020, in-person CAT is available through Invisalign®, ClearCorrect®, and 3M™ Clarity™ and DTC CAT is available through SmileDirectClub®, CandidCo®, Smilelove®, byte®, SnapCorrect™, and ALIGNERCO®.

Conventional Fixed Orthodontic Appliances

Conventional fixed orthodontic appliances are provided to patients by licensed dentists or orthodontists and involve periodic office visits. Fixed orthodontic appliances are a system of brackets and wires that apply light, continuous forces to move teeth. Brackets act as a handle to attach a tooth to the wire, which provides the force to move the tooth. Contemporary fixed “straight-wire” brackets are custom made for individual types of teeth to compensate for differences in morphology to incorporate the appropriate tip, torque, and rotation of teeth to address a patient’s malocclusion (Andrews 1979). A practitioner can then insert a pre-formed archwire into the bracket slot to express the tip, torque and placement of

those brackets without needing to incorporate compensating wire bends in order to align teeth.

Brackets are bonded to the facial or lingual surfaces of teeth with light-activated filled acrylic resins, self-adhesive resins, or glass ionomers. Brackets are available in metal, esthetic ceramics, and esthetic plastic. In the past, ceramic brackets were less prone to staining and friction and have greater dimensional stability and size precision than plastic brackets; therefore ceramics are the most commonly used esthetic bracket (Eliades et al. 2004; Gkantidis et al. 2012; Proffit et al. 2012) In comparison to metal brackets, ceramic brackets are more prone to problems that impact treatment outcomes such as fracture, friction within the slot, and enamel damage (Cochrane et al. 2017). Esthetic ceramic brackets are available with or without metal slots and in monocrystalline and polycrystalline forms. Ceramic brackets have significantly higher coefficients of friction than ceramic brackets with stainless steel metal slots, which have coefficient of friction values comparable to that of conventional metal brackets (Williams and Khalaf 2014; Arici et al. 2015). The polycrystalline form is non-translucent and more visually perceptible than the translucent monocrystalline form (Lopes Filho et al. 2012).

There are several types of metal archwires for fixed appliances, but most fall into three main categories: stainless steel, beta-titanium, and nickel-titanium alloys. These three alloys have different properties and advantages for certain stages of orthodontic treatment. Esthetic archwires made from clear polymers or coated metals that appear clear or white are also available and even have properties that are considered equivalent to that of metal wires (Proffit and Sarver 2012).

Orthodontic Records, Diagnosis, and Treatment for Fixed Orthodontic Appliances

A comprehensive orthodontic diagnosis for treatment with conventional fixed orthodontic appliances is developed from a considerable amount of data collected from a patient interview, clinical examination, and diagnostic records. In the patient interview and examination, an orthodontic specialist or dentist elicit the patient's chief concern regarding treatment, evaluate their medical and dental history, determine physical growth potential, and identify social and behavioral factors (Proffit and Sarver 2012). During a typical clinical examination, the clinician determines oral health, jaw and occlusal function, and facial and dental characteristics. The facial and dental characteristics include macro-esthetics or facial proportions in three planes of space, mini-esthetics or the dentition relative to the face, and micro-esthetics or the teeth relative to each other. The data from the facial and dental examination are typically recorded in the patient chart and also documented with extraoral photographs (facial profile, facial front in repose, and facial front smiling) and intraoral photographs (maxillary occlusal, mandibular occlusal, left and right lateral in maximum intercuspation, and center in maximum intercuspation).

The diagnostic records needed differ depending on the patient. However, at the minimum, Proffit and Sarver urge that diagnostic records should include digital or diagnostic casts that represent the occlusal relationship, data from the facial and dental examination, and radiographs (2012).

In terms of radiographs, bite-wings and panoramic images are typically used to assess pre-orthodontic periodontal health, caries, tooth root and bony pathologies, which should be evaluated and addressed prior to orthodontic treatment. A lateral cephalometric radiograph is

often included to aid in orthodontic diagnosis except in patients with minor needs (e.g. Class I malocclusions or ¼ cusp Class II or Class III with no apparent skeletal discrepancies) (Proffit and Sarver 2012; Manosudprasit et al. 2017). More complex cases, such as those with ectopically erupting teeth, impacted canines, skeletal discrepancies, skeletal asymmetries, syndromes, or facial trauma, require three-dimensional radiographs from cone-beam computed tomography. The clinician uses these records to formulate a diagnosis and treatment plan options for that patient’s treatment. The clinician then presents the treatment plan options to the patient.

In-Person CAT

The concept of removable aligners was postulated by Kesling in 1945, but was finally realized and made readily available by Align Technologies in 1999 through the Invisalign® system, a series of clear and removable polyurethane trays (1945; AlignTechnology 2018c). Since then, the Invisalign® clear aligner system has accomplished incremental tooth movement in over 5 million patients without the use of conventional fixed orthodontic appliances (AlignTechnology 2018c). Invisalign® was the sole supplier of CAT in the United States until ClearCorrect® obtained FDA approval in 2009 (ClearCorrect 2018). Currently, there are several other companies developing clear aligner systems for in-person CAT. In-person CAT is defined as clear aligner therapy with direct oversight from a licensed dentist or orthodontist and periodic office visits. With in-person CAT, a patient visits a qualified dentist or orthodontist for diagnostic records and a diagnosis. In-person CAT prescriptions are formulated by the dentist or orthodontist and records are sent to the CAT company to fabricate the clear aligner trays. The dentist or orthodontist delivers the patient’s clear aligners directly to a patient in a physical clinic.

There are several benefits for in-person CAT compared to fixed orthodontic appliances. In-person CAT is considered a comfortable and more esthetic option for patients seeking orthodontic care (Rosvall et al. 2009; Galan-Lopez et al. 2019). Additionally, studies have shown that patients treated with in-person CAT have better periodontal health and report lower levels of pain in the first week of treatment compared to conventional fixed orthodontic appliances (Almasoud 2018; Lu et al. 2018). Patients with fixed orthodontic appliances have been shown to have increased incidence of gingivitis and increased bacterial counts around brackets and bands (Bloom and Brown 1964; Boyd et al. 1989).

Orthodontic Records, Diagnosis, and Treatment for In-Person CAT

The records and diagnosis procedure for CAT differs slightly from fixed orthodontic treatment. Patients can still directly visit a dentist or orthodontist for CAT orthodontic treatment. However, CAT companies market directly to consumers which means that patients can visit the CAT company website to learn about the clear aligners, get an estimate on whether or not CAT may be a good option for that patient, and find a dentist or orthodontist that can provide that patient with CAT through that company.

Similar to conventional fixed orthodontic appliances, patients seeking in-person CAT treatment meet with a qualified, licensed dentist or orthodontist for records, a diagnosis, and consultation. As with fixed orthodontic appliances, records are obtained by the clinician or trained staff members. The records required include maxillary and mandibular impressions or 3D scan, and intraoral photographs (maxillary occlusal, mandibular occlusal, left and right lateral in maximum intercuspation, and center in maximum intercuspation) (AlignTechnology 2018b). In-person CAT companies use photographs to relate maxillary

and mandibular relationships from the impressions or 3D scans as opposed to interocclusal records. Optional record submissions include extraoral photographs (facial profile, facial front in repose, and facial front smiling), panoramic or full mouth radiographs, and an interocclusal record. The clinician uses these records to formulate a diagnosis and treatment plan. However, in contrast to fixed orthodontic therapy, the diagnostic records are sent to the in-person CAT company. The CAT company uses these records along with a prescription from the clinician to formulate a digital set-up that the clinician can modify. The digital set-up predicts the movements of the teeth from the beginning to end of treatment. Once the clinician approves the digital set-up, the aligners are fabricated and delivered to the clinician, who then oversees the fit of the aligners and treatment progress.

Direct-to-Consumer CAT

Within the last 6 years, several companies have been established to deliver DTC CAT. DTC CAT is defined as CAT treatment where patients' treatment are overseen by dentists or orthodontists via teledentistry i.e. remote technologies. These companies claim:

With remote teledentistry, our invisible aligners let you straighten your teeth on your schedule, from the comfort of your own home. You'll be assigned a duly licensed dentist or orthodontist. He or she will check in with you every 90 days through your customer account, and monitor your progress remotely. (SmileDirectClub 2018a)

With DTC CAT, patients submit diagnostic records to the DTC CAT company and are sent a complete set of clear aligners directly without visiting the dentist or orthodontist office in person.

DTC CAT costs approximately \$1900 for a patient; around \$4000 less than the average fee for fixed orthodontic and in-person CAT options (Keim et al. 2015; SmileDirectClub 2018b). At this time, the largest DTC CAT company in the United States

constitutes approximately 95% of the DTC CAT industry and has treated more than 1 million patients (SmileDirectClub 2020a). However, currently there is no evidence available regarding the benefits of DTC CAT compared to conventional fixed orthodontic therapy or in-person CAT.

Orthodontic Records, Diagnosis, and Treatment for DTC CAT

As with in-person CAT, direct-to-consumer (DTC) CAT companies also market directly to potential patients (Kravitz and Bowman 2016). Patients can also browse a DTC CAT website and fill out a questionnaire to determine eligibility for CAT treatment (fig. 1) (SmileDirectClub 2018c). If considered a good candidate, a patient has the option to visit a DTC CAT scanning site and obtain a 3D intraoral scan or can purchase an impression kit, which the patient uses to self-obtain polyvinyl siloxane impressions. The patient sends the DTC CAT company their medical history, facial photos, intraoral photographs (maxillary occlusal, mandibular occlusal, and center smiling), and two maxillary and mandibular impressions (SmileDirectClub 2018d). In contrast to fixed orthodontic appliances or in-person CAT where the supervising dentist or orthodontist can decide whether radiographs, additional photographs, or interocclusal records are indicated on a case by case basis, these records were not initially provided to direct-to-consumer CAT clinicians. Recent updates to the SmileDirectClub website state that “Any necessary X-rays, as determined by your treating doctor, can be obtained from your local dentist to continue with your invisible aligner plan (Sulitzer 2020).

The largest DTC CAT company employs 225 dentists or orthodontists who are responsible for reviewing the patient records, formulating a diagnosis, and overseeing the

digital set-up. Once the patients approve the digital set-up, they are shipped their aligners. A direct-to-consumer CAT company clinician monitors the treatment progress through remote teledentistry (SmileDirectClub 2018a).

Use code FALLSMILES to get a grin you'll love for \$80/mo. GET STARTED

smile DIRECT CLUB HOW IT WORKS RESULTS PRICING INSURANCE LOCATIONS ACCESSORIES SIGN IN AM I A CANDIDATE? GET STARTED

Free 30-second Smile Assessment

Take 30 seconds to answer these questions and find out if SmileDirectClub is right for you.

- Have you worn braces or invisible aligners in the past?

YES NO
- Of the images below, which one best describes your teeth crowding?

none, or no crowding moderate extreme
- Of the images below, which one best describes your teeth spacing?

none, or no extra space moderate extreme
- Enter your zip code (to make sure you're in our service area).

64104
- Enter your email address to get results.

EMAIL ADDRESS

GET YOUR RESULTS

CONGRATULATIONS!

You're a great candidate.

Get started on the smile you'll love in just three easy steps.

- 1 Make a Good Impression**
Visit a SmileShop for a 3D scan of your smile, or have an at-home impression kit sent to you. A licensed dentist or orthodontist will review your smile plan and guide your new smile remotely from beginning to end.
- 2 Get Aligned for \$1850 or \$80 a Month.**
We send your invisible aligners and premium whitening directly to you.
- 3 Smiles Are Forever**
After you complete your smile journey, order retainers to help maintain the smile you love. We recommend getting a new pair every 6 months to keep them fresh.

Figure 1. 20-Second smile assessment from DTC CAT website. (SmileDirectClub 2018c) Patients interested in DTC CAT select most applicable options, enter their email address, and receive an email regarding CAT eligibility. In this example, a patient with no history of prior orthodontic treatment, self-reported crowding, and mild to no spacing is a great candidate for DTC CAT.

CAT Attachments, Auxiliaries, and Interproximal Reduction

The first generations of in-person CAT relied on the aligner to achieve the predicted movements without the use of attachments or auxiliaries. Later generations included the use of attachments, which are composite buttons bonded to the teeth, to improve specific tooth movements (Kravitz et al. 2009; Hennessy and Al-Awadhi 2016).

Current generations of in-person CAT include auxiliaries such as attachments, optimized attachments, power ridges, bite ramps, pressure areas, buttons, and elastics (AlignTechnology 2018a). Optimized attachments are patient and tooth specific attachments to maximize certain tooth movements. Power ridges provide additional force in the aligner to increase torque in selected teeth. Bite ramps can be placed on upper incisors to disocclude the posterior teeth. Buttons used in conjunction with elastics can improve the extrusion of a tooth or rescue a tooth that has not been following the movements prescribed with the aligner. Elastics can also be used with cuts in the aligners to correct minor antero-posterior jaw relationships. With these improvements, the manufacturer claims improved treatment outcomes and better control of movements, but these claims have very little if any supporting evidence (Goto et al. 2017; AlignTechnology 2018d). Similar to conventional fixed orthodontic treatment, in-person CAT may involve interproximal reduction (IPR), which is the careful removal of interproximal enamel to slenderize crowded teeth. IPR may also be prescribed with in-person CAT to avoid tooth collisions that would hinder and even prevent tooth movement.

As DTC CAT does not entail any in-office dental visits, these companies do not currently include attachments, auxiliaries, or IPR (SmileDirectClub 2018b). The largest

direct-to-consumer CAT company claims that the straight trim of the aligners versus scalloped trim provides “optimal turning force” so that attachments or buttons are not needed to straighten teeth. There is no current literature to support or refute these claims.

Efficacy of In-Person and DTC CAT Versus Conventional Fixed Orthodontic Appliances

At this time, there is a lack of data evaluating the efficacy of direct-to-consumer CAT; however, there is literature evaluating the efficacy of in-person CAT and conventional fixed orthodontic appliances. There is mixed evidence for the efficacy of clear aligners compared to fixed appliances. As with conventional fixed appliances, several studies have illustrated the ability of CAT to successfully align and level the arches and improve malocclusion (Rossini et al. 2015; Gu et al. 2017).

CAT was developed to correct cases with low and moderate crowding and to close small spaces. Evaluations of earlier generations of in-person CAT products comparing the treatment results of the two modalities reported that fixed orthodontic appliances and in-person CAT interventions were similar in correcting rotations, marginal ridge heights, root alignment, and space closure (Djeu et al. 2005). Conversely, the same study suggested that fixed appliances were better in controlling posterior torque, correcting occlusal contacts, and correcting antero-posterior discrepancies.

Following these studies, the manufacturer modified the CAT system by changing the tray material and tooth movement algorithms and added of composite attachments for specific tooth movements. Gu et al. suggested that in-person CAT can accurately control orthodontic tooth movements including anterior intrusion, posterior buccolingual inclination, and 1.5 mm of maxillary molar bodily movements (2017). However, the reliability of CAT in

producing accurate tooth movements compared to conventional fixed appliances is reduced in anterior extrusion, rotation of rounded teeth such as canines and premolars, and anterior buccolingual inclination movements. Additionally, in-person CAT movements are limited in terms of arch expansion, bodily movements such as in extraction sites, and overbite control such as correction of deep or open bites (Krieger et al. 2011; Krieger et al. 2012; Khosravi et al. 2017; Papadimitriou et al. 2018).

Both in-person CAT and fixed appliances are successful when treating class I adult extraction cases; however in-person CAT American Board of Orthodontics Objective grading system (ABO-OGS) scores were lower than fixed appliances for buccolingual inclinations and occlusal contacts and treatment time was significantly greater in-person CAT (Li et al. 2015). Other evidence suggest that patients treated with CAT had shorter treatment times than those treated with conventional fixed appliances, but agreed with Li et al. that the ability of attaining improvement of a malocclusion is greater with fixed appliances (Djeu et al. 2005; Li et al. 2015; Gu et al. 2017). Successful and predictable treatment with CAT is dependent on the use of interproximal reduction (IPR), attachments, and interarch elastics (Rossini et al. 2015). Overall, recent studies suggest treating malocclusions with clear aligner systems is possible but the results are not as accurate as those with conventional fixed appliances (Galan-Lopez et al. 2019).

Stability and Retreatment of In-Person and DTC CAT versus Conventional Fixed Orthodontic Appliances

Orthodontic relapse is the tendency for teeth to return to pre-treatment positions. There are a number of factors hypothesized to contribute to orthodontic relapse including growth, periodontal factors, occlusal factors, and soft tissue pressures (Proffit 2012). To

combat the unstable nature of tooth positioning following active orthodontic treatment, retention is considered a necessary phase of orthodontic treatment (Proffit 2012). There are many methods and appliances available for retention (e.g. fixed retainers, clear removable thermoplastic retainers, and removable Hawley retainers); however, there is insufficient evidence on which to base the clinical practice of retention (Littlewood et al. 2016). Even with an indefinite retentive phase, retention may not be successful. Relapse or tooth movement may occur from poor compliance with removable retainers, debonding of fixed retainers, and iatrogenic factors (i.e. unstable tooth position and wire distortion) (Littlewood et al. 2006; Shaughnessy et al. 2016).

While the decision for orthodontic retreatment is subjective, dental professionals have a lower tolerance for malalignment than lay people (Kokich et al. 1999; Alqahtani et al. 2012; Ma et al. 2014; Kearney et al. 2016). Though there is little evidence regarding the patient's decision to pursue orthodontic retreatment, a previous study found that a multitude of factors contribute to an adult's motivations (Kearney et al. 2016). The most important factor for an adult seeking retreatment was a desire for improvement in dental esthetics. Participants reported that dental appearances impacts self-confidence and behavior. However, some adults would avoid pursuing retreatment due to time, cost, and personal commitment.

At this time, there is no evidence for treatment stability with direct-to-consumer CAT and sparse evidence regarding post-treatment changes with in-person CAT treatment versus conventional fixed appliances. The single retrospective study available found that post-treatment dental changes, or relapse, of in-person CAT-treated patients is greater than that of those treated with fixed appliances after one to three years when both groups wore removable

thermoplastic retainers after treatment (Kuncio et al. 2007). The relapse of those patients was greatest in the alignment of the maxillary anterior segment.

Petitions against DTC CAT

Since 1998, U.S. Food and Drug administration (FDA) classifies dental impression material, such as elastomeric materials, as a class II device and should be labelled: “Caution: Federal law restricts this device to sale by or on the order of a dentist” (FDA 1998). As of July 8th, 2020, dental impression kits are available for consumer purchase for \$49 USD from direct-to-consumer CAT companies, without the direct prescription of a dentist (SmileDirectClub 2020b).

On April 25, 2019, the American Dental Association (ADA) filed a petition with the FDA regarding the evasion of FDA restrictions on “by prescription only” dental impression materials and plastic teeth aligners (Cole 2019). Additionally, in a statement from the ADA president on May 1, 2019:

ADA policies oppose Do-It-Yourself Teeth Straightening and Direct to Consumer Dental Laboratory Services because dentists are concerned about the potential for irreversible harm to patients. For example, orthodontic treatment, if not done correctly, could lead to potential bone loss and receding gums, changed bites, and other issues. (Cole 2019)

Problem Statement

Due to the lack of evidence regarding the treatment outcomes of CAT-based (in-person and direct-to-consumer) treatment as compared to conventional fixed appliances, the purpose of this study was to evaluate the retreatment rates of the three main orthodontic treatment modalities.

Hypotheses

1. Among patients seeking retreatment in an Advanced Orthodontic program, there will be a difference in the proportion of patients reported that have been previously treated by a direct-to-consumer CAT than previously treated directly by an orthodontist or dentist with clear aligner therapy or conventional fixed orthodontic appliances.
2. There will be a difference in reported proportion of patients with occlusal discrepancies, periodontal concerns, anterior crowding, and anterior spacing in those patients previously treated through direct-to-consumer CAT versus those treated directly by orthodontists and dentists with CAT or fixed orthodontic appliances.

CHAPTER 2

MATERIALS AND METHODS

Survey Development and Description

In order to investigate the differences in patient seeking orthodontic retreatment, a cross-sectional survey was administered to U.S. accredited orthodontic residency programs from October 2019 through November 2019. Study data was collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the Center for Health Insights of the University of Missouri–Kansas City (UMKC) (Harris et al. 2009). REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. The survey included questions aimed at determining the approximate percentage of patients seeking retreatment and the type of orthodontic treatment those patients received: Conventional fixed orthodontic appliances, in-person CAT, or direct-to-consumer CAT. The survey elicited the proportion of these patients with occlusal discrepancies, periodontal concerns, anterior crowding, and anterior spacing for each of the treatment modalities (APPENDIX 1). The survey items were pre-tested with nine UMKC Advanced Education Orthodontics and Dentofacial Orthopedics (AEODO) residents and faculty for content, face validity, and to correct any errors prior to distribution.

The Institutional Review Board (IRB) at UMKC approved the protocol and associated documents as Exempt (IRB #2016848 KC). The IRB approval form is located in APPENDIX 2.

Distribution of Surveys and Data Collection

Sixty-six U.S. accredited orthodontic residency programs were identified by the Commission on Dental Accreditation (CODA). Orthodontic programs located in Canada and Puerto Rico were excluded. The goal was to invite all U.S. accredited orthodontic residency programs.

The following methods were used to maximize responses from advanced orthodontic programs:

1. A formal email from the student investigator was sent to the designated U.S. advanced orthodontic program directors or chairpersons as identified by the CODA (APPENDIX 2). This email contained an invitation to the REDCap survey, which was hosted at the Center for Health Insights of the University of Missouri-Kansas City. REDCap allowed for data collection and secure information storage. The survey was accompanied by a cover letter explaining the aims and procedures. Completing the survey indicated informed consent. No compensation was given to participants. Recipients were asked to complete the survey, or forward the survey to the faculty or staff member within the program most qualified to complete the survey, within 14 days from receiving it.
2. Follow-up contact was made to ensure survey completion. Follow-up emails were sent 7 and 14 days after the formal email containing the survey invitation was sent to remind the recipient to complete the survey (APPENDIX 3).

Study Design and Sample Size

The survey was sent to 66 U.S. accredited orthodontic residency programs. The independent variables were the treatment modality: conventional fixed appliances, in-person CAT, and DTC CAT. The dependent variables assessed in the survey were diagnoses

including occlusal discrepancies, periodontal concerns, anterior crowding, and anterior spacing. Table 1 illustrates the experimental design with variables to be tested.

TABLE 1
EXPERIMENTAL DESIGN

| Groups | Reported Retreatment rate (# retreatments /total retreatments) | Reported Treatment outcomes: Occlusal discrepancies | Reported Treatment outcomes: periodontal concerns | Reported Treatment outcomes: anterior crowding | Reported Treatment outcomes: anterior spacing |
|-------------------------------------|--|---|---|--|---|
| Fixed (n=?) | | | | | |
| In-person CAT (n=?) | | | | | |
| Direct-to- consumer CAT (n=?) | | | | | |

Data Analysis

Statistical analyses were performed with a statistical data analysis program¹ with level of significance set at $\alpha=0.05$ for all testing. Descriptive statistics including means, standard deviations, counts, percentages, minimums, and maximums were calculated for all variables from the survey data. One-way analysis of variance (ANOVA), Welch’s ANOVA and Tukey post-hoc tests were used to compare between means to determine if there were any associations between treatment modality and retreatment proportions, and treatment modality and treatment outcomes. When groups did not have equal variance, Welch’s ANOVA was used in place of one-way ANOVA.

¹ IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp. Armonk, NY)

Program Directors submitted the majority of responses (77%), followed by Program Chairs (15%) with the remainder submitted by various other program-related personnel (8%). The size of the programs ranged from 4-18 new residents per year, with most programs supporting four (23%) or 5-7 new residents per year (46%). The programs were heterogeneous in the number of patients seeking treatment and percentage of patients seeking retreatment. The programs ranged from 200-900 patients seeking treatment annually, with 38% of programs between 400-500 patients, 23% between 200-300 patients, and 15% between 600-700 patients. Annually, programs estimated from 1-50% of the patients seeking treatment had been previously treated and seeking retreatment. Most estimated between 1-5% (31% of the programs) and 20% (23% of the programs) of their patients were seeking retreatment.

The reported proportion of patients seeking retreatment for DTC CAT was on average lower than that of in-person CAT and conventional fixed orthodontic appliances (table 2). The reported proportion of patients seeking retreatment from conventional fixed appliances was on average significantly higher than that of both in-person and DTC CAT (table 2). Reported percentages of patients seeking retreatment from DTC CAT ranged from 0-10% and in-person CAT ranged from 0-40%. Those of conventional fixed appliances ranged from 50-100% of reported patient seeking retreatment. Although we found no difference in the proportion of reported patients seeking retreatment of DTC CAT and in-person CAT, the first hypothesis was supported as we found a significantly higher proportion of reported patients seeking retreatment of conventional fixed appliances than that of DTC CAT.

TABLE 2
 REPORTED PERCENTAGE OF PATIENTS SEEKING RETREATMENT
 BETWEEN TREATMENT MODALITY

| | N | Mean Percentage (SD) | (Min, Max) | p-value |
|--------------------|----|-------------------------|------------|---------|
| Treatment modality | | | | <0.01* |
| Fixed | 11 | 88.0 (14.39) | (50, 100) | |
| In-Person CAT | 11 | 10.3 (11.82)** | (0, 40) | |
| DTC CAT | 11 | 1.7 (3.20)** | (0, 10) | |

*One-way ANOVA

**Significantly different than Conventional Fixed appliances (Tukey's HSD) $p < 0.01$

TABLE 3
 REPORTED TREATMENT CONCERNS BETWEEN
 TREATMENT MODALITY

| | N | Mean Percentage (SD) | (Min, Max) | p-value |
|-------------------------------|----|-------------------------|------------|---------|
| Occlusal Discrepancies | | | | 0.54* |
| Fixed | 11 | 14.0 (17.0) | (0, 50) | |
| In-person CAT | 10 | 20.7 (25.7) | (0, 60) | |
| Direct-to-consumer CAT | 7 | 32.9 (46.7) | (0, 100) | |
| Periodontal Concerns | | | | 0.19* |
| Fixed | 10 | 8.7 (8.9) | (0, 25) | |
| In-person CAT | 8 | 4.0 (8.7) | (0, 25) | |
| Direct-to-consumer CAT | 8 | 27.4 (35.3) | (0, 100) | |
| Anterior Crowding | | | | 0.37** |
| Fixed | 11 | 57.1 (27.6) | (3, 95) | |
| In-person CAT | 11 | 51.0 (34.3) | (0, 95) | |
| Direct-to-consumer CAT | 7 | 32.9 (46.7) | (0, 100) | |
| Anterior Spacing | | | | 0.16** |
| Fixed | 11 | 14.0 (12.2) | (1, 40) | |
| In-person CAT | 11 | 13.5 (12.0) | (0, 40) | |
| Direct-to-consumer CAT | 7 | 3.9 (9.4) | (0, 25) | |

*Welch's ANOVA

**One-way ANOVA

We did not find significant differences between treatment modalities among the reported treatment concerns; however, among the three treatment modalities, the mean percentage of patients with occlusal discrepancies was highest for DTC CAT, then in-person CAT. DTC CAT had the highest number of reported periodontal concerns, followed by fixed orthodontic treatment. In all three treatment modalities, anterior crowding had the highest mean percentage of all the treatment concerns with 57.1% for fixed conventional appliances, 51.0% for in-person CAT, and 32.9% (table 3). Based on the results, the second hypothesis was not supported as there were no significant differences between treatment modalities and the reported proportion of treatment outcome concerns.

CHAPTER 4

DISCUSSION

The purpose of this investigation was to determine associations between patients previously treated by comprehensive orthodontics and seeking orthodontic retreatment following the original orthodontic treatment modality. The study also sought to determine whether differences in original treatment modality were associated with the reported proportions of occlusal discrepancies, periodontal concerns, anterior crowding, and anterior spacing.

We did not have any program responses from states west of Colorado. However, recently published literature report that the largest percentage of DTC CAT patients are located in California (Wexler et al. 2020). Additionally, the typical patients pursuing DTC CAT were white, female millennials.

Clinical Implications

Recently published studies have reported that patients' level of interest in pursuing orthodontic care, concern for quality of care, convenience, and cost influence whether a patient seeks care with an orthodontist or a DTC modality (Olson et al. 2020; Wexler et al. 2020). The patients that tended to prefer treatment with an orthodontist had the highest level of interest in pursuing orthodontic treatment, whereas those with only moderate interest and concerns for convenience and cost preferred DTC options. Although there are some previously published literature reporting data on factors that contribute to a patient seeking retreatment, currently there are no published rates of patients seeking retreatment by these treatment modalities. Previous studies have found that relapse is greater with in-person CAT than with conventional fixed appliances (Kuncio et al. 2007). However, we found that the

reported retreatment rates for DTC CAT and in-person CAT were significantly lower than those reported for conventional fixed appliances and in-person CAT treatment modalities. This may be due to the larger proportion of patients originally treated with conventional fixed orthodontics than clear aligners. As DTC CAT has only been available to the public since 2014, and the number of patients treated initially by this novel treatment modality continue to increase, it is reasonable to expect that the number of patients seeking retreatment from this modality will also increase with time. One program reported in their survey response:

We have not seen a significant number of patients that are seeking retreatment after aligner therapy, except for those that [*sic*] with existing skeletal problems. I am sure the number will continue to increase as more individuals are being treated with aligners and are given a clear essix retainer.

Additionally, CAT is indicated for treating less severe malocclusions than what can be accomplished by fixed orthodontic treatment, so patients treated with CAT may have started with less severe malocclusions than that of conventional fixed appliances. Thus patients treated by CAT initially could have less indications for retreatment.

Similar to previous literature, anterior crowding was the most prevalent condition of the occlusal conditions of patients among the patient seeking retreatment (Tuominen et al. 1994). Although there were no significant differences between initial treatment modality and the reported treatment outcomes in patient seeking retreatment, there was a higher proportion of patients that had been initially treated with DTC CAT with reported occlusal discrepancies and periodontal concerns. One program stated:

Patients were very disappointed with their outcome from direct-to-consumer orthodontic treatment. They stated that they thought maybe their teeth were straighter but nowhere near straight. Many were also shocked to find that they now had recession and bone loss that they did not believe they previously had.

Another program reported “we have seen several cases in the pre-doctoral clinic, but none have followed through with treatment in our clinic. All of the [patients] that I have seen in the general clinic had excessive tooth mobility or periodontal issues.”

Current Legal Proceedings

As of October 15, 2019, the ADA had an open citizen petition with the FDA against SmileDirectClub accusing that “this practice does not meet the applicable standard of care, and it evades the FDA’s designation of plastic aligners as a Class II medical device requiring a prescription. SmileDirectClub customers also waive any right to recourse in the event of a negative outcome.”

On October 16th, 2019, Jeffery Sulitzer, DMD, the Chief Clinical Officer of SmileDirectClub and SmileDirectClub filed a lawsuit against the California Board of Dentistry, individual board members and an investigator complaining that the board “continue to depict, at most, an agreement to undertake the functions of a dental-industry regulatory agency, at least as much as an agreement to restrict or to restrain competition” and that the “Board’s misconduct was not related to any legitimate state interest”, among other complaints. These complaints were dismissed by the Federal Court on July 9th, 2020 (Jeffrey sulitzer, d.M.D, et al. V. Joseph tippins, et al. 2020).

On November 12, 2019, the Dental Board of California filed a complaint against Jeffery Sulitzer, DMD, the Chief Clinical Officer of SmileDirectClub citing nine clauses for discipline (Accusation against jeffery alan sulitzer, dmd 2019). These clauses include the use of fraud in the procurement of fictitious name permits and additional office permits; illegal use of false, assumed or fictitious name; use of advertising tending to deceive or mislead the public; treatment of patients not of record; aiding and abetting the unlicensed practice of

dentistry; aiding and abetting dental assistants to practice dentistry in a negligent or incompetent manner; requiring or permitting the delivery of dental care that discourages necessary or permits clearly excessive treatment, incompetent treatment, grossly negligent treatment, repeated negligent acts, or unnecessary treatment ...; violations of telehealth statute; and operation of non-permitted mobile dental unit. As of August 30, 2020 the complaint is still open and Dr. Sulitzer remains the Chief Clinical Officer of SmileDirectClub.

Study Limitations

The limitations of this cross-sectional study include a small sample size due to the low response rate. The 20% response rate in this study was lower than the 55.6% average rate expected from academic surveys (Baruch 1999). We found there was a higher reported mean percentage of patients with occlusal discrepancies and periodontal concerns following DTC CAT compared to in-person and conventional fixed appliances. However, due to the small number of responses, were unable to determine significant differences between treatment conditions. Our results demonstrated high variability. The range of reported percentages of occlusal discrepancies, periodontal concerns, and anterior crowding following treatment with DTC CAT was greater than that of the other two modalities. This is most likely due to the small sample size.

Due to the retrospective and cross-sectional nature of our study, we relied on respondents to recall data, so our findings may exhibit recall bias. As the majority of programs reported that they did not (73%) or did not know (9%) if their program kept track of the number of retreatment cases, it is possible that respondents overestimated the percentages of patients seeking retreatment from certain modalities and/or treatment

concerns. In particular, the reported percentages of occlusal discrepancies and periodontal concerns following DTC CAT were higher than that of conventional fixed appliances and in-person CAT. Since DTC CAT is still a novel and controversial treatment modality, it is possible that respondents are more likely to recall patients seeking retreatment following DTC CAT than patients initially treated by conventional fixed appliances and in-person CAT.

Additionally, DTC CAT is a relatively novel treatment modality and only available to the U.S. public since 2014. With DTC CAT companies claiming an average treatment time of six months, our survey may have only captured patients seeking retreatment within the five years prior to our survey administration. According to previously published data, only 39% of patients seeking retreatment were doing so within 5 years of the completion of their initial orthodontic treatment (Ren et al. 2008). In the future, with more patients utilizing the DTC treatment modality and more time elapsing after initial treatment, we predict higher proportions of patients seeking retreatment through the DTC modality.

Furthermore, patients initially treated by DTC CAT and experiencing treatment concerns, like periodontal issues or fractured teeth, may not be seeking orthodontic retreatment at an Advanced Orthodontic Clinic. Instead, patients may seek out retreatment at a private practice Orthodontist, which are more prevalent than Advanced Orthodontic clinics. Additionally, patients with treatment concerns such as occlusal discrepancies and periodontal issues following orthodontic treatment may not seek orthodontic retreatment, but instead visit the general dentist to address those concerns. Our study may under sample the population of patients with these concerns.

Future Investigations

With the growing market for teledentistry amid the Covid-19 pandemic, we anticipate larger numbers of patients utilizing DTC CAT, and consequently a higher proportion seeking retreatment a few years in the future. It will be prudent to continue evaluating retreatment rates and treatment conditions among the various treatment modalities and expand the survey to achieve larger sample sizes. Prospective studies or studies with a population of private practice orthodontic clinics or general dental practices may better capture the treatment conditions after treatment by the various treatment modalities. Furthermore, investigations with access to patients' records could be more accurate than recollected data to capture the severity of the treatment concerns following orthodontic treatment.

CHAPTER 5

CONCLUSIONS

1. The reported proportion of patients seeking retreatment following DTC CAT and in-person CAT was significantly lower than that of conventional fixed appliances.
2. There were no significant differences between reported proportions of patients with treatment outcome concerns including periodontal concerns, occlusal discrepancies, anterior spacing, or anterior crowding by previous treatment modality.

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APPENDIX A

SURVEY TO ADVANCED EDUCATION ORTHODONTIC PROGRAMS

APPENDIX A

SURVEY TO ADVANCED EDUCATION ORTHODONTIC PROGRAMS

Section 1: Program description

1. In what state is your academic institution located?

2. How many new residents are enrolled in your Advanced Education Orthodontic Program each year?

3. What is your role in the Advanced Education Orthodontic Program?

Chair

Program Director

Clinic Director

Office Manager

Other (specify):

[reset](#)

3a. You selected "Other" as your role in the Advanced Education Orthodontic Program. Please tell us what your role is.

[Expand](#)

4. To the best of your knowledge, approximately how many patients sought orthodontic treatment through your Advanced Education orthodontic resident clinic in the last year?

Section 2: Retreatment

The following questions refer to patients seeking **retreatment** through your advanced education orthodontic resident clinic in the last year.

Retreatment is defined as **patients previously completing comprehensive orthodontic treatment at any clinic.**

Please exclude lingual braces, hybrid treatments (comprehensive orthodontics including more than one treatment modality such as combined clear aligner therapy and fixed conventional appliance) and early (phase I) treatments (such as limited anterior orthodontics, expansion, space maintenance, serial extraction, and habit appliances).

5. To the best of your knowledge, what percentage of patients were seeking retreatment of previous orthodontic treatment?

6. To the best of your knowledge, what percentage had the following as their original orthodontic treatment?

Please ensure that the total adds to 100%.

a. Conventional fixed braces
(such as bonded brackets and wires)

%

b. In-person Clear Aligner Therapy
(such as Invisalign, Clarity, Clearcorrect, or In-office manufactured)

%

c. Direct-to-Consumer Clear Aligner Therapy
(such as SmileDirectClub, Candid Co. etc)

%

Your percentage above adds to

[View equation](#)

Section 3: Clinical findings during patient assessment for retreatment

The following questions apply to patients seeking retreatment after they had **conventional fixed braces as their original treatment modality** (such as bonded brackets and wires) in your orthodontic resident clinic in the last year.

7. What percentage had the following diagnoses? (Percentages do not need to add up to 100%)

a. Occlusal discrepancies (such as anterior end to end occlusion or posterior open bite)

b. Periodontal conditions (such as recession or tooth mobility)

c. Anterior crowding

d. Anterior spacing

8. If you would like to add any additional thoughts on retreatment of **conventional fixed braces**, please feel free to do so in the box below:

[Expand](#)

Section 4: The following questions apply to patients seeking retreatment after they had [in-person aligner therapy as their original treatment modality](#) (such as Invisalign, Clarity, Clearcorrect, or In-office manufactured aligners) in your orthodontic resident clinic in the last year.

9. What percentage had the following diagnoses? (Percentages do not need to add up to 100%)

a. Occlusal discrepancies (such as anterior end to end occlusion or posterior open bite)

b. Periodontal conditions (such as recession or tooth mobility)

c. Anterior crowding

d. Anterior spacing

10. If you would like to add any additional thoughts on retreatment of [in-person](#) Clear Aligner Therapy, please feel free to do so in the box below:

[Expand](#)

Section 5: The following questions apply to patients seeking retreatment after they had [Direct-to-Consumer Clear Aligner Therapy as their original treatment modality](#) (such as SmileDirectClub, Candid Co. etc.) in your orthodontic resident clinic in the last year.

11. What percentage had the following diagnoses? (Percentages do not need to add up to 100%)

a. Occlusal discrepancies (such as anterior end to end occlusion or posterior open bite)

b. Periodontal conditions (such as recession or tooth mobility)

c. Anterior crowding

d. Anterior spacing

12. If you would like to add any additional thoughts on retreatment of [Direct-to-Consumer](#) Clear Aligner Therapy, please feel free to do so in the box below:

[Expand](#)

13. Does your orthodontic resident clinic track orthodontic retreatment rate or numbers?

- Yes
- No
- I don't know

[reset](#)

Thank you for completing this survey.

APPENDIX B

REDCAP INITIAL EMAIL TO PROGRAM DIRECTORS

APPENDIX B

REDCAP INITIAL EMAIL TO PROGRAM DIRECTORS

Subject Line:

Reply by 11/13/2019: Retreatment related to 3 ORTHO Treatment Modalities

Dear Program Director:

My name is Kendall Tada, a graduate student in the MS program of Oral and Craniofacial Sciences at UMKC School of Dentistry. I am conducting a research study to better understand orthodontic retreatment for patients who previously had traditional appliances, in-person aligner therapy, or direct-to-consumer aligner therapy. I would appreciate if you could complete the following brief survey regarding retreatments in your Advanced Education Orthodontics program. The information will be used to identify potential associations between retreatments and orthodontic treatment modalities.

This survey will take approximately 10 to 15 minutes to complete.

Please complete this survey by 11/13/2019.

[survey-link]

If you feel that another person in your program is better suited to complete this survey, please forward the survey link below to that person.

<https://is.gd/orthodonticretreatmentsurvey>

Your participation is entirely voluntary and kept confidential. You may skip any questions that you do not want to answer or choose to stop participating at any time. You will not be identified in any reports about this research.

If you have any questions or concerns regarding the research that is begin conducted by a student investigator at UMKC School of Dentistry, please contact me at tadak@umkc.edu.

If you have questions or concerns about your rights as a research participant, you can call the UMKC Research Compliance at 816-235-5927.

Thank you for your assistance in my project. I truly appreciate your time and effort.

Sincerely,
Kendall Tada

APPENDIX C

REDCAP EMAIL REMINDER TO PROGRAM DIRECTORS

APPENDIX C

REDCAP EMAIL REMINDER TO PROGRAM DIRECTORS

Subject Line:

Reply by 11/13/2019 Retreatment related to 3 ORTHO Treatment Modalities

Dear Program Director:

My name is Kendall Tada, a graduate student in the MS program in Oral and Craniofacial Sciences at UMKC School of Dentistry. You should have already received an email from me requesting your help with my thesis project which is focused on orthodontic retreatment for patients who previously were treated with traditional appliances, in-person aligner therapy, direct-to-consumer aligner therapy.

The survey will take approximately 10-15 minutes to complete and will be used to identify potential associations between retreatments and orthodontic treatment modalities.

If you have not completed the online survey, please do so by 11/13/2019. [survey-link]

If you feel that another person in your program is better suited to complete this survey, please forward the survey link below to that person.

<https://is.gd/orthodonticretreatmentsurvey>

Thank you in advance for your time and assistance with my project.

Sincerely,

Kendall Tada

APPENDIX D
IRB APPROVAL LETTER

APPENDIX D

IRB APPROVAL LETTER



Institutional Review Board
University of Missouri-Kansas City

5319 Rockhill Road
Kansas City, MO 64110
816-235-5927
umkcirb@umkc.edu

August 23, 2019

Principal Investigator: Mary P Walker
Department: Dean, School of Dentistry

Your IRB Application to project entitled "RETREATMENT WITH IN-PERSON CLEAR ALIGNER THERAPY, REMOTE CLEAR ALIGNER THERAPY, AND CONVENTIONAL FIXED ORTHODONTIC APPLIANCES" was reviewed and determined to qualify for IRB exemption according to the terms and conditions described below:

| | |
|-----------------------------------|-------------------|
| IRB Project Number | 2016848 |
| IRB Review Number | 252714 |
| Initial Application Approval Date | August 23, 2019 |
| IRB Expiration Date | |
| Level of Review | Exempt |
| Project Status | Active - Exempt |
| Exempt Categories | 45 CFR 46.101b(2) |
| Risk Level | Minimal Risk |

The principal investigator (PI) is responsible for all aspects and conduct of this study. The PI must comply with the following conditions of the determination:

1. No subjects may be involved in any study procedure prior to the determination date.
2. Changes that may affect the exempt determination must be submitted for confirmation prior to implementation utilizing the Exempt Amendment Form.
3. The Annual Exempt Form must be submitted 30 days prior to the determination anniversary date to keep the study active or to close it.
4. Maintain all research records for a period of seven years from the project completion date.

If you are offering subject payments and would like more information about research participant payments, please click here to view the UM system Policy on Research Subject Payments: https://www.umsystem.edu/oei/sharedservices/apss/nonpo_vouchers/research_subject_payments

If you have any questions, please contact the IRB at 816-235-5927 or umkcirb@umkc.edu.

Thank you,
UMKC Institutional Review Board

VITA

NAME:

Kendall Reiko Gum Oi Tada

DATE AND PLACE OF BIRTH:

July 29th, 1992; Honolulu, Hawaii

EDUCATION:

| | | |
|------|---------------------------|--|
| 2010 | Diploma | Hilo High School Hilo, Hawaii |
| 2014 | B.A./Biological Chemistry | Wellesley College Wellesley, Massachusetts |
| 2014 | D.D.S. | University of Missouri-Kansas City School of Dentistry Kansas City, Missouri |

RESIDENCY:

| | | |
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| 2018-2020 | Orthodontics & Dentofacial Orthopedics | University of Missouri-Kansas City School of Dentistry Kansas City, Missouri |
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PROFESSIONAL ORGANIZATIONS:

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| 2018-Present | American Association of Orthodontics, Member |
| 2018-Present | American Dental Association, Member |
| 2018-Present | Omicron Kappa Upsilon, Member |
| 2015-2018 | American Association of Dental Research – Student Research Member |
| 2014-2018 | American Student Dental Association, Member |
| 2014-2018 | Student National Dental Association, Member |
| 2014-2018 | Students Take Action, Member |
| 2014-2018 | Delta Sigma Delta Dental Fraternity, Treasurer, Member |
| 2014-2017 | UMKC Association of Women Dentists, Vice President, Member |

SELECTED HONORS:

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| 2018 | American Association of Orthodontists Award |
| 2018 | American Academy of Oral and Maxillofacial Pathology Award |
| 2017 | Omicron Kappa Upsilon Award |
| 2015-2016 | UMKC Top Scholar Award |
| 2014 | Phi Beta Kappa Honor Society |
| 2014 | Sigma Xi Scientific Research Society |
| 2014 | Doctor Leila C. Knox Prize in Biology Award |

