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INVISALIGN FIRST: A QUALITATIVE STUDY ON THE PERCEIVED BENEFITS AND DRAWBACKS OF INVISALIGN FIRST AS A TREATMENT MODALITY FOR MIXED DENTITION PATIENTS

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PREVALENCE OF SHORT ROOT ANOMALY IN PATIENTS SEEKING ORTHODONTIC TREATMENT

by

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ABSTRACT

Given the recent implementation of Invisalign First for early interceptive orthodontic treatment, a limited number of orthodontists have had experience with this treatment modality and there currently are no published studies on the topic. The present study aims to use a qualitative survey to identify common themes in providers' perceptions of Invisalign First as a new treatment option for early interceptive orthodontics. Twenty-three orthodontists in the private practice sector voluntarily participated in an open-ended survey via email. The results of the survey indicate the following common themes in regards to benefits of Invisalign First: fewer emergencies, patient comfort, patient experience, patient happiness, ability to correct multiple things at once, and arch development. Some of the commonly cited drawbacks of Invisalign First are the following: attachment bonding issues, poor retention, and cost. Overall, all participants except for two (of twenty three) will continue to offer Invisalign First in some capacity. Seventeen participants spoke favorably of the treatment modality and would recommend Invisalign First to other providers. The results of this study provide a framework from which a more robust survey can be constructed. The intent of the future study is to gather and synthesize orthodontists' perceptions based on experience with Invisalign First in a way that readers can constructively evaluate the potential for this treatment modality in their orthodontic practices.

INTRODUCTION

One of the most controversial aspects of orthodontics is the decision to treat patients in the mixed dentition rather than waiting to treat patients in one comprehensive phase once all permanent teeth have erupted. Numerous studies have been conducted to determine the ideal time to start treatment, but like many controversial topics in orthodontics, no final conclusion regarding ideal treatment timing has been reached. Furthermore, there are many conflicting opinions about the best treatment modality for early interceptive orthodontics.

Invisalign First, Invisalign's new technology and treatment modality for early interceptive orthodontics, presents orthodontists with a new treatment option to consider when evaluating patients in the mixed dentition. The decision to implement Invisalign First into practice is multifactorial and compounded by an already controversial topic of implementing interceptive orthodontic treatment regardless of treatment modality.

Due to the very recent development of Invisalign First, relatively few orthodontists have committed to incorporating this treatment modality into their armamentarium. Perhaps orthodontists are fearful that Invisalign First will not achieve clinical treatment goals or will not support practice management in financially beneficial manner.

Given the vast unknown and minimal experience with this new technology, the purpose of this study is to further explore orthodontists' perceptions of Invisalign First. The intent is to understand the potential benefits and drawbacks of this treatment modality to provide preliminary guidance to those considering

adopting this technology. This initial qualitative study of perceptions of Invisalign First will provide the framework for developing a quantitative study, which will ultimately serve to guide evidence-based decision-making processes for implementing Invisalign First into practice.

Performing this initial survey fulfills a key step in creating a validated survey. In analyzing the responses provided, it has become clear which topics need further development. In terms of collecting data, it will be important to obtain more demographic information that will be relevant in terms of analyzing the impact of Invisalign First in relation to the type of practice that is offering the treatment modality. In order to better understand the clinical and non clinical benefits and drawbacks of Invisalign First, the future study will be comprised of questions with close-ended questions with answer options based on results from the initial survey.

REVIEW OF THE LITERATURE

Traditional early interceptive orthodontic treatment modalities will be discussed with a thorough review of clinical capabilities, efficiencies, and drawbacks. Non-clinical aspects of traditional mixed dentition will be reviewed to further understand the decision to offer two-phase orthodontic treatment. As potential pitfalls of traditional mixed dentition treatment are elucidated, the areas of improvement of early interceptive treatment in terms of efficiency and efficacy will be explored.

Advocates of early interceptive orthodontics cite a number of benefits including: crowding resolution and creation of space (Moyers et al), greater insurance against extraction treatment (B.F Dewel, Brennan, Arvystas 98), reduction in the complexity of later treatment (Tulloch, Dugoni, Popovich, Ackerman, Vakiparta, Mirabelli et al, Jolley et al), positive psychosocial impacts (Dann et al, Tung) and better patient

compliance (King). Each of these benefits of early interceptive orthodontic treatment will be examined in greater detail to provide the reader with a more thorough understanding of the support for incorporating early interceptive orthodontics in practice.

As the case is made in support of early treatment orthodontics, it is important to consider the drawbacks of traditional early interceptive orthodontic treatment. One of the most common treatment protocol for early interceptive orthodontics is upper 2x4 fixed appliances along with a lower lingual holding arch. Though this may be an effective treatment modality, patients must be seen in office with high frequency for routine appliance adjustments in addition to the increased likelihood of emergency visits associated with early interceptive traditional orthodontic treatment. Inefficiency of early interceptive orthodontics in terms of practice management may indeed be a barrier to implementation of a two-phase treatment protocol. Furthermore, fixed appliances in children of all ages have and will continue to be problematic in terms of patient hygiene.

For the orthodontist that is interested in taking advantage of the benefits of early interceptive orthodontic treatment, but is concerned about clinical inefficiencies, frequent emergencies, and poor oral hygiene, there may be a preferable treatment modality: Invisalign First. Clear aligners have been an effective and efficient treatment for adult and teen patients for many years now. Furthermore, the biomechanics and functionality of Invisalign First mirror that of traditional interceptive orthodontic treatment modalities such as finger spring Hawley's, lower expansion arches, and Crozat appliances. The similarities in function of these appliances with Invisalign First make it easy for providers to implement and utilize Invisalign First as a treatment alternative with similar functionality. Clear aligners provide an esthetic and comfortable treatment experience, facilitate oral hygiene, cause less pain as compared to fixed orthodontic appliances, reduce the number and duration of appointments, and require less emergency visits (Fujiyama and Miller).

Given the reported benefits of clear aligners in teens and adults, the introduction of Invisalign First as a clear aligner option for patients in the mixed dentition is a promising development. Key findings in the present literature about clear aligner treatment will be discussed to provide a case to extrapolate the benefits and potentially apply them to mixed dentition treatment.

Mixed Dentition Malocclusions

Some of the most common principles of early intervention are the elimination of primary etiologic factors if possible. Treatment goals include the elimination of occlusal discrepancies such as unilateral, bilateral posterior crossbites (Baccetti), anterior crossbite, and correction of skeletal dysaplasia (Tulloch). Early intervention is recommended for resolution of crowding as spontaneous relief of mandibular anterior crowding is unlikely after lateral incisors have erupted (Moorees). Dr. Gerald Nelson, in a brief published in the AJODO, provides a succinct list of some of the primary indications for early interceptive treatment. His list includes: craniofacial anomalies, posterior and anterior crossbites, greater than 8mm overjet in females, maxillary midface deficiency, moderate crowding that would benefit from saving E space, crowding problems that put the gingival soft tissue support at risk, congenitally missing teeth requiring creative treatment planning, management of supernumerary teeth, some midline discrepancies, and habits (Nelson).

Mixed Dentition Maxillary Arch Treatment: 2x4 Appliance

One of the more readily accepted modalities of early interceptive orthodontic treatments is the 2x4 appliance. A typical 2x4 appliance includes brackets bonded to the upper four incisors in addition to bands cemented on first molars. Continuous archwires are used to provide or maintain good arch form and control of the incisors (Dowsing & Sandler). The appliance is activated using vertical and/or transverse bends in the wire between the incisors and the molars (Isaacson). This type of treatment has the ability to address alignment issues in all three dimensions (steps, rotations, and torque). The 2x4 appliance offers a high level

of control of translational movement and in the presence of rotations, is superior to a removable appliance in order to allow full alignment of the labial segment (Loli).

Beyond the ability to translate and rotate teeth with the 2x4 appliance is one of the major advantages of the appliance to address impacted or ectopic incisors. This appliance holds the possibility to control the force magnitude and vector with much more precision than with a removable appliance (Dowsing, Mckeown, Wiedel). Furthermore, it is a particularly appealing treatment modality with no associated lab fee. The cost of four brackets, two bands, and archwires is very minimal in comparison to the cost of a lab-fabricated appliance.

The functional and cost-effective aspects of the 2x4 appliance in addition to the esthetic outcome of improving incisor alignment makes the 2x4 appliance an appealing choice for orthodontists incorporating early interceptive orthodontics into practice.

Mixed Dentition Maxillary Arch Treatment: Maxillary Expansion

Approximately 7% of children in the American population have a crossbite, and based on the inability of crossbites to self-correct, the prevalence of crossbites in the adult population increases to 9.5% (Proffit). Maxillary expansion is a widely accepted procedure performed to correct posterior crossbites and transverse maxillary deficiency. Furthermore, early treatment characterized by maxillary expansion has the benefit of addressing the deficiency prior to the closure of midpalatal sutures. This type of early treatment has the potential to decrease the likelihood of extraction treatment in the permanent dentition (Arvystas).

Maxillary expansion has been proposed as one method to address impacted canines, since it has been found that transverse maxillary deficiency may be associated with both labially (Mitchell 2007) and palatally impacted canines (McConnell et al & Schindel et al). Based on these findings, Baccetti et al. conducted a randomized clinical trial in which they found that the use of rapid maxillary expansion in early mixed dentition is an effective procedure to increase the rate of eruption of palatally displaced maxillary canines when compared with an untreated control group

Mixed Dentition Mandibular Arch Treatment: Lower Lingual Arch

In the mixed dentition, maintaining the leeway space to preserve arch length can often provide adequate space to resolve lower incisor crowding. According to Moyers et al, as much as 4.8mm of space can become available as the permanent canines and premolars replace their primary successors (Moyers at al). Without intervention, lower molars will drift into the leeway space and arch length decreases (Moorees et al). Several studies have indicated that a passive lower lingual arch appliance serves to maintain this space and allow resolution of lower incisor crowding in many cases (Singer, DeBaets & Chiarini, Dugoni et al., Brennan & Giannelly). The lower lingual arch is therefore a commonly used appliance in early interceptive treatment as a means to resolve lower incisor crowding. The fundamental notion of preventing lower molars from mesial drift is a useful concept in developing early interceptive treatment plans and deciding whether or not to intervene orthodontically during the mixed dentition phase.

Mixed Dentition Mandibular Arch Treatment: Crozat Appliance and Schwarz Appliance

Lower arch crowding is a very common malocclusion that can be treated with positive outcomes in mixed dentition. If dental arch expansion is performed in actively growing children, favorable results can be expected, such as a simplification of the second phase of full-fixed treatment and a reduction of the potential need for tooth extraction or even orthognathic surgery (Shen et al. 2020). In most cases of mandibular crowding or decreased transverse width, the deficiency is dental rather than basal—the posterior

dentition has a lingual inclination (McNamara 2000, Handelman 2012). Therefore, mandibular arch widening is due primarily to expanding and uprighting of the mandibular posterior teeth.

One approach to lower expansion is by using the crozat appliance. In a study evaluating treatment effects and short-term relapse of maxillomandibular expansion during the early to mid mixed dentition, Varo et al. found that a mandibular banded Crozat/lip bumper produced clinically useful increases in arch dimensions. Clinically significant net changes in arch width were maintained, net gains in arch perimeter were produced, and incisor irregularity increased only slightly in the short-term post retention period (Vargo et al. 2005). In addition to the crozat appliance, the Schwarz appliance may be used to obtain mandibular arch expansion. O'Grady et al. found that the mandibular Schwarz appliance resulted in significant increase in transverse width of the mandibular arch perimeter and uprighting of the mandibular posterior teeth buccaly. Wendling et al. also found the Schwarz appliance to prevent mesial movement of lower first molars, indicating its function as a space maintainer on the lower arch (Wendling et al. 2004).

Mixed dentition: Class II and Class III correction

A class II malocclusion is one of the clinical presentations that often prompts orthodontists to provide early interceptive treatment. Though there are a number of different modalities to approach class II correction in the mixed dentition, the most relevant in the context of this study is to evaluate the Twin-block appliance as it is a removable appliance. Both Tulloch et al. and O'Brien et al. found evidence to support the effectiveness of the appliance to successfully reduce dental overjet, molar discrepancies, and severity of malocclusion (Tulloch et al. & O'Brien et al. 2003). The findings in both of these studies indicate that improvement of the Class II malocclusion was due to primarily dentoalveolar changes with a small element of favorable skeletal change.

Interceptive Orthodontics and Risk of Trauma

As traumatic dental injuries are one of the most prevalent diseases globally, it is certainly of interest to incorporate preventing orthodontic treatment to mitigate this risk in high-risk children. Arraj et al found that there is an association between increased overjet and dental trauma. A child in the primary dentition could be considered as having an overjet at risk for trauma when it is greater than or equal to 3mm. Therefore, it is advantageous to treat these patients in the mixed dentition to prevent dental trauma (Arraj et al & Batista et al). Though the present literature is inconclusive in regards to the supported validity of orthodontics as a means to trauma prevention, it remains to be a potential motivator for initiating orthodontic treatment in the mixed dentition.

Interceptive Orthodontics and psychosocial impacts

By the age of 6 years, children have internalized cultural values of physical attractiveness. By age 8 their criteria for attractiveness are the same as those of adults (Cavrio & Lombardi). A teacher's perceptions of a child's attractiveness can influence the teacher's expectations and evaluation of the child (Kayak & Bell). Children perceived as more attractive are not only more socially accepted by their peers, they are also believed to be more intelligent and to possess better social skills. In addition, people perceived as attractive by their peers are considered more desirable as friends than are unattractive people (Vander Zanden). Furthermore, numerous studies have indicated that malocclusions, specifically excess overjet, are key contributors to bullying among children (Al-Omari, Artese). Each of these areas of concern have an impact on children in the mixed dentition age group and should certainly be a contributing factor in deciding whether or not to initiate treatment in this age group. As with the risk of trauma as an indication for early interceptive treatment, the literature is inconclusive. However, many orthodontist continue to offer early interceptive treatment with the consideration that it has the potential to have psychosocial impacts on young patients.

Invisalign: Treatment outcomes

Invisalign has the capacity to serve as a viable treatment option for a number of malocclusions. The efficacy of Invisalign as a treatment modality has been studied in a variety of capacities and settings to indicate that it serves to accomplish many common goals in orthodontic treatment planning. One positive clinical aspect of orthodontic treatment with Invisalign is that is has been shown to have shorter treatment times in mild non-extraction cases (Tang et al. 2017, Grunheid et al. 2016, Djeu et al. 2005). Since its implementation, Align technology has made advances in Invisalign treatment to obtain better treatment outcomes, those of which can be observed in more recent studies. For example, in a study by Krieger et al. Invisalign treatment successfully accomplished the resolution of anterior crowding and found that achieved tooth movement was in concordance with predicted movement for all parameters except overbite (Krieger et al. 2012). In addition, a study by Simon et al. showed that bodily movements such as molar distalization, incisor torque, as well as premolar derotation can be accomplished using Invisalign (Simon et al. 2014). In terms of evaluating the ability of Invisalign to effectively treat the vertical dimension, Khosravi et al. found that in the majority of patients treated with Invisalign, their deep bite was corrected to normal overbite values (Khosravi et al 2017). Khosravi's findings contrasted to prior studies (such as the one by Krieger et al) that suggest difficulty in Invisalign's ability to correct deep bites. As the literature on clinical efficacy of Invisalign continues to develop as the technology advances, it behooves the practitioner to continue to delve into the latest research especially in regards to Invisalign.

Invisalign: Benefits beyond treatment outcomes

There have been a number of proposed benefits of Invisalign beyond clinical outcomes. One of the commonly sited rationale in favor of aligner treatment is that is a more comfortable orthodontic treatment modality. One aspect of the decreased level of pain is that aligners are a removable appliance. According to a study by Sergle, fixed appliances resulted in a significantly higher pain level than removable appliance. Higher values of the intensities of pressure, tension, pain, and sensitivity of the teeth were reported in patients treated with fixed appliances in contrast to those wearing functional appliances (Sergle HG).

Furthermore, Miller found that aligners cause much less patient discomfort compared to fixed appliances for mucosal irritation, soreness of the teeth, and several other areas of potential discomfort usually experienced by patients during orthodontic treatment with fixed appliances (Miller).

In addition to patient comfort with clear aligner treatment, there are observed benefits to enamel and periodontal health. Fixed appliances lead to increased plaque accumulation and reduced oral hygiene during orthodontic treatment (Balenseifen), which have clear deleterious effects on dental and periodontal health. In Azaripour's study, it was found that adolescent and adult invisalign patients have significantly better gingival when compared to those in fixed appliance treatment (Azaripour 2015). Beyond the inherent benefit of less plaque accumulation with a removable appliance such as Invisalign, Teenagers treated with removable appliances display better compliance with oral hygiene, less plaque, and fewer gingival inflammatory reactions than their peers with fixed appliances (Abbate et al). In terms of benefits beyond oral health and clinical outcomes, patient satisfaction of treatment with Invisalign is shown to be greater when compared to orthodontic treatment with fixed appliances.

Based upon the vast existing literature on the topics of early interceptive orthodontic treatment and Invisalign as an appliance, there are a number of reasons to support an endeavor in evaluating the two topics merged into the new treatment modality that is Invisalign First. As orthodontists consider implementing Invisalign First into their armamentarium as a possible treatment in early interceptive orthodontics, it is of value to provide an analysis of provider perceptions based on experience with the treatment. The intent of this study is to serve as the first step in creating a survey that will yield results that enable orthodontists to appropriately consider the potential benefits and drawbacks of Invisalign First in private practice.

MATERIALS & METHODS

The basis for developing a questionnaire based study was to gather data about opinions and beliefs on a relatively new technology that cannot be directly observable. The Association for Medical Education in Europe (AMEE) published an article outlining seven specific steps to create a high quality survey. The steps are as follows: (1) conduct a literature review, (2) carry out interviews and/or focus groups, (3) synthesize the literature review and interviews/focus groups, (4) develop items, (5) collect feedback on the items through an expert validation, (6) employ cognitive interviews to ensure that respondents understand the items as intended and (7) conduct pilot testing (Artino et al. 2014). The present study is comprised of the first four steps in this process with the intention of next creating a validated survey.

This study was approved by the Institutional Review Board at the University of the Pacific in Stockton, California (IRB protocol review number 20-86). Data was collected from survey responses from collected from 23 orthodontists practicing orthodontics in a private practice setting. Inclusion criteria was only that the individual had started at least one Invisalign First case. Participants were recruited via email after obtaining contact information via word of mouth and from private Facebook groups of orthodontists. Recruitment of volunteers via Facebook groups and word of mouth recruitment enabled a broad reach of participants that was not geographically restricted. By providing survey via email, a larger representation of opinions was obtained to collect data that reflect a wide variety of demographics. Logistically speaking, doing in-person interviews or phone interviews would severely limit the accessibility to data as the target participant would be less likely to take the extra time and effort involved. Though there are inherent biases and shortcomings with incorporating an email survey via word of mouth and Facebook posts, the benefit of reducing barriers to obtaining data far exceed the drawbacks of this method of recruitment.

Participation in the survey was voluntary. Participants were emailed a cover letter providing background information and contact information for the investigator. The format of the survey was an open-ended questionnaire distributed as a google sheet. Responses were collected anonymously and organized in an excel spreadsheet.

The specific questions that made up the questionnaire were designed to first gather relevant information and a baseline for understanding the context of the subsequent answers. The first questions aim to decipher how prevalent aligner treatment already is in the respondent's practice. In order to appropriately evaluate responses to the survey, it is helpful to understand if the practice is already structured in a way that lends itself to implementing additional aligner treatment or if the practice is not entirely adjusted to cater to aligner treatment. The answers to the first questions give an indication if the later responses are related to an existing practice management framework. Subsequent questions were then focused on differences in perceived benefits and drawbacks in comparison to observed benefits and drawbacks. The survey concluded with an opportunity for participants to give a free response answer to summarize their experiences and thoughts they would like to share.

RESULTS

Of the 36 orthodontists that were contacted individually from the aforementioned recruitment process, 23 individuals provided responses to the survey, which yielded a response rate of 63.9%. Based on the limited amount of published research on the topic of Invisalign First and the generalized, open-ended questionnaire, it was predicted that there would be common themes that would be evident with even a smaller sample size. The method of recruitment of participants ensured that the reach of the survey would surpass geographical barriers and offer a wide array of responses without the potential geographic limitations of an in-person study.

The earliest adopter of Invisalign in any capacity started using the technology in 2000. In contrast, the most recent adopter of Invisalign started using Invisalign in late 2019. Five respondents failed to provide the start date in which they began using Invisalign. Of those that provided an answer to this question, the average year in which they adopted Invisalign in private practice was 2010. Of the 17 respondents that provided the

date in which they first started using Invisalign First, the earliest adopter started his/her first case in November of 2017. Given that Invisalign First only became available to all providers on July 1st, 2018, this early adopter in addition to one other respondent had to have been part of the limited market release program offered by Invisalign to a small subset of selected providers. These individuals were given the opportunity to use Invisalign First prior to the public release.

Individuals were asked what percentage of their practice is comprised of aligners (vs. fixed appliances). The range of responses spanned from 20%-95%. Based on all 23 responses, the average reported percentage of aligners in practice was 44.78%.

Participants were asked to explain what prompted them to implement Invisalign First into practice. Three of the respondents indicated that their positive experience with Invisalign in general for teens and adults was the primary reason they wanted to try Invisalign in their practices. Similarly, one individual cited "convenience" as the reason for trying Invisalign First. Of the 23 responses to this question, the notion of "fewer emergencies" was mentioned four distinct times. Another common reason for implementing Invisalign First was the influence of another individual. One respondent cited the Invisalign Summit as the motivator. Two others noted that other doctors' experience prompted their interest in using Invisalign First. The fourth individual of this group noted that an Invisalign sales rep encouraged him/her to try Invisalign First. Two of the individuals cited the Mandibular Advancement feature as the reason for trying Invisalign First. Two individuals indicated that there was a demand from patients and parents for aligner therapy in the mixed dentition. Only one individual cited "esthetics" as a driving factor. Some of the other responses indicated case-specific rationale such as: "patient could not tolerate braces" and "I wanted to try it on my son."

As the inclusion criteria specified, individuals were invited to participate in the study as long as they had started at least one Invisalign First case—there was no requirement to have completed a case with Invisalign First. Of the 23 individuals that responded, two of them had not completed any cases. Nineteen of the participants had completed 10 or fewer cases. The average number of completed cases was 8.52. Outliers in this data are seen in responses indicating 24, 40, and 50 completed Invisalign First cases.

Participants were provided an opportunity to discuss the benefits they observed during treatment with Invisalign First. Individuals were not limited in the number of benefits they could report. Of the 23 responses, the words “emergency,” “emergencies”, or “repair” were mentioned 13 times. Of those, 6 participants indicated “no emergencies/repairs” and 7 indicated “fewer emergencies.” Another commonly reported benefit was improved oral hygiene, which was mentioned 8 times. Five individuals reported that patients had “better compliance.” Falling under the category of patient experience, “patient comfort” was mentioned 5 times in addition to “patient/parent happiness” mentioned 3 times. In addition to the aforementioned common responses, providers listed specific positive clinical outcomes including: “AP correction” (3 responses), “arch length/development” (3 responses), and “expansion” (3 responses). Two participants indicated that one of the benefits they observed was the ability to correct multiple issues simultaneously. Of the 23 total responses, only one participant indicated that there were no benefits observed. When evaluating expected benefits with observed outcomes, 14 of the 23 respondents indicated that expectations were met or exceeded. Five participants indicated that observed benefits were less than expected. Two of the participants did not appropriately answer the question.

Participants were asked to describe drawbacks of Invisalign First treatment. As with the question regarding benefits, individuals were not limited in the number of drawbacks they could report. One of the most common drawbacks was the inability of Invisalign First to achieve skeletal expansion and the need for

additional appliances to meet these treatment goals, which was cited by five participants. Some of the other common drawbacks were “poor retention” (6 responses) and “attachment bonding” issues (3 responses), which participants indicated were likely due to anatomy of primary teeth and structure of the trays that are adapted for small crowns, unerupted teeth, and partially erupted teeth. Similarly, 4 individuals indicated that “timing” and “eruption” were drawbacks to this treatment modality. Three individuals also reported the need for multiple refinements and longer treatment as a drawback. Beyond clinical outcomes, 5 responses indicated the cost of treatment to be a drawback. Five responses indicated that compliance was another area of concern. Two individuals described the need to “convince” or “coach” patients and parents to start and follow through with treatment as a drawback. Of the 23 responses, 8 participants indicated that the drawbacks were significant enough to deter them from doing utilizing Invisalign First as a treatment modality. Fifteen of the participants plan to continue using Invisalign First despite mentioned drawbacks.

Given their perceptions of Invisalign First, participants were asked how they would proceed with this treatment modality in the next year. Twenty one of the twenty three respondents indicated that they would continue to offer Invisalign First in at least some capacity. Of those 21, 6 individuals plan to actively increase the number of patients they treat with Invisalign First. Of the 21 that will continue to offer Invisalign First, 6 indicated that they plan to use Invisalign First in a limited capacity (i.e. for certain clinical presentations or treatment goals). Of the two individuals that do not necessarily plan to offer Invisalign First, one individual cited high lab fee as the barrier and the other indicated that further guidance on technique for attachment placement would be necessary to utilize this treatment modality.

The final question of the survey provided participants an opportunity to write a sentence to their colleagues about their experience with Invisalign First. In the absence of prompting, respondents confirmed what they had already identified in the previous targeted survey questions. Several domains of interest from this

specific open-ended question can be drawn. One of the common themes reiterated in this section was that the cost of Invisalign may be a prohibitive factor, but that ultimately most participants would recommend trying this treatment modality despite this drawback. Another common theme of the responses was that the benefits and success of Invisalign First are case specific and that it should be used as a "tool" for the right patients. Overall, 17 of the 23 respondents spoke optimistically of Invisalign First. The other 6 participants had a more cautionary tone to their responses.

DISCUSSION

As outlined in the methods of survey design, one of the important data points to gather initially was an indication of the type of practice in which each of the respondents performs treatment. For practices that operate with a high percentage of fixed appliance treatment, integrating clear aligner treatment such as Invisalign, can be cumbersome in a number of ways. For practices that use Invisalign at a limited capacity, the lab fee is significantly higher. As of January 1, 2020 the lab fee for dual arch Invisalign First treatment is $1,179. The Invisalign Advantage Point system rewards high volume Invisalign users by providing incremental discounts that go as high as 40% off for providers starting at least 200 comprehensive cases in a 6 month period. It is also significant to note that the Advantage Points for Invisalign First are only half that of comprehensive cases, so providers would have to do twice as many Invisalign First starts to provide the Advantage Point equivalent of a comprehensive case.

In addition to a higher lab fee for Invisalign treatment, integrating this treatment modality involves a completely different skill set for orthodontic staff. In a practice that does not treat many cases with Invisalign, the staff may not have a streamlined approach to obtaining records (scanning), patient coaching, and delivering the appliance. Invisalign delivery and follow up appointments may even be viewed as a disruption to the flow of practice in a low-volume Invisalign practice. Conversely, practices that maintain a high number of Invisalign cases are more likely to have systems in place to streamline all aspects of

Invisalign treatment. Though there is no published statistic on the percentage of Invisalign or aligner use in private practice orthodontic offices, it seems significant to note that the average percentage of Invisalign use in respondents was 44.78%. Understanding that the respondents mostly had high percentage Invisalign practices, it is not surprising that these providers would be more willing to try Invisalign First and more optimistic about the treatment modality. Furthermore, as previously mentioned, the barriers to implementing Invisalign First are much lower in high volume Invisalign practices in terms of lower lab fees and ease of integrating into current practice systems. In reference to the present study, it was mentioned repeatedly that providers were interested in offering Invisalign First based on their success with implementing Invisalign for teens and adults. The respondents are inherently more likely to have a more optimistic view of Invisalign First in comparison with those practices that are not as adapted to clear aligner therapy in general.

The present study did not prompt participants to provide information about the percentage of their practices that is comprised of early interceptive treatment in general. In the next study, it will be important to establish the likelihood of respondents to treat early interceptive orthodontic cases with any treatment modality. It would be of interest to discern whether or not Invisalign First has the potential of expanding this sector of patients in treatment or if Invisalign First is more likely to be a replacement for traditional treatment modalities.

In order to develop a better understanding of the impact of current practice systems on implementation of Invisalign First, the next step in surveying participants will include questions such as the following:

- What percentage of your practice is currently treated with Invisalign (excluding other aligner treatment options)?
- What percentage of your practice is made up of early interceptive orthodontic treatment?

- Have you increased the percentage of early interceptive orthodontic treatment in general by adding Invisalign First as a treatment modality? In other words, are you treating cases with Invisalign First that you would have considered not treating without the appliance?
- Which Invisalign provider tier does your practice fall under? In other words, what percentage of a discount are you currently receiving on your Invisalign lab fee?

Given the relatively short period of time in which Invisalign First has been publicly available for use, it is not surprising that the respondents have completed relatively few cases with this treatment modality. Despite the low volume of data from which the providers have to draw from, prompting providers to reflect upon their experience with these cases helps to provide feedback for developing a future validated study. Based on the amount of time that will have lapsed between initial distribution of this foundational study and the validated study, it is likely that not only will participation in the study increase, but also that participants will have greater data to draw from (i.e. a greater number of started cases and a greater number of completed cases).

Generally speaking, respondents cited more benefits than drawbacks overall in terms of number of benefits listed in the free response prompt. As previously discussed, the type of setting in which respondents practice in and the inherent bias in the population pool, likely primed participants to have more favorable experiences. In addition to citing more benefits of Invisalign First, most respondents noted that the observed benefits aligned well with their perceived benefits. In other words, for the most part, providers were largely not disappointed by observed outcomes. Despite inherent potential bias, it is worth noting the specific nature of the cited benefits as these outcomes would not necessarily be attributed exclusively to aligner-heavy practices.

Several participants mentioned specific desirable clinical outcomes, such as the ability to correct multiple issues at once. Though the respondents did not elaborate upon this statement, an understanding of early interceptive treatment goals in general indicates that providers may use Invisalign First to address problems in various locations and dimensions (i.e. anterior, posterior, maxillary, mandibular, first order,

second order, third order, vertical, and sagittal). For example, Invisalign First enables the correction of a single tooth anterior crossbite, while also addressing lower crowding, anterior torque, class II, and a deep bite. In comparison, traditional early interceptive treatment to address each of these issues would necessitate the use of multiple appliances (Hawley with a bite plane and finger spring, a removable functional appliance, braces, and/or a lower expansion appliance) to correct each of these problems. Furthermore, the desire to correct a single tooth anterior crossbite stems from a need to address gingival tissue damage, in which case, Invisalign First may be a superior appliance in that clear aligners are associated with less gingival inflammation when compared to fixed appliances (Boyd 1989). The ability of Invisalign First to more efficiently address multiple issues simultaneously is an appealing aspect of the modality and should be explored in greater detail in the next survey.

It is interesting to note that many of the repeated responses in regards to observed benefits were non-clinical outcomes (i.e. fewer emergency visits, patient comfort, patient happiness, and improved oral hygiene). Though some respondents cited favorable clinical outcomes, the majority of positive outcomes were related to the aforementioned non-clinical aspects. In interpreting this data, it is important to consider again the small population that was assessed and that these results are an indication of how to construct a validated questionnaire to more accurately assess provider experiences with Invisalign First. Positive non-clinical outcomes are significant from a practice management point of view and can undoubtedly drive provider decisions in terms of adopting new technologies in practice. Expanding upon both non-clinical and clinical outcomes in a future study will provide a more clear framework for interested providers to evaluate the potential benefits of Invisalign First in their practices.

The next step to further exploring the observed benefits of Invisalign First treatment will likely include some of the following more targeted questions that we created based off the responses from the initial study:

- On average, for patients you treated with Invisalign First, what was the primary alternative: no treatment or traditional early interceptive orthodontic treatment?

- On average, on a scale of 1-5, how compliant are Invisalign First patients with aligners?
- What percentage of your treatment goals are met with Invisalign First treatment?
- In comparison to traditional early interceptive orthodontic treatment, how satisfied, on a scale of 1-5, are patients and parents with Invisalign First treatment?
- Have you seen practice growth as a direct result of offering Invisalign First as a treatment option?
- Have you seen financial growth (or loss) as a direct result of offering Invisalign First?

In assessing providers' perceived drawbacks of Invisalign First, it is evident that a larger percentage of the outcomes noted are clinical outcomes (i.e. aligner fit, retention issues, and skeletal outcome limitations). The prevalence of repeated common themes with this question provide a clear indication for structuring future questions that probe these issues in a quantitative fashion. One of the commonly cited drawbacks had to do with poor retention and increased need for refinements. It will be interesting to assess how prevalent this issue is as providers try more cases and the technology develops. At this point it is unclear if retention and aligner fit/tracking are due to user error (treatment plan design or delivery of the appliance) or due to software shortcomings. Both of these potential sources of unfavorable outcomes may potentially improve with time as the software develops and providers gain experience with the technology. Another point to consider is to take into account the types of malocclusions providers choose to address with Invisalign First. For those providers using Invisalign First to treat more challenging malocclusions, the clinical outcomes may not be as favorable as those more mild cases. Case selection indeed is a critical component of evaluating the technology and as a future study is developed, it will be important to distinguish case selection as it pertains to clinical outcomes. The validated survey will likely be more robust in data supporting both the prevalence and severity of clinical issues as they pertain to a variety of malocclusions. The following questions will support this endeavor:

- Which clinical presentations are not suitable for treatment with Invisalign First?
    - For those clinical presentations not suitable for treatment with Invisalign First, would you be able to address the concern with braces?

    - Which particular malocclusions have you observed to be treated more effectively with braces in comparison with Invisalign without the use of auxiliary appliances?
- Have any of your Invisalign First patients switched to traditional early interceptive treatment? Why?
- How often do you need to order a set of warranty fit aligners due to poor fit or retention or aligners?
- How many refinements are needed on average?
- How would you rate patient compliance on a scale of 1-5?
- If you were unsatisfied with the clinical outcome of treatment with Invisalign First, do you believe fixed appliances (i.e. braces) would have better achieved your treatment goals?

In addition to clinical shortcomings of Invisalign First, several providers cited cost to be a drawback and deterrent for treating more cases with this treatment modality. Again, the cost associated with this treatment is dependent upon how much Invisalign in general the practice is doing. As previously mentioned, the Advantage Point discount can be as high as 40% for high volume Invisalign practices. This difference is substantial in evaluating cost as a contributing factor for evaluation of a new technology. Another aspect of the evaluation of cost of a treatment modality is to consider the cost of chair time or doctor time. As cost was cited frequently, it may be worthwhile to prompt respondents to consider the cost of chair time and doctor time to see if there may be an offset in overall cost that perhaps they did not consider initially when responding to the question and evaluating drawbacks. Participants repeatedly indicated fewer emergency visits as a benefit to Invisalign First, which should also be taken into consideration in the overall financial analysis of this treatment modality. In terms of the perception of cost, it would also be beneficial to ask respondents to compare the average cost of traditional early interceptive treatment with Invisalign First to provide a more clear picture of the cited difference in cost.

To elaborate further on the questions targeted at understanding the participant pool, the following questions would provide a more clear picture of the financial impact of incorporating Invisalign First into practice:

- What is your average lab fee for traditional early interceptive treatment?
- How many office visits are associated with traditional early interceptive treatment? Average number of emergency visits?
- How many office visits are associated with Invisalign First treatment? Average number of emergency visits?
- In comparison to traditional early interceptive treatment, how long is Invisalign First treatment?
- How much are you charging for early interceptive orthodontic treatment?
- How much are you charging for Invisalign First?
- In terms of a cost/benefit analysis, do you see Invisalign First as having a positive impact on your practice?

The discussion above and sample questions reflect a small portion of the details that will be considered as the future study is developed. In reference to the previously discussed paper outlining the seven steps for survey design, the questions that have been crafted as a result of the preliminary study are a part of the fourth step. As the selection of questions posed will be expanded upon and refined, the next part of this step is to select the response options that will be used for each item. Closed ended survey items will have unordered (nominal) response options that have no natural order or ordinal response options. Some survey items will ask respondents to complete a ranking task (i.e. “rank the following items, where 1=best and 6=worst) or a rating task to a posed question. The questions and responses will be tailored to deliver the most robust and clear data set as a result.

Once the survey has been constructed, the next step will be to begin collecting validity evidence based on the survey’s content (AERA, APA & NCME 1999). The significance of this step is to use experts to systematically review the survey’s content to improve the overall quality and representativeness of the scale items (Polit & Beck 2006). Though there is no consensus on the number of experts required for validation, Rubio et. al. recommend using 6-10 experts, while acknowledging that more experts (up to 20) may generate a more clear consensus (Rubio et al. 2003). These experts have the opportunity to assess the survey

and provide feedback on each of the items as they see necessary. Upon review of the survey, experts will give qualitative input in addition to quantitative data to improve the content validity until the final product functions as is it is intended.

The sixth step in the process toward creating the next survey will be to collect evidence of response process validity to assess how prospective participants interpret the items and response anchors (AERA, APA & NCME 1999). One of the methods to collecting such evidence is through cognitive interviewing (Willis 2005). Cognitive interviewing enables survey developers to have a better understanding of survey participants' comprehension of the questions and experience of answering the questions. It is critically important that survey respondents understand each item in the way it was intended by the survey creator.

The final step in the process to creating a survey is to conduct pilot testing. During pilot testing, members of the target population will complete the survey in the same method in which the final study will be distributed. The resulting data will then be reviewed to evaluate range and variance and assess reliability of the survey. Conducting a reliability analysis will likely be done by calculating a Cronbach's alpha coefficient, which is a measure of the internal consistency of the item scores (Schmitt 1996). Beyond reliability, the survey needs to be evaluated to assess uni-dimensionality and internal consistency to ensure that the test is valid (AERA, APA & NCME 1999).

Given the level of detail and analysis that is involved in creating a validated survey, it is clear that the present study of providers' perceptions of Invisalign First is a critical initial step. With such little research and low volume of providers using Invisalign First, it is important to take this first step in gathering data to provide information for a future survey that will reliably produce robust and valid results in such a way that readers can assimilate into their working knowledge of the new technology.

CONCLUSION

Our results indicate that there are a number of key themes in regards to perceptions of Invisalign First that should be explored in a future validated survey. Provider responses in the present study support the notion that there are significant benefits and drawbacks to using Invisalign First as a treatment modality for early interceptive orthodontics. The common themes in perceptions elucidated from this survey provide a framework for creating the next survey. Data from the next survey will enable orthodontists to evaluate Invisalign First as they consider implementing this treatment modality into their armamentarium for early interceptive orthodontic treatment.

REFERENCES

J.L. Ackerman, W.R. Proffit. Preventive and interceptive orthodontics: a strong theory proves weak in practice. Angle Orthodontist, 50 (1980), pp. 75-87

Al-Omari IK, Al-Bitar AB, Sonbol HN, Al-Ahmad HT, Cunningham SJ, Al-Omiri M. Impact of bullying due to dentofacial features on oral health-related quality of life. Am J Orthod Dentofacial Orthop. 2014;146:734–739

American Educational Research Association (AERA), American Psychological Association (APA) & National Council on Measurement in Education (NCME) Standards for education and psychological testing. Washington, DC: American Educational Research Association; 1999.

Arraj GP, Rossi-Fedele G, Doğramacı EJ. The association of overjet size and traumatic dental injuries-A systematic review and meta-analysis. Dent Traumatol. 2019;35(4-5):217-232. doi:10.1111/edt.12481

Artese, F. The orthodontist's reach in bullying. *Dental Press J Orthod. 2019 May 20; 24(2):15-16.*

Artino AR Jr, La Rochelle JS, Dezee KJ, Gehlbach H. Developing questionnaires for educational research: AMEE Guide No. 87. Med Teach. 2014;36(6):463-474.

Arvystas. The rationale for early orthodontic treatment. AJO-DO. Vol 113(1); 15-18, January 1998

Azaripour A, Weusmann J, Mahmoodi B, et al. Braces versus Invisalign®: gingival parameters and patients' satisfaction during treatment: a cross-sectional study. *BMC Oral Health*. 2015;15:69. Published 2015 Jun 24. doi:10.1186/s12903-015-0060-4

Baccetti T, Franchi L, McNamara JA, Tollaro I. Early dentofacial features of Class II malocclusion. Am J Orthod Dentofacial Orthop 1997;111:502-9

Baccetti T, Mucedero M, Leonardi M, Cozza P. Interceptive treatment of palatal impaction of maxillary canines with rapid maxillary expansion: A randomized clinical trial. Am J Orthod Dentofacial Orthop 2009;136:657–61.

Balenseifen JW, Madonia JV. Study of dental plaque in orthodontic patients. *J Dent Res. 1970 Mar-Apr; 49(2):320-4.*

Batista KB, Thiruvenkatachari B, Harrison JE, O'Brien KD. Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children and adolescents. Cochrane Database Syst Rev. 2018;3(3):CD003452. Published 2018 Mar 13. doi:10.1002/14651858.CD003452.pub4

Boyd RL, Oh HS, Fallah M, Vlaskalic V. An update on present and future considerations of aligners. *J Calif Dent Assoc* 2006; **34**(10):793–805.

Boyd RL, Leggott PJ, Quinn R, Eakle WS, Chambers D. Periodontal implications of orthodontic treatment in adults with reduced or normal periodontal tissues vs. adolescents. *Am J Orthod* 1989; **96**:191–8

Brennan M, Gianelly AA. The use of the lingual arch in the mixed dentition to resolve incisor crowding. *Am J Orthod Dentofacial Orthop*. 2000;117:81–85

N Carvior, DA Lombardi. Developmental aspects of judgment of physical attractiveness in children. Dev Psychol, 8 (1973), pp. 67-71

Dann C, Phillips C, Broder HL, Tulloch JFC. Self-concept, Class II malocclusion, and early treatment. *Angle Orthod*. 1995; 65: 411–416

DeBaets J, Chiarini M. The pseudo Class I: a newly defined type of malocclusion. J Clin Orthod 1995;29:73-87

Dewel BF. Objectives of mixed dentition treatment in orthodontics. *Am J Orthod*. 1964; 50:504-520

Dowsin P & Sandler PJ. How to effectively use a 2X4 appliance Journal of Orthodontics, Vol. 31, 2004, 248–258

Dugoni, SA. Comprehensive mixed dentition treatment. Am J Orthod Dentofac Orthop, 113 (1) (1998), pp. 75-84

Fujiyama K, Honjo T, Suzuki M, Matsuoka S, Deguchi T. Analysis of pain level in cases treated with Invisalign aligner: comparison with fixed edgewise appliance therapy. Prog Orthod 2014; 15: 64.

G.J. King, S.D. Keeling, R.A. Hocevar, T.T. Wheeler. The timing of treatment for Class II malocclusions in children: a literature review.Angle Orthodontist, 60 (1990), pp. 87-97

Handelman CS. Adult nonsurgical maxillary and concurrent mandibular expansion; treatment of maxillary transverse deficiency and bidental arch constriction. Semin Orthod, 18 (2012), pp. 134-151

Isaacson RJ, Lindauer SJ, Rubenstein LK. Activating a 2x4 appliance. *Angle Orthod 1993 Spring*; 63(1):17-24

Jolley CJ, Huang GJ, Greenlee GM, Spiekerman C, Kiyak HA, King GJ. Dental effects of interceptive orthodontic treatment in a Medicaid population: interim results from a randomized clinical trial. *Am J Orthod Dentofacial Orthop. 2010 Mar; 137(3):324-33.*

HA Kiyak, R. Bell. Psychosocial considerations in surgery and orthodontics WR Profitt, R White (Eds.), Surgical-orthodontic treatment., Mosby–Year Book, St. Louis (1990), pp. 71-91

Krieger E, Seiferth J, Marinello I, et al. Invisalign® treatment in the anterior region: were the predicted tooth movements achieved?. *J Orofac Orthop*. 2012;73(5):365-376. doi:10.1007/s00056-012-0097-9

R. Khosravi, B. Cohanim, P. Hujoel, S. Daher, M. Neal, W. Liu, *et al.*Management of overbite with the Invisalign appliance. Am J Orthod Dentofacial Orthop, 151 (2017), pp. 691-699.e2

Loli D. The versatility of the 2X4 appliance. WebmedCentral ORTHODONTICS 2017;8(11):WMC00539

Malterud K. Qualitative research: standards, challenges, and guidelines. Lancet. 2001 Aug 11; 358(9280):483-8.

McNamara JA. Maxillary transverse deficiency. Am J Orthod Dentofacial Orthop, 117 (2000), pp. 567-570

McConnell TL, Hoffmann DL, Forbes DP, Janzen EK, Weintraub NH. Maxillary canine impaction in patients with transverse maxillary deficiency. ASDC J Dent Child 1996;63:190-5

Mckeown HF, Sandler J. The Two by Four Appliance: A Versatile Appliance. Dent Update 2001; 28: 496–500

Miller KB, McGorray SP, Womack R, Quintero JC, Perelmuter M, Gibson
J, et al. A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment. Am J Orthod Dentofacial Orthop 2007; 131: 302.e1-9

Mirabelli JT, Huang GJ, Siu CH, King GJ, Omnell L. The effectiveness of phase I orthodontic treatment in a Medicaid population. *Am J Orthod Dentofacial Orthop. 2005 May; 127(5):592-8.*

Mitchell L, editor. An Introduction to Orthodontics. 3rd ed. New York: Oxford University Press; 2007. pp. 147–56.
Moorrees CFA, Chadha JM. Available space for the incisors during dental development: a growth study based on physiologic age. Angle Orthos 1965;35:12-22

Moyers RE, van der Linden FPGM, Riolo ML, McNamara JA Jr. Standards of human occlusal development. Monograph 5. Craniofacial Growth Series. Ann Arbor: Center of Human Development, The University of Michigan, 1976

Nelson G. Phase I treatment. Am J Orthod Dentofac Orthop 1997;111:239-40

O'brien K, Wright J, Conboy F, et al. Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 2: psychosocial effects. *Am J Orthod Dentofacial Orthop.* 2003;124:488-495

Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health. 2006 Oct; 29(5):489-97.*

Popovich F, Thompson GW. Evaluation of preventive and interceptive treatment between three and eighteen years of age. J.T. Cook (Ed.), Transactions of the third orthodontic congress, London; 1973 August 13–18, Crosby, Lockwood and Staples, London (1975), pp. 260-28

Proffit WR, Fields HW, Jr, Moray LJ. Prevalence of malocclusion and orthodontic treatment need in the United States estimates from the NHANES III survey. Int J Adult Orthodon Orthognath Surg. 1998;13(2):97–106

Rubio DM, Berg-Weger M, Tebb SS, Lee ES, Rauch S. Objectifying content validity: Conducting a content validity study in social work research. Soc Work Res. 2003;27(2):94–104.

Schindel RH, Duffy SL. Maxillary transverse discrepancies and potentially impacted maxillary canines in mixed-dentition patients. Angle Orthod 2007;77:430-5

Sergl HG, Klages U, Zentner A. Pain and discomfort during orthodontic treatment: causative factors and effects on compliance. *Am J Orthod Dentofacial Orthop. 1998 Dec; 114(6):684-91*

Shen T, Zhao B, Wang C, Xiao Y, Han Y, Zhao G, Ke J. Efficacy of different designs of mandibular expanders: A 3-dimensional finite element study. *Am J Orthod Dentofacial Orthop. 2020 May;* 157(5):641-650.

Simon M, Keilig L, Schwarze J, Jung BA, Bourauel C. Treatment outcome and efficacy of an aligner technique--regarding incisor torque, premolar derotation and molar distalization. *BMC Oral Health.* 2014;14:68. Published 2014 Jun 11. doi:10.1186/1472-6831-14-68

Singer J. The effect of the passive lingual arch on the lower denture. Angle Orthod 1974;44:146-55

Tulloch JFC, Proffit WR, Phillips C. Outcomes in a 2-phase randomized clinical trial of early Class II treatment- *Am J Orthod Dentofacial Orthop*. 2004;125:657–667

Tung AW, Kiyak HA. Psychological influences on the timing of orthodontic treatment. Am J Orthod Dentofacial Orthop 1998;113(1):29–39

Väkiparta MK, Kerosuo HM, Nyström ME, Heikinheimo KA Orthodontic treatment need from eight to 12 years of age in an early treatment oriented public health care system: a prospective study. *Angle Orthod. 2005 May; 75(3):344-9.*

JW Vander Zanden. Human development. Alfred A. Knopf, New York (1985)

J. Vargo, P.H. Buschang, J.C. Boley, J.D. English, R.G. Behrents, A.H. Owen 3rd. Treatment effects and short-term relapse of maxillomandibular expansion during the early to mid mixed dentition. Am J Orthod Dentofacial Orthop, 131 (2007), pp. 456-463

Wendling LK, McNamara JA, Franchi L, Baccetti L. A prospective study of the short term treatment effects of the acrylic-splint rapid maxillary expander combined with the lower Schwarz appliance. Angle Orthod, 75 (2004), pp. 7-14

Wiedel AP. Fixed or removable appliance for early orthodontic treatment of functional anterior crossbite. Swed Dent J Suppl. 2015;(238):10-7

Willis GB. Cognitive interviewing: A tool for improving questionnaire design. Thousand Oaks, CA: Sage Publications; 2005