Investigation and Comparison of Patient Experiences with Removable Functional Appliances: Invisalign Teen with Mandibular Advancement® versus Twin Block

by

Tyrone Zybutz

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Department of Preventive Dental Science
University of Manitoba
Winnipeg

Abstract

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Purpose: Describe the similarities and differences in various aspects of the patient experience while being treated with the Invisalign Teen with Mandibular Advancement® (ITMA) and Twin Block appliance (TB).

Methods: Sixty-eight (68) patients completed an anonymous survey approved by the Health Research Ethics Board after at least two months of wearing TB or ITMA. Forty-five (45) patients treated with ITMA (18 males, 27 females, mean age 13.62 years, SD ± 1.54) and twenty-three (23) patients treated with TB (13 males, 10 females, mean age 10.60 years SD ± 1.92) were included in the study.

Results: More TB patients found their appliance to be visually intimidating compared to ITMA (21.7% vs 8.9%). TB was more noticeable than the ITMA (69.6% vs 22.2%). Appliance insertion was more difficult for TB patients (21.8% vs ITMA - 4.4%). After several months, reporting of tooth soreness and lip/cheek soreness was greater in the ITMA group. TB patients were more embarrassed even after several months (14.3% vs ITMA - 0%). More TB patients required extra appointments for breakages (50% vs ITMA - 22.2%). Speech, drooling, jaw, lip/cheek soreness worsened initially for both groups but improved over time. There were no differences between the groups regarding visible facial changes, satisfaction with treatment experience or time to acclimatize to the appliance.

Conclusion: TB and ITMA patients shared similar experiences for the majority of the parameters measured but there were statistically significant differences between the groups in relation to appliance appearance, wear and management, discomfort, social and functional impact.

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Dedication

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Chapter 1

Introduction and Background

Orthodontic malocclusion classifications describe the unique orientation of a patient's cranial skeleton and dentition (Alhammadi et al. 2018). A Class II relationship is a very common malocclusion presentation and can most simply be described as occurring when the mandible and its dentition are behind that of the maxilla. The prevalence of Class II malocclusion can differ amongst age groups and ethnicities but is reported to be almost 20% globally (Alhammadi et al. 2018).

Various modalities and approaches for the treatment of Class II malocclusion exist; the selection of a particular treatment option is based on multiple factors including the extent of the patient's skeletal and dental imbalance. Treatment to correct a Class II malocclusion and develop an ideal skeletal and dental relationship may include surgery to adjust the positioning of the maxilla and the mandible with or without extractions. If a Class II relationship is due to the positioning of the teeth rather than a skeletal imbalance it is possible to correct it with orthodontic appliances alone, such as braces or clear aligners. When a growing patient presents with a skeletal Class II malocclusion, orthodontists can employ growth modification techniques that aim to encourage growth of the mandible and impede the growth of the maxilla (Marsico et al. 2011). Functional appliances, such as the Twin Block (TB), are the convention in treating growth modification cases and work by holding the mandible in an advanced position (Figure 1). This anterior posturing of the mandible aims to stimulate its favourable forward growth, thereby aiding in correction of the Class II malocclusion (Cozza et al. 2006). After an initial phase of growth modification with a functional appliance patients typically require a second phase of treatment for alignment with braces or clear aligners.

Invisalign® technology offers a desirable aesthetic option for correcting orthodontic malocclusion through the use of consecutive clear aligner trays. Until recently, Invisalign®'s focus was in treating adult dentition only with no option for patients requiring growth modification. In March 2017, Invisalign® presented a new appliance, Invisalign Teen with Mandibular Advancement® (ITMA), aimed at treating growing patients with Class II malocclusions (Figure 2). The appliance incorporates "precision wings" along the buccal aspect of the trays to posture the mandible forward, while alignment of the teeth occurs contemporaneously (Pascaud 2017). This concurrent approach, to both alignment and growth modification simultaneously correcting a Class II malocclusion, eliminates the need for two-phase orthodontic treatment with the potential to reduce overall treatment time.

The long-term viability of any orthodontic appliance depends primarily on the patient's ability to adapt to it quickly and the appliance's amenability for consistent use. If an appliance does not allow for quick acclimatization and ease of wear, then patients are unlikely to be compliant resulting in ineffectual orthodontic movements and prolonged treatment time. Determining appliance acceptability to a patient is considered invaluable to ensuring compliance and ultimately treatment efficacy (Sergl and Zentner 1998). Lena, Bozkurt, and Yetkiner recommend using a survey-based approach to examine the experiences of patients with a given appliance and using that information to make appropriate allocations of specific treatment modality based on the information derived therefrom (2017).

This survey-based study offers valuable information about how well patients accept the Invisalign Teen with Mandibular Advancement® appliance and how it differs from traditional growth modification appliances, like the Twin Block, in terms of the patient experience. Information from this study gives orthodontists context for their selection of growth modification devices and

enables them to choose the appliance that will be well tolerated by their patients. The elicited information from this survey will also help orthodontists prepare their patients for these appliances by offering realistic insights into what challenges they may encounter during their treatment, thereby maximizing compliance and promoting the best orthodontic outcome.

Figure 1 - Twin Block Functional Appliance

Figure 2 - Invisalign Teen with Mandibular Advancement® (ITMA)

Literature Review

Skeletal Class II – Features and Prevalence

The term malocclusion was first employed by Dr. Edward Angle to describe the antero-posterior relationships between the dentition of the maxilla and mandible. Dr. Angle characterized a Class II malocclusion as having the lower first molar occlude more distally relative to the position of the upper first molar (1900). More specifically, the mesiobuccal cusp of the upper molar occludes with the lower molar mesial to the buccal groove, where it should ideally sit in a Class I occlusion (Joshi et al. 2014). This mesio-distal disharmony between the upper and lower molars can be resultant of multiple scenarios, through either a dental or skeletal discrepancy or a combination of both (McNamara 1981). For instance, a dental Class II may occur in a patient with normal upper and lower jaw positions, but where an anterior positioning of the maxillary dentition and/or a posterior positioning of the mandibular dentition exists. Alternatively, a Class II dental relationship can accompany a true Class II skeletal relationship, when the maxilla and its dentition as a unit are positioned more anteriorly, or likewise the mandible and its dentition are more posteriorly positioned relative to the cranial base. A combination of both maxillary and mandibular malposition can be contributory to a Class II malocclusion, but it is more often that the mandible is at fault and in a retruded position (Meikle 2007). Class II malocclusions can be further divided into divisions to describe the positioning and inclination of the anterior maxillary teeth (Prasad et al. 2014). A Class II division 1 patient presents with increased overjet due to upper incisor proclination and often protrusion as well (Da Silva Filho, Ferrari, and Ozawa 2008). Division 1 patients are further characterized by transverse constriction of the maxillary arch and increased sagittal length often associated with a deep narrow palatal vault (Da Silva Filho, Ferrari, and Ozawa 2008). Class II division 2 malocclusion, which occurs less commonly,

is typified by retroclined upper incisors and an associated skeletal deep bite. Contrasting with division 1 patients, Class II division 2 patients exhibit a wide maxillary arch and horizontal growth pattern (Prasad et al. 2014). Pancherz, Zieber, and Hoyer noted that a retrognathic mandible is a prevalent feature of both Class II division 1 and division 2 malocclusion (1997).

A recent systematic review determined that the global distribution of Class II malocclusion in permanent dentition was 19.56% and 23.11% in mixed dentition (Alhammadi et al. 2018). The same review reported that European populations had the largest incidence of Class II malocclusion in both the permanent (33.51%) and mixed dentitions (31.95%), followed by American populations (15.25% and 27.22%), Asian populations (12.26% and 21.42%), and finally African populations (11.45% and 7.5%) (Alhammadi et al. 2018). This trend for a reduction in Class II prevalence from the mixed to the permanent dentition seen in most of the racial groups is indicative of correction of the malocclusion due to pubertal growth, except within African populations (Alhammadi et al. 2018).

Impact of Class II Malocclusion

While each individual manages the impact of dental malocclusion differently, there is research that demonstrates there are unique physical and psychological tolls that specifically affects patients with Class II malocclusion. It is worth noting, that while these impacts can negatively affect the quality of life for a patient with Class II malocclusion, they are not always the primary reason behind seeking orthodontic treatment.

Physical Impact of Class II Malocclusion

One of the earliest physical impacts that a skeletal Class II malocclusion can induce is a clefting of the hard and soft palate. A severely retrognathic mandible in fetal development can hinder

normal horizontal closure of the palatal shelves, as the tongue is forced into a superior position obstructing their fusion (Smarius et al. 2017). Class II skeletal malocclusions due to mandibular retrognathism, especially those with a vertical growth pattern, show a predilection for sleep-related breathing disorders (SRBDs), due to a retruded tongue position and a diminished oro-pharyngeal lumen (Joshi et al. 2014). Untreated SRBDs can lead to episodic but chronic hypoxias, which in turn can have several detrimental sequelae including reduced attention and poor academic performance, behavioural problems, nocturnal enuresis, and pulmonary hypertension (Chan, Edman, and Koltai 2004; Yaman Dosdogru et al. 2017)

As stated, protrusion of maxillary central incisors is a common feature of Class II division 1 malocclusion. The forward positioning of the incisors often results in lip protrusion and lip incompetence. The combination of forward tooth placement and minimal soft tissue coverage creates a high risk for incisor trauma in Class II division 1 cases, especially in the mixed dentition. The prevalence of trauma to the upper incisors in mixed dentition has been reported to be as high as 30% (Bauss, Röhling, and Schwestka-Polly 2004). This trauma risk prioritizes early treatment for Class II division 1 malocclusions in an effort to offset a lifelong restorative cycle associated with anterior tooth fractures (Koroluk et al. 2003).

Oral function in terms of swallowing, speech, and mastication is related to the positioning of the mandible, the maxilla, and surrounding soft tissues, and thereby is inherently influenced by skeletal and dental malocclusion. Class II malocclusion patients have an adaptive abnormal swallowing pattern. During swallowing, Class II division 1 patients display an increased intensity in suprahyoid and perioral muscle contraction, compared to those with normal Class I occlusion (Morari et al. 2019; Subtelny and Subtelny 1962). This pattern of increased effort during swallowing is a muscular modification induced by the antero-posterior relationship

between a protruded maxilla and retruded mandible. Malocclusion induced changes to swallowing can be seen in the presence of speech pathologies as well. Distortion in the production of sibilant sounds ("s" and "z") occur in both Class II malocclusion divisions, due to deep bites and reduced oral opening as found in division 2 cases, but also from increased overjet as seen in division 1 cases (Subtelny and Subtelny 1962; O'Gara and Wilson 2007). Additionally, the increased overjet between associated with Class II division 1 malocclusion patients can induce defective production of bilabial consonants ("p", "b" and "m"), which require contact of the upper and lower lips for normal articulation (O'Gara and Wilson 2007). Class II division 1 patients will often substitute the upper incisors in place of the upper lip in order to produce bilabial consonants as means to overcome their overjet-induced lip incompetence. Masticatory efficiency is reported to be reduced in patients with malocclusions compared to a Class I normal occlusion, and is attributed to a reduced number of occlusal contacts and decreased bite force (Joshi et al. 2014; Picinato-Pirola et al. 2012). The literature reports that while Class III patients have the most inefficient mastication requiring the most effort, Class II malocclusion also negatively impact one's ability to chew and process foods, especially compared to Class I controls (Picinato-Pirola et al. 2012).

Deep bite in Class II malocclusion is due to a combination of an over extrusion of the lower incisors and upper incisors; in Class II division 2 cases, deep bite is also exacerbated by the retroclined angulation of the upper incisors (Daokar and Agrawal 2016). When overbite is sufficiently deep, it may result in the lower incisors contacting the palatal gingiva behind the upper teeth – a configuration known as a deep impinging bite. Caucasian populations show the greatest prevalence of deep impinging bite compared to other ethnicities at 11.7% with higher rates found amongst males than females (Kelly JE 1977; Shalish et al. 2013). Impinging deep

bites can lead to traumatic ulceration, progressive periodontal tissue loss and even temporomandibular joint disorders (TMD) (Sreedhar and Baratam 2009). Further to malocclusion related TMD, there is evidence that supports mandibular retrognathia as a risk factor for temporomandibular disc derangement. Miller, Mancl, and Critchlow, acknowledging the many confounding factors involved in TMD, found that severe retrognathia as seen in Class II skeletal malocclusion was strongly associated with symptomatic TMJ disorders in adult females (2005). Similarly, Henrickson and Nilner concluded that Class II malocclusion was a contributing risk factor for TMD development (2003). Their study showed Class II cases benefitted from orthodontic treatment in terms of their TMD, with amelioration of their signs and symptoms (Henrikson and Nilner 2003).

Psychosocial Impact of Class II Malocclusion

Several studies have documented the negative social impact of Class II malocclusion, and its further effects on the mental health and wellbeing of afflicted individuals. As social animals, humans rely on visual appraisals of outward appearances to assist in forming assumptions and developing interpersonal relationships with others. Facial disharmonies associated with Class II malocclusions have an adverse influence on peer perception and ultimately social acceptance. Pithon et al. (2017) demonstrated that people with soft tissue dysplasia stemming from an underlying Class II malocclusion were perceived as less attractive, less intelligent, and socially incompetent. It was also noted that after treatment for the Class II malocclusion, the same individuals were viewed as being more extroverted, contented, and self-confident (Pithon et al. 2017). Contrastingly, other research has found that a child's self-concept and self-esteem were not adversely affected by the extent of their Class II, as measured by the severity of their overjet (Dann et al. 1995). Their research also showed that an improvement in the children's dentofacial

appearance with treatment to correct their Class II malocclusion was not manifested in an improved sense of self either. That being said, amongst school-age children Fonte et al. (2008) found that there was greater social acceptance of individuals with harmonic facial appearances over those with marked retrognathism and long face syndromes. Children are more likely to seek friendship with facially attractive subjects and assumed they were better behaved and more intelligent than their, seemingly, less attractive counterparts (William C. Shaw 1981). This bias, according to Shaw was particularly attributed to children that have protrusion of their upper teeth – a strong characteristic of Class II malocclusion (1981).

The negative first impression associated with dentofacial dysplasias, such as a Class II malocclusion and a retrognathic profile directly impacts a person's potential for developing positive relationships with their peers. For adolescents, exclusion and repudiation from their peer group can hinder normal social development, and this pattern can continue into adulthood further limiting their social integration and potentially their employment opportunities and educational success. The potential professional disadvantage that facial appearance can have was highlighted by Pithon et al. (2014). Their study determined that people with intact and idealized smiles were more likely to be considered for job positions by hiring managers than those with marked dental malocclusions. In general, it has been suggested that students with untreated malocclusion tend to have reduced achievement motivation, which can lead to poorer academic performance when compared to their orthodontically treated peers (Hilzenrath and Baldwin 1970; Glew et al. 2005).

Negative social perception by peers often precedes negative social interactions, such as teasing, bullying and harassment, which in turn can propagate negative self-perception and physical distress amongst victims. Diabase and Sandler (2001) noted that patients with mild to moderate facial disharmonies, such as protruded front teeth or "buck teeth" were more likely to be teased

about their appearance than patients with other marked dental dysplasia, which were met more often with pity or aversion. Similarly, Shaw, Meek and Jones (1980) found that dental characteristics were the fourth most common feature to elicit teasing amongst school-aged children, and in their sample, the majority of teasing and nicknaming referenced prominent anterior teeth as seen in Class II Division 1 malocclusion. Compared to other nicknamed children, those with a dental feature based nicknames reported feeling more hurt and upset when their peers called them by their moniker. Beyond just having an assigned nickname, children with a dental feature as the focus of their teasing were twice as likely to be harassed and bullied for their appearance than those teased for non-dental features (Shaw, Meek, and Jones 1980). Consistent verbal harassment can have negative physical impacts with increased rates of sleep disturbance, headaches, anxiety and depression being noted as commonly associated symptoms (Seehra, Newton, and Dibiase 2011). One of the most consistent and salient outcomes for individuals that endure chronic bullying is a consistent reporting of low self-esteem (Helm, Kreiborg, and Solow 1985; Seehra, Newton, and Dibiase 2011; Olweus 1994). This sense of low self-esteem as a result of bullying in childhood can be life long persisting into adulthood, well after the experiences of bullying cease (Seehra, Newton, and Dibiase 2011; Helm, Kreiborg, and Solow 1985).

Treatment of Class II Malocclusion

It is possible to manage Class II malocclusion in a variety of ways, however as with any orthodontic treatment, a definitive diagnosis involving proper photographic and radiographic imaging with complementary analysis and a detailed clinical history is required. It is important to understand the etiology of a Class II malocclusion and to determine if it is due to a dental discrepancy, skeletal Class II relationship, or a combination of both. Thoughtful consideration of

the severity of the Class II malocclusion in combination with the patient's treatment objectives is necessary before embarking on any treatment efforts. Additionally, orthodontists should consider the timing of their treatment in order to exploit the growth potential of an adolescent patient, or for when it is appropriate to apply combined orthognathic surgery as part of their therapy.

Class II treatment for Non-growing patients

For a non-growing patient, orthodontic treatment to correct a Class II malocclusion should be considered in the context of the severity of the case and with the patient's objectives in mind. If the soft tissue profile is severely dysplastic due to a marked sagittal discrepancy between the maxilla and mandible wherein the mandible is retrognathic relative to the cranial base, then the ideal treatment plan should involve orthognathic surgery. Advancement of a retruded mandible is a common method for correcting a retrognathic skeletal pattern, but surgical treatment for Class II skeletal malocclusion may also involve manipulation of the maxilla (Proffit, Phillips, and Douvartzidis 1992; Mihalik, Proffit, and Phillips 2003). Orthognathic treatment is typically done in combination with orthodontic appliances, and can involve extractions to facilitate alignment and sufficient decompensation for the surgical movements required. In cases with increased overjet of 10mm or more, and especially in the presence of a reduced mandibular unit length (condylion – pogonion) of less than 70mm, it is suggested that the Class II correction should be carried out with a combined orthodontic-orthognathic surgical approach for the most predictable and stable outcome (Proffit et al. 1992; Tucker 1995). It should be noted, however, that the extreme magnitude of overjet mandating an orthognathic surgical approach to treatment is reported in only 1.6% of teenage malocclusions in the United States (Kelly JE 1977).

Patients with less severe skeletal discordance and a more balanced soft tissue profile are reasonably treated with what is described as Class II camouflage. Camouflage treatment

addresses increased overjet and Class II canine dental relationships through extractions of the upper first premolars. The anterior incisors are retracted into the extraction space to produce a Class I canine and normalize the overjet. As such, this treatment method is best suited to patients with maxillary protrusion rather than mandibular deficiency (Kinzinger, Frye, and Diedrich 2009; Mihalik, Proffit, and Phillips 2003). When moderate to severe crowding in the lower arch is present, mandibular premolar extractions can be considered to manage arch length discrepancies while also facilitating correction of the molar classification to Class I. An alternative to first maxillary premolar extractions in Class II camouflage is maxillary molar distalization. Distalization of the maxillary molars allows for conservation of the full permanent dentition (except third molars), allowing the patient to finish in both a Class I molar and canine relationship. This can be preferable in cases with short vertical dimension and associated deep bite where distalization will have the effect of increasing the vertical opening of the bite. Distalization is accomplished with various orthodontic modalities, such as headgear, distal jet, pendulum appliances, and Carriere Motion appliance (Jeong Choi et al. 2011). No changes to the jaw positions in relation to each other or relative to the cranial base occur in Class II camouflage treatment. The soft tissue changes noted in Class II camouflage are not as considerable or pronounced when compared to outcomes from a surgical treatment approach (Kinzinger, Frye, and Diedrich 2009).

Class II Growth Modification

Growth modification is an orthopedic treatment used to treat both Class II and Class III skeletal malocclusions. For Class II cases, growth modification encourages forward growth of the mandible in an anterior and horizontal direction in an effort to improve the relative antero-posterior relationship of the jaws in a growing Class II skeletal malocclusion patient. As previously stated, orthodontists need to consider the timing for treatment in their young patients, especially when considering an orthopaedic approach to maximize the efficacy of their growth modification treatment. More specifically, growth modification treatment should be employed during the patient's pubertal growth spurt for optimal response to the therapy (Baccetti, Franchi, and Toth 2000). There are several indicators used to determine a patient's growth phase including body height, dental development, presence of secondary sexual characteristics, and hand-wrist radiographs. Evaluation of the cervical vertebrae morphology, as captured in lateral cephalograms, however, has proved an effective and reliable marker of patient skeletal maturation (Franchi, Baccetti, and McNamara 2000). The cervical vertebral maturation stage (CVMS) in conjunction with the other growth indicators enables clinicians to determine the pubertal growth peak found to occur between stages 3 and 4 (O'Reilly and Yanniello 1988) (Figure 3).

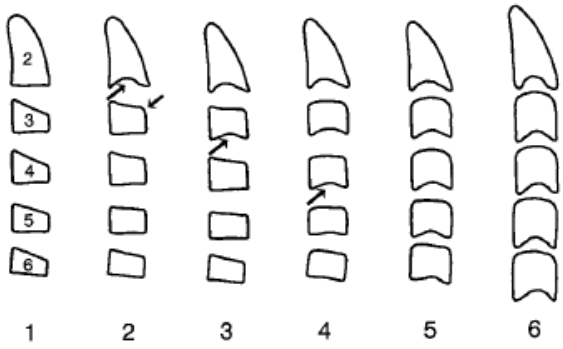

Figure 1 - Developmental Stages of Cervical Vertebrae

Growth modification for Class II malocclusion includes appliances that either restrict forward growth of maxilla, allowing the mandible to catch up as with extraoral headgear, or functional appliances that hold the mandible in protrusion in an effort to stimulate growth at the condyle and increase the overall length of the lower jaw. Patients with true maxillary protrusion as the etiology of their Class II skeletal malocclusion are more appropriately treated with headgear appliance growth modification (Tulloch, Phillips, and Proffit 1998). Functional appliances are best suited in growth modification cases with mandibular retrognathism, as the treatment aims to stimulate condylar cartilage formation by holding the lower jaw forward.

The proposed mechanism for Class II growth modification with a functional appliance asserts that forward posturing of the mandible will induce physiological changes and remodelling in the temporomandibular joint (Meikle 2007; Rabie, She, and Harley 2003). Experiments with mandibular protrusion in rats saw increased levels of the SOX-9 transcription factor, which then upregulated gene expression of type II collagen in the extracellular matrix of glenoid fossa cartilage. Type II collagen is a requisite for cartilage formation, which can then undergo endochondral ossification to become bone as part of the remodelling process (Shen and Darendeliler 2005; Rabie, She, and Harley 2003). With the advancement of the mandible Indian hedgehog (Ihh) signalling molecule expression in the proliferative zone mesenchymal cells of condylar cartilage are also increased (Meikle 2007). The mesenchymal cells proliferate and go on to differentiation into chondroblasts and then mature into chondrocytes, which ultimately become bone through the endochondral ossification process (Shen and Darendeliler 2005). With mandibular protrusion, as the condyle moves out of the mandibular fossa endochondral ossification creates bone deposition on the anterior surface of the posterior tubercle and along the

posterior surface of the condyle. This occurs in concert with compensatory resorption along the posterior aspect of the posterior tubercle and at the neck of the condyle. This pattern of deposition and resorption works to achieve and maintain the ideal seating of the condyle in the anterior superior aspect of the fossa, as is shown in Figure 4 (Meikle 2007). These cellular changes in the periarticular cells produced by the mandibular protrusion are the biomechanical basis for Class II growth modification with functional appliances.

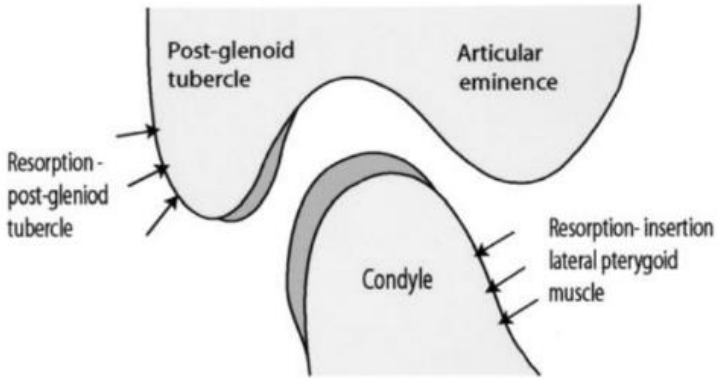

Figure 2 - Remodelling changes of TMJ induced by functional appliance growth modification

Types of Functional Growth Modification Appliances

Functional appliances can be categorized based on whether they are supported by the dentition or the soft tissues, and whether they are active or passive in nature (Proffit et al. 2019). There exists only a single true tissue-supported or tissue-borne functional appliance, the Fränkel, developed by Rolf Fränkel in 1966. The Fränkel attempts to relieve the perioral muscular pressure from the dentition by means of cheek and lip shields (Figure 5). This, in turn, leads to passive arch expansion and permits forward movement of the mandible to address a Class II malocclusion (Janson et al. 2003).

Figure 3 - Fränkel II Appliance

Of the tooth-borne functional appliances, there exist active and passive types. Active tooth-borne functional appliances include a force-generating component, such as a spring or screw designed to induce tooth movement. Incorporation of midline screws into functional appliance design, for instance, helps offset the potential for the development of a posterior crossbite as the mandible advances into a Class I molar relationship. A posterior crossbite is characterized by the aberrant positioning of the maxillary buccal cusps in the fossa of the mandibular teeth, rather than the palatal cusps. Conventional tooth-borne functional appliances are passive rather than active and rely on the stretching of soft tissue combined with muscular activation while in mandibular protrusion to produce a Class II malocclusion skeletal correction (Proffit et al. 2019). There are many passive tooth-borne functional appliances including the Andresen Activator, Van Beek, Bionator and Twin Block. The Andresen Activator, developed by Viggo Andresen in 1908, is a single-piece monoblock appliance designed to fit loosely. The relaxed fit requires the patient to actively position the device in their mouth thereby stimulating muscular activity (Figure 6). Fluting in the acrylic facilitated dentoalveolar movement, and eruption of permanent teeth into a Class I relationship (Bishara and Ziaja 1989).

Figure 4 - Andresen Activator

The Van Beek Activator, developed by Herman Van Beek in the 1980s, is also a monobloc appliance design but is combined with high-pull headgear using two bows that are embedded in the acrylic, which facilitates maxillary counter-clockwise rotation and anterior restriction (Figure 7). The Van Beek Activator has the other advantage of incisal edge coverage, which can help prevent unwanted proclination of the lower incisors – a common side effect of functional appliance wear (Al-Kurwi, Bos, and Kuitert 2017).

Figure 5 - Van Beek Appliance with Headgear Bows

Like the Van Beek and the Andreasen Activator, the Bionator Appliance is a monoblock design developed by Wilhelm Balters in the 1950's (Landázuri et al. 2013). Balters attempted to create a less bulky monoblock appliance that would be patient-friendly and facilitate compliance. The Bionator treats both deep and open bite Class II malocclusions with selective occlusal acrylic coverage in the anterior or posterior, respectively (Figure 8).

Figure 6 - Deep Bite Bionator & Open Bite Bionator Appliances

William Clark wanted to overcome the functional restrictions of other Class II growth modification appliances that limited a patient's ability to talk and eat (Dibiase, Cobourne, and Lee 2015). In 1977, Clark developed the Twin Block appliance, which offered a novel design compared to other removable tooth-borne passive functional appliances, in that it was comprised of two separate components rather than a single monoblock design (Figure 9).

Figure 7 - Twin Block Appliance

Each component of the appliance has large acrylic blocks with a sloping bite ramp inclined to 70 degrees; when the blocks are in occlusion, the mandible is held a protruded position (Dibiase, Cobourne, and Lee 2015). Retention of the Twin Block is through a combination of Adams, Delta, and ball clasps, depending on the stage of dentition (W. Clark 2010). Labial bows can be included to improve retention and retract upper incisors while acrylic capping of the lower incisors is possible to limit proclination. The wax construction bite used in the fabrication of the appliance is taken in an edge-to-edge sagittal incisal position with 2mm over the vertical opening, and care is taken not to extend the advancement beyond 70% of the patient's maximum protrusion (W. Clark 2010). This design promotes a closed-lip posture, which can facilitate retraction of the upper incisors especially in Class II Division 1 malocclusion. Transverse midline screw incorporation in the maxillary component of the Twin Block appliance prevents creation of a buccal crossbite as the mandible moves anteriorly (Mezio et al. 2017). The Twin Block's design also allows for control of the vertical dimension through management of the acrylic blocks. Not only do the blocks themselves limit molar eruption, but also acting as

shields, they prevent the lateral expansion of the tongue into the interocclusal space. As such, over time as the sagittal correction is accomplished a posterior open bite develops in the patient's dentition. The clinician can then direct the eruption of the lower molars by progressively reducing the acrylic block of the upper appliance.

The Twin Block design allows the patient to separate their jaws normally, allowing them to speak and eat easily compared to other functional appliances. As normal mandibular movements and speech are only slightly impeded with the Twin Block appliance, full-time wear can be carried out by the patient as Clark originally prescribed (Clark 2010; 2019). Clark also advocated for temporary cementation of the upper appliance to improve initial compliance and increased efficacy of the appliance (2019). Clark contested the recent study by Parekh et al. (2019) that determined there was no statistically significant difference in the skeletal or dental outcomes for patients that wore the Twin Block appliance for approximately 8 hours a day versus 12 hours a day.

Having reviewed the conventional removable functional appliances, it is worth summarizing some of the literature around the effectiveness of Clark's Twin Block in treating Class II malocclusion. There exists a division amongst clinicians as to what the ideal approach to treating Class II malocclusion in the growing patient is. Some clinicians advocate for a two-phase treatment with growth modification and fixed braces while others endorse only a single phase of fixed braces treatment in the permanent dentition. Results from the landmark randomized clinical trial by Tulloch, Proffit, and Phillips indicated that there were no long term differences between two-phase or single-phase Class II treatment, and that early treatment did not reduce the need for subsequent extractions or orthognathic surgery (2004). Note that this study did not look at only the Twin Block, but included other functional appliances and headgear as growth modification

treatment modalities as well. Despite the evidence from this study, many clinicians still support early treatment with the use of a functional appliance, such as a Twin Block, to offset the aforementioned physical and psychosocial impacts of living with a Class II malocclusion. Indeed, the literature documents the efficacy of early Class II skeletal and dental malocclusion treatment with the Twin Block appliance. Toth and McNamara compared Twin Block appliance to Fränkel -2 appliance and untreated controls and found that both appliances produced a significant increase in mandibular length, but by a greater magnitude in Twin Block treated patients (1999). Baccetti, Franchi, and Toth established that the use of the Twin Block appliance with optimized timing at the onset of the pubertal growth spurt resulted in significant skeletal changes, including increased mandibular length and ramus height (2000). Similarly, Šidlauskas found that compared to an untreated cohort, those who underwent growth modification with the Twin Block appliance saw a significant increase in their mandibular length and a reduction in their overjet that was attributed to skeletal changes rather than just dentoalveolar compensation (2005). Skeletal changes of reduced Wits Appraisal, reduced ANB angle, and increased anterior positioning of the boney chin resultant of Twin Block appliance treatment have been noted in conjunction with improved vertical control compared to other removable functional appliances, such as the Bionator (Siara-Olds et al. 2010). A systematic review found that Twin Block treatment increased mandibular length, but advised that maxillary restraint is not a concurrent outcome, and so the overall changes to facial type can be limited, as the maxilla continues to grow unabated (Ehsani et al. 2014). Finally, Elfeky et al. employed 3D imaging to compare skeletal and dental changes in Twin Block patients, compared to those attributed to normal growth in untreated patients (2018). They found that Twin Block treated patients saw increased dimensional changes of the mandible in all three planes of space, and that the condyle was

repositioned anteriority and inferiorly after growth modification (Elfeky et al. 2018). The same study found that Twin Block patients developed greater increases in ramus length, leading to improvements in the skeletal profile both antero-posteriorly and vertically. The literature supports the efficacy of Twin Block treatment in growing patients for treating a Class II malocclusion.

The Invisalign Teen with Mandibular Advancement® (ITMA) is a recent design development in the clear aligner forum. Align Technology Incorporated announced the appliance in March 2017 and it was immediately available in Canada, Australia, parts of Europe, South America, and South East Asia. After obtaining clearance from the Food and Drug Administration, the ITMA became commercially available in the United States as of November 2018 (Werner 2018). Taking design cues from Clark's Twin Block, the ITMA is comprised of two separate appliances, which fit separately onto the maxilla and the mandible. Both appliances feature a set of "precision wings" (Figure 10) that work together to hold the mandible in a protruded position, similar to the sloping bite blocks of Clark's functional appliance (Pascaud 2017).

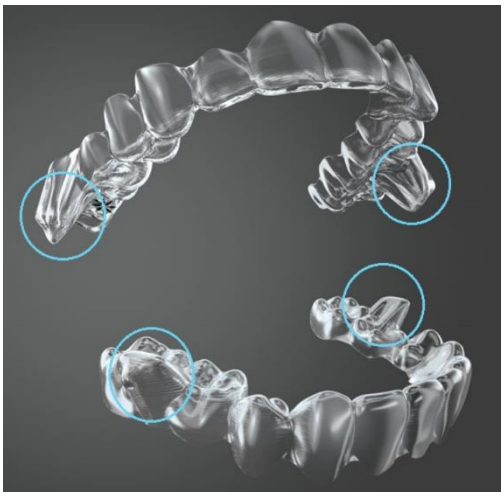

Figure 8 - Invisalign Teen with Mandibular Advancement® with Precision Wings

Like other clear aligner therapies, ITMA appliances come with sequential aligner trays meant to be worn from 7-14 days at a time, before changing and moving to the subsequent tray. The precision wings are programed at intervals of 2mm advancements every 8 aligners, ultimately providing sequential advancement over time, unlike the Twin Block, which typically has a single set advancement dimension (O'Brien 2019). This sequential advancement approach used with the ITMA has been recommended in conventional removable functional appliances, such as the Fränkel, as means to maintain the condylar position in the glenoid fossa and to reduce dentoalveolar movements (Falck et al. 1989). Contrastingly, Banks, Wright, and O'Brien found that there were no measurable differences in the overall orthopaedic effect between sequential versus a singular maximum advancement, and that there was no increase in the dentoalveolar changes amongst those with maximum advancement despite the associated larger magnitude of force application (2004). A sequential advancement approach also facilitates ease of patient acclimation to their new appliance, reducing issues with comfort of wear and speech. Making a functional appliance easier to wear by reducing the extent of advancement could arguably increase compliance, although it was not determined to be a factor in the completion of Twin Block treatment by Banks, Wright, and O'Brien (2004). Unlike other removable functional appliances, such as the Twin Block, the ITMA simultaneously aligns dentition while holding the mandible in protrusion, and is said by Align Technology to offer greater efficiency in treating Class II malocclusion (Pascaud 2017). At the 2019 American Association of Orthodontists Conference Dr. Barry Glaser reported on a North American multicentre clinical study reviewing the ITMA (2019). Their study found that the ITMA yields similar results, compared to other functional appliances in mild Class II malocclusion cases, by decreasing overjet, ANB and Wits appraisal values as well as increasing the mandibular unit length (Glaser 2019). This study also

reviewed patient quality of life pre and post-treatment, and found that there high levels of patient satisfaction following treatment along with improvements in self-image and self-esteem (Glaser 2019). Owing to the relatively new release of the ITMA, there is an absence of peer-reviewed studies discussing its efficacy in the literature.

Compliance as Related to Functional Appliance Patient Experience

Owing to their typical construction as removable therapies, the successful outcome of any growth modification treatment with a functional appliance relies on compliance from the patient (Casutt et al. 2007; Čirgić et al. 2015; Sergl and Zentner 1998). In medical terminology, compliance is defined as a patient's willingness and adherence to following a prescribed treatment course (*Compliance.(Definition)* 2001). For successful growth modification treatment, the patient is expected to comply with consistent wear of the appliance for the clinician prescribed daily wear time. That being said, compliance with removable functional appliances is difficult to measure without the use of appliance borne thermal sensors, and relies on clinician observation and patient reporting. Patient reporting tends to be grossly overestimated, with patients stating they wear their appliance on average 5 hours more than they do (Al-Moghrabi et al. 2017). The literature on compliance with removable functional appliances varies greatly with non-compliance rates ranging from 10-49% (Caldwell and Cook 1999; Lee, Kyi, and Mack 2007). What influences a patient's commitment to wearing any appliance as instructed is understood to be multifactorial, but it is implicit that a patient's overall experience with their treatment modality impacts their compliance. It can be assumed that the more positive a patient's experience with their appliance, the more likely they are to start and continue wearing it as prescribed.

El- Huni et al. undertook a study aimed at qualitatively assessing the multiple factors associated with different levels of compliance with the Twin Block appliance (2019). They determined several themes influencing a patient's compliance including self-motivation, quality of life impairment, and perceived treatment progress (El-Huni et al. 2019). Social and functional impairment caused by the Twin Block appliance was one of the main factors that lead to reduced initial compliance. These functional and social impairments reported included reduced aesthetics, discomfort, difficulty eating and sleeping, speech impediment, and incidents of teasing about the appliance. While initial compliance was reduced for many patients before their becoming accustomed to the functional side effects, it was patients that reported self-motivation for treatment, which were seen to more readily improve their wear times. Recommendations from the authors to improve compliance with Twin Block included ensuring the clinician used clear and effective communication to highlight the problem with a patient's malocclusion and how the appliance would improve it. Demonstrating the positive changes to dentition and soft tissues as treatment progressed were strong motivating factors promoting ongoing compliance. Modifying the design of the appliance to reduce the social and physical impairment burden was also recommended, as a means to increase compliance. These design modifications included decreasing the vertical dimension of the blocks to reduce interincisal space, just as Clark himself has recommended, and insuring effective retentive mechanisms to prevent appliance movement and dislodgement (El-Huni et al. 2019; Charavet et al. 2019; Sergl and Zentner 1998).

Patient experiences with removable functional appliances and how they relate to compliance was the focus of Čirgić et al.'s 2015 study. Like El-Huni et al., this study used patient interviews, which highlighted how the social and functional experiences with their appliance directly impacted their compliance in terms of wear time. Discomfort and difficulty with appliance

retention was reported as a barrier to compliance, especially early in treatment. Appliance conspicuousness, either due to visibility or observable functional impairment, such as changes in speech, was noted as a factor limiting compliance, especially as it often resulted in teasing or bullying by peers (Čirgić et al. 2015). Interestingly, social impairment leading to embarassment was noted by Sergl, Klages, and Zentner to have a greater negative impact on compliance than physical discomfort caused by the appliance (2000). Like the patients in El-Huni et al.'s study, those that were able to subjectively detect changes in their Class II malocclusion, such as a reduction in overjet, were more likely to continue wearing their appliance consistently. Clear, uncomplicated, and tailored communication from the clinician, especially at the appliance delivery appointment, was noted as being essential to a patient's understanding of why compliance was necessary to increase treatment efficacy (Čirgić et al. 2015). Additionally, the first impression of an appliance has also been noted to have a lasting influence on the overall experience with it during treatment. While an acclimatization period is expected for any new treatment modality, an appliance that appears discrete, unintimidating, and is comfortable to insert and wear is more likely to generate an initial positive attitude toward it. This positive impression, both in terms of appearance and tactile sensation upon insertion, tends to persist during treatment improving overall treatment experience and enhancing compliance (Sergl and Zentner 1998; Doll et al. 2000). The importance of managing a patient's expectation of discomfort and accurately estimating the time until acclimatization are major contributing factors to ongoing compliance and finishing treatment (Kavaliauskiene et al. 2012; Lena, Bozkurt, and Yetkiner 2017).

As previously noted, conventional removable functional appliances tend to be bulky in their design, making them noticeable and inducing marked functional impairments, such as increased

salivation, changes in speech and sleep, discomfort and soft tissue irritation, as well as changes to the patient's oro-facial appearance. These types of functional impairments were quantitatively evaluated by Kavaliauskiene et al. amongst patients wearing different types of orthodontic appliances including braces, braces with headgear, removable appliances, and removable functional appliances (2012). Of the test groups, functional appliance wearers reported the highest levels of increased salivation, and impaired sleep, due to fear of appliance dislodgement. In terms of discomfort, functional appliance wearers, along with those in fixed braces, reported higher pain intensity, but unlike the braces group, this discomfort was not associated with soft tissue irritation or ulceration. Rather, pain intensity within the functional appliance group was related to muscle stretching and pressure on the mucosa, and has been similarly noted in other studies (Kavaliauskiene et al. 2012; Sergl and Zentner 1998). Functional appliance patients also reported greater social impairment compared to the other test groups, including being more self-concious of their smile, the visibility of their appliance, and the changes in their speech. As a result, these patients admitted to avoiding verbal communication and smiling less often, as well as reporting experiencing negative comments from peers aimed at their appliances (Kavaliauskiene et al. 2012). The same observation of compliance being negatively impacted by a patient's experience of pain, reduced aesthetics, social, and functional impairment imparted by their appliance has been noted by several other authors (Oliver and Knapman 1985; Sergl and Zentner 1998).

Statement of the problem

Owing to the relatively recent release of the Invisalign Teen with Mandibular Advancement®, there is limited data available on how well patients tolerate the appliance throughout their treatment.

Purpose of the study

This study investigated different aspects of the patient experience that were being treated with Invisalign Teen with Mandibular Advancement® and compared it directly to the experience of patients using the conventional functional appliance, Twin Block.

Objectives of the study

- To assess patients' first impression of their appliance
- To asses the initial side effects of the appliance on patients' daily function including speech, sleep, drinking, appearance, and how these functions changed over time
- To investigate patients' comfort while wearing their appliance initially and how it changed over time
- To evaluate the social impact of appliance wear initially and over time
- To compare the difference in the frequency of emergency appointments between TB and ITMA
- To compare the distribution of responses in each investigated category for both TB and ITMA and report any significant differences between the groups

Null Hypotheses

H_{01}: There are no differences in patient experience *between* TB and ITMA treatment groups in terms of the delivery appointment, initial insertion and appliance retention and their personal first impressions as well as the conspicuousness of their appliance to family and friends.

H_{02}: There are no differences in patient experience *between* TB and ITMA treatment groups with regard to appliance management, discomfort, functional, and social impacts *from their treatment start time and after at least two months of wear*.

H_{03}: There are no differences in patient experience *between* TB and ITMA treatment groups with regard to appliance management, discomfort, functional, and social impacts *from their treatment start time and after at least two months of wear*.

Chapter 2

Materials and methods

Research Ethics Approval

This anonymous survey-based study received approval from the Bannatyne Campus Research Ethics Boards at the University of Manitoba on April 4, 2018 (Appendix 1). Annual Approval for the study was obtained on March 25, 2019 and again on March 26, 2020 (Appendix 2).

Survey Design and Validation

The survey used in this study was modified from the survey developed by Bowman et al. 2013, which looked at the experience of patients treated with a fixed appliance, the Forsus Fatique Resistance Device™. This study's survey was written with regard to the removable functional

appliances investigated, the Twin Block and the Invisalign Teen with Mandibular Advancement® (Appendix 3 and 4). A total of 20 questions were asked, in addition to having the respondent state their age and gender. Of the 20 questions asked, one question employed a visual analogue scale, two questions were yes/no response format, and the remainder used Likert Scale responses. A total of 17 Likert Scale questions were used, 15 of which made use of a 5-point scale while the remaining 2 made use of a 3-point scale.

Surveys were validated by the principal investigator using interviews with two respondents to determine that all questions asked were relevant to their patient experience with removable functional appliances and were being correctly interpreted. The two respondents involved in the survey validation both had the ability to read and write English as their first language. Both respondents were being treated for Class II malocclusion; one individual was wearing the ITMA and the other individual was wearing a TB. The validation respondents were asked to read the questions aloud to the principal investigator and explain in their own words, their interpretation of its meaning. Based on these interviews, minor changes were made to the original survey to better reflect the removable nature of the appliance and to improve question comprehension. The wording of one question was improved to a statement respondents could reflect on, which improved comprehensibility from the original question form for both validation respondents. Two questions regarding how music and sports were impacted by appliance wear were omitted from the final validated survey, as patients at all research locations were instructed to remove their appliances for these types of activities, and therefore were anticipated to be of limited interest to the researcher.

Sample Selection

This study aimed to assess a total sample size of 50 patients between the ages of 8-17 years with efforts to ensure an equal amount of respondents for each appliance group surveyed. Previous research reviewing patient experience with orthodontic appliances have used similar sample sizes and were used as a guideline for determining the number of patients included in this study (Wu et al. 2008; Elkordy et al. 2015; El-Huni et al. 2019;)

The acquisition of the survey population for each appliance was from three orthodontic offices. All of the TB appliance respondents with the exception of four individuals treated at the University of Manitoba's Graduate Orthodontic Clinic were obtained from a single orthodontic specialist working from two private practice clinical locations in Winnipeg, Manitoba. The ITMA respondents were obtained from a different orthodontic specialist working from a single combined pediatric dentistry-orthodontic private practice in Winnipeg, Manitoba.

Surveys were distributed to patients meeting the following inclusion and exclusion criteria:

Inclusion criteria:

- Adolescent patients (ages 8-17 years)
- Use of the Invisalign Teen with Mandibular Advancement® or the Twin Block appliance as part of their orthodontic therapy for a minimum of two months or longer
- Subjects are still in active treatment with the Invisalign Teen with Mandibular Advancement® or the Twin Block appliance at the time of completing the survey
- Late mixed and permanent dentition cases
- For patients being treated with the Invisalign Teen with Mandibular Advancement®
    - Planned dual arch orthodontic treatment exclusively using Invisalign®
    - Aligners made of SmartTrack® material (year 2012 to present)

- Dental Class II (requiring Anterior-Posterior correction)
- Treatment protocol followed by the practitioner – Interproximal reduction (IPR) as prescribed
- Good compliance during treatment, as assessed by the practitioner

Exclusion criteria:

- Surgical cases
- Extraction cases
- Cases employing Temporary Anchorage Devices
- Presence of a cleft lip or palate, or any other syndromic orofacial malformations

Data Collection

In order to optimize the completion rate of the survey study, the staff members at each study site were given a brief orientation and training seminar regarding the study and the specific questionnaires. The principal researcher, Dr. Tyrone Zybutz, attended each study site and worked with the staff members and head orthodontic practitioner to ensure that they understood the participant selection process based on the inclusion and exclusion criteria, and understood when to issue the questionnaire in the patient's treatment timeline.

A member of the particular orthodontic practice or the principal investigator issued a hard copy of the survey package (distinct for each appliance) directly to the patient and their guardian for completion.

The survey package contained the following:

- Patient Experience Survey for either Twin Block appliance or Invisalign Teen with Mandibular Advancement® (Appendices 3 and 4)

- Consent disclosure statement outlining the purpose of the study and the obligations, risks and benefits of participating in the survey (Appendices 5 and 6)
- Draw card for incentive prize with preaddressed and postage-paid envelope (Appendix 7)

The patient and their guardian or caregiver were given a chance to read the consent disclosure statement before agreeing to participate in the study. The consent disclosure agreement included the principal researcher's contact information should there have been any questions or concerns from potential or active participants in the study.

Each individual was asked to complete the survey to the best of their ability with the assistance of their guardian or caregiver while they were at their specific treating orthodontic practitioner's office. Once completed, the participants were instructed to hand the survey and their draw card for the incentive prize back to their practitioner or to a staff member. Draw cards were kept separate from the completed surveys to avoid bias and maintain the anonymity of the survey respondent. Draw cards were stored in a secure filing cabinet until the lottery was completed on June 30, 2019 after which all draw cards were destroyed.

Statistical Analysis

Following data collection, survey responses were analysed using the IBM SPSS Statistics for Windows Version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were employed to explore the data set. As Likert Scale responses are ordinal and as normal distribution of the data set could not be assumed, non-parametric tests were carried out for all Likert Scale questions. Mann-Whitney *U* tests were used to compare the responses for each treatment group for all questions. Wilcoxon signed-rank tests were employed to determine the changes in the responses within each test group from T1 to T2.

Chi-squared tests were used to compare responses between the treatment groups to all questions with yes/no scoring. Independent Student's t-tests were used to determine significant differences between the patient age, patient gender, and the time for acclimatization for each treatment group.

A significance level of $\alpha = 0.05$ was used for all statistical analyses applied.

Chapter 3

Results

A summary table of responses from both treatment groups can be found in Appendix 8, while summary tables of the results from the statistical tests applied can be found in Appendix 9 – 12.

Demographic Data

Sixty-eight (68) patients in total completed the survey; forty-five (45) patients treated with ITMA (18 males, 27 females, mean age 13.62 years, SD ± 1.54) and twenty-three (23) patients treated with TB (13 males, 10 females, mean age 10.60 years SD ± 1.92) (Table 1). There was no statistically significant difference between the treatment groups based on their gender distribution. An Independent Student's t-test revealed that there was a statistically significant difference between the groups in terms of age with ITMA having an older patient population compared to TB (p=0.00).

Table 1 - Summary of Respondent Age and Gender

Appliance Group	Total Number	Males	Females	Mean Age (years)	Standard Deviation	Age Range (years)
ITMA	45	18	27	13.62	1.54	10-17
TB	23	13	10	10.60	1.92	8-14

Question Response Distributions and Statistical Test Results

A summary of the statistically significant findings can be found in Tables 2- 5.

Table 2 - Summary of significant findings: mean and median responses to questions 2, 5, 7, 13a-13c from ITMA and TB treatment groups

Question*	ITMA mean (median)	TB mean (median)	p value
2. When I first saw it, the appliance looked scary/overwhelming	2.0 (2)	2.61 (2)	0.01
5. The appliance was noticeable to your friends and family	2.78 (3)	3.74 (4)	0.001
7. The appliance was difficult to put in my mouth and wear	1.89 (2.0)	2.70 (3)	0.003
13b. Right now, while wearing the appliance how much has the following affected you: sore teeth	1.60 (2)	1.29 (1)	0.03
13c. Right now, while wearing the appliance how much has the following affected you: sore lips	1.37 (1)	1.10 (1)	0.03
13d. Right now, while wearing the appliance how much has the following affected you: feeling embarrassed	1.00 (1)	1.14 (1)	0.01

**Q2, 5 and 7: 1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree; Q13a-13c: 1 = not at all, 2 = a little, 3 = a lot*

Table 3 - Summary of significant findings: responses to questions 16 and 17 from ITMA and TB treatment groups

Question	ITMA	TB	p value
16. Have you had any extra visits because your appliance was broken or not fitting well *Yes (%)*	10 (22.2)	11 (50)	0.03
17. If you had extra visits because your appliance was broken or not fitting properly, has this bothered you *1 = not at all, 2 = a little, 3 = a lot, 4 = it did not break/it has always fit well*	3.44 (4)	2.76 (3)	0.02

Table 4 - Summary of significant findings: Comparison of ITMA responses to questions at initial time point (9-11) to questions after at least two months of appliance wear (12-14)

Question*	**Initially mean (median)**	**After at least 2 months mean (median)**	**p value**
9a v 12a: while wearing the appliance how much has the following affected you: **speech**	2.51 (2)	3.18 (3)	0.00
10a v 13a: while wearing the appliance how much has the following affected you: **sore jaw**	1.95 (2)	1.37 (1)	0.00
10b v 13b: while wearing the appliance how much has the following affected you**: sore teeth**	2.20 (2)	1.60 (2)	0.00
10c v 13c: while wearing the appliance how much has the following affected you: **sore lips/cheeks**	1.76 (2)	1.37 (1)	0.002
10d v 13d: while wearing the appliance how much has the following affected you: **drooling/spitting**	1.60 (2)	1.30 (1)	0.004
10f v 13f: while wearing the appliance how much has the following affected you: **difficulty opening wide/yawning**	1.18 (1)	1.05 (1)	0.03

** Q9 - 14: 1 = not at all, 2 = a little, 3 = a lot*

Table 5 - Summary of significant findings: Comparison of TB responses to questions at initial time point (9-11) to questions after at least two months of appliance wear (12-14)

Question*	**Initially mean (median)**	**After at least 2 months mean (median)**	**p value**
9a v 12a: while wearing the appliance how much has the following affected you: **speech**	2.23 (2)	3.00 (3)	0.02
10a v 13a: while wearing the appliance how much has the following affected you: **sore jaw**	1.74 (2)	1.19 (1)	0.01
10b v 13b: while wearing the appliance how much has the following affected you**: sore teeth**	1.83 (2)	1.29 (1)	0.01
10c v 13c: while wearing the appliance how much has the following affected you: **sore lips/cheeks**	1.43 (1)	1.10 (1)	0.03
10e v 13e: while wearing the appliance how much has the following affected you: **drooling/spitting**	1.57 (1)	1.29 (1)	0.01

** Q9 - 14: 1 = not at all, 2 = a little, 3 = a lot*

Table 6 shows the distribution of responses to questions 1 through 4 for both ITMA and TB patient groups. Mann-Whitney *U* tests revealed there was no difference in the responses between the treatment groups regarding the description of the appliance, clarity of wear and care instructions, or the ease of the delivery appointment (questions 1, 3 and 4).

Table 6 - Distribution of Patient Responses to Questions 1-4

	Provision of complete appliance description		**Provision of wear and care instructions**		**Ease of first appointment**		**Appliance appearance as scary/overwhelming**	
appliance score	**ITMA** *(n=45)*	**TB** *(n=23)*	**ITMA** (n=45)	**TB** *(n=23)*	**ITMA** *(n=45)*	**TB** (n=23)	**ITMA** *(n=45)*	**TB** *(n=23)*
Strongly Disgree (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	15 (33.3)	2 (8.7)
Disgree (2)	1 (2.2)	0 (0)	0 (0)	0 (0)	2 (4.4)	1 (4.4)	20 (44.4)	10 (43.5)
Neutral (3)	1 (2.2)	3 (13)	1 (2.2)	0 (0)	13 (28.9)	3 (13)	6 (13.3)	6 (26.1)
Agree (4)	16 (35.5)	6 (26.1)	7 (15.6)	7 (30.43)	18 (40)	8 (34.8)	3 (6.7)	5 (21.7)
Strongly Agree (5)	27 (60)	14 (60.9)	37 (82.2)	16 (69.6)	12 (26.7)	11 (47.8)	1 (2.2)	0 (0)

Values are expressed as number (% among respondents)

In question 2, when asked if their appliance appeared to them as scary or overwhelming at first, significantly more TB patients responded in the affirmative compared to ITMA patients (21.7% vs 8.9%, p=0.01). The response distribution to question 2 for the two treatment groups is graphically represented in Figure 11.

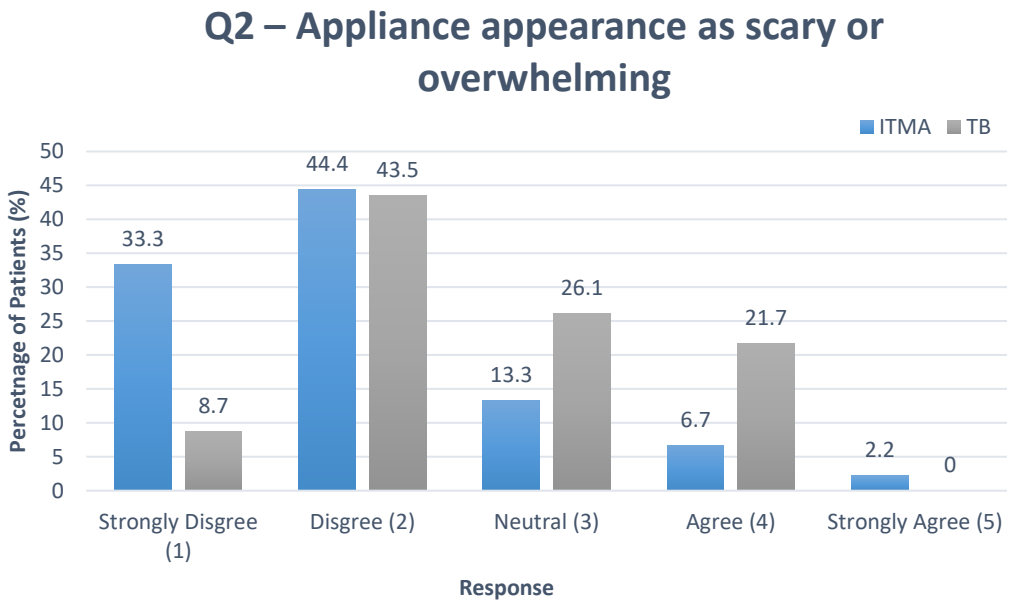

Figure 9 - Response distributions between treatment groups to question 2: "The appliance appeared scary or overwhelming"

Table 7 shows the distribution of responses to questions 5 through 8 for ITMA and TB patient groups. There was a significant difference in the responses between the groups regarding the noticeability of their appliance (p = 0.001). More TB patients agreed or strongly agreed (combined total - 69.6%) that their appliance was noticeable to friends and family compared to ITMA patients (combined total – 22.2%) (Figure 12). There was, however, no significant difference in the responses between the groups regarding the importance of having an inconspicuous appliance. The largest proportion of both treatment groups responded that they were neutral about having a discrete appliance and that visibility was not considered important to them. No correlation was noted between the ages of each appliance's patient group and their priority or desire for a device that was not noticeable.

Table 7 - Distribution of Patient Responses to Questions 5-8

	Appliance is noticeable to others		Importance of appliance being unnoticeable		Difficult to insert appliance		Difficult to retain appliance	
appliance	**ITMA**	**TB**	**ITMA**	**TB**	**ITMA**	**TB**	**ITMA**	**TB**
score	(n=45)	(n=23)	(n=45)	(n=23)	(n=45)	(n=23)	(n=44)	(n=23)
Strongly Disgree (1)	8 (17.8)	3 (13)	1 (2.2)	3 (13)	18 (40)	3 (13)	13 (29.6)	2 (8.7)
Disgree (2)	6 (13.3)	1 (4.4)	4 (8.9)	3 (13)	16 (35.6)	7 (30.4)	9 (20.5)	8 (34.8)
Neutral (3)	21 (46.7)	3 (13)	18 (40)	10 (43.5)	9 (20)	8 (34.8)	4 (9.1)	4 (17.4)
Agree (4)	8 (17.8)	8 (34.8)	11 (24.4)	4 (17.4)	2 (4.4)	4 (17.4)	11 (25)	9 (39.1)
Strongly Agree (5)	2 (4.4)	8 (34.8)	11 (24.4)	3 (13)	0 (0)	1 (4.4)	7 (15.9)	0 (0)

Values are expressed as number (% among respondents)

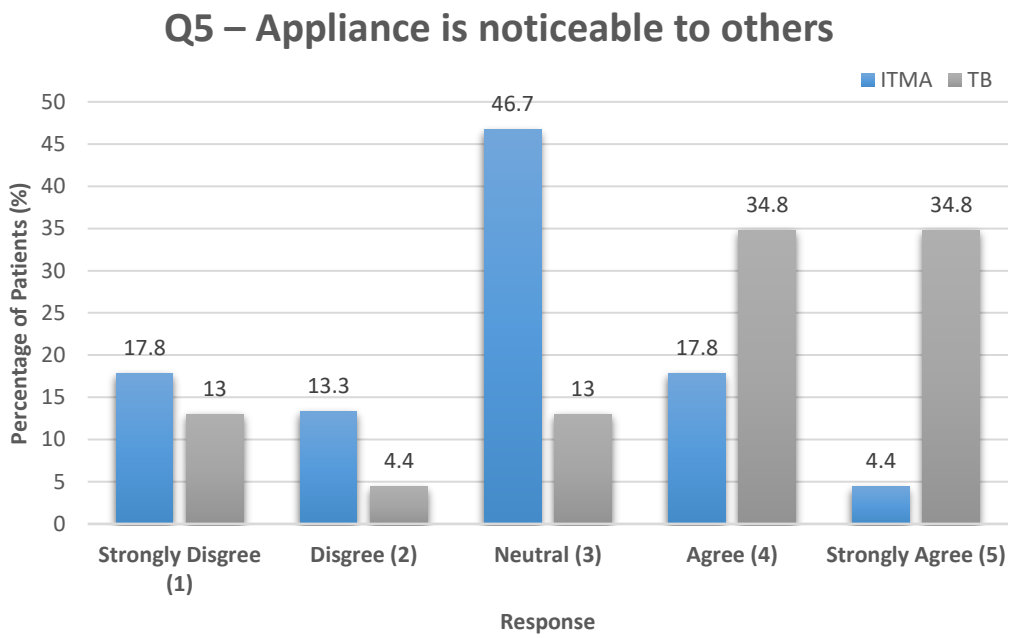

Figure 10 – Response distributions between treatment groups to question 5: "The appliance is noticeable to friends and family"

Figure 13 shows that the responses regarding appliance insertion were different between the groups, with more TB patients reporting they agreed or strongly agreed the appliance was difficult to place in their mouth (21.8% vs ITMA - 4.4%, p= 0.003). When asked about ease of appliance retention, however, there was no difference in responses between the groups.

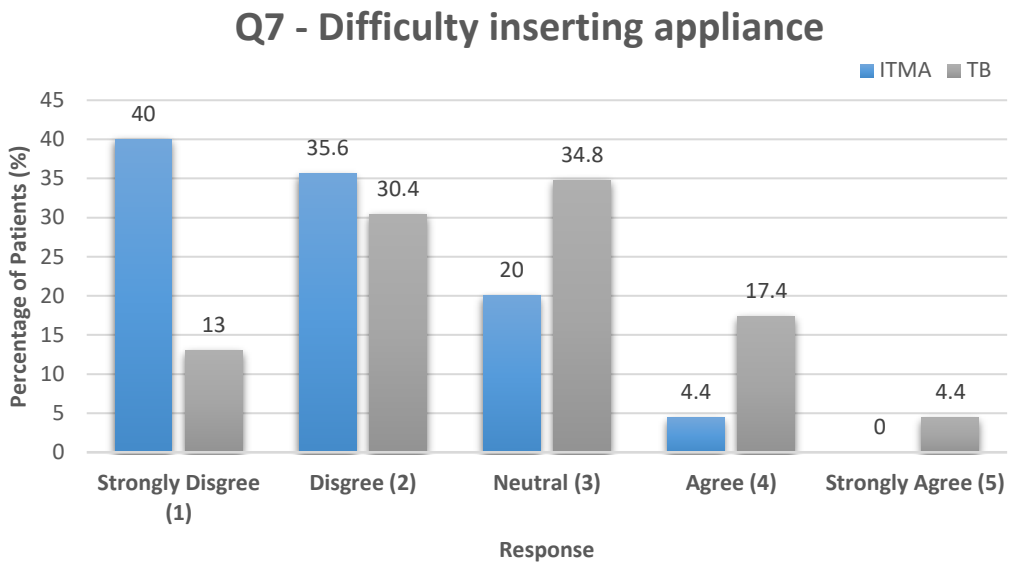

Figure 11 - Response distributions between treatment groups to question 7: "The appliance was difficult to put in my mouth"

Tables 7 summarizes the response distribution between the treatment groups for questions 9a-9e at the start of treatment, while Table 8 shows the response distribution for the same questions after two months of appliance wear time (Q12a-12e). There was no difference in the responses between the treatment groups for changes in speech, drinking, sleep, appearance or incidence of teasing either while initially wearing the appliance or after two months of wear. No differences in responses, both initially and after two months wear, were noted with respect to relationships with family and friends (questions 11 and 14).

Table 6 - Distribution of Patient Responses to Questions 9a-9e at start of treatment

	Impact on speech		Impact on drinking		Impact on sleeping		Impact on appearance		Influence on teasing	
appliance	ITMA	TB	ITMA	TB	ITMA	TB	ITMA	TB	ITMA	TB
score	(n=45)	(n=22)	(n=45)	(n=22)	(n=45)	(n=22)	(n=44)	(n=22)	(n=44)	(n=22)
Much Worse (1)	0 (0)	4 (18.2)	0 (0)	1 (4.5)	1 (2.2)	2 (9.1)	0 (0)	0 (0)	1 (2.2)	0 (0)
Slightly Worse (2)	26 (57.8)	11 (50)	6 (13.3)	3 (13.6)	7 (15.6)	4 (18.2)	3 (6.7)	4 (18.2)	2 (4.4)	4 (18.2)
Unchanged (3)	16 (35.6)	5 (22.7)	38 (69.1)	17 (30.9)	36 (80)	15 (68.2)	28 (62.2)	15 (68.2)	38 (84.5)	15 (68.2)
Slightly Improved (4)	2 (4.4)	2 (9.1)	1 (2.2)	0 (0)	1 (2.2)	0 (0)	10 (22.2)	3 (13.6)	1 (2.2)	1 (4.6)
Much Improved (5)	1 (2.2)	0 (0)	0 (0)	1 (4.5)	0 (0)	1 (4.6)	4 (8.9)	0 (0)	5 (6.7)	2 (9.1)

Values are expressed as number (% among respondents)

Table 7 - Distribution of Patient Responses to Questions 12a-12e at start of treatment

	Impact on speech		Impact on drinking		Impact on sleeping		Impact on appearance		Influence on teasing	
appliance	ITMA	TB	ITMA	TB	ITMA	TB	ITMA	TB	ITMA	TB
score	(n=44)	(n=22)	(n=45)	(n=22)	(n=44)	(n=21)	(n=44)	(n=20)	(n=44)	(n=20)
Much Worse (1)	0 (0)	0 (0)	0 (0)	1 (4.8)	0 (0)	1 (4.8)	0 (0)	0 (0)	1 (2.3)	0 (0)
Slightly Worse (2)	5 (11.4)	6 (27.3)	1 (2.3)	1 (4.8)	0 (0)	1 (4.8)	0 (0)	3 (15)	0 (0)	0 (0)
Unchanged (3)	28 (63.6)	11 (50)	36 (83.7)	15 (71.4)	40 (90.9)	14 (66.7)	25 (56.8)	10 (50)	41 (93.2)	16 (80)
Slightly Improved (4)	9 (20.5)	4 (18.2)	6 (14)	3 (14.3)	4 (9.1)	1 (4.8)	13 (29.6)	4 (20)	1 (2.3)	3 (15)
Much Improved (5)	2 (4.6)	1 (4.6)	0 (0)	1 (4.76)	0 (0)	4 (19.1)	6 (13.6)	3 (15)	1 (2.3)	1 (5)

Values are expressed as number (% among respondents)

Table 9 collates the response distribution between the treatment groups for questions 10a-10d at the start of treatment, while Table 10 shows the response distribution for the same questions after two months of appliance wear time (Q13a-13d).

Table 8 - Distribution of Patient Responses to Questions 10a-10d at start of treatment

	Sore jaw		**Sore teeth**		**Sore lips or cheeks**		**Feeling embarrassment**	
appliance *score*	**ITMA** (n=44)	**TB** (n=23)	**ITMA** (n=45)	**TB** (n=23)	**ITMA** (n=45)	**TB** (n=23)	**ITMA** (n=45)	**TB** (n=20)
Not At All (1)	12 (27.3)	10 (43.5)	7 (15.6)	9 (39.1)	18 (40)	14 (60.9)	42 (93.3)	18 (78.3)
A Little (2)	22 (50)	9 (39.1)	22 (48.9)	9 (39.1)	20 (44.4)	8 (34.8)	2 (4.4)	5 (21.7)
A Lot (3)	10 (22.7)	4 (17.4)	16 (35.6)	5 (21.7)	7 (15.6)	1 (4.35)	1 (2.2)	0 (0)

Values are expressed as number (% among respondents)

There were no differences in the responses between the groups regarding jaw, tooth, lip and cheek soreness, difficulty cleaning the appliance or difficulty opening wide and yawning when the patients first received their appliances. Similarly, there were no differences in the responses between the groups with respect to drooling, spitting, or feeling embarrassment as a result of their initial appliance use.

After at least two months of appliance wear, there were still no differences between the responses from the treatment groups regarding jaw soreness, drooling and spitting, difficulty cleaning the appliance, or difficulty opening wide or yawning. At this time point, however, there were marked differences in the responses between the groups in relation to how the appliance impacted their incidence of sore teeth, lips, and cheeks as well as their feeling of embarrassment.

Table 9 - Distribution of Patient Responses to Questions 13a-13c & 13f after two months of appliance wear

	Sore jaw		Sore teeth		Sore lips or cheeks		Feeling embarrassment	
appliance / *score*	**ITMA** (n=43)	**TB** (n=21)	**ITMA** (n=43)	**TB** (n=21)	**ITMA** (n=43)	**TB** (n=21)	**ITMA** (n=42)	**TB** (n=21)
Not At All (1)	27 (62.8)	18 (85.7)	20 (46.5)	16 (76.2)	28 (65.1)	19 (90.5)	42 (100)	18 (85.7)
A Little (2)	16 (37.2)	2 (9.52)	20 (46.5)	4 (19.1)	14 (32.6)	2 (9.5)	0 (0)	3 (14.3)
A Lot (3)	0 (0)	1 (4.76)	3 (7)	1 (4.8)	1 (2.33)	0 (0)	0 (0)	0 (0)

Values are expressed as number (% among respondents)

Reporting of tooth soreness after at least two months of appliance wear was found to be greater in the ITMA group, in which 53.5% of patients were still experiencing a little or a lot of tooth pain compared to only 23.9% of the TB group (p = 0.03, Figure 14).

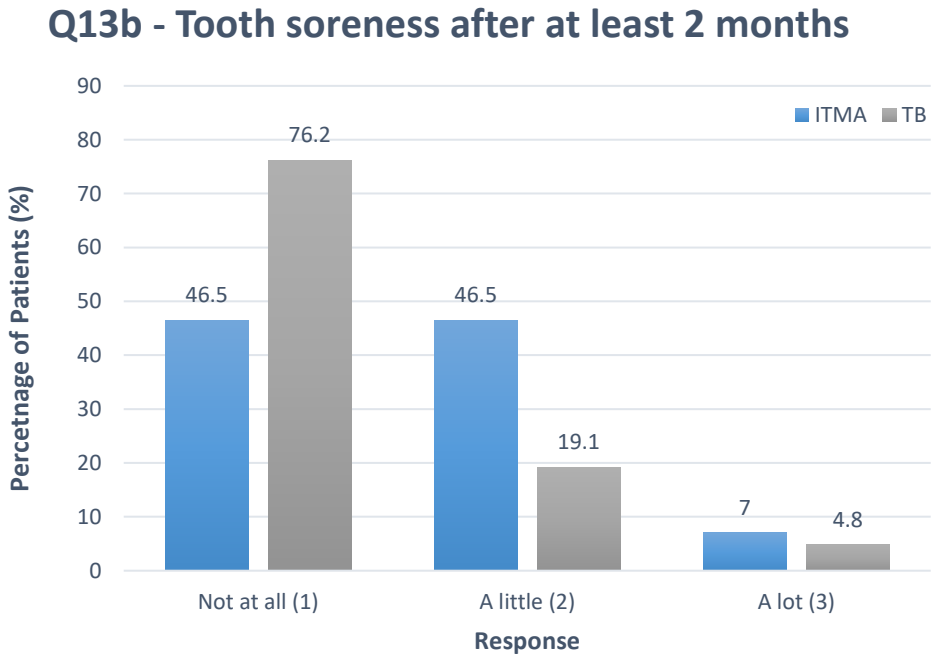

Figure 12 - Response distributions between treatment groups to question 13b: "Right now with your appliance, how often does tooth soreness affect you?"

After at least two months of appliance wear, the reporting of sore lips and cheeks was greater amongst ITMA patients with 34.9% of the group experiencing a little or a lot of soft tissue soreness, while only 9.5% of TB patients experienced the same (Figure 15). Unlike their ITMA counterparts, significantly more TB patients had zero experience of lip or cheek soreness after at least two months of appliance wear (90.5% vs ITMA – 65.1%, p = 0.03).

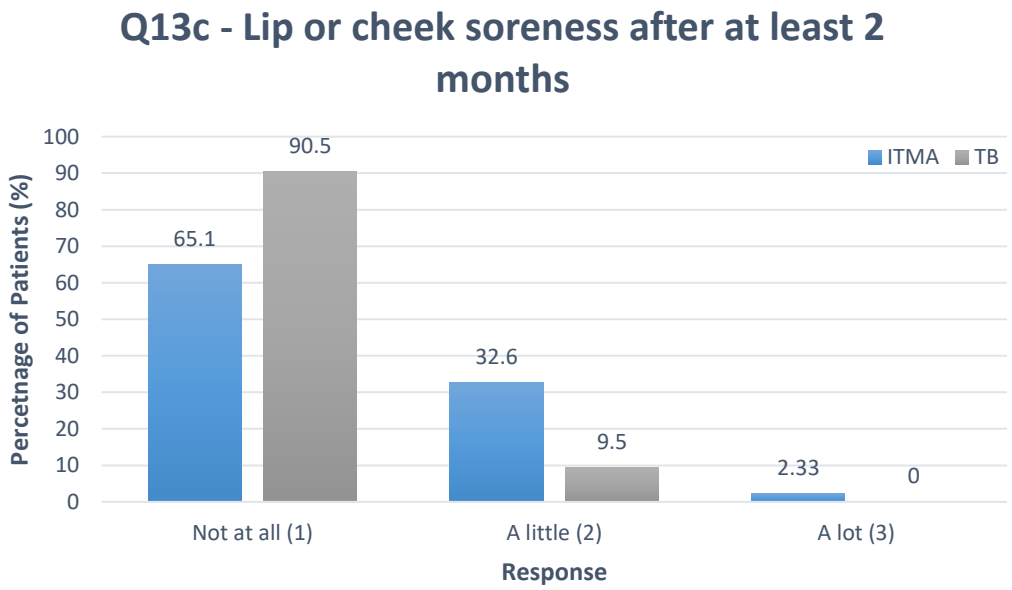

Figure 13 - Response distributions between treatment groups to question 13c: "Right now with your appliance, how often does lip and cheek soreness affect you?"

Patients from the TB and ITMA groups reported significantly different levels of embarrassment after at least two months of wearing their appliance (p = 0.01). None of the ITMA patients at this time reported feeling embarrassed, 14.3% of TB patients, however, were still experiencing a little embarrassment due to their appliance (Figure 16).

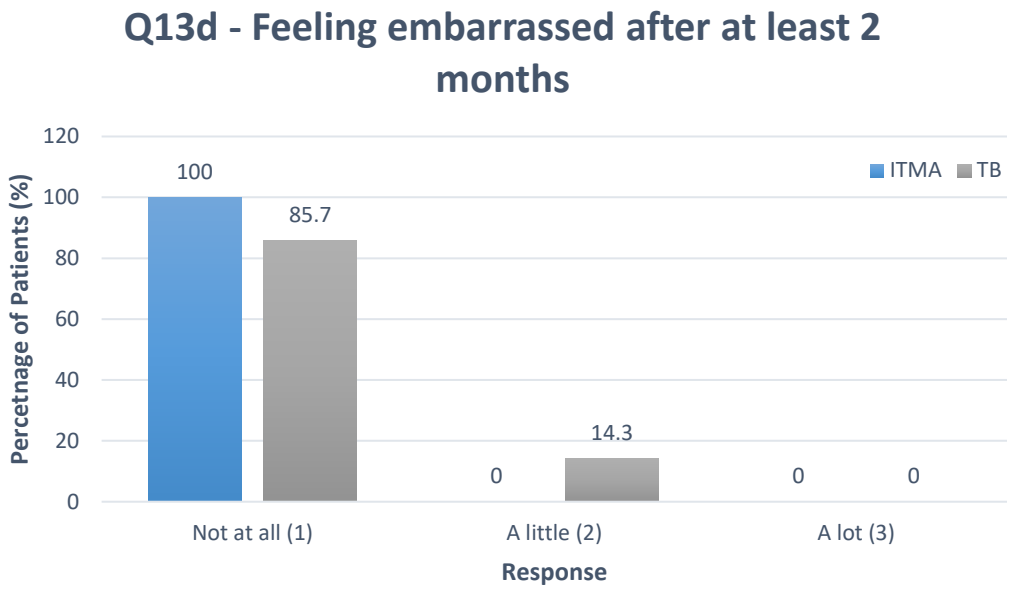

Figure 14 - Response distributions between treatment groups to question 13d: "Right now with your appliance, how often does feeling embarrassed affect you?"

No differences were found between the treatment groups in relation to their responses regarding drooling and spitting, or difficulty in keeping their appliance clean, both when they first received their device or after at least two months of wear time (questions 10e/13e and 10f/13f, respectively).

Extra visits to manage fit issues or breakages were required by both groups, however, significantly more TB patients experienced this during their treatment (p=0.03). Half the TB patients reported a need for extra visits to address breakages or fit issues during their treatment, while only 22.2% of ITMA patients had extra visits for these reasons (Figure 17). When asked if these extra visits were found to be bothersome or annoying significantly more TB patients agreed that they were perturbed by them compared to the ITMA group (p = 0.08). Of the patients wearing TB, 28.6% were bothered a little or a lot by the extra visits, while only 11.1% of the ITMA group reported the same.

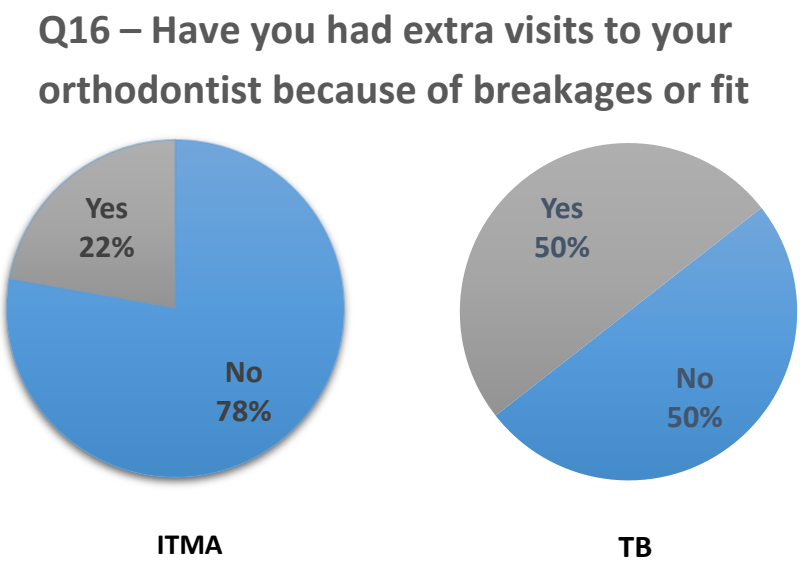

Figure 15 - Responses from treatment groups to questions 16: "Have you had extra visits to your orthodontist because of breakages or fit issues with your appliance?"

A correlation was carried out to determine if there was any link between patient's experience with fit or breakage issues, and their response to the quality and clarity of wear and care instructions provided when they first received the appliance. The correlation looked at reporting disagreement or strong disagreement with questions 4 ("I was given instructions on how to wear and care for the appliance") and related it to an experience of increased breakages or fit issues. No correlation was determined in the data set overall or when applied to the groups by appliance type.

When asked if they noticed any visible changes in their face since beginning their treatment, there was no significant difference found between the treatment groups.

There was no significant difference in the mean time required to acclimatize to either appliance; TB patients took 2.59 weeks ± 1.87 and ITMA patients took 2.49 weeks ± 1.66. When asked to reflect on their overall treatment experience there was no significant difference in the responses

between the groups. The majority of patients in both groups reported that they felt good or really good about their treatment (TB – 73.9% vs ITMA – 87.8%).

Within Group Comparisons over Treatment Time

Wilcoxon signed-rank tests highlighted the changes experienced over time with regard to the variables measured within each treatment group. For both the ITMA and TB groups, significant differences were noted in how their appliance impacted their speech as treatment progressed ($p = 0.00$ and $p = 0.02$, respectively). Speech was reported to have worsened during initial appliance wear for both groups, with 57% of ITMA patients and 68.2% of TB patients stating that their speech immediately became slightly or much worse. Comparing this to after at least two months of appliance use, 72.8% of TB patients and 88.7% of ITMA patients saw their speech return to base line or improve (Figure 19).

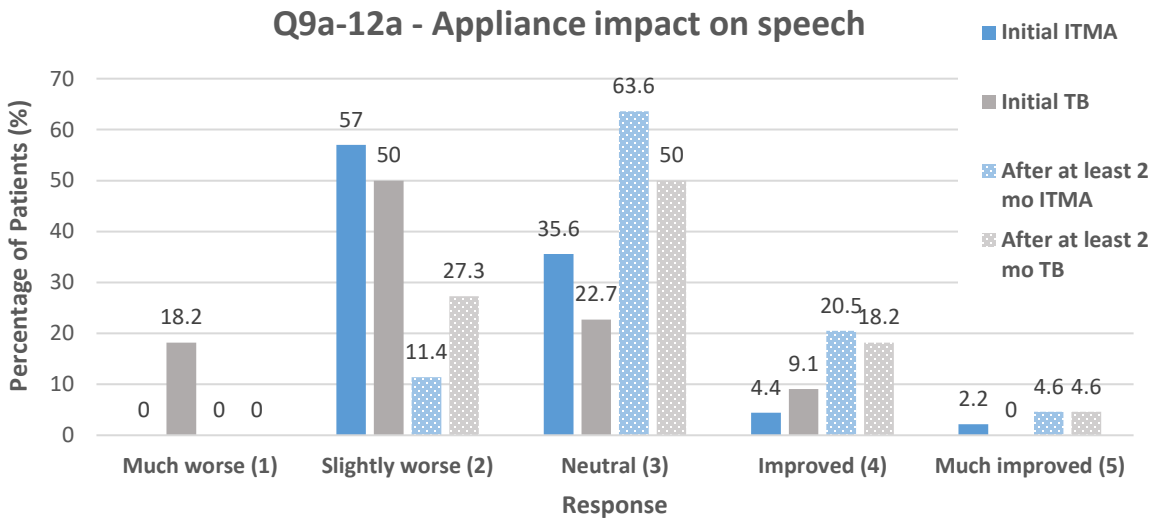

Figure 16 – Appliance impact on speech for ITMA and TB over duration of treatment

Both groups experienced a significant difference in how jaw soreness impacted them throughout their treatment (p = 0.00 and p = 0.01, respectively). When they initially wore their appliance, 72.7% of ITMA patients and 56.5% of TB patients reported a little or a lot of jaw soreness (Figure 19). After at least two months of appliance wear, both groups experienced a reduction in their jaw soreness with the majority from both groups experiencing no jaw soreness at all (ITMA – 62.8% vs TB – 85.7%). Despite the absence of jaw soreness for the bulk of both groups, more ITMA patients continued to have persistence of discomfort in their jaw compared to TB after at least two months of appliance wear (37.2% vs TB – 14.3%).

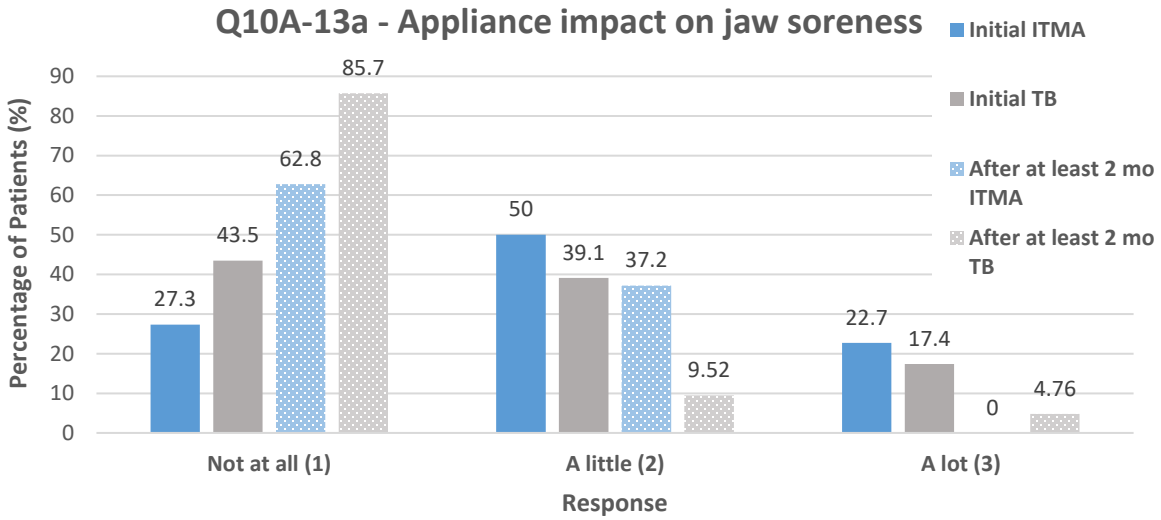

Figure 17 – Appliance impact on jaw soreness for ITMA and TB over duration of treatment

A significant difference in the soreness of lips and/or cheeks from initial use to after at least two months of appliance wear was found for both the ITMA and TB groups (p = 0.002 and p = 0.03, respectively). The ITMA and TB groups both experienced a trend of lip and cheek soreness decreasing as treatment progressed, although this occurred at different degrees for each appliance (Figure 20). Initially, 60% of the ITMA group reported a little or a lot of lip and cheek soreness,

while only 39.2% of the TB patients reported the same. As treatment time progressed, there were fewer patients in each group experiencing a little or a lot of lip and cheek soreness; the ITMA group declined to 34.9% while the TB reduced to the very low level of 9.5%. Recall, that the treatment groups' reporting on lip and cheek soreness after two months of appliance wear was also found to be significantly different from each other (Figure 15, p = 0.03).

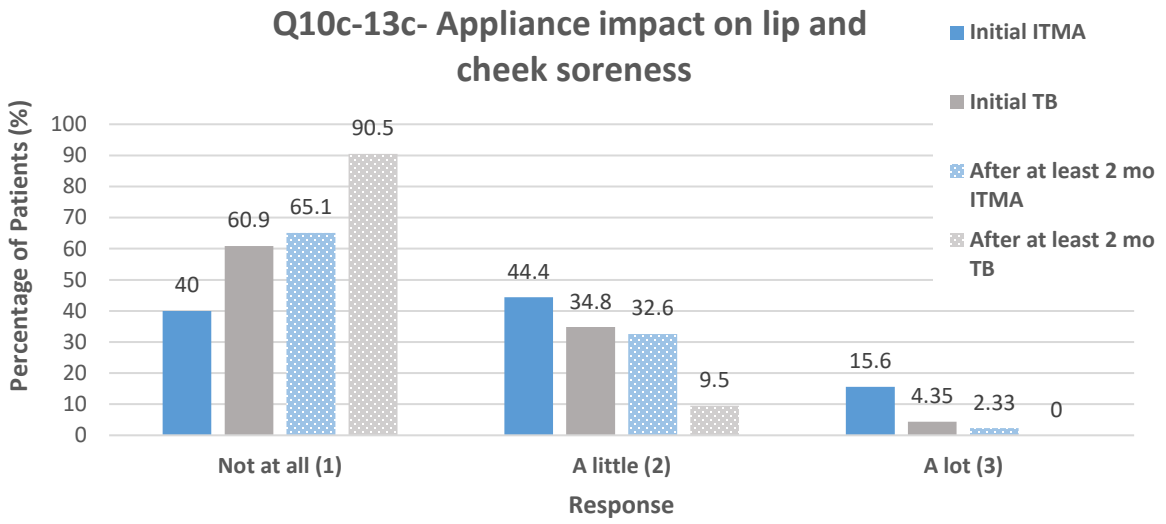

Figure 18 – Appliance impact on lip and cheek soreness for ITMA and TB over duration of treatment

Drooling and spitting with appliance wear was another measure that was seen to change significantly for both groups as treatment progressed (ITMA p = 0.004, TB p = 0.01). Similar to the previous measures, drooling and spitting reduced throughout treatment in both appliance groups (Figure 21). Initially, 51.1% of the ITMA group reported drooling and spitting a little or a lot with the use of the appliance, which was similar to the 47.8% of the TB group that experienced the same. After at least two months of appliance wear, both groups saw their drooling and spitting reduce with 30.2% of the ITMA and 23.9% of the TB patients reporting a little or a lot of drooling and spitting.

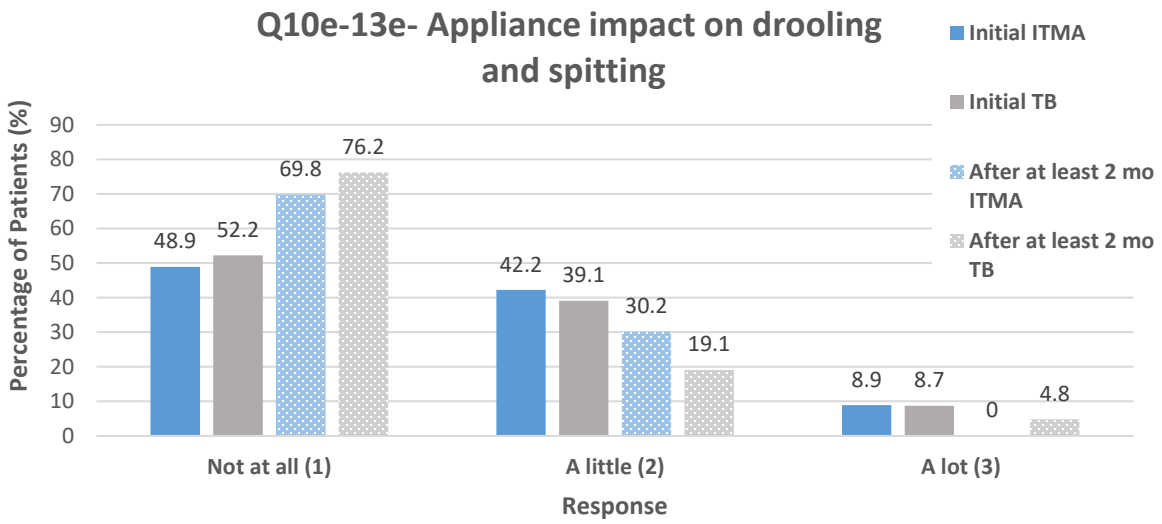

Figure 19 – Appliance impact on drooling and spitting for ITMA and TB over duration of treatment

Only the ITMA group experienced significant change with regard to difficulty opening wide or yawning as treatment with their appliance progressed (p = 0.03). While 17.8% of the ITMA patients found it a little difficult to yawn or open wide with the initial use of their appliance this fell to only 4.7% after at least two months of wear (Figure 22). Almost all ITMA patients (95.4%) had no difficulty with yawning/wide opening after at least two months of appliance use.

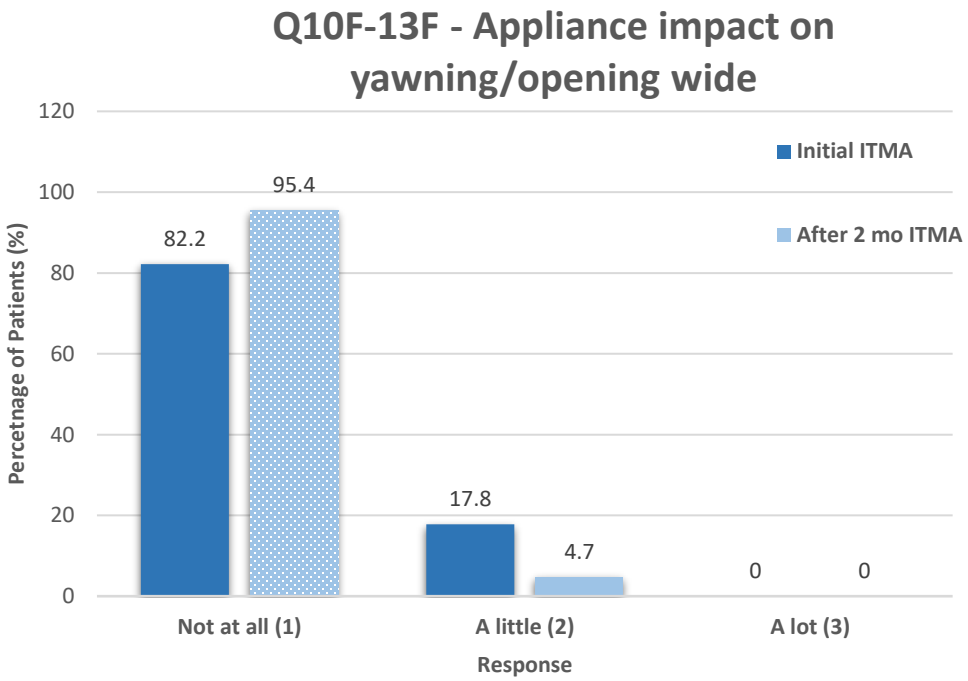

Figure 20 - Appliance impact on yawning or opening wide for ITMA over duration of treatment

Advice from ITMA and TB patients – common themes

All survey respondents were given an opportunity to impart advice to other potential appliance users in question 20. The most common theme that emerged in both groups were statements that provided encouragement to new appliance users reassuring them that they will soon "get used to" their device. Survey respondents from both ITMA and TB groups also stressed the importance of continuing to wear the appliance through treatment and to maintain the appliances with regular cleaning. Patients with the ITMA appliance gave more advice on describing the discomfort they experienced with their appliance including adjectives, such as "hurts", "pain", "uncomfortable", and "sore". This differed from the TB group's advice, which did not include any of these words or any others words denoting discomfort.

Chapter 4

Discussion

As class II malocclusions account for over 20% of the global population, the management of these cases will continue to be a large part of orthodontic practice (Alhammadi et al. 2018). Growth potential in young patients can be exploited to stimulate condylar remodelling using functional appliances, a treatment approach known as growth modification. While the Twin Block remains one of the most popular functional appliances, new developments in growth modification modalities continue to be developed, as with the new device Invisalign Teen with Mandibular Advancement®. If the efficacy between two growth modification appliances is comparable, clinicians may choose to base their modality decision on the patient experience associated with a particular device especially if treatment is compliance dependent. Patient

experiences with an appliance directly influences their acceptance of a device, which then, in turn, impacts compliance and ultimately the achievement of a successful treatment outcome (Lena, Bozkurt, and Yetkiner 2017). This study aimed to investigate and compare the patient experiences with the classic Twin Block and the new Invisalign Teen with Mandibular Advancement® highlighting their similarities and differences for both clinicians and patients. Patient's first impressions, wearability, associated pain and discomfort, social and functional impact and clinical management of the two appliances, as well as patient acclimatization over time, were explored in this qualitative survey.

Lena, Bozkurt, and Yetkiner (2017) and El-Huni et al. (2019) both stress the importance of clinicians taking time to provide thoughtful and customized descriptions of any prescribed device ensuring patients are aware of potential side effects in order to maximize their compliance. For this study, no differences between the TB and ITMA patients were reported in response to questions about the ease of the appliance delivery appointment or the thoroughness of the clinician's description of the device or their instructions on how to wear and care for it. This indicates a similar patient experience regarding appliance delivery for both treatment groups.

A significant difference was found between the groups regarding the visual first impression for each appliance. More TB patients (21.7%) strongly agreed or agreed that the appliance appeared scary, overwhelming or intimidating compared to ITMA (8.9%, $p = 0.01$). This reporting may be attributed to the significant age difference between the groups; TB patients had a mean age that was 3 years younger than ITMA and this may have caused them to find any device more intimidating no matter the design. That being said, the appliances have different appearances and are alike only in that they both have separate maxillary and mandibular components. The Twin Block appliance is fabricated with metal elements including a labial bow and ball clasps that are

visibly located on the anterior dentition and may appear confronting to a new orthodontic patient even regardless of age. Contrastingly, the ITMA is fabricated from thermoformed translucent plastic that fits closely to tooth contours and has no metal or acrylic components that could be considered intimidating to patients. This finding is discordant with Lena, Bozkurt, and Yetkiner in their comparison of TB to other Class II correction appliances, including a Functional Mandibular Advancer and a Forsus Fatique Resistance Device™ (2017). Their study reported that patients found the TB appliance to be the least intimidating and least anxiogenic compared to the other appliances reviewed, although none of these were directly comparable to the ITMA in terms of appearance. It is worth noting the difference between the groups with regard to the first visual impression of their appliances, as Sergl and Zentner advise, that a positive first impression is an important aspect of the patient experience engendering early acceptance and promoting consistent wear as prescribed (1998).

When asked about the noticeability of the appliance there was a significant difference in the response distributions between the groups with more TB patients agreeing or strongly agreeing (combined total - 69.6%) that their appliance was noticeable to friends and family compared to ITMA patients (combined total – 22.2%). The bulk of the TB's acrylic blocks generating an interincisal gap, the retentive wire-work on the facial aspect of anterior teeth and the optional addition of colour to the acrylic all contribute to the increased conspicuousness of this device compared to the ITMA (El-Huni et al. 2019). The ITMA's thermoformed translucent plastic produces only a slight interincisal gap fitting closely to the contours of the teeth making it a relatively unobtrusive and discrete appliance.

Despite a reporting in this study that the TB was more conspicuous and noticeable to friends and family than the ITMA, the largest proportion of both treatment groups responded that they were

neutral about having a discrete appliance and that visibility was not considered important to them. This similarity in response could be related to the age range of the test groups, which within the TB group were from 8-14 years and 10-17 years for ITMA patients. Compared to adults, adolescents tend to have greater acceptance of more visible appliances and reducing metal display is not considered a priority in their aesthetic demands for dental devices (Walton et al. 2010). Owing to the younger age group of this study's test population, especially that of the TB group, which had a mean age 10.6 ± 1.9 years, the concern for appliance aesthetics was not given high importance amongst respondents. That being said, Walton et al. (2010) also noted that amongst adolescents, older children have a preference for clear appliances. With this in mind, a correlation was run to determine if the difference in the age of the two treatment groups impacted their desire for having a discrete appliance. No significant correlation was noted between the ages of each appliance's patient group and their desire for a device that was unnoticeable.

Regarding the wearability of the appliance, more TB patients reported that they agreed or strongly agreed that the appliance was difficult to place in their mouth (21.8% vs ITMA - 4.4%, p= 0.003). This could be related to TB's bulky acrylic blocks, which require a large opening for insertion into the mouth. According to Clark, the designer of the original TB, many clinicians fabricate their TB appliances using a construction bite with an excessive interincisal gap resulting in increased vertical height of the acrylic blocks and leading to difficulty inserting and wearing the appliance (2010). The recommendation for TB fabrication is to use a construction bite that results in an interincisal gap of no more than 2mm, thereby ensuring smaller vertical blocks that are easier to insert consistently (Clark 2010). In this study, there was no attempt made for standardization of the TB appliance fabrication including the height of the wax construction bite. It is possible the TBs worn by respondents were made with an increased interincisal gap

contributing to the differences in responses from the two groups regarding the difficulty of appliance insertion.

Regarding pain and discomfort associated with appliance wear, differences in the responses were noted between the ITMA and TB groups. While there were no differences between the groups with regard to jaw pain, a significant difference was found between the groups with respect to tooth soreness, but this was only after at least two months of appliance wear. Reporting of tooth soreness after at least two months of appliance wear was found to be significantly greater in the ITMA group, in which 53.5% of patients were still experiencing a little or a lot of tooth pain compared to only 23.9% of the TB group ($p = 0.03$). This finding is not unexpected given the variation in the treatment objectives of the two appliances. The conventional TB is a functional appliance used for the primary objective of correcting a Class II malocclusion through growth modification by stimulating condylar development. As a tooth-borne functional appliance, the retentive components of the TB can exert forces onto the teeth. This force application may generate some tooth soreness associated with limited dentoalveolar movement even though the appliance does not attempt to move or align teeth directly. The ITMA is a combination of a functional appliance with a device that aligns teeth; the precision wings work to hold the mandible in protrusion to stimulate condylar growth, while composite attachments adhered to the teeth engage the aligner undercuts and generate dentoalveolar movement intended to straighten the teeth. Most research investigating pain as an orthodontic treatment side effect have compared conventional Invisalign (without the mandibular advancement feature) to full fixed orthodontic appliances rather than other removable orthopaedic devices. As such, this study's results differ with reports in the literature, in which Invisalign is found to cause less tooth pain but only in comparison to traditional braces and fixed archwire devices (Almasoud 2018; White et al. 2017;

Fujiyama et al. 2014). This difference in tooth pain experience is seen throughout treatment, but especially in the first 2-7 days following bonding of attachments or brackets. At this time in treatment, the inflammatory process is fully initiated and local nociceptors in the periodontal ligament have undergone increased sensitization responding to inflammatory mediators, which results in hyperalgesia (White et al. 2017). Patients wearing the ITMA can be expected to experience more tooth pain consistently throughout their treatment compared to TB patients as levelling, aligning, and derotating the teeth are movements actively programmed into each aligner along with the mandibular protrusion for growth modification.

Experience of lip and cheek soreness was also found to be significantly different amongst the treatment groups, but like tooth soreness, this difference was only manifested after at least two months of appliance wear. While there were no significant differences at the start of treatment, after at least two months of appliance wear, the reporting of sore lips and cheeks was significantly greater amongst ITMA patients with 34.9% of the group experiencing a little or a lot of soft tissue soreness while only 9.5% of TB patients experienced the same ($p = 0.03$). Unlike their ITMA counterparts, after at least two months of appliance wear more TB patients experienced zero lip or cheek soreness (90.5% vs ITMA – 65.1%). Both the TB and ITMA appliances lack the defined hard edges, hooks and wings of conventional metal brackets that are most commonly attributed to complaints of lip and cheek irritation in orthodontic treatment. However, while both appliances are capable of causing soft tissue irritation, the ITMA group's increased reporting of discomfort may be related to the titratable precision wings used in the device. Unlike the acrylic blocks of the TB that remain interocclusal, the precision wings of the ITMA are buccal to the dentition and may impinge on the cheeks during insertion and function. In the first few sets of aligners, the precision wings are not present and as such, the patient does

not have to manage the increased bulk of the wings in their buccal vestibule. Precision wings are typically initiated at aligner tray eight and continually increased in anterior positioning at 8 week intervals by 2mm at a time (Werner 2018). For most patients, aligners are worn for 1 week before progressing to the subsequent aligner tray set as was the case with this study's ITMA test group. All patients were given the survey after at least two months of appliance wear, which means that some of the ITMA group may have just begun their first set of precision wing aligners when they responded. In this instance, the individuals who were just beginning their precision wing aligners would not have had a long enough acclimatization period to adjust to the increased bulk of their appliance and may report more lip and cheek soreness even after being in treatment for at least two months. Again, the increased reporting of lip and cheek soreness with the ITMA is counter to what is reported in the literature but only in that other studies compare Invisalign to fixed orthodontic appliances. In one of these studies comparing braces to Invisalign, causes for pain in the Invisalign group were further broken down into defects with the aligner (Fujiyama et al.2014). Several aligner irregularities were identified that might cause pain with three of them specifically capable of inducing lip and cheek soreness. Unfinished, rough margins, missing material on the buccal aspect of the aligners, and tray deformation may lead to increased lip and cheek soreness, as the irregular thermoformed plastic contacts the mucosa and abrades the epithelium leading to inflammation and ulceration (Fujiyama et al. 2014; Sweeney Jr et al. 2016). Understanding the extent and the causes for discomfort associated with any orthodontic appliance is important for clinicians, as fear of pain is often cited as one of the reasons for avoiding orthodontic treatment (Oliver and Knapman 1985). Patients can gain valuable insight from their orthodontist and better manage their expectations by understanding the causes and intensity of discomfort associated with their appliance.

The embarrassment associated with appliance use can be deleterious for patient compliance especially with removable devices (El-Huni et al. 2019). A significant difference was found between the ITMA and TB groups regarding their experience of embarrassment but only after at least two months of appliance wear ($p = 0.01$). At this time, all of the patients in the ITMA group advised they were no longer experiencing any embarrassment, while 14.3% of patients in the TB group still reported feeling a little embarrassed from the use of their appliance. This reported difference in embarrassment is most likely attributed to the TBs bulk, size, and even the colour of the acrylic as all these elements contribute to the appliance's conspicuousness. Patients in the study completed by El-Huni et al. (2019) reported that the size and colour of the TB blocks were considered barriers to their compliance as patients desired a more discrete and unnoticeable device. Even after a period of acclimatization and increased patient acceptance, a highly visible appliance can still be seen to cause social concerns especially when encountering new people and situations.

Appliance breakages requiring additional visits are incidents most clinicians are keen to avoid as they tend to reduce office schedule efficiency and can be detrimental for patient – clinician relationships. Between the two test groups, there was a significant difference regarding issues of appliance breakage and fit with more TB patients requiring extra appointments for these reasons (50% vs ITMA - 22.2%, $p = 0.08$). The disposable nature of ITMA and its series of consecutive aligners contributes to this difference, as clinicians will often advocate for patients to move to the next set of aligners if there are any particular fit issues with their current ones. The TB design has wire work aiding in retention including Adams clasps and labial bows that can be distorted if care is not taken with storage of the appliance or its handling at insertion or removal. No correlation was determined in the data set overall or when applied to the groups by appliance

type with regard to their response to questions 4 ("I was given instructions on how to wear and care for the appliance") and the experience of increased breakages or fit issues. Additionally, the TB appliance is often delivered to patients in the late mixed dentition as this stage can correspond with the peak height velocity period indicated as optimal timing for growth modification treatment (Baccetti, Franchi, and Toth 2000). As patients move from the late mixed dentition to the permanent dentition, exfoliating and erupting teeth may contribute to issues with fit and require additional visits for the clinician to modify or adjust appliances.

Wilcoxon signed-rank tests were used to review how experiences with their appliance changed over time within the two treatment groups. For both groups, the speech was reported to have worsened during initial appliance wear, with 57% of the ITMA patients and 68.2% of TB patients stating that their speech immediately became slightly or much worse ($p = 0.00$ and $p = 0.02$, respectively). Comparing this to after at least two months of appliance use, 72.8% of TB patients and 88.7% of ITMA patients saw their speech return to base line or improve. This pattern, seen in both the ITMA and TB groups, of worsening speech with initial appliance wear is frequently reported in the literature and can be attributed to the encroachment of the device's components on the tongue. Over extension of lingual flanges in removable devices have been noted as a major contributor to the changes in speech seen in new appliance wearers (Chen, Wan, and You 2018). The results reported in this study regarding TB, were similar to the results found by Lena, Bozkurt, and Yetkiner (2017), which reported that patients experienced pronunciation difficulties with the TB appliance. Thirumurthi, Felicita, and Jain's (2017) study found that 21.43% of patients had speech alterations initially with their use of the TB appliance. As with the TB group in this study, after a period of acclimatization, their TB patients found their speech to improve over time (Thirumurthi, Felicita, and Jain 2017). Similarly, Livas, Delli, and Pandis

(2018) reported that changes in speech and specifically lisping was a reported negative side effect for conventional Invisalign users. Like this study in which more than half of ITMA patients reported worsening of their speech, Nedwed and Miethke (2005) found that 52% of conventional Invisalign patients experienced slight speech impairment with their appliance. While more patients from the TB group reported changes in speech initially compared to the ITMA patients, this difference was not found to be significant. That being said, the finding that more TB patients experienced speech worsening is not surprising. Both the TB and ITMA appliances have lingual extensions that impinge on the tongue space but the TB has the added feature of larger sized acrylic blocks that require the patient to strain more to achieve lip competence required for bilabial consonants during speech (Clark 2010).

Both groups experienced a significant difference in how their jaw soreness affected them over the duration of their treatment ($p = 0.00$ and $p = 0.01$, respectively). A reduction in the experience of jaw soreness overtime was noted in both groups with 37.2% of ITMA patients and only 14.3% of TB patients reporting a little or a lot of jaw soreness. Similarly, a significant difference in the soreness of lips and/or cheeks from initial use to after at least two months of appliance wear was found for both the ITMA and TB groups ($p = 0.002$ and $p = 0.03$, respectively). Like with jaw soreness, both treatment groups saw a decrease in their experience of lip and cheek soreness overtime. As treatment time progressed, there were fewer patients in each group experiencing a little or a lot of lip and cheek soreness; the ITMA group declined to 34.9% while the TB reduced to a mere 9.5%. This progressive reduction in the amount of jaw, lip and cheek soreness experienced by both groups is related to their period of appliance adaptation. For conventional Invisalign, a period of 1-2 weeks for appliance adaptation has been reported while 10-14 days is considered the normal acclimatization time for TB patients

(Nedwed and Miethke 2005; Clark 2019). These acclimatization periods support the findings of decreased jaw, lip and cheek soreness occurring after at least two months of appliance wear and are similar to the adaptation periods of approximately two and half weeks reported by the TB and ITMA groups in this study.

Drooling and spitting were found to change significantly over time for both the ITMA and TB groups and as with jaw, lip and cheek soreness, patients saw a reduction in their drooling and spitting as they progressed with their treatment ($p = 0.004$, $p = 0.01$, respectively). Initially, approximately half of the patients in each group experienced a little or a lot of drooling and spitting (ITMA - 51.1%, TB - 47.8%). After at least two months of appliance wear, both groups saw their drooling and spitting reduce with the ITMA reporting 30.2% and the TB 23.9%. Once more, the diminishing experience of drooling and spitting overtime is mainly attributed to the adaptation of patients in both groups to their specific appliance.

Study Limitations

Patient appliance types for this study were specific to their recruitment location even though three orthodontic practices were involved. As stated previously all TB patients save for four individuals, who were treated at the University of Manitoba's Graduate Orthodontic Clinic, were aquired from a single orthodontic specialist working from two practice locations. Likewise, all ITMA patients were recruited from a different orthodontic specialist working from a single combined pediatric dentistry-orthodontic practice. Having the same orthodontist delivering only one specific appliance can ensure that there is consistency in the device design, the description of the appliance, and the instructions given at the delivery appointment. That being said, there is a risk of inherent bias within each group in how patients are treatment planned and managed based

on the location and practitioner with which they were being treated. No attempt to standardize the treatment plan or protocol of each treating clinician was made and, as such there could be confounding factors in this study related to each clinician. Acknowledging this, the results of this survey may not be reflective of all TB or ITMA patients in the general population.

Ideally, this study should have been designed as a non-blinded prospective randomized control trial in which patients were selected based on the inclusion criteria and randomly assigned to either the ITMA or TB treatment group. This would have allowed for even distribution of patient numbers per treatment group and even distribution based on age and gender. While all efforts were made to have an adequate study sample with even numbers in both groups, as well as having even age and gender distribution, there was a marked discrepancy in the n number per treatment group and a significant difference in the ages of the groups. The statistics applied to this study's data set, the Mann Whitney U test, can manage uneven sample sizes. However, uneven sample sizes can still have the affect of diminishing the statistical power of the results and the potential for detecting a true difference between the treatment groups. Put another way, having uneven subject numbers in each treatment group can increase the Type I error of the study – the chance of rejecting a true null hypothesis or recording false positives.

With regard to the actual survey used in this study, despite being validated by the principal investigator, some respondents did not complete all questions, indicating that its length may have been excessive and burdensome to the test group. A shortened survey with even further simplified language may have been more suitable to maximize completion by all patients and improve the appropriateness of their responses.

Finally, in an effort to increase the sample size of both treatment groups no attempt at standardization was made to ensure patients were completing their survey at the same timepoint in their treatment. Patients were eligible to complete the survey once they had been wearing their appliance for at least two months, however, the survey did not require patients to disclose how long they had been in treatment. This impacts the study negatively in two ways; firstly, the survey asks patients to reflect back on when they first received the appliance, which may introduce recall bias. Secondly, there may have been a large variation on how long patients had been in treatment at the time of responding to the questionnaire. Again, this may have impacted their responses especially with recall and resulted in inaccurate feedback on the survey with regard to how variables measured changed over the duration of their treatment. A randomized control trial design would have allowed for the control of the time points at which the survey was delivered. With this approach, the survey could have been issued after two weeks of use to get responses for questions 1-11 and a second survey with questions 12-20 issued at two months of appliance wear.

Chapter 5

Conclusions

The outcomes from this study highlight that while there were some differences between the treatment groups overall their experiences with their appliance were comparable. The differences and similarities determined between the treatment experiences of TB and ITMA patients were as follows:

- More TB patient's reported their appliance appeared intimidating or scary looking.

- The TB appliance was more noticeable to friends and family compared to the ITMA although there was no difference between the patient groups regarding their desire for an inconspicuous device.
- The ITMA appliance was found to be easier to insert than the TB, but there was no difference between the groups with regard to the effective retention of the appliance.
- ITMA patients experienced greater tooth pain throughout treatment compared to TB patients.
- Both ITMA and TB groups had similar initial experiences with regard to the functional and social impacts of their appliances. This included changes to speech, drinking, sleeping, appearance, teasing by peers, soreness in the jaw, teeth, lips and cheeks, yawning or opening wide, keeping their appliance clean, and getting along with family and friends.
- After at least two months of appliance wear, more ITMA patients experienced tooth, lip and cheek soreness compared to TB patients.
- After at least two months of appliance wear, more TB patients reported still feeling embarrassed by their appliance.
- More TB patients experienced issues with appliance fit and breakages requiring additional appointments.
- There was no difference between the ITMA and TB patients' evaluation of visible changes in their face as a result of treatment.
- There was no difference between the ITMA and TB patients for the time taken to acclimatize to their appliance.
- The majority of both groups reported high levels of satisfaction with their treatment.

- Patients from both treatment groups gave advice focused on assuring future patients that they would eventually "get used" to their appliance.
- Only ITMA patients made comments regarding appliance discomfort when advising future patients.

Hypotheses Revisited

H_{01}: : There are no differences in patient experience *between* TB and ITMA treatment groups in terms of the delivery appointment, initial insertion and appliance retention and their personal first impressions as well as the conspicuousness of their appliance to family and friends.

- Significant differences were found between the groups with regard to first impressions of their appliances, its noticeability and its insertion - **Null hypothesis rejected**

H_{02}: There are no differences in patient experience *between* TB and ITMA treatment groups with regard to appliance management, discomfort, functional, and social impacts *from their treatment start time and after at least two months of wear*.

- Significant differences were found between the groups with regard to the management, discomfort, functional, and social impact of their devices over the duration of their treatment – **Null hypothesis rejected**

H_{03}: There are no differences in patient experience *between* TB and ITMA treatment groups with regard to appliance management, discomfort, functional, and social impacts *from their treatment start time and after at least two months of wear*.

- Significant differences were found within the groups over the duration of their treatment with regard to discomfort, functional, and social impact of their devices – **Null hypothesis rejected**

Future Recommendations

Based on the findings from this study, clinicians can confidently make appropriate appliance allocations for their patients based on their assessment of their individual personalities and expectations for treatment experience. This study demonstrates that while both TB and ITMA devices may offer similar experiences there are some differences that may benefit specific patients. Those wanting a more inconspicuous appliance may be better suited to the ITMA appliance. Additionally, patients in mixed dentition with parents and clinicians looking to avoid extra visits for breakages or fit issues may prefer the ITMA appliance with its multiple consecutive aligners rather than the use of a singular TB appliance. If patients and parents want to limit the experience of tooth, lip and cheek discomfort throughout treatment, the TB appliance may be the more appropriate device for their growth modification phase before moving on to full fixed orthodontic treatment for final tooth alignment. With these understandings and careful evaluation of the specific treatment experience expectations of each individual, clinicians can provide their patients with the most suitable appliance along with relevant information about how the device will affect them. In this way, clinicians will be able to prepare their patients best

for their growth modification treatment, ensuring that they are in a position to maximize their compliance with their removable device and achieve a successful treatment outcome.

Future studies investigating patient experience can benefit from the limitations found in this research project. A recommendation is made for a shorter, less burdensome survey with delivery at two controlled time points to promote accurate and complete responses. Executing this study as a prospective randomized control trial to compare appliances will allow researchers to ensure even treatment group allocation for patient numbers, gender, and age thereby enhancing the power of their research findings.

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Images Used

Figure 1 - Dibiase,Cobourne, and Lee. *Twin Block Functional Appliance. 2015, in* "The Use of Functional Appliances in Contemporary Orthodontic Practice." *British Dental Journal* 218 (3): 124.

Figure 2 – Invisalign Treatment with Mandibular Advancement. Innovative Ortho Centres. Accessed October 12, 2019. https://www.innovativeorthocenters.com/invisalign-treatment-with-mandibular-advancement/

Figure 3 - Baccetti, Franchi, and Toth. *Developmental Stages. 2000, in* "ORIGINAL ARTICLE Treatment Timing for Twin-Block Therapy." *Am J Orthod Dentofacial Orthop* 118: 161.

Figure 4 – Meikle. *Summary of TMJ Surface Remodelling.* 2007 in "CRITICAL REVIEWS IN ORAL BIOLOGY & MEDICINE Remodeling the Dentofacial Skeleton : The Biological Basis of Orthodontics and Dentofacial Orthopedics." *Critical Reviews in Oral Biology & Medicine* 86 (1): 17. (Meikle 2007)

Figure 5 – Frankel II. Dynaflex. Accessed November 7, 2019. https://www.dynaflex.com/orthodontic-laboratory/removable-appliances/frankel-appliances/

Figure 6 – Activator Andresen!. OrthoArt Lab Facebook. Accessed November 7, 2019. https://touch.facebook.com/orthoartlab.lab/photos/a.122664169069086/1265379273483894/?type=3&source=54

Figure 7 – Van Beek Appliance. Ortholab. Accessed November 7, 2019. http://www.ortholab.nl/en/van-beek-appliance.php

Figure 8 – Bionator II - Deep Bite and Open Bite. North Star Orthodontics. Accessed November 7, 2019. http://northstarorthodontics.com/lab-services/functional-therapy/bionator-ii-53.html

Figure 9 – Twin Block. North Star Orthodontics. Accessed November 7, 2019. https://www.northstardental.com/lab-services/functional-therapy/twin-block-92.html

Figure 10 – Invisalign Clear Aligners with Mandibular Advancement. Invisalign. Accessed Dec 17, 2019. https://www.invisalign.com/the-invisalign-difference/mandibular-advancement

Appendices

Appendix 1

UNIVERSITY OF MANITOBA | Research Ethics and Compliance

Research Ethics - Bannatyne
P126-770 Bannatyne Avenue
Winnipeg, MB
Canada R3E 0W3
Phone +204-789-3255
Fax +204-789-3414

HEALTH RESEARCH ETHICS BOARD (HREB)
CERTIFICATE OF FINAL APPROVAL FOR NEW STUDIES
Delegated Review

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. Tyrone Zybutz	U of M/Preventative Dental Sciences/Orthodontics	HS21774 (H2018:177)
APPROVAL DATE: April 4, 2018	**EXPIRY DATE:** April 4, 2019	
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. Robert Drummond		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE;
NA	Investigation and Comparison of Patient Experiences with Invisalign Teen with Mandibular Advancement® and Twin Block Appliance
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NA	

Submission Date of Investigator Documents:	HREB Receipt Date of Documents:
March 26, 2018	April 2, 2018

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Protocol (undated)		submitted April 2, 2018
Consent and Assent Form(s):		
Consent Disclosure Statement - (Twin Block Appliance)		April 1, 2018
Consent Disclosure Statement - (Invisalign Teen with Mandibular Advancement)		April 1, 2018
Other:		
Questionnaires/Scales/Instruments Appendix		01/04/18

CERTIFICATION
The above named research study/project has been reviewed in a ***delegated manner*** by the University of Manitoba (UM) Health Research Board (HREB) and was found to be acceptable on ethical grounds for research involving human participants. The study/project and documents listed above was granted final approval by the Chair or Acting Chair, UM HREB.

HREB ATTESTATION
The University of Manitoba (UM) Research Board (HREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba. In respect to clinical trials, the HREB complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

Appendix 2

UNIVERSITY OF MANITOBA | Research Ethics and Compliance

Research Ethics - Bannatyne
P126-770 Bannatyne Avenue
Winnipeg, MB
Canada R3E 0W3
Phone +204-789-3255
Fax +204-789-3414

HEALTH RESEARCH ETHICS BOARD (HREB)

CERTIFICATE OF ANNUAL APPROVAL

PRINCIPAL INVESTIGATOR: Dr. Tyrone Zybutz	INSTITUTION/DEPARTMENT: U of M/Preventive Dental Sciences/ Orthodontics	ETHICS #: HS21774 (H2018:177)
HREB MEETING DATE (If applicable):	APPROVAL DATE: March 25, 2019	EXPIRY DATE: April 4, 2020
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. Robert Drummond		

PROTOCOL NUMBER: NA	PROJECT OR PROTOCOL TITLE: Investigation and Comparison of Patient Experiences with Invisalign Teen with Mandibular Advancement® and Twin Block Appliance
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NA	

Submission Date of Investigator Documents: February 4, 2019	HREB Receipt Date of Documents: February 4, 2019

REVIEW CATEGORY OF ANNUAL REVIEW: Full Board Review ☐ Delegated Review ☒

THE FOLLOWING AMENDMENT(S) and DOCUMENTS ARE APPROVED FOR USE:

Document Name(if applicable)	Version(if applicable)	Date

Annual approval

*Annual approval implies that the most recent **HREB approved** versions of the protocol, Investigator Brochures, advertisements, letters of initial contact or questionnaires, and recruitment methods, etc. are approved.*

Consent and Assent Form(s):

CERTIFICATION

The University of Manitoba (UM) Health Research Board (HREB) has reviewed the annual study status report for the research study/project named on this ***Certificate of Annual Approval*** as per the category of review listed above and was found to be acceptable on ethical grounds for research involving human participants. Annual approval was granted by the Chair or Acting Chair, UM HREB, per the response to the conditions of approval outlined during the initial review (full board or delegated) of the annual study status report.

HREB ATTESTATION

The University of Manitoba (UM) Health Research Board (HREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba. In respect to clinical trials, the HREB complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

University of Manitoba | Research Ethics and Compliance

Research Ethics Bannatyne
P126-770 Bannatyne Avenue
Winnipeg, MB R3E 0W3
T: 204 789 3255
F: 204 789 3414
bannreb@umanitoba.ca

HEALTH RESEARCH ETHICS BOARD (HREB)

CERTIFICATE OF ANNUAL APPROVAL

PRINCIPAL INVESTIGATOR: Dr. Tyrone Zybutz	INSTITUTION/DEPARTMENT: U of M/Preventive Dental Sciences/ Orthodontics	ETHICS #: HS21774 (H2018:177)
HREB MEETING DATE (if applicable):	APPROVAL DATE: March 23, 2020	EXPIRY DATE: April 4, 2021
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (if applicable): Dr. Robert Drummond		

PROTOCOL NUMBER: NA	PROJECT OR PROTOCOL TITLE: Investigation and Comparison of Patient Experiences with Invisalign Teen with Mandibular Advancement® and Twin Block Appliance
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NA	

Submission Date of Investigator Documents: February 4, 2020	HREB Receipt Date of Documents: February 4, 2020

REVIEW CATEGORY OF ANNUAL REVIEW: **Full Board Review** ☐ **Delegated Review** ☒

THE FOLLOWING AMENDMENT(S) and DOCUMENTS ARE APPROVED FOR USE:

Document Name(if applicable)	Version(if applicable)	Date

Annual approval

Annual approval implies that the most recent HREB approved versions of the protocol, investigator Brochures, advertisements, letters of initial contact or questionnaires, and recruitment methods, etc. are approved.

Consent and Assent Form(s):

CERTIFICATION

The University of Manitoba (UM) Health Research Board (HREB) has reviewed the annual study status report for the research study/project named on this ***Certificate of Annual Approval*** as per the category of review listed above and was found to be acceptable on ethical grounds for research involving human participants. Annual approval was granted by the Chair or Acting Chair, UM HREB, per the response to the conditions of approval outlined during the initial review (full board or delegated) of the annual study status report.

HREB ATTESTATION

The University of Manitoba (UM) Health Research Board (HREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba. In respect to clinical trials, the HREB complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

Appendix 3

Experiences with Twin Block

First, please tell us about yourself.

Age: _____ years old

Gender: ☐ Male ☐ Female

*These questions are about when you **FIRST** got the Twin Block appliance. Please circle only one answer.*

1. I was given a complete description of the Twin Block appliance before wearing it.

   Strongly Agree Agree Neutral Disagree Strongly Disagree

2. When I first saw it, the Twin Block appliance looked scary, overwhelming or intimidating.

   Strongly Agree Agree Neutral Disagree Strongly Disagree

3. The appointment to get the Twin Block appliance was quick and easy.

   Strongly Agree Agree Neutral Disagree Strongly Disagree

4. I was given instructions on how to wear and care of the Twin Block appliance.

   Strongly Agree Agree Neutral Disagree Strongly Disagree

5. The Twin Block appliance was noticeable to your friends and family

   Strongly Agree Agree Neutral Disagree Strongly Disagree

6. It is important to me to have an appliance that is not noticeable.

   Strongly Agree Agree Neutral Disagree Strongly Disagree

7. The Twin Block appliance was difficult to put in my mouth and wear.

   Strongly Agree Agree Neutral Disagree Strongly Disagree

8. The Twin Block appliance was easily dislodged and would come out of my mouth.

   Strongly Agree Agree Neutral Disagree Strongly Disagree

*These questions are about **WHEN YOU FIRST GOT THE TWIN BLOCK APPLIANCE.** Please circle only one answer.*

9. WHEN YOU FIRST GOT THE Twin Block, how much did the following things

- **Speech** Much improved Improved Same Slightly worse Much worse
- **Drinking** Much improved Improved Same Slightly worse Much worse
- **Sleeping** Much improved Improved Same Slightly worse Much worse
- **Appearance** Much improved Improved Same Slightly worse Much worse
- **I am teased** Much improved Improved Same Slightly worse Much worse

10. WHEN YOU FIRST GOT THE Twin Block, how much did the following affect you?

- **Sore jaw** Not at all A little A lot
- **Sore teeth** Not at all A little A lot
- **Sore lips/cheeks from rubbing** Not at all A little A lot
- **Feeling embarrassed** Not at all A little A lot
- **Drooling/Spitting** Not at all A little A lot
- **Difficult to open wire/yawn** Not at all A little A lot
- **Keeping the Twin Block clean is difficult** Not at all A little A lot

11. WHEN YOU FIRST GOT THE Twin Block, how did wearing the appliance

I am teased

Much improved Improved Same Slightly worse Much worse

Getting along with your friends?

Much improved Improved Same Slightly worse Much worse

Getting along with your family?

Much improved Improved Same Slightly worse Much worse

These questions are about how you feel about the Twin Block *appliance* ***RIGHT NOW****.*
Please circle only one answer.

12. RIGHT NOW, while wearing the Twin Block, how much have the following things changed?

- **Speech** Much improved Improved Same Slightly worse Much worse
- **Drinking** Much improved Improved Same Slightly worse Much worse
- **Sleeping** Much improved Improved Same Slightly worse Much worse
- **Appearance** Much improved Improved Same Slightly worse Much worse
- **I am teased** Much improved Improved Same Slightly worse Much worse

13. RIGHT NOW, while wearing the Twin Block, how much have the following affected you?

- **Sore jaw** Not at all A little A lot
- **Sore teeth** Not at all A little A lot
- **Sore lips/cheeks from rubbing** Not at all A little A lot
- **Feeling embarrassed** Not at all A little A lot
- **Drooling/Spitting** Not at all A little A lot
- **Difficult to open wire/yawn** Not at all A little A lot
- **Keeping the Twin Block clean is difficult** Not at all A little A lot

14. RIGHT NOW, while you are wearing the Twin Block, how has wearing the appliance affected…

I am teased

Much improved Improved Same Slightly worse Much worse

Getting along with your friends?

Much improved Improved Same Slightly worse Much worse

Getting along with your family?

Much improved Improved Same Slightly worse Much worse

These questions are about how you feel about the Twin Block *appliance* ***RIGHT NOW****. Please circle only one answer.*

15. I have noticed a difference in my facial appearance since I first started wearing the Twin Block?

Strongly Agree Agree Neutral Disagree Strongly Disagree

16. Have you had any extra visits to the orthodontist because the Twin Block was broken or not fitting properly?

Yes No

17. If you had to make extra visits the orthodontist because the Twin Block was broken or not fitting properly, has this bothered you?

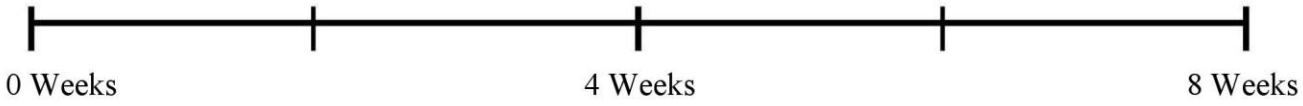
Not at all A little A lot It did not break / It always has fit well

18. At this time, do you feel like you have gotten used to the Twin Block? Yes No

If you answered YES, please answer 18a below. If you answered NO, go to question 19

18a. How long did it take for you to get used to the Twin Block?

Please draw an "X" anywhere on the line that matches closest with your answer



19. Overall, how do you feel about your experience with the Twin Block appliance?

Really Good Good Neutral Bad Really Bad

20. <u>Advice to other patients:</u>
Based on your own experience wearing a Twin Block appliance what would you say to someone who was about to start wearing one? What kind of advice would you give them?

Thank you so much for your participation!
Please return your survey to your orthodontist or a staff member.

Don't forget to fill out and return your draw card for the $50 pre-paid VISA prize!

Appendix 4

Experiences with Invisalign Teen with Mandibular Advancement® (ITMA) Survey

First, please tell us about yourself.

Age: _____ years old

Gender: ☐ Male ☐ Female

*These questions are about when you **FIRST** got the ITMA appliance. Please circle only one answer.*

1. I was given a complete description of the ITMA appliance before wearing it.

Strongly Agree Agree Neutral Disagree Strongly Disagree

2. When I first saw it, the ITMA appliance looked scary, overwhelming or intimidating.

Strongly Agree Agree Neutral Disagree Strongly Disagree

3. The appointment to get the ITMA appliance was quick and easy.

Strongly Agree Agree Neutral Disagree Strongly Disagree

4. I was given instructions on how to wear and care of the ITMA appliance.

Strongly Agree Agree Neutral Disagree Strongly Disagree

5. The ITMA appliance was noticeable to your friends and family

Strongly Agree Agree Neutral Disagree Strongly Disagree

6. It is important to me to have an appliance that is not noticeable.

Strongly Agree Agree Neutral Disagree Strongly Disagree

7. The ITMA appliance was difficult to put in my mouth and wear.

Strongly Agree Agree Neutral Disagree Strongly Disagree

8. The ITMA appliance was easily dislodged and would come out of my mouth.

Strongly Agree Agree Neutral Disagree Strongly Disagree

*These questions are about **WHEN YOU FIRST GOT THE ITMA APPLIANCE.***
Please circle only one answer.

9. WHEN YOU FIRST GOT THE ITMA, how much did the following things change?

- **Speech** Much improved Improved Same Slightly worse Much worse
- **Drinking** Much improved Improved Same Slightly worse Much worse
- **Sleeping** Much improved Improved Same Slightly worse Much worse
- **Appearance** Much improved Improved Same Slightly worse Much worse
- **I am teased** Much improved Improved Same Slightly worse Much worse

10. WHEN YOU FIRST GOT THE ITMA, how much did the following affect you?

- **Sore jaw** Not at all A little A lot
- **Sore teeth** Not at all A little A lot
- **Sore lips/cheeks from rubbing** Not at all A little A lot
- **Feeling embarrassed** Not at all A little A lot
- **Drooling/Spitting** Not at all A little A lot
- **Difficult to open wire/yawn** Not at all A little A lot
- **Keeping the ITMA clean is difficult** Not at all A little A lot

11. WHEN YOU FIRST GOT THE ITMA, how did wearing the appliance affect…

I am teased

Much improved Improved Same Slightly worse Much worse

Getting along with your friends?

Much improved Improved Same Slightly worse Much worse

Getting along with your family?

Much improved Improved Same Slightly worse Much worse

*These questions are about how you feel about the ITMA appliance **RIGHT NOW**. Please circle only one answer.*

12. RIGHT NOW, while wearing the ITMA, how much have the following things changed?

- **Speech** Much improved Improved Same Slightly worse Much worse
- **Drinking** Much improved Improved Same Slightly worse Much worse
- **Sleeping** Much improved Improved Same Slightly worse Much worse
- **Appearance** Much improved Improved Same Slightly worse Much worse
- **I am teased** Much improved Improved Same Slightly worse Much worse

13. RIGHT NOW, while wearing the ITMA, how much have the following affected you?

- **Sore jaw** Not at all A little A lot
- **Sore teeth** Not at all A little A lot
- **Sore lips/cheeks from rubbing** Not at all A little A lot
- **Feeling embarrassed** Not at all A little A lot
- **Drooling/Spitting** Not at all A little A lot
- **Difficult to open wire/yawn** Not at all A little A lot
- **Keeping the ITMA clean is difficult** Not at all A little A lot

14. RIGHT NOW, while you are wearing the ITMA, how has wearing the appliance affected…

I am teased

Much improved Improved Same Slightly worse Much worse

Getting along with your friends?

Much improved Improved Same Slightly worse Much worse

Getting along with your family?

Much improved Improved Same Slightly worse Much worse

*These questions are about how you feel about the ITMA appliance **RIGHT NOW**. Please circle only one answer.*

15. I have noticed a difference in my facial appearance since I first started wearing the ITMA?

Strongly Agree Agree Neutral Disagree Strongly Disagree

16. Have you had any extra visits to the orthodontist because the ITMA was broken or not fitting properly?

Yes No

17. If you had to make extra visits the orthodontist because the ITMA was broken or not fitting properly, has this bothered you?

Not at all A little A lot It did not break / It always has fit well

18. At this time, do you feel like you have gotten used to the ITMA? Yes No

If you answered YES, please answer 18a below. If you answered NO, go to question 19

18a. How long did it take for you to get used to the ITMA?

Please draw an "X" anywhere on the line that matches closest with your answer

0 Weeks 4 Weeks 8 Weeks

19. Overall, how do you feel about your experience with the ITMA appliance?

Really Good Good Neutral Bad Really Bad

20. <u>Advice to other patients:</u>
Based on your own experience wearing Invisalign Teen with Mandibular Advancement®, what would you say to someone who was about to start wearing one? What kind of advice would you give them?

Thank you so much for your participation!
Please return your survey to your orthodontist or a staff member.

Don't forget to fill out and return your draw card for the $50 pre-paid VISA prize!

Appendix 5

UNIVERSITY OF MANITOBA

Consent Disclosure Statement

Project Title: Investigation and Comparison of Patient Experiences with Removable Functional Appliances: Invisalign Teen with Mandibular Advancement versus Twin Block

Principal Investigator: Dr Tyrone Zybutz, University of Manitoba

Project Supervisors: Dr Milos Lekic and Dr Robert Drummond, University of Manitoba

My name is Dr Tyrone Zybutz and I am an orthodontic resident at the University of Manitoba. As part of my studies at the university, I am conducting a research project aimed at evaluating the overall experience patients had while using the Twin Block as part of their comprehensive orthodontic treatment.

This study has been approved by the University of Manitoba's Health Research Ethics Board.

Why are you asking me?

You have been asked to participate in this survey study because the Twin Block is part of your customized orthodontic treatment as recommended by your doctor and decided by you.

What will I have to do once I agree to participate in the study?

It's simple. After at least two months of wearing the Twin Block you will be asked to complete an anonymous short written survey that should take no longer than 15 minutes.

The survey will ask you questions about your unique experience using the Twin Block. You may only answer the questions you feel comfortable answering..

How will you keep my information confidential?

You are not required to provide any personal information such as your name, address or telephone number. Your responses will be anonymous as we will not know who has completed the survey and it will not be linked to any other information about you.

The only personal information we collect is your age and gender. The survey will be issued to you by your orthodontist and will be mailed directly to the research team after completion.

The information gathered in this study will be used for scholarly purposes and will be shared with University of Manitoba and Align Technology representatives.

Are there any dangers or risks to participating in this study?

Participation in this anonymous survey poses minimal to no risk for its participants.

If there are any questions, concerns or complaints about this study or the benefits or risks associated with participating in the study you can address them to Dr Tyrone Zybutz who can be contacted at:

zybutzt@myumanitoba.ca

P: 1-204-789-3699

Are there any benefits to me for participating in this survey study?

While there are no direct benefits to you as an individual for participating in this study the information collected will be used to improve the design and use of the Twin Block.

This means orthodontists will be able to learn from your experiences and insure that the patients they treat in the future with the Twin Block will have the best experience possible.

There are no costs to you for participating in this survey study. Likewise, there will be no direct compensation for your participation in the survey study.

Upon completion of the survey, however, you are eligible to be entered into a draw for a $50 pre-paid VISA card. The odds of winning are 1/50 and the draw will take place in no later than June 30th 2019. Under federal law, it is necessary that you answer a skill-testing question correctly in order to qualify for a chance to win the prize. Please provide your name and contact information on the separate incentive prize draw card in order to be entered into the draw. This information will be handled separately for the purposes of contacting you should you be drawn for the prize and will not be linked to any other information about you.

What if I do not want to participate in the study?

You participation in the survey is very important to us but it is also completely voluntary. You may exercise your right to refuse to participate in the study without any consequence.

Also, please note that once you submit your completed survey you will not be able to withdraw your survey responses, as we cannot link the survey responses back to you.

Voluntary Consent by Participant

By completing this survey you are agreeing to participate in the study. You are also acknowledging that you understand the purpose and nature of this study and that you are participating voluntarily.

Appendix 6

UNIVERSITY
OF MANITOBA

Consent Disclosure Statement

Project Title: Investigation and Comparison of Patient Experiences with Removable Functional Appliances: Invisalign Teen with Mandibular Advancement versus Twin Block

Principal Investigator: Dr Tyrone Zybutz, University of Manitoba

Project Supervisors: Dr Milos Lekic and Dr Robert Drummond, University of Manitoba

My name is Dr Tyrone Zybutz and I am an orthodontic resident at the University of Manitoba. As part of my studies at the university, I am conducting a research project aimed at evaluating the overall experience patients had while using the Invisalign Mandibular Advancement Device® as part of their comprehensive orthodontic treatment.

This study has been approved by the University of Manitoba's Health Research Ethics Board.

Why are you asking me?

You have been asked to participate in this survey study because the Invisalign Mandibular Advancement Device® is part of your customized orthodontic treatment as recommended by your doctor and decided by you.

What will I have to do once I agree to participate in the study?

It's simple. After at least two months of wearing the Invisalign Mandibular Advancement Device® you will be asked to complete an anonymous short written survey that should take no longer than 15 minutes. The survey will ask you questions about your unique experience using the Invisalign Mandibular Advancement Device®. You may only answer the questions you feel comfortable answering.

How will you keep my information confidential?

You are not required to provide any personal information such as your name, address or telephone number. Your responses will be anonymous as we will not know who has completed the survey and it will not be linked to any other information about you.

The only personal information we collect is your age and gender. The survey will be issued to you by your orthodontist and will be mailed directly to the research team after completion.

The information gathered in this study will be used for scholarly purposes and will be shared with University of Manitoba and Align Technology representatives.

Are there any dangers or risks to participating in this study?

Participation in this anonymous survey poses minimal to no risk for its participants.

If there are any questions, concerns or complaints about this study or the benefits or risks associated with participating in the study you can address them to Dr Tyrone Zybutz who can be contacted at:

zybutzt@myumanitoba.ca
P: 1-204-789-3699

Are there any benefits to me for participating in this survey study?

While there are no direct benefits to you as an individual for participating in this study the information collected will be used to improve the design and use of the Invisalign Mandibular Advancement Device®.

This means orthodontists will be able to learn from your experiences and insure that the patients they treat in the future with the Invisalign Mandibular Advancement Device® will have the best experience possible.

There are no costs to you for participating in this survey study. Likewise, there will be no direct compensation for your participation in the survey study.

Upon completion of the survey, however, you are eligible to be entered into a draw for a $50 pre-paid VISA card. The odds of winning are 1/50 and the draw will take place in no later than June 30th 2019. Under federal law, it is necessary that you answer a skill-testing question correctly in order to qualify for a chance to win the prize. Please provide your name and contact information on the separate incentive prize draw card in order to be entered into the draw. This information will be handled separately for the purposes of contacting you should you be drawn for the prize and will not be linked to any other information about you.

What if I do not want to participate in the study?

You participation in the survey is very important to us but it is also completely voluntary. You may exercise your right to refuse to participate in the study without any consequence. Also, please note that once you submit your completed survey you will **not** be able to withdraw your survey responses, as we cannot link the survey responses back to you.

Voluntary Consent by Participant

By completing this survey you are agreeing to participate in the study. You are also acknowledging that you understand the purpose and nature of this study and that you are participating voluntarily.

Appendix 7

ENTER TO WIN a $50 Prepaid VISA!

Name:

Email:

Phone:

If you wish to be considered for this prize, then please answer the following question and provide your answer in the blank space provided.

(6+4) divided by 2 = _____

Appendix 8

Summary of Responses from Treatment Groups

		Appliance				Appliance	
Question number	**Answers**	**ITMA**	**TB**	**Question number**	**Answers**	**ITMA**	**TB**
Q1	Strongly Disagree (1)	0 (0)	0 (0)	Q5	Strongly Disagree (1)	8 (17.8)	3 (13)
	Disgree (2)	1 (2.2)	0 (0)		Disgree (2)	6 (13.3)	1 (4.4)
	Neutral (3)	1 (2.2)	3 (13)		Neutral (3)	21 (46.7)	3 (13)
	Agree (4)	16 (35.5)	6 (26.1)		Agree (4)	8 (17.8)	8 (34.8)
	Strongly Agree (5)	27 (60)	14 (60.9)		Strongly Agree (5)	2 (4.4)	8 (34.8)
Q2	Strongly Disagree (1)	15 (33.3)	2 (8.7)	Q6	Strongly Disgaree (1)	1 (2.2)	3 (13)
	Disgree (2)	20 (44.4)	10 (43.5)		Disgree (2)	4 (8.9)	3 (13)
	Neutral (3)	6 (13.3)	6 (26.1)		Neutral (3)	18 (40)	10 (43.5)
	Agree (4)	3 (6.7)	5 (21.7)		Agree (4)	11 (24.4)	4 (17.4)
	Strongly Agree (5)	1 (2.2)	0 (0)		Strongly Agree (5)	11 (24.4)	3 (13)
Q3	Strongly Disagree (1)	0 (0)	0 (0)	Q7	Strongly Disagree (1)	18 (40)	3 (13)
	Disgree (2)	2 (4.4)	1 (4.35)		Disgree (2)	16 (35.6)	7 (30.4)
	Neutral (3)	13 (28.9)	3 (13.0)		Neutral (3)	9 (20)	8 (34.8)
	Agree (4)	18 (40)	8 (34.8)		Agree (4)	2 (4.4)	4 (17.4)
	Strongly Agree (5)	12 (26.7)	11 (47.8)		Strongly Agree (5)	0 (0)	1 (4.4)
Q4	Strongly Disagree (1)	0 (0)	0 (0)	Q8	Strongly Disagree (1)	13 (29.6)	2 (8.7)
	Disgree (2)	0 (0)	0 (0)		Disgree (2)	9 (20.5)	8 (34.8)
	Neutral (3)	1 (2.2)	0 (0)		Neutral (3)	4 (9.1)	4 (17.4)
	Agree (4)	7 (15.6)	7 (30.43)		Agree (4)	11 (25)	9 (39.1)
	Strongly Agree (5)	37 (82.2)	16 (69.6)		Strongly Agree (5)	7 (15.9)	0 (0)

Values are expressed as number (% among respondents)

		Appliance				Appliance	
Question number	Answers	ITMA	TB	Question number	Answers	ITMA	TB
Q9A	Much Worse (1)	0 (0)	4 (18.2)	Q9E	Strongly Disagree (1)	1 (2.2)	0 (0)
	Slightly Worse (2)	26 (57.8)	11 (50)		Disagree (2)	2 (4.4)	4 (18.2)
	Same (3)	16 (35.6)	5 (22.7)		Neutral (3)	38 (84.5)	15(68.2)
	Improved (4)	2 (4.4)	2 (9.1)		Agree (4)	1 (2.2)	1 (4.6)
	Much Improved (5)	1 (2.2)	0 (0)		Strongly Agree (5)	5 (6.7)	2 (9.1)
Q9B	Strongly Disagree (1)	0 (0)	1 (4.5)	Q10A	Not At All (1)	12 (27.3)	10 (43.5)
	Disagree (2)	6 (13.3)	3 (13.6)		A Little (2)	22 (50)	9 (39.1)
	Neutral (3)	38 (69.1)	17 (30.9)		A Lot (3)	10 (22.7)	4 (17.4)
	Agree (4)	1 (2.2)	0 (0)				
	Strongly Agree (5)	0 (0)	1 (4.5)				
Q9C	Strongly Disagree (1)	1 (2.2)	2 (9.1)	Q10B	Not At All (1)	7 (15.6)	9 (39.1)
	Disagree (2)	7 (15.6)	4 (18.2)		A Little (2)	22 (48.9)	9 (39.1)
	Neutral (3)	36 (80)	15 (61.2)		A Lot (3)	16 (35.6)	5 (21.7)
	Agree (4)	1 (2.2)	0 (0)				
	Strongly Agree (5)	0 (0)	1 (4.6)				
Q9D	Strongly Disagree (1)	0 (0)	0 (0)	Q10C	Not At All (1)	18 (40)	14 (60.9)
	Disagree (2)	3 (6.7)	4 (18.2)		A Little (2)	20 (44.4)	8 (34.8)
	Neutral (3)	28 (62.2)	15 (68.2)		A Lot (3)	7 (15.6)	1 (4.35)
	Agree (4)	10 (22.2)	3 (13.6)				
	Strongly Agree (5)	4 (8.9)	0 (0)				

		Appliance				Appliance	
Question number	Answers	ITMA	TB	Question number	Answers	ITMA	TB
Q10D	Not At All (1)	42 (93.3)	18 (78.3)	Q11A	Strongly Disagree (1)	1 (2.2)	0 (0)
	A Little (2)	2 (4.4)	5 (21.7)		Disagree (2)	1 (2.2)	3 (14.3)
	A Lot (3)	1 (2.2)	0 (0)		Neutral (3)	40 (88.9)	16 (76.2)
					Agree (4)	2 (4.4)	0 (0)
					Strongly Agree (5)	1 (2.2)	2 (9.5)
Q10E	Not At All (1)	22 (48.9)	12 (52.2)	Q11B	Strongly Disagree (1)	0 (0)	0 (0)
	A Little (2)	19 (42.2)	9 (39.1)		Disagree (2)	0 (0)	1 (4.8)
	A Lot (3)	4 (8.9)	2 (8.7)		Neutral (3)	43 (95.6)	18 (85.7)
					Agree (4)	2 (4.4)	1 (4.8)
					Strongly Agree (5)	0 (0)	1 (4.8)
Q10F	Not At All (1)	37 (82.2)	15 (65.2)	Q11C	Strongly Disagree (1)	0 (0)	0 (0)
	A Little (2)	8 (17.8)	5 (21.7)		Disagree (2)	0 (0)	2 (9.5)
	A Lot (3)	0 (0)	3 (4.4)		Neutral (3)	44 (97.8)	18 (85.7)
					Agree (4)	1 (2.2)	0 (0)
					Strongly Agree (5)	0 (0)	1 (4.8)
Q10G	Not At All (1)	16 (35.6)	11 (47.8)	Q12A	Much Worse (1)	0 (0)	0 (0)
	A Little (2)	26 (57.8)	6 (26.1)		Slightly Worse (2)	5 (11.4)	6 (27.3)
	A Lot (3)	3 (6.7)	6 (26.1)		Same (3)	28 (63.6)	11 (50)
					Improved (4)	9 (20.5)	4 (18.2)
					Much Improved (5)	2 (4.6)	1 (4.6)

		Appliance				Appliance	
Question number	Answers	ITMA	TB	Question number	Answers	ITMA	TB
Q12B	Much Worse (1)	0 (0)	1 (4.8)	Q13A	Not At All (1)	27 (62.8)	18 (85.7)
	Slightly Worse (2)	1 (2.3)	1 (4.8)		A Little (2)	16 (37.2)	2 (9.52)
	Same (3)	36 (83.7)	15 (71.4)		A Lot (3)	0 (0)	1 (4.76)
	Improved (4)	6 (14)	3 (14.3)				
	Much Improved (5)	0 (0)	1 (4.76)				
Q12C	Much Worse (1)	0 (0)	1 (4.8)	Q13B	Not At All (1)	20 (46.5)	16 (76.2)
	Slightly Worse (2)	0 (0)	1 (4.8)		A Little (2)	20 (46.5)	4 (19.1)
	Same (3)	40 (90.9)	14 (66.7)		A Lot (3)	3 (7)	1 (4.8)
	Improved (4)	4 (9.1)	1 (4.8)				
	Much Improved (5)	0 (0)	4 (19.1)				
Q12D	Much Worse (1)	0 (0)	0 (0)	Q13C	Not At All (1)	28 (65.1)	19 (90.5)
	Slightly Worse (2)	0 (0)	3 (15)		A Little (2)	14 (32.6)	2 (9.5)
	Same (3)	25 (56.8)	10 (50)		A Lot (3)	1 (2.33)	0 (0)
	Improved (4)	13 (29.6)	4 (20)				
	Much Improved (5)	6 (13.6)	3 (15)				
Q12E	Much Worse (1)	1 (2.3)	0 (0)	Q13D	Not At All (1)	42 (100)	18 (85.7)
	Slightly Worse (2)	0 (0)	0 (0)		A Little (2)	0 (0)	3 (14.3)
	Same (3)	3 (93.2)	16 (80)		A Lot (3)	0 (0)	0 (0)
	Improved (4)	1 (2.3)	3 (15)				
	Much Improved (5)	1 (2.3)	1 (5)				

		Appliance				Appliance	
Question number	Answers	ITMA	TB	Question number	Answers	ITMA	TB
Q13E	Not At All (1)	30 (69.8)	16 (76.2)	Q14B	Much Worse (1)	0 (0)	0 (0)
	A Little (2)	13 (30.2)	4 (19.1)		Slightly Worse (2)	0 (0)	0 (0)
	A Lot (3)	0 (0)	1 (4.8)		Same (3)	42 (97.7)	18 (90)
					Improved (4)	1 (2.3)	1 (5)
					Much Improved (5)	0 (0)	1 (5)
Q13F	Not At All (1)	41 (95.4)	17 (81)	Q14C	Much Worse (1)	0 (0)	0 (0)
	A Little (2)	2 (4.7)	2 (9.5)		Slightly Worse (2)	0 (0)	2 (10.5)
	A Lot (3)	0 (0)	2 (9.5)		Same (3)	42 (97.7)	15 (79)
					Improved (4)	1 (2.3)	1 (5.3)
					Much Improved (5)	0 (0)	1 (5.3)
Q13G	Not At All (1)	18 (41.9)	10 (47.6)	Q15	Much Worse (1)	5 (11.1)	0 (0)
	A Little (2)	22 (51.2)	6 (28.6)		Slightly Worse (2)	4 (8.9)	1 (4.4)
	A Lot (3)	3 (7)	5 (23.8)		Same (3)	5 (11.1)	10 (43.5)
					Improved (4)	18 (40)	8 (34.8)
					Much Improved (5)	13 (28.9)	4 (17.4)
Q14A	Much Worse (1)	1 (2.3)	0 (0)	Q16	No (1)	35 (77.8)	11 (50)
	Slightly Worse (2)	0 (0)	1 (5)		Yes (2)	10 (22.2)	6 (50)
	Same (3)	40 (93)	16 (80)				
	Improved (4)	2 (4.7)	2 (10)				
	Much Improved (5)	0 (0)	1 (5)				

		Appliance	
Question number	Answers	ITMA	TB
Q17	Not At All (1)	5 (11.1)	5 (23.8)
	A Little (2)	5 (11.1)	5 (23.8)
	A Lot (3)	0 (0)	1 (4.8)
	It Did Not Break (4)	35 (77.8)	10 (47.6)
Q18	Strongly Disagree (1)	2 (4.4)	3 (13)
	Disagree (2)	43 (95.6)	19 (82.6)
	Neutral (3)	0 (0)	1 (4.4)
Q19	Really (1)	0 (0)	0 (0)
	Bad (2)	1 (2.4)	1 (4.4)
	Neutral (3)	4 (9.8)	5 (21.7)
	Good (4)	14 (34.2)	10 (43.5)
	Really Good (5)	22 (53.7)	7 (30.4)

Appendix 9

Differences observed between ITMA and TB appliance groups questions 1 -11C

Variable	ITMA (n=45)	Twin Block (n=23)	Statistic (sig), *effect*
Age (years) (m, sd)	13.63 (1.54)	10.61 (1.92)	t=6.49 (p=.000)
Gender (male) n (%)	18 (40%)	13 (56.5%)	Chisq=1.68 (p=.211)
Q1_Description (m, med)	4.53 (5.0)	4.48 (5.0)	U=505.5 (p=.86), *.0005*
Q2_Scary (m, med)	2.0 (2.0)	2.61 (2.0)	U=329.5 (p=.01), *.10*
Q3_EasyAppt (m, med)	3.89 (4.0)	4.26 (4.0)	U=387.5 (p=.07), *.05*
Q4_Instructions (m, med)	4.80 (5.0)	4.70 (5.0)	U=455.5 (p=.26), *.02*
Q5_Noticeable (m, med)	2.78 (3.0)	3.74 (4.0)	U=274.5 (p=.001), *.16*
Q6_Nb_NoNotice (m, med)	3.60 (3.0)	3.04 (3.0)	U=383.0 (p=.07), *.05*
Q7_DiffPutIn (m, med)	1.89 (2.0)	2.70 (3.0)	U=297.0 (p=.003), *.13*
Q8_EaseDislodge (m, med)	2.77 (2.5)	2.87 (3.0)	U=479.5 (p=.72), *.002*
Q9a_ImprovSpeech_First (m, med)	2.51 (2.0)	2.23 (2.0)	U=399.0 (p=.15), *.03*
Q9b_ImprovDrink_First (m, med)	2.89 (3.0)	2.86 (3.0)	U=479.0 (p=.75), *.002*
Q9c_ImprovSleep_First (m, med)	2.82 (3.0)	2.73 (3.0)	U=454.0 (p=.46), *.008*
Q9d_ImprovAppear_First (m, med)	3.33 (3.0)	2.95 (3.0)	U=369.0 (p=.05), *.06*
Q9e_ImprovTease_First (m, med)	3.07 (3.0)	3.05 (3.0)	U=466.5 (p=.59), *.004*
Q10a_SoreJaw_First (m, med)	1.95 (2.0)	1.74 (2.0)	U=423 (p=.24), *.02*
Q10b_SoreTeeth_First (m, med)	2.20 (2.0)	1.83 (2.0)	U=378.5 (p=.052), *.06*
Q10c_SoreLips_First (m, med)	1.76 (2.0)	1.43 (1.0)	U=391.5 (p=.07), *.05*
Q10d_Embarrass_First (m, med)	1.09 (1.0)	1.22 (1.0)	U=442.0 (p=.08), *.05*
Q10e_Drool_First (m, med)	1.60 (2.0)	1.57 (1.0)	U=501.5 (p=.82), *.001*
Q10f_DiffYawn_First (m, med)	1.18 (1.0)	1.48 (1.0)	U=417.5 (p=.08), *.05*
Q10g_KeepClean_First (m, med)	1.71 (2.0)	1.78 (2.0)	U=512 (p=.94), *.0001*
Q11a_Teased_First (m, med)	3.02 (3.0)	3.05 (3.0)	U=445.5 (p=.55), *.001*
Q11b_GetAlongFs_First (m, med)	3.04 (3.0)	3.10 (3.0)	U=469.0 (p=.92), *.0002*
Q11c_GetAlongFam_First (m, med)	3.02 (3.0)	3.00 (3.0)	U=441.0 (p=.29), *.02*

*Note – t=independent samples t test, Chisq = ChiSquared (exact sig), U=Mann Whitney U

Appendix 10

Differences observed between ITMA and TB appliance groups questions 12a- 19

Variable	ITMA (n=45)	Twin Block (n=23)	Statistic (sig), *effect*
Q12a_ImprovSpeech_Now (m, med)	3.18 (3.0)	3.00 (3.0)	U=417.0 (p=.30), *.02*
Q12b_ImprovDrink_Now (m, med)	3.12 (3.0)	3.10 (3.0)	U=448.5 (p=.95) *.0001*
Q12c_ImprovSleep_Now (m, med)	3.09 (3.0)	3.29 (3.0)	U=426.0 (p=.44), *.009*
Q12d_ImprovAppear_Now (m, med)	3.57 (3.0)	3.35 (3.0)	U=374.0 (p=.29), *.02*
Q12e_ImprovTease_Now (m, med)	3.02 (3.0)	3.25 (3.0)	U=365.0 (p=.05), *.06*
Q13a_SoreJaw_Now (m, med)	1.37 (1.0)	1.19 (1.0)	U=356.0 (p=.09), *.05*
Q13b_SoreTeeth_Now (m, med)	1.60 (2.0)	1.29 (1.0)	U=321.5 (p=.03), *.07*
Q13c_SoreLips_Now (m, med)	1.37 (1.0)	1.10 (1.0)	U=336.0 (p=.03), *.07*
Q13d_Embarrass_Now (m, med)	1.00 (1.0)	1.14 (1.0)	U=378.0 (p=.01), *.10*
Q13e_Drool_Now (m, med)	1.30 (1.0)	1.29 (1.0)	U=429.0 (p=.68), *.003*
Q13f_DiffYawn_Now (m, med)	1.05 (1.0)	1.29 (1.0)	U=384.5 (p=.06), *.06*
Q13g_KeepClean_Now (m, med)	1.65 (2.0)	1.76 (2.0)	U=431.5 (p=.75), *.002*
Q14a_Teased_Now (m, med)	3.00 (3.0)	3.15 (3.0)	U=396.0 (p=.36), *.01*
Q14b_GetAlongFs_Now (m, med)	3.02 (3.0)	3.15 (3.0)	U=396.5 (p=.18), *.03*
Q14c_GetAlongFam_Now (m, med)	3.02 (3.0)	3.05 (3.0)	U=400.5 (p=.80), *.001*
Q15_DiffFace (m, med)	3.67 (4.0)	3.65 (4.0)	U=460.0 (p=.44), *.009*
Q16_ExtraVisits YES (n %)	10 (22.2%)	11 (50.0%)	ChiSq=5.30 (p=.03)
Q17_VisitsBothered (m, med)	3.44 (4.0)	2.76 (3.0)	U=335.0 (p=.02), *.08*
Q18_GotUsed YES (n %)	43 (95.6%)	20 (87.0%)	ChiSq=1.66 (p=.33)
Q18a_HowLongUsed (m, med)	2.50 (2.0)	2.60 (2.0)	U=411.5 (p=.90) *.0003* (t=-.202, (p=.84))
Q19_OverallExp (m, med)	4.39 (5.0)	4.00 (4.0)	U=345.0 (p=.06), *.06*

*Note – t=independent samples t test, Chisq = ChiSquared (exact sig), U=Mann Whitney U

Appendix 11

Comparisons within ITMA treatment group between initial and after at least two months of wear time points

	First Got	Right Now	Statistic (sig), *effect*
Q9a – Q12a ImprovSpeech (m, med)	2.51 (2.0)	3.18 (3.0)	Z=4.22 (p=.000), *.64*
Q9b – Q12b ImprovDrink (m, med)	2.89 (3.0)	3.12 (3.0)	Z=2.64 (p=.008), *.40*
Q9c – Q12c ImprovSleep (m, med)	2.82 (3.0)	3.09 (3.0)	Z=2.59 (p=.010), *.39*
Q9d – Q12d ImprovAppear (m, med)	3.33 (3.0)	3.57 (3.0)	Z=2.00 (p=.05), *.30*
Q9e – Q12e ImprovTease (m, med)	3.07 (3.0)	3.02 (3.0)	Z=0.65 (p=.52), *.10*
Q10a – Q13a SoreJaw (m, med)	1.95 (2.0)	1.37 (1.0)	Z=4.02 (p=.000), *.61*
Q10b – Q13b SoreTeeth (m, med)	2.20 (2.0)	1.60 (2.0)	Z=3.99 (.000), *.61*
Q10c – Q13c SoreLips (m, med)	1.76 (2.0)	1.37 (1.0)	Z=3.09 (p=.002), *.47*
Q10d – Q13d Embarrass (m, med)	1.09 (1.0)	1.00 (1.0)	Z=1.63 (p=.10), *.25*
Q10e – Q13e Drool (m, med)	1.60 (2.0)	1.30 (1.0)	Z=2.92 (p=.004), *.45*
Q10f – Q13f DiffYawn (m, med)	1.18 (1.0)	1.05 (1.0)	Z=2.24 (p=.03), *.34*
Q10g – Q13g KeepClean (m, med)	1.71 (2.0)	1.65 (2.0)	Z=1.00 (p=.32), *.15*
Q11a – Q14a Teased (m, med)	3.02 (3.0)	3.00 (3.0)	Z=0.45 (p=.66), *.07*
Q11b – Q14b GetAlongFs (m, med)	3.04 (3.0)	3.02 (3.0)	Z=1.00 (p=.32), *.15*
Q11c – Q14c GetAlongFam (m, med)	3.02 (3.0)	3.02 (3.0)	Z=0.00 (p=1.00), *n/a*

*Note –Wilcox Signed rank

Appendix 12

Comparisons within TB treatment group between initial and after at least two months of wear time points

	First Got	Right Now	Statistic (sig) *effect*
Q9a – Q12a ImprovSpeech (m, med)	2.23 (2.0)	3.00 (3.0)	Z=2.39 (p=.02), *.51*
Q9b – Q12b ImprovDrink (m, med)	2.86 (3.0)	3.10 (3.0)	Z=0.83 (p=.41), *.18*
Q9c – Q12c ImprovSleep (m, med)	2.73 (3.0)	3.29 (3.0)	Z=1.84 (p=.07), *.40*
Q9d – Q12d ImprovAppear (m, med)	2.95 (3.0)	3.35 (3.0)	Z=2.00 (p=.05), *.45*
Q9e – Q12e ImprovTease (m, med)	3.05 (3.0)	3.25 (3.0)	Z=1.27 (p=.21), *.28*
Q10a – Q13a SoreJaw (m, med)	1.74 (2.0)	1.19 (1.0)	Z=2.65 (p=.01), *.58*
Q10b – Q13b SoreTeeth (m, med)	1.83 (2.0)	1.29 (1.0)	Z=2.81 (p=.01), *.61*
Q10c – Q13c SoreLips (m, med)	1.43 (1.0)	1.10 (1.0)	Z=2.24 (p=.03), *.49*
Q10d – Q13d Embarrass (m, med)	1.22 (1.0)	1.14 (1.0)	Z=1.41 (p=.16), *.31*
Q10e – Q13e Drool (m, med)	1.57 (1.0)	1.29 (1.0)	Z=2.45 (p=.01), *.53*
Q10f – Q13f DiffYawn (m, med)	1.48 (1.0)	1.29 (1.0)	Z=1.63 (p=.10), *.36*
Q10g – Q13g KeepClean (m, med)	1.78 (2.0)	1.76 (2.0)	Z=1.41 (p=.16), *.31*
Q11a – Q14a Teased (m, med)	3.05 (3.0)	3.15 (3.0)	Z=0.56 (p=.58), *.22*
Q11b – Q14b GetAlongFs (m, med)	3.10 (3.0)	3.15 (3.0)	Z=0.58 (p=.56), *.13*
Q11c – Q14c GetAlongFam (m, med)	3.00 (3.0)	3.05 (3.0)	Z=1.00 (p=.32), *.23*

*Note –Wilcox Signed rank

Appendix 13 – Journal Article

Patient Experiences with Functional Appliances

Abstract

Objective: To compare patients' experiences with the Invisalign Teen with Mandibular Advancement® (ITMA) and Twin Block appliance (TB both initially and after several months of wear.

Materials and Methods: Sixty-eight patients completed an anonymous survey after at least 2 months of wearing TB or ITMA. Forty-five patients treated with ITMA (18 males, 27 females, mean age 13.6 years, SD ± 1.54) and twenty-three patients treated with TB (13 males, 10 females, mean age 10.60 years SD ± 1.92) were included.

Results: More TB patients found their appliance to be visually intimidating compared to ITMA (21.7% vs 8.9%). TB was more noticeable than the ITMA (69.6% vs 25%). Appliance insertion was more difficult for TB patients (21.8% vs ITMA - 4.44%). After several months, reporting of tooth soreness and lip/cheek soreness was greater in the ITMA group. TB patients were more embarrassed even after several months (14.3% vs ITMA - 0%). More TB patients required extra appointments for breakages (50% vs ITMA - 22.2%). Speech, drooling, jaw, lip/cheek soreness worsened initially for both groups but improved over time. There were no differences between the groups regarding visible facial changes, satisfaction with treatment experience or time to acclimatize to the appliance.

Conclusion: TB and ITMA patients shared similar experiences for the majority of the parameters measured, but there were significant differences between the groups in relation to appliance wear and management, discomfort and function.

Introduction

When a growing patient presents with a skeletal Class II malocclusion, orthodontists can employ growth modification techniques that aim to encourage growth of the mandible.[1] Conventional functional appliances, such as the Twin Block (TB) work by holding the mandible in an advanced position aiming to stimulate favourable growth of the condyle thereby aiding in correction of the Class II malocclusion.[2]

Invisalign Teen with Mandibular Advancement® (ITMA) treats growing patients with Class II malocclusions. The appliance incorporates "precision wings" along the buccal aspect of the trays to posture the mandible forward while alignment of the teeth occurs contemporaneously.[3]

The viability of any orthodontic appliance is improved if patients can adapt to it quickly and find it amenable for consistent use. If an appliance does not allow for quick acclimatization and ease of wear, patients are unlikely to be compliant resulting in ineffectual orthodontic movements and prolonged treatment time. Determining appliance acceptability to a patient is invaluable to insuring compliance and ultimately treatment efficacy.[4]

Information from this survey study enables clinicians to choose an appliance well tolerated by patients and allows them to offer realistic insights into what challenges patients may face during their treatment maximizing compliance and promoting the best orthodontic outcome.

Materials and methods

The survey used in this study was modified from that developed by Bowman et al.[5] This study's survey was written for the removable functional appliances investigated and was approved by the Research Ethics Boards at the University of Manitoba.

Surveys were validated by the principal investigator using interviews to determine that all questions asked were relevant to the patient experience with removable functional appliances and were being correctly interpreted by respondents.

Acquisition of the survey population was from three orthodontic offices including the University of Manitoba's Graduate Orthodontic Clinic and two private orthodontic practices in Winnipeg, MB. Subjects were invited to participate in the anonymous study if they were between the ages of 8-17 years old and being treated with the ITMA or TB appliance for a minimum of two months or longer and demonstrated good compliance as assessed by their practitioner.

Following data collection, survey responses were analysed using the IBM SPSS Statistics for Windows Version 25.0 (IBM Corp., Armonk, NY, USA). Mann-Whitney *U* tests were used to compare the responses for each treatment group for all questions. Chi-squared tests were used to compare responses between the treatment groups to all questions with yes/no scoring. Independent Student's t-test were used to determine significant differences between the patient age, patient gender and the time for acclimatization for each treatment group.

Results

Sixty-eight (68) patients completed the survey; forty-five (45) patients treated with ITMA (18 males, 27 females, mean age 13.62 ± 1.54 years) and twenty-three (23) patients treated with TB (13 males, 10 females, mean age 10.60 ± 1.92 years). There was no significant difference between the groups based on their gender distribution. There was a significant difference between the groups in terms of age with ITMA having an older patient population compared to TB (p=0.00).

A summary of the statistically significant findings can be found in Tables 1 and 2.

Table 1 - Summary of significant findings: mean and median responses to questions 2, 5, 7, 13a-13c

Question*	ITMA mean (median)	TB mean (median)	p value
2. When I first saw it, the appliance looked scary/overwhelming	2.0 (2)	2.61 (2)	0.01
5. The appliance was noticeable to your friends and family	2.78 (3)	3.74 (4)	0.001
7. The appliance was difficult to put in my mouth and wear	1.89 (2.0)	2.70 (3)	.003
13b. Right now, while wearing the appliance how much has the following affected you: sore teeth	1.60 (2)	1.29 (1)	0.03
13c. Right now, while wearing the appliance how much has the following affected you: sore lips	1.37 (1)	1.10 (1)	0.03
13d. Right now, while wearing the appliance how much has the following affected you: feeling embarrassed	1.00 (1)	1.14 (1)	0.01

**Q2, 5 and 7: 1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree; Q13a-13c: 1 = not at all, 2 = a little, 3 = a lot*

Table 2 - Summary of significant findings: responses to questions 16 and 17

Question	ITMA	TB	p value
16. Have you had any extra visits because your appliance was broken or not fitting well *Yes (%)*	10 (22.2)	11 (50)	0.03
17. If you had extra visits because your appliance was broken or not fitting properly, has this bothered you *1 = not at all, 2 = a little, 3 = a lot, 4 = it did not break/it has always fit well*	3.44 (4)	2.76 (3)	0.02

When asked if their appliance appeared to them as scary or overwhelming, significantly more TB patients responded in the affirmative compared to ITMA patients (21.7% vs 8.9%, p=0.01). Significantly, more TB patients agreed or strongly agreed (combined total - 69.6%) that their appliance was noticeable compared to ITMA patients (combined total – 22.2%) (Figure 1). There was, however, no significant difference in the responses between the groups regarding the importance of having an inconspicuous appliance.

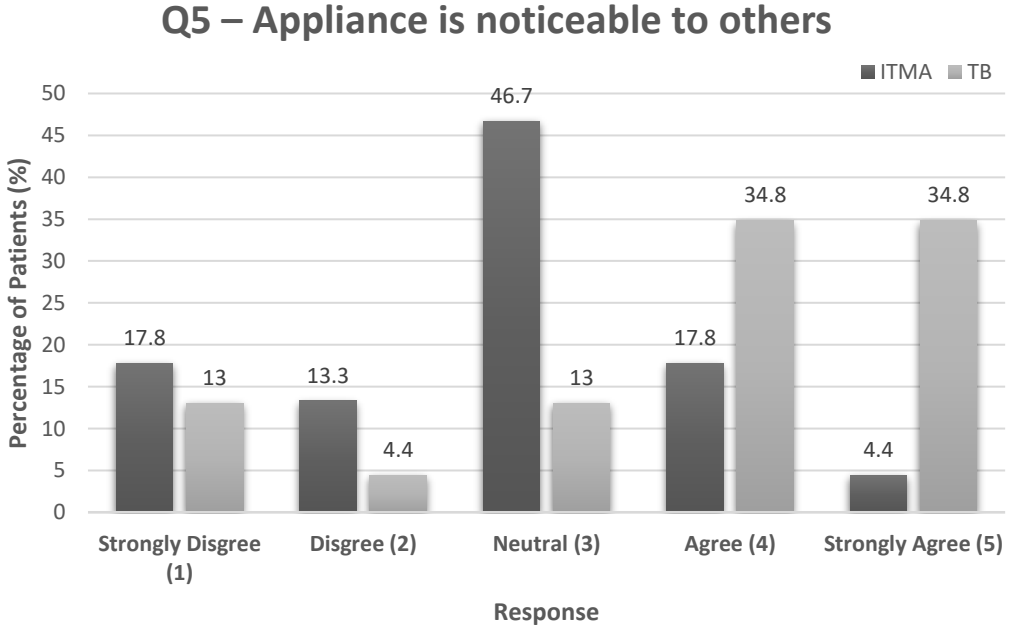


Figure 1 – Response distributions to question 5: "The appliance is noticeable to friends and family"

More TB patients reported they agreed or strongly agreed that the appliance was difficult to place in their mouth (21.8% vs ITMA - 4.4%, p= 0.003). When asked about ease of appliance retention, however, there was no difference in responses between the groups.

There was no difference in the responses between the treatment groups for changes in speech, drinking, sleep, appearance or incidence of teasing either while initially wearing the appliance or after two months of wear. No differences in responses, both initially and after two months wear, were noted with respect to changes in relationships with family and friends.

There were no differences in the responses between the groups regarding jaw, tooth, lip and cheek soreness, difficulty cleaning the appliance or difficulty opening wide and yawning initially. Similarly, there were no differences in the responses between the groups with respect to drooling, spitting or feeling embarrassment as a result of their initial appliance use.

After at least two months of treatment, there were still no differences between the groups regarding jaw soreness, drooling and spitting, difficulty cleaning the appliance or difficulty opening wide or yawning. At this time point, however, there were differences in the responses between the groups in relation to their incidence of sore teeth, lips and cheeks and their feeling of embarrassment. Reporting of tooth soreness after at least two months was found to be greater in the ITMA group, in which 53.5% of patients were still experiencing a little or a lot of tooth pain compared to only 23.9% of the TB group (p = 0.03, Figure 2).

After at least two months, the reporting of sore lips and cheeks was greater amongst ITMA patients with 34.9% experiencing a little or a lot, while only 9.5% of TB patients experienced the same. Patients from the TB and ITMA groups reported significantly different levels of embarrassment after at least two months of appliance wear (p = 0.01). None of the ITMA

patients at this time reported feeling embarrassed, however, 14.3% of TB patients still experienced a little embarrassment.

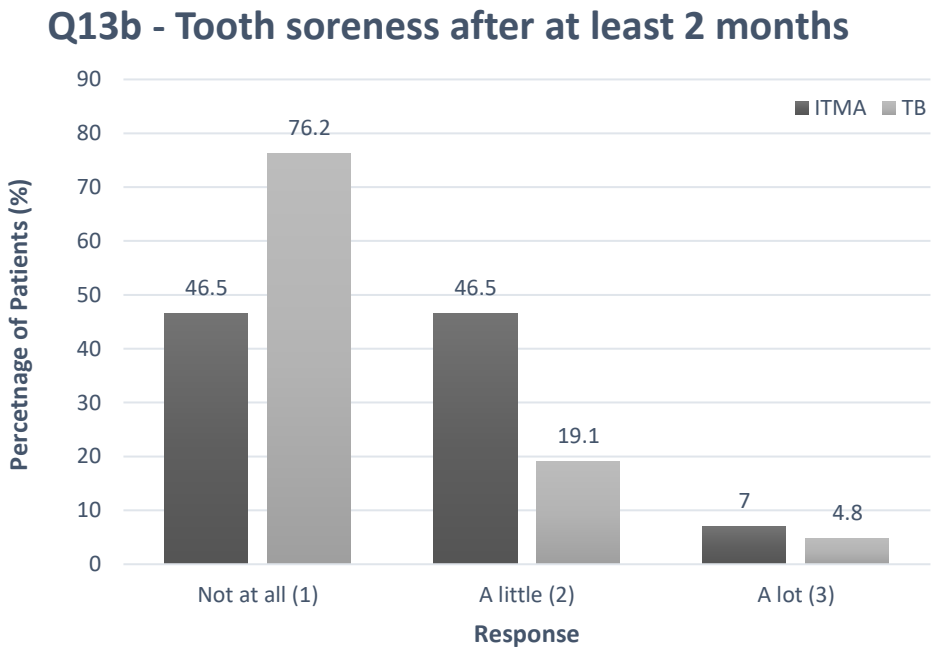


Figure 2 - Response distributions to question 13b: "Right now with your appliance, how often does tooth soreness affect you?"

No differences were found between the treatment groups regarding drooling and spitting or cleaning the appliance, both when they first received their device or after at least two months of wear time.

Extra visits to manage fit issues or breakages were required by both groups, however, significantly more TB patients experienced this during their treatment (p=0.03). Half the TB patients reported a need for extra visits to address breakages or fit issues during their treatment, while only 22.2% of ITMA patients had extra visits for these reasons (Figure 3).

There was no significant difference in the mean time required to acclimatize to either appliance; TB patients took 2.59 weeks ± 1.87 and ITMA patients took 2.49 weeks ± 1.66. When asked to reflect on their overall treatment experience there was no significant difference in the responses between the groups. The majority of patients in both groups reported that they felt good or really good about their treatment (TB – 73.9% vs ITMA – 87.8%).

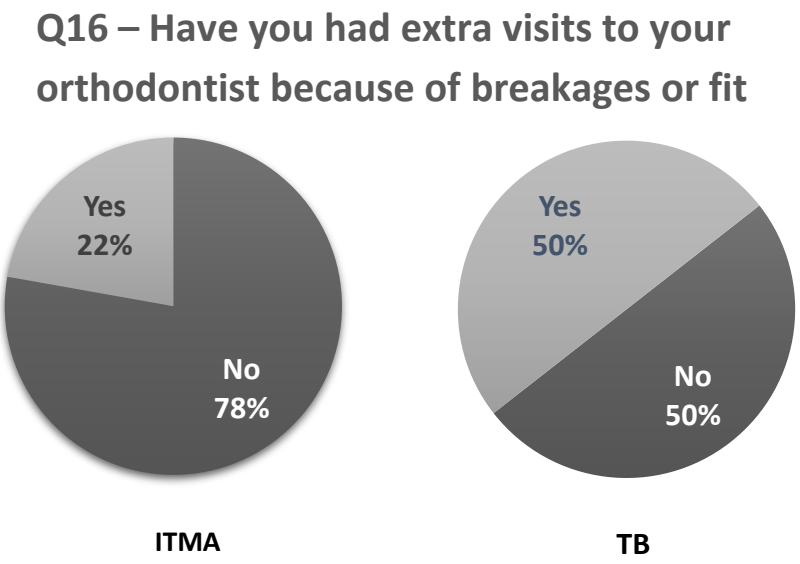


Figure 3 – Response distribution to question 16: "Have you had extra visits to your orthodontist because of breakages or fit issues with your appliance?"

Discussion

More TB patients strongly agreed or agreed that the appliance appeared scary, overwhelming or intimidating compared to ITMA. This reporting may be attributed to the significant age difference between the groups; TB patients had a mean age 3 years younger than ITMA and this may have caused them to find any device more intimidating no matter its design. Additionally, the appliances have different appearances and are alike only in that they both have separate

maxillary and mandibular components. The Twin Block includes a labial bow and ball clasps that are visibly located on the anterior dentition and may appear confronting to a new orthodontic patient regardless of age. It is worth noting the difference between the groups regarding the first visual assessment of their appliances as a positive first impression is an important aspect of the patient experience engendering early acceptance and promoting consistent wear as prescribed.[4]

When asked about the noticeability of the appliance, there was a significant difference more TB patients agreeing or strongly agreeing that their appliance was noticeable to friends and family compared to ITMA patients. The bulk of the TB's acrylic blocks generating an interincisal gap, the retentive wire-work on the anterior teeth and the addition of colour to the acrylic all contribute to the increased conspicuousness of this device compared to the ITMA.[6]

Despite a reporting in this study that the TB was more conspicuous and noticeable to friends and family than the ITMA, the largest proportion of both groups advised they were neutral about having a discrete appliance and that visibility was not important to them. This similarity could be related to the age range of the groups, which within the TB group was from 8-14 years and 10-17 years for ITMA patients. Compared to adults, adolescents tend to have greater acceptance of more visible appliances and reducing metal display is not considered a priority for their aesthetic demands.[7]

More TB patients reported that they agreed or strongly agreed the appliance was difficult to place in their mouth. This could be attributed to TB's bulky acrylic blocks, which require a large opening for insertion into the mouth. According to Clark, the designer of the original TB, many clinicians fabricate their TBs using a construction bite with an excessive interincisal gap resulting in increased vertical height of the acrylic blocks and leading to difficulty inserting the

appliance.[8] The recommendation for TB fabrication is to use a construction bite that results in an interincisal gap of no more than 2mm, thereby insuring smaller vertical blocks that are easier to insert consistently.[8] In this study, there was no attempt made for standardization of the TB appliance fabrication, including the height of the wax construction bite. The TBs worn by respondents may have had an increased interincisal gap contributing to the differences in responses from the two groups regarding the difficulty of appliance insertion.

While there were no differences between the groups with regard to jaw pain, a significant difference was found with respect to tooth soreness, but this was only after at least two months of appliance wear. Reporting of tooth soreness after at least two months was found to be significantly greater in the ITMA group. This finding is not unexpected given the variation in the treatment objectives of the two appliances. The conventional TB is a functional appliance, which corrects a Class II malocclusion through growth modification by stimulating condylar development. As a tooth-borne appliance, the retentive components of the TB can exert forces onto teeth, which may cause tooth soreness even though the appliance does not attempt to move or align teeth directly. The ITMA is both a functional appliance and a device that aligns teeth; the precision wings work to hold the mandible in protrusion to stimulate condylar growth, while composite attachments engage the aligner undercuts and generate dentoalveolar movement to straighten the teeth. Most research investigating pain as a side effect have compared conventional Invisalign to braces rather than other removable orthopaedic devices. As such, this study's results differ with reports in the literature, where Invisalign is found to cause less tooth pain but only in comparison to braces.[9–11] Patients wearing the ITMA experienced more tooth pain consistently throughout their treatment compared to TB patients as levelling, aligning and

derotating the teeth are movements actively programmed into each aligner along with the mandibular protrusion for growth modification.

While there were no significant differences at the start of treatment, after at least two months, the reporting of sore lips and cheeks was significantly greater amongst ITMA patients. Both the TB and ITMA lack the hooks and wings of conventional brackets that cause lip and cheek irritation. However, while both appliances are capable of causing soft tissue irritation, the ITMA group's increased reporting of discomfort may be related to the precision wings used in the device. Unlike the acrylic blocks of the TB, which remain interocclusal, the precision wings of the ITMA are buccal to the dentition and may impinge on the cheeks during function. In the first few sets of aligners, the precision wings are not present, and as such, the patient does not have to manage the increased bulk of the wings. Precision wings are typically initiated at aligner tray 8 and continually increased in anterior positioning at 8 week intervals by 2mm at a time. All patients were given the survey after at least two months of treatment, so some of the ITMA group may have just begun their first set of precision wing aligners when they responded. In this instance, the individuals who were just beginning their precision wing aligners may not have adjusted to the increased bulk and may report more soft tissue soreness even after being in treatment for at least two months. Causes for soft tissue pain in Invisalign have also been associated with defects with the aligner.[11] Rough margins, missing aligner material and tray deformation may lead to increased lip and cheek soreness as the irregular thermoformed plastic contacts the mucosa leading to inflammation and ulceration.[11,12] Understanding the extent and the causes for discomfort associated with any appliance is essential for clinicians as fear of pain is often cited as one of the reasons for avoiding orthodontic treatment.[13] Valuable insight from

their orthodontist can help patients better manage their expectations by understanding the causes and intensity of discomfort associated with their appliance.

A significant difference was found between the ITMA and TB groups regarding their experience of embarrassment but only after at least two months of appliance wear. At this time, all of the ITMA group advised they were no longer experiencing any embarrassment, while patients in the TB group still reported feeling a little embarrassed from use of their appliance. This reported difference in embarrassment is most likely attributed to the TB's bulk, size and even the colour of the acrylic as all these elements contribute to the appliance's conspicuousness. Patients in the study completed by El-Huni et al.[6] reported that size and colour of the TB blocks were considered barriers to their compliance as patients desired a more discrete and unnoticeable device. Even after a period of acclimatization and increased patient acceptance, a highly visible appliance can still be seen to cause social concerns, especially when encountering new people and situations.

Appliance breakages requiring additional visits are incidents most clinicians are keen to avoid as they tend to reduce office schedule efficiency and can be detrimental for patient – clinician relationships. Between the two groups, there was a significant difference regarding issues of appliance breakage and fit with more TB patients requiring extra appointments for these reasons. The disposable nature of ITMA and its series of consecutive aligners contributes to this difference, as clinicians will often advocate for patients to move to the next set of aligners if there are any particular fit issues with their current ones. The TB design has wire-work aiding in retention, including Adams clasps and labial bows that can be distorted if care is not taken with storage of the appliance or its handling. Additionally, the TB appliance is used in the late mixed dentition as this stage can correspond with the peak height velocity period indicated as optimal

timing for growth modification treatment.[14] As patients move from the late mixed dentition to the permanent dentition, exfoliating and erupting teeth may contribute to issues with fit and require additional visits for the clinician to modify or adjust appliances.

Study Limitations

Designing this study as a non-blinded prospective randomized control trial in which patients were randomly assigned to either the ITMA or TB treatment group would have allowed for even distribution of patient numbers as well as age and gender.

A shortened survey with even further simplified language may have been more suitable to maximize completion by all patients and improve the appropriateness of their responses.

This survey asked patients to reflect back on when they first received the appliance, which may have introduced recall bias, and as no standardization was attempted there may have been a large variation in how long patients had been in treatment before responding to the questionnaire.

Conclusions

The outcomes from this study highlight that while there were some differences between the treatment groups overall their experiences with their appliance were comparable. The differences and similarities determined were as follows:

- More TB patients reported their appliance appeared intimidating.
- The TB appliance was more noticeable compared to the ITMA.
- The ITMA appliance was found to be easier to insert than the TB.
- ITMA patients experienced greater tooth pain throughout treatment compared to TB patients.

- Both ITMA and TB groups had similar initial experiences with regard to the functional and social impacts of their appliances.
- After at least two months of treatment, more ITMA patients experienced tooth, lip and cheek soreness while more TB patients reported still feeling embarrassed by their appliance.
- More TB patients experienced issues with fit and breakages requiring additional appointments.
- The ITMA and TB patients had similar times taken to acclimatize to their appliance.
- The majority of both groups reported high levels of satisfaction with their treatment.

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Appendix 14 – Journal Receipt Confirmation

THE ANGLE ORTHODONTIST
ONLINE MANUSCRIPT SUBMISSION AND PEER REVIEW

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Home

Detailed Status Information

Manuscript #	050520-393
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Running Title	Patient Experiences with Functional Appliances
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Corresponding Author	Tyrone Zybutz (University of Manitoba)
Contributing Authors	Robert Drummond , Milos Lekic , Meredith Brownlee
Financial Disclosure	I have no relevant financial interests in this manuscript.
Abstract	Patient Experiences with Removable Functional Appliances Objective: To compare patients' experiences with the Invisalign Teen with Mandibular Advancement® (ITMA) and Twin Block appliance (TB both initially and after several months of wear. Materials and Methods: Sixty-eight patients completed an anonymous survey after at least 2 months of wearing TB or ITMA. Forty-five patients treated with ITMA (18 males, 27 females, mean age 13.6 years, SD ± 1.54) and twenty-three patients treated with TB (13 males, 10 females, mean age 10.60 years SD ± 1.92) were included. Results: More TB patients found their appliance to be visually intimidating compared to ITMA (21.7% vs 8.9%). TB was more noticeable than the ITMA (69.6% vs 22.2%). Appliance insertion was more difficult for TB patients (21.8% vs ITMA - 4.4%). After several months, reporting of tooth soreness and lip/cheek soreness was greater in the ITMA group. TB patients were more embarrassed even after several months (14.3% vs ITMA - 0%). More TB patients required extra appointments for breakages (50% vs ITMA - 22.2%). Speech, drooling, jaw, lip/cheek soreness worsened initially for both groups but improved over time. There were no differences between the groups regarding visible facial changes, satisfaction with treatment experience or time to acclimatize to the appliance. Conclusion: TB and ITMA patients shared similar experiences for the majority of the parameters measured but there were significant differences between the groups in relation to appliance wear and management, discomfort and function.
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