

Investigation and comparison of patient experiences with removable functional appliances:

Invisalign Teen with Mandibular Advancement versus Twin Block

Tyrone Zybutz^a; Robert Drummond^b; Milos Lekic^c; Meredith Brownlee^d

ABSTRACT

Objectives: To compare patients' experiences with the Invisalign Teen with Mandibular Advancement® (ITMA) and Twin Block (TB) appliances, 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 ITMA or TB. Forty-five patients treated with ITMA (18 boys, 27 girls, mean age 13.6 years, SD ± 1.54) and 23 patients treated with TB (13 boys, 10 girls, mean age 10.60 years, SD ± 1.92) were included.

Results: More patients using the TB found their appliance to be visually intimidating as compared with patients using the 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 4.44% for ITMA). After several months, there were more reports of tooth soreness and lip/cheek soreness in the ITMA group. TB patients were more embarrassed even after several months (14.3% vs 0% for ITMA). More TB patients required extra appointments for breakage (50% vs 22.2% for ITMA). Speech, drooling, and jaw and 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.

Conclusions: TB and ITMA patients shared similar experiences for most of the parameters measured, but there were significant differences between the groups regarding appliance wear and management, discomfort, and function. (*Angle Orthod.* 2021;91:490–495.)

KEY WORDS: Patient experience; Functional appliance; Invisalign Teen with Mandibular Advancement®; Twin Block

^a Graduate Orthodontic Resident, Department of Preventative Dental Science, Gerald Niznick College of Dentistry, University of Manitoba, Winnipeg, Manitoba, Canada.

^b Assistant Professor and Graduate Orthodontic Clinic Director, Department of Preventative Dental Science, Gerald Niznick College of Dentistry, University of Manitoba, Winnipeg, Manitoba, Canada.

^c Assistant Professor, Department of Preventative Dental Science, Gerald Niznick College of Dentistry, University of Manitoba, Winnipeg, Manitoba, Canada.

^d Assistant Professor and Division Head of Oral and Maxillo-facial Radiology, Dental Diagnostic and Surgical Sciences, Gerald Niznick College of Dentistry, University of Manitoba, Winnipeg, Manitoba, Canada.

Corresponding author: Dr Tyrone Zybutz, Graduate Orthodontic Resident, Department of Preventative Dental Science, Gerald Niznick College of Dentistry, Room D341, University of Manitoba, 780 Bannatyne Avenue, Winnipeg, Manitoba R3E 0W2, Canada (e-mail: tyronezybutz@gmail.com)

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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 favorable growth of the condyle, thereby aiding in correction of the Class II malocclusion.²

Invisalign Teen with Mandibular Advancement® (ITMA) was designed to treat 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 concurrently.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

Table 1. Summary of Significant Findings: Mean and Median Responses to Questions 2, 5, 7, 13a–13c

Question ^a	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)	.01
5. The appliance was noticeable to your friends and family	2.78 (3)	3.74 (4)	.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)	.03
13c. Right now, while wearing the appliance how much has the following affected you: sore lips	1.37 (1)	1.10 (1)	.03
13d. Right now, while wearing the appliance how much has the following affected you: feeling embarrassed	1.00 (1)	1.14 (1)	.01

^a 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*.

unlikely to be compliant, resulting in ineffective orthodontic movements and prolonged treatment time. Determining appliance acceptability to a patient is invaluable to ensuring compliance and ultimately treatment efficacy.⁴

Information from this survey study was intended to better enable clinicians to choose an appliance well tolerated by patients and allow them to offer realistic insights into what challenges patients may face during their treatment, thus 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 Graduate Orthodontic Clinic, and two private orthodontic practices in Winnipeg, Manitoba. Subjects were invited to participate in the anonymous survey if they were between the ages of 8 and 17 years and being treated with the ITMA or TB appliance for a minimum of 2 months or longer and demonstrated good compliance as assessed by their practitioner.

After data collection, survey responses were analyzed using IBM SPSS Statistics for Windows (version 25.0, IBM Corp, Armonk, NY). 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 *t* tests were used to determine significant differences between age, gender distribution, and time for acclimatization for each treatment group.

RESULTS

Sixty-eight patients completed the survey, including 45 patients treated with ITMA (18 boys, 27 girls, mean age 13.62 ± 1.54 years) and 23 patients treated with TB (13 boys, 10 girls, 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 in mean age between the groups, with the patients using ITMA being older as compared with those using the TB (*P* < .01).

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

When asked if their appliance appeared to them as scary or overwhelming, significantly more TB patients responded in the affirmative as compared with ITMA patients (21.7% vs 8.9%, *P* = .01). Significantly more TB patients agreed or strongly agreed (combined total: 69.6%) that their appliance was noticeable as compared with 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.

More TB patients reported they agreed or strongly agreed that the appliance was difficult to place in their mouth (21.8% vs 4.4% for ITMA; *P* = .003). When asked about ease of appliance retention, however, there was no difference in responses between the groups.

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)	.03
17. If you had extra visits because your appliance was broken or not fitting properly, has this bothered you 1 = <i>not at all</i> , 2 = <i>a little</i> , 3 = <i>a lot</i> , 4 = <i>it did not break/it has always fit well</i>	3.44 (4)	2.76 (3)	.02

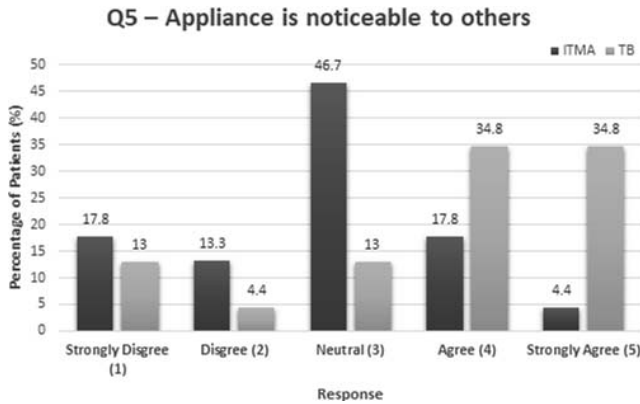


Figure 1. Response distribution to question 5: “The appliance is noticeable to friends and family.”

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 2 months of wear. No differences in responses, both initially and after 2 months of 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 2 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 regarding the incidence of sore teeth, lips, and cheeks and their feeling of embarrassment. Reporting of tooth soreness after at least 2 months of wear was greater in the ITMA group, in which 53.5% of patients were still experiencing a little or a lot of tooth pain, as compared with 23.9% of the TB group ($P = .03$; Figure 2).

After at least 2 months of wear, the reporting of sore lips and cheeks was greater among ITMA patients, with 34.9% experiencing a little or a lot, whereas only 9.5% of TB patients reported this soreness. Patients from the TB and ITMA groups reported significantly different levels of embarrassment after at least 2 months of appliance wear ($P = .01$). None of the ITMA patients reported feeling embarrassed after 2 months of appliance wear; however, 14.3% of TB patients still experienced a little embarrassment.

No differences were found between the treatment groups regarding drooling and spitting or cleaning the

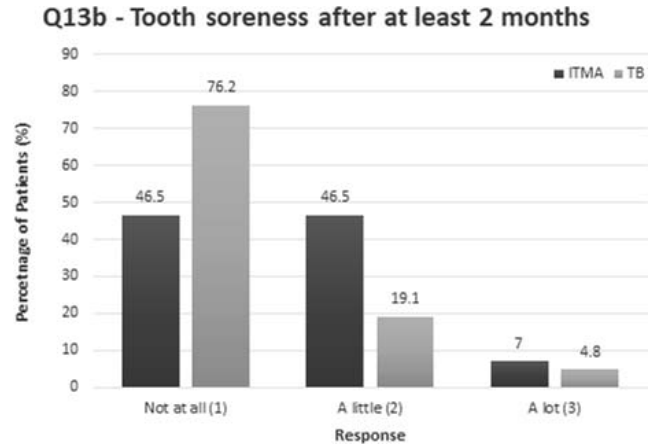


Figure 2. Response distributions to question 13b: “Right now with your appliance, how often does tooth soreness affect you?”

appliance, both when patients first received their device and after at least 2 months of wear time.

Extra visits to manage fit issues or breakage were required by both groups. However, significantly more TB patients experienced breakage during their treatment ($P = .03$). Half of the TB patients reported a need for extra visits to address breakage or fit issues during their treatment, whereas 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 the appliances between the groups. TB patients required 2.59 ± 1.87 weeks, and ITMA patients reported 2.49 ± 1.66 weeks. When asked to reflect on their overall treatment experience, there was no significant difference in response between the groups. Most patients in both groups reported that they felt good or really good about their treatment (TB 73.9% vs ITMA 87.8%).

Q16 – Have you had extra visits to your orthodontist because of breakages or fit

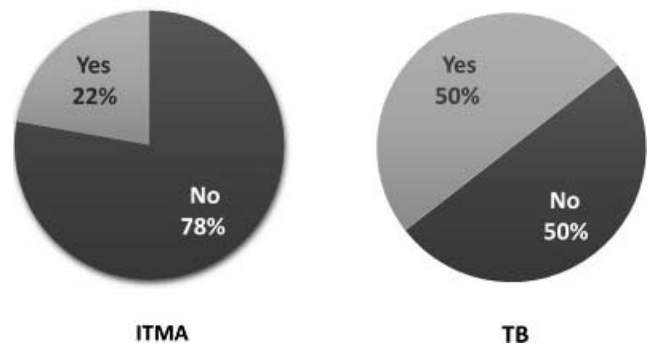


Figure 3. Response distribution to question 16: “Have you had extra visits to your orthodontist because of breakages or fit issues with your appliance?”

DISCUSSION

More TB patients agreed or strongly agreed that their appliance appeared scary, overwhelming, or intimidating as compared with those in the ITMA group. This reporting may have been due to the significant age difference between the groups; TB patients had a mean age of 3 years younger than ITMA, and this may have caused them to find any device more intimidating, no matter its design. In addition, the appliances had different appearances and were alike only in that they both had separate maxillary and mandibular components. The TB included a labial bow and ball clasps that were visibly located on the anterior dentition and may have appeared 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 because 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, with more TB patients agreeing or strongly agreeing that their appliance was noticeable to friends and family as compared with 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 color to the acrylic all contributed to the increased conspicuousness of the TB as compared with 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 have been related to the age range of the groups, which, for the TB group, was from 8–14 years and for the ITMA group was 10–17 years. As compared with adults, adolescents tend to have greater acceptance of more visible appliances, and reducing the metal display is not considered a priority for their esthetic demands.⁷

More TB patients reported that they agreed or strongly agreed that the appliance was difficult to place in their mouth. This could be attributed to the TB's bulky acrylic blocks, which required a large opening for insertion into the mouth. According to Clark,⁸ the designer of the original TB, many clinicians fabricated 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. The recommendation for TB fabrication was to use a construction bite that resulted in an interincisal gap of no more than 2 mm,

thereby ensuring smaller vertical blocks that are easier to insert consistently.⁸ In this study, there was no attempt made to standardize the TB appliance fabrication, including the height of the wax construction bite. The TBs worn by respondents may have had an increased interincisal gap, thus contributing to the differences in responses from the two groups regarding the difficulty of appliance insertion.

Although there were no differences between the groups regarding jaw pain, a significant difference was found in reported tooth soreness, but this was only after at least 2 months of appliance wear. Reporting of tooth soreness after at least 2 months was significantly greater in the ITMA group. This finding was not unexpected given the difference in the treatment objectives between the two appliances. The conventional TB is a functional appliance meant to correct a Class II malocclusion through growth modification by stimulating condylar development. As a tooth-borne appliance, the retentive components of the TB could exert forces on 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, whereas the 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 to other removable orthopaedic devices. Therefore, this study's results differed from reports in the literature, in which Invisalign was found to cause less tooth pain but only compared with bonded appliances.^{9–11} Patients wearing the ITMA experienced more tooth pain consistently throughout their treatment as compared with TB patients, because leveling, aligning, and derotating the teeth were movements actively programmed into each aligner along with the mandibular protrusion for growth modification.

Although there were no significant differences at the start of treatment, the reporting of sore lips and cheeks was significantly greater among ITMA patients after at least 2 months. Both the TB and ITMA lack the hooks and wings of conventional brackets that cause lip and cheek irritation. However, although both appliances could be capable of causing soft-tissue irritation, the ITMA group's increased reporting of discomfort may have been due to the precision wings used in the device. Unlike the acrylic blocks of the TB, which remained interocclusal, the precision wings of the ITMA were buccal to the dentition and may have impinged on the cheeks during function. In the first few sets of aligners, the precision wings are not present, and therefore, the patient does not have to manage the increased bulk of the wings. Precision wings are

typically initiated at aligner tray 8 and then continually increased by 2 mm at a time in anterior positioning at 4-week intervals. All patients were given the survey after at least 2 months of treatment, so some of the ITMA group may have just begun their first set of precision wing aligners when they responded. Those individuals who were just beginning their precision wing aligners may not have adjusted to the increased bulk and may have reported more soft-tissue soreness even after being in treatment for at least 2 months. Causes for soft-tissue pain with aligners have also been associated with defects in the aligners.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 because fear of pain is often cited as one of the reasons for avoiding orthodontic treatment.¹³ Valuable insight from the patient's orthodontist can help him or her better manage expectations by understanding the causes and intensity of discomfort associated with the appliance.

A significant difference was found between the ITMA and TB groups regarding experiencing embarrassment but only after at least 2 months of appliance wear. At that time, all of the ITMA group expressed they were no longer experiencing any embarrassment, whereas patients in the TB group still reported feeling a little embarrassed from use of their appliance. This difference in embarrassment was most likely attributable to the TB's bulk, size, and even the color of the acrylic, because all of these elements contributed to the appliance's conspicuousness. Patients in the study completed by El-Huni et al.⁶ reported that size and color of the TB were considered barriers to their compliance because patients desired a more discrete and unnoticeable device. Even after a period of acclimatization and increased patient acceptance, a highly visible appliance may still be seen to cause social concerns, especially when encountering new people and situations.

Appliance breakages that require additional visits are incidents most clinicians would prefer 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 contributed to this difference, as clinicians would often advocate for patients to move to the next set of aligners if there were any particular fit issues with their current ones. The TB

design had wire work aiding in retention, including Adams clasps and labial bows, that could be distorted if care was not taken with the storage of the appliance or its handling. In addition, the TB appliance is used in the late mixed dentition since this stage can correspond with the peak height velocity period indicated as optimal timing for growth modification treatment.¹⁴ As patients moved from the late mixed dentition to the permanent dentition, exfoliating and erupting teeth may have contributed to issues with fit and required additional visits for the clinician to modify or adjust appliances.

Study Limitations

Designing this study as a nonblinded 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. In addition, 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. Lastly, the survey asked patients to reflect back on when they first received the appliance, which may have introduced recall bias, and, because 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, although there were some differences between the treatment groups, their experiences with their appliance were overall comparable.
- More TB patients reported their appliance appeared intimidating.
- The TB appliance was more noticeable as compared with the ITMA.
- The ITMA appliance was found to be easier to insert than the TB.
- ITMA patients experienced greater tooth pain throughout treatment as compared with TB patients.
- Both ITMA and TB groups had similar initial experiences regarding the functional and social impacts of their appliances.
- After at least 2 months of treatment, more ITMA patients experienced tooth, lip, and cheek soreness, whereas more TB patients reported still feeling embarrassed by their appliance.
- More TB patients experienced issues with fit and breakage requiring additional appointments.
- The ITMA and TB patients had similar times taken to acclimatize to their appliance.

- Most patients in both groups reported high levels of satisfaction with their treatment.

REFERENCES

1. Marsico E, Gatto E, Burrascano M, Matarese G, Cordasco G. Effectiveness of orthodontic treatment with functional appliances on mandibular growth in the short term. *Am J Orthod Dentofac Orthop.* 2011;139:24–36.
2. Cozza P, Baccetti T, Franchi L, De Toffol L, McNamara JA. Mandibular changes produced by functional appliances in Class II malocclusion: a systematic review. *Am J Orthod Dentofac Orthop.* 2006;129:599.
3. Pascaud R. New teen solution with introduction of Invisalign Teen with Mandibular Advancement. Align Technology Invisalign treatment with mandibular advancement will be available commercially in the United States on November 19, 2018. Published 2017. Available at: <http://investor.aligntech.com/releasedetail.cfm?ReleaseID=1016092>. Accessed April 19, 2018.
4. Serogl HG, Zentner A. A comparative assessment of acceptance of different types of functional appliances. *Eur J Orthod.* 1998;20:517–524.
5. Bowman AC, Saltaji H, Flores-Mir C, Preston B, Tabbaa S. Patient experiences with the Forsus fatigue resistant device. *Angle Orthod.* 2013;83:437–446.
6. El-Huni A, Colonio Salazar FB, Sharma PK, Fleming PS. Understanding factors influencing compliance with removable functional appliances: a qualitative study. *Am J Orthod Dentofac Orthop.* 2019;155:173–181.
7. Walton DK, Fields HW, Johnston WM, et al. Orthodontic appliance preferences of children and adolescents. *Am J Orthod Dentofac Orthop.* 2010;138:698–710.
8. Clark W. Design and management of Twin Blocks: reflections after 30 years of clinical use. *J Orthod.* 2010;37:209–216.
9. Almasoud NN. Pain perception among patients treated with passive self-ligating fixed appliances and Invisalign® aligners during the first week of orthodontic treatment. *Korean J Orthod.* 2018;48:326–332.
10. White DW, Julien KC, Jacob H, Campbell PM, Buschang PH. Discomfort associated with Invisalign and traditional brackets: a randomized, prospective trial. *Angle Orthod.* 2017;87:801–808.
11. Fujiyama K, Honjo T, Suzuki M, Matsuoka S, Deguchi T. Analysis of pain level in cases treated with Invisalign aligner: comparison with fixed edgewise appliance therapy. *Prog Orthod.* 2014;15:64.
12. Sweeney W Jr, Rinchuse D, Rinchuse D, Zullo T, King B. Patient perceptions of speech, discomfort, and salivary flow while wearing Invisalign® aligners—research—orthodontic practice US. *Orthod Pract.* Published 2016. Available at: <https://www.orthopracticeus.com/research/patient-perceptions-speech-discomfort-salivary-flow-wearing-invisalign-aligners>. Accessed February 5, 2020.
13. Oliver RG, Knapman YM. Attitudes to orthodontic treatment. *Br J Orthod.* 1985;12:179–188.
14. Baccetti T, Franchi L, Toth R. Treatment timing for Twin-Block therapy. *Am J Orthod Dentofac Orthop.* 2000;118:159–170.