Clinical Outcomes Using the Invisalign Palatal Expander (IPE) System

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ABSTRACT

Objective: Assess the clinical outcomes of patients who have received expansion through the Invisalign Palatal Expander System.

Methods and Materials: This study assessed 30 patients who met the inclusion criteria and were treated with an IPE. Pre- and post-expansion digital models were acquired and measurements for maxillary permanent intermolar width, intercanine width, tipping of the maxillary molar, presence of diastema and diastema width were collected. Data for intercanine and molar widths were compared to an existing data set (Torbaty et al., 2024) to assess how the IPE compared to controls, Hyrax expansion and Invisalign First.

Results: Statistically significant ($p<.001$) increases occurred for all measurements after treatment with IPE. Intermolar and intercanine widths increased on average by 3.18mm (8.18%) and 1.46mm (4.76%) respectively. Diastema width increased an average 1.42mm, for 70% of patients. Compared to Torbaty et al., IPE performed better than Invisalign First for intermolar changes, but worse for intercanine changes. Hyrax expansion outperformed IPE for both intermolar and intercanine widths.

Conclusions:

- IPE increases intermolar and intercanine widths
- Skeletal expansion with IPE is possible based on diastema development in 70% of subjects
- IPE is less effective at increasing intercanine width than alternative expansion modalities
- IPE is less effective than traditional rapid palatal expanders (e.g. Hyrax) at increasing interdental widths

TABLE OF CONTENTS

INTRODUCTION

Orthodontic patients of all ages regularly present to offices with maxillary transverse deficiency, with an average estimated 25% of orthodontic cases exhibiting a narrow upper jaw [1,2]. Adverse dentofacial deformities, both esthetic and functional, can occur if this problem is not addressed. Manifestations of maxillary transverse deficiency include crowding, posterior crossbites (uni or bilateral), dark buccal corridors, and unstable dental tipping [3]. If untreated during childhood or adolescent years, a narrow maxilla is unlikely to self-correct and can greatly affect the permanent dentition treatment options[4].

The most common correction of a narrow maxilla is to expand at the intermaxillary suture. This suture becomes more convoluted and fused as a child ages, and splitting of the suture can become very challenging in the late teens. Due to this phenomenon, skeletal expansion of the maxilla is ideally completed during the early adolescent years, as fusion of the suture typically begins around age 14 [5]. However, Stuart and Wiltshire (2003) challenged this notion with skeletal expansion seen on patients as old as 19 without the use of mini-implants or surgery [6].

When assessing techniques to distract the intermaxillary suture, three treatment modalities are used today: rapid maxillary expansion, slow maxillary expansion and surgically assisted maxillary expansion. This study will examine potential rapid maxillary expansion in children and adolescents.

A bonded rapid palatal expander (RPE) appliance is considered the Gold Standard for true non-surgical skeletal correction in an adolescent[5]. The objective of these appliances is to separate the intermaxillary suture, not just widen the dental arch by tipping or moving teeth within the alveolus. A RPE appliance applies forces to the posterior dentition at a rapid rate, and due to insufficient time for tooth movement to occur, the force is transferred to the intermaxillary suture, causing skeletal distraction and subsequent widening of the maxilla[5]. The presence of a maxillary central diastema is often recorded as an easily identifiable marker to determine if skeletal expansion has occurred. This diastema is transient and self-correcting due to the elastic nature of trans-septal fibers between the incisors and some skeletal relapse[5,7–9].

Since its inception in the late 1990's, Invisalign has corrected over 20 million smiles worldwide, making it the largest manufacturer of clear aligners. Invisalign extended into the treatment of younger patients with early mixed dentitions with the announcement of Invisalign First clear aligners in 2018. The main solution for maxillary transverse deficiency with Invisalign first was dental expansion [10]. The efficacy of dental expansion with Invisalign First has been reported at a similar rate to their traditional aligner systems for the permanent dentition (62%), and comparative studies between Invisalign First and traditional removable acrylic expanders showed Invisalign First as having less overall expansion and predictability [11] [12] [13]. Despite maxillary transverse deficiency being a common problem in mixed dentition patients, Invisalign First never claimed to be able to skeletally expand an arch.

In 2023, the Invisalign Palatal Expander system was introduced as a series of custom 3D printed, fully removable maxillary expanders. The expanders are designed to be changed daily with 0.25mm of expansion programmed with every subsequent appliance[14]. Align claims that their new palatal expanders decrease chair time, provide less patient discomfort and anxiety, and simplify oral hygiene, all while creating skeletal expansion of the maxilla[15]. Currently there are no known, published studies which investigate the claims made by Align, or that assess the clinical effectiveness of the Invisalign Palatal Expander.

LITERATURE REVIEW

Average Transverse Growth of the Jaws

Growth of the craniofacial complex occurs in three planes of space – sagittal, vertical, and transverse – with each offering unique information on overall growth amount and direction. The timing of growth in the three spatial planes also varies, with transverse growth peaking at a different time of life than sagittal and vertical growth [5]. When treatment planning children or adults, understanding the timing of growth in each plane is an essential component in successful orthodontic treatment.

In infancy, the jaws are proportionally largest in the transverse dimension compared with the vertical and sagittal dimensions. Growth in the transverse plane is largely completed before puberty, whereas sagittal and vertical growth continue well into adulthood [17]. However, assigning specific ages at which growth stops is challenging as craniofacial structures and dental arches show great variability when comparing dental age, skeletal age and chronologic age [18].

Bishara and colleagues[19] analyzed arch width changes from infancy to adulthood in 1997 and summarized the changes by age category. Between 6 weeks and 2 years of age there were significant increases in maxillary and mandibular anterior and posterior widths. This showed there is early transverse growth potential in both jaws before the eruption of a complete deciduous dentition. Between the ages of 3 and 13, intercanine and intermolar widths increased significantly in both dental arches, and no appreciable change in intermolar width occurs between 13 to 45 years. They concluded that dimensions of the arch width were generally established by the mixed dentition (around age 8), with small continuous increases until the early permanent dentition (around age 13), followed by some, but minimal decreases into adulthood [19].

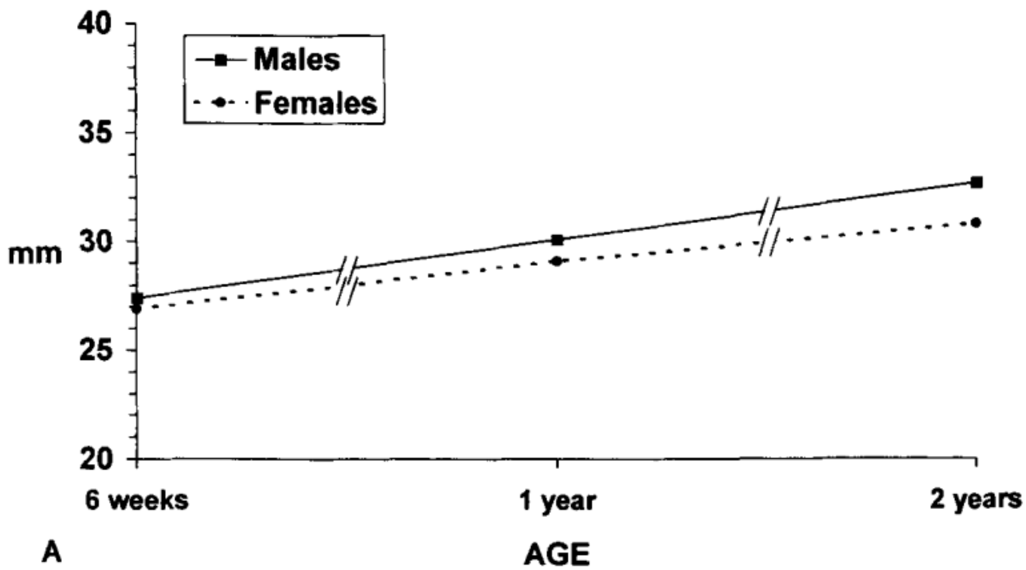

Figure 1: Changes in maxillary posterior arch widths ages 6 weeks to 2 years [19]

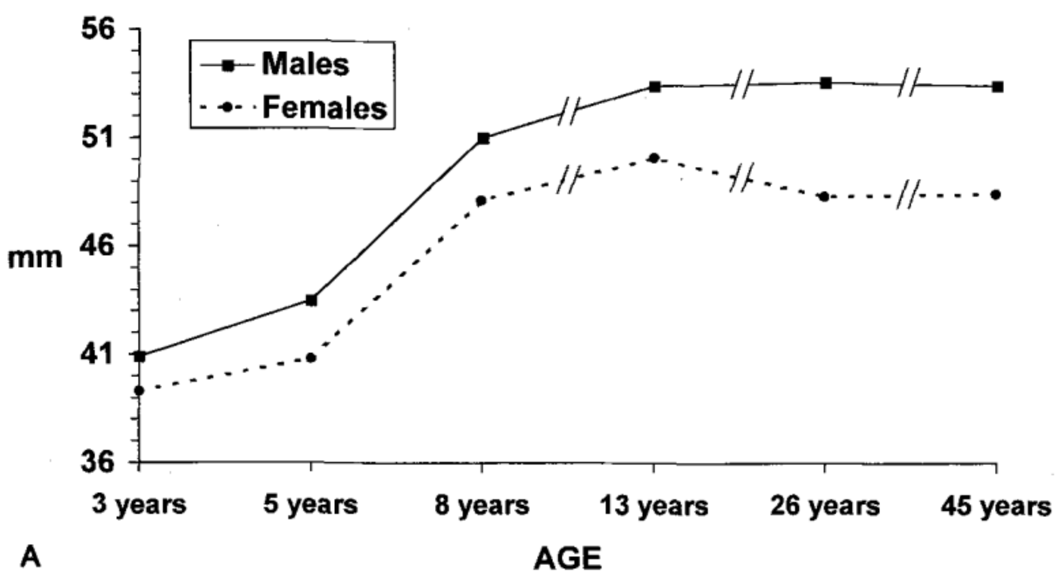

Figure 2: Changes in maxillary intermolar widths ages 3 to 45 years [19]

These findings are similar to those found in 1999 by Lee, stating that minimal changes in arch width occur after the age of 12, and those by Wagner and Chung in 2005, which stated a plateau in transverse growth started around age 14 for the maxilla and high-angle mandibles. [20,21]

It can be concluded that adults show minimal changes in transverse arch dimension due to growth, and that the maxillary transverse dimension should be established by the age of 14.

Maxillary Transverse Deficiency

Maxillary transverse deficiency (MTD) is a highly prevalent malocclusion present in all age groups, from the primary to permanent dentition. The prevalence of MTD is reported to be between 13-23% in children, and near 30% of adult orthodontic patients. If untreated as a child, a narrow maxilla will likely affect the permanent dentition as it is very unlikely to self-correct. [4]

There is not one single cause of maxillary transverse deficiency, with genetic and environmental factors both playing roles. Influences include mouth breathing, digit sucking habits, cleft lip and/or palate, or improper swallow habits. Manifestations of MTD in the dentition can appear as dental crowding, posterior crossbites, dark buccal corridors and buccolingual tip of molars in a compensating direction (maxillary molars tipped buccally and mandibular molars tipped lingually). [5]

Diagnosis of MTD can show a dental or skeletal origin, each with its own unique treatment modalities. The skeletal origin often shows a high vaulted palate and a dental arch width that is wider than the palatal width. Teeth will not have compensating angulations but still show crossbites or dark buccal corridors. MTD of dental origin typically shows reduced values for dental and palatal width, and crossbites or dark buccal corridors that are attributed to improper buccolingual inclinations of the teeth. [5]

Treatment of dental MTD often includes dental expansion from arch wires or appliances such as a Quad Helix or a Schwartz expander that will tip the maxillary molars buccally. Skeletal MTD treatment is more involved, requiring skeletal expansion of the maxillary bone down the midpalatal suture. Modalities of skeletal expansion vary with the patient's age and treatment objectives, and include traditional rapid palatal expansion with appliances such as a Hyrax or Haas, MARPE or SARPE.

Expanding the Maxillary Arch

Arch expansion has become a common approach to increase the perimeter of the dental arch to correct common dental malocclusions such as crowding and dental crossbites. Maxillary expansion can be categorized as dental, orthopedic, or surgically assisted. Dental expansion typically expects no skeletal changes to occur, while orthopedic and surgically assisted methods rely on both dental and skeletal expansion.

While dental expansion often needs orthodontic archwires alone, skeletal expansion always requires the use of secondary appliances. Skeletal expansion occurs when forces are applied to the posterior dentition or alveolar basal bone at a rapid rate. There is insufficient time for tooth movement to occur, and the force is transferred to the intermaxillary suture. Expansion can occur rapidly or slowly (RPE vs. SPE) depending on the protocol used for turning the screw in the appliance. Appliance design and activation protocol are often dependent on the practitioner's personal preference, the patient's age and malocclusion.

Due to the distraction of the midpalatal suture during skeletal expansion, the creation of a transient midline diastema is an easily identifiable indicator of successful skeletal expansion. Although a lack of diastema does not correlate with an absence of skeletal expansion[6–8].

In children and teens, skeletal expansion using RPE with orthopedic appliances is completed relatively easily. Before the age of 15, the likelihood of opening the midpalatal suture is close to 100%, but then it gradually decreases as the suture becomes more convoluted and fused. Once the suture has started to close, expansion is less predictable and dental tipping along with alveolar remodeling is likely to take place over true sutural expansion [5]. There is no definitive cutoff age for orthopedic maxillary expansion, as chronological age is often a poor indicator for stages of growth and development. In 2005, a systematic review by Lagravère et al. concluded that RPE skeletal changes are statistically significant only if patients are treated before the peak of puberty [22]. However, alternative studies have shown successful skeletal expansion of the maxilla using an orthopedic appliance in patients as old as 19 [6].

A fixed rapid palatal expander (RPE) appliance is considered the Gold Standard for true non-surgical skeletal correction in an adolescent. Typical RPE appliances consist of a central, expandable jackscrew with arms that attach to posterior teeth through bonding or banding. One activation of the jackscrew typically equates to 0.25mm of expansion and turning protocols range from 2 activations per day, to 1 activation every other day, depending on treatment goals and provider preferences. A standard tooth-borne Hyrax appliance can deliver a maximum of 11-13 mm of expansion. [5]

Expansion to the arch perimeter gained does not follow a 1:1 ratio, and actual arch length gained from expansion may be less than expected. The ratio of arch perimeter gained / premolar expansion is 0.7, meaning that 10mm of interpremolar expansion would equate to about 7mm of gained arch perimeter [23]. It is also generally accepted that palatal changes are more significant with skeletal expansion in the anterior and canine regions than in the molar regions. Vanarsdall found the ratio of palatal changes to be 3:2 (canine:molar), and associated this difference in expansion to a combination of skeletal, dental and alveolar changes[24].

Retention and Relapse

Retention is required after Orthodontic treatment, regardless of how stable the movements are, to prevent relapse. Relapse can occur for a variety of different reasons, with remodeling of periodontal tissues, changes in tissue pressure, and changes in growth cited as major reasons [5]. Relapse in the maxillary transverse dimensions is common and should be accounted for during treatment planning[14–16, 25–27]. Beltrami and colleagues performed a meta-analysis on 22 studies of maxillary expansion and found that 19.3% of the total expansion relapsed, concluding that the long-term stability of a posterior crossbite in a growing child is unfavourable in approximately 1 in 5 cases [26]. Gurel and colleagues looked at the long-term changes in maxillary width after expansion by measuring intercanine, interpremolar and intermolar widths on patients after 3 months of retention. They found a 37% rate of relapse in the intercanine width, with significant but lower relapse occurring in the interpremolar and intermolar regions (19% and 17% respectively) [25].

To reduce relapse, a retention phase should always be implemented after maxillary skeletal expansion. Skeletally, it takes approximately 3 months for bone to fill in any distraction space created at the intermaxillary suture. It is natural to have some skeletal relapse during this period, but once this bone has filled and ossified, the stability of the skeletal expansion is relatively stable [5,27,28]. In 2017, Costa and colleagues conducted a systematic review of retention periods after maxillary expansion as they felt there was no consensus among authors regarding the ideal retention timeline. Various methods of retention were used, including fixed (Haas, Hyrax, acrylic plate, and Quad-Helix) and removable (Hawley and Hawley expander) appliances. The literature reviewed showed retention periods ranging from 4 weeks to 16 months, with the authors concluding a 6 month retention period with either a fixed or removable appliance seemed to be enough to avoid relapse in the short term [29] .

Invisalign Treatment

The term "Clear Aligner Therapy" refers to an orthodontic treatment modality used to correct dental malocclusions. A series of custom 3D printed, removable, transparent trays gradually change the position of teeth, often using auxiliaries such as elastics and adhesive attachments to assist movements. Although the use of clear aligners continues to grow, questions about their effectiveness remain. Upadhyay and Arqub summarized aligner efficacy for different tooth movements and found that average efficacy was 50% for all movements, with tipping of teeth being the most predictable movement (80%), while root movements were the most challenging to achieve (<10%) [30]. Similar findings were also found in a 2014 systematic review of the efficacy of clear aligners in controlling orthodontic tooth movements. Rossini and colleagues found that [31];

- clear aligners are effective for levelling and aligning the arches
- anterior intrusion is achievable, while anterior extrusion was poorly controlled
- posterior vertical changes had conflicting results, and conclusions could not be drawn
- rotations were poorly corrected especially on rounded teeth
- bodily movement of maxillary molars showed high control

Invisalign has been the leading provider of clear aligners since its inception in 1998. Earliest systems relied on the plastic surrounding the teeth to achieve the desired tooth movement, however their approach has evolved dramatically since then. Material changes and the addition of auxiliaries such as attachments, power ridges, inter-arch elastics, bite ramps and IPR have allowed Invisalign to move teeth greater distances in shorter periods of time. Despite these improvements, 70-80% of clinicians still report the need for mid-treatment corrections or case refinement [30].

Transverse Expansion with Invisalign

Up until recently, Invisalign systems could only treat transverse malocclusions with dental expansion. The predictability of posterior expansion with clear aligners has been variable, due to the aligner's tendency to tip teeth, rather than correct bucco-lingual root positions through bodily movement. Houle et al. found the mean accuracy of dentoalveolar expansion planned with Invisalign for the maxilla was between 70-80% when measured from the cusp tips, and found it became less accurate in posterior regions [32]. Similarly, Galluccio and colleagues found 70% efficacy in maxillary arch transverse expansion when using Invisalign [33].

Invisalign expanded into Phase 1 treatment in 2018 with the development of their Invisalign First products. This system was designed to treat simple or complex dental alignment issues for children ages 6-10. Product setup and delivery are almost identical to their original clear aligners. Similar to their traditional Invisalign aligner system for adults, Invisalign First never claimed to be able to skeletally expand an arch, but can provide dental transverse expansion [34] [35]. When analyzing digitally predicted versus true intra-oral transverse dental expansion with Invisalign First, Gonçalves et al. found the effectiveness of the aligner system was around 62% for both arches [11]. These values are clinically comparable to those of their traditional system previously mentioned.

When comparing the dental expansion of Invisalign First to a traditional removable expander, results vary. In 2024 Pamukçu and colleagues used a sample size of 17 cases to compare transverse changes with Invisalign First and a removable acrylic expander and found statistically significant results. Data measuring intercanine and intermolar width were compared between the two appliances, and Invisalign First showed less expansion predictability in the first molar region. Changes in intercanine width were comparable between the two groups [12]. A similar study was published in 2023, comparing Invisalign First to a removable acrylic palatal expander, that also included a natural growth control group to rule-out growth effects. Results showed no significant changes in the natural growth group, and the removable expander exhibited greater expansion than the Invisalign First group in the intercanine, intermolar, and inclination of molar categories [13]. Despite showing promise as a means for dental expansion when compared to removable appliances, neither are as effective as a cemented Hyrax appliance [11,36].

Invisalign Palatal Expander

In September of 2023, Align Technology introduced the Invisalign Palatal Expander System. The system consists of a series of Invisalign Palatal Expanders which complete active expansion, and Invisalign Palatal Holders which maintain expansion after active treatment [14]. The system is completely removable and custom 3D printed for each patient. The expanders are staged to be changed daily and create 0.25mm of expansion with every subsequent appliance. Align has claimed many benefits to their new expansion treatment system when compared to a traditional RPE. They state their appliances decrease chair time, provide less discomfort and anxiety for the patient, and simplify oral hygiene, all while creating true skeletal expansion at the intermaxillary suture [36]. Current literature searches show no studies on the new Invisalign Palatal Expander System, including the efficacy of the product or claims made by Invisalign.

PURPOSE

The purpose of this study is to assess the clinical findings present in patients who have received expansion through the Invisalign Palatal Expander System.

NULL HYPOTHESIS

1. Maxillary expansion completed with the Invisalign Palatal Expander System will not statistically significantly increase interdental widths, diastema width or tip of molars.
2. There is no statistically significant difference in the change of intermolar and intercanine widths between patients treated with the Invisalign Palatal Expander System and those treated with control, Hyrax and Invisalign First modalities as reported by Torbaty et al. (2024)[16]

MATERIALS AND METHODS

Ethics

Ethics approval was provided by the Bannatyne Campus Research Ethics Board at the University of Manitoba in February 2025, before data collection of this study had begun.

Sample Size Calculation

Calculations were made based on a power of 0.8 and an alpha of 0.05 using different effect sizes. At a 1.0 effect size, the required sample was n=33 between two groups. A sample of n=30 was decided on.

Sample Selection

Data of the patients was obtained from a single orthodontic practice in Winnipeg, Manitoba, Canada from a single experienced practitioner (RD) implementing consistent protocols. Patient scans were obtained by a trained and registered dental assistant and analyzed retrospectively based on the following inclusion and exclusion criteria:

Inclusion Criteria:

- Non-extraction
- Fully erupted maxillary first molars
- Presence of intra-oral canine teeth (permanent or primary)
- Patient aged 6-14 at start of treatment
- Good compliance during treatment as assessed by the Orthodontist

Exclusion Criteria:

- Additional mechanics to the Invisalign Palatal Expander System (i.e. Bonded brackets or additional appliances)
- Auxiliaries beyond Invisalign attachments (i.e. Intraoral elastics)
- Previous orthodontic treatment
- Midcourse correction
- Presence of supernumerary teeth, syndromes, dental anomalies, tooth agenesis or craniofacial deformities

Patient's age, gender, as well as the pre-treatment and post-treatment digital scans (.stl files) were obtained. Records were selected randomly for patients who met the inclusion/exclusion criteria. The final sample size was 30 patients: 13 male and 17 female (Table 1). Their mean age was 8.95 years old, and the age range was from 6 to 12 years old. All patients had the maxillary arch treated by the IPE only.

	Table of Gender Distribution	
Gender	Frequency	Percentage
Female	17	56.66%
Male	13	43.33%
Total	30	100%

Table 1: Gender distribution of the sample size

Data Collection

Data was collected from an Orthodontic practice in Winnipeg, Canada. Pre- and post-treatment digital models were created from an iTero digital scanner, with the pre-treatment scan representing the occlusion at the first consult, and was treatment planned and sent to Invisalign. Teeth had no attachments or previous treatment at that time. Post-treatment scans were taken once expansion was deemed complete by the Orthodontist, typically when the lingual cusp tips of the maxillary molars were in line with the buccal cusp tips of the mandibular molars. Patient confidential information was removed, and unique patient identifiers were used during data collection.

Digital .stl files were uploaded from the iTero scanner to the OrthoCad software. All measurements were completed on the OrthoCad software by the primary investigator. Arch width and width of diastema were measured using the software's arch measurement function. Landmarks used for linear measurements were as follows:

Intercanine Width (figure 3)

- Canine cusp tip to canine cusp tip on the contralateral side (mm)

Intermolar Width (figure 4)

- Mesiolingual cusp tip of maxillary first molar to mesiolingual cusp tip of maxillary first molar on contralateral side (mm)

Diastema Width (figure 5)

- Mesial point of maxillary central incisor to mesial point of maxillary central incisor on contralateral side (mm)

A non-descriptive binary (present or absent) was recorded for a diastema of each case as well.

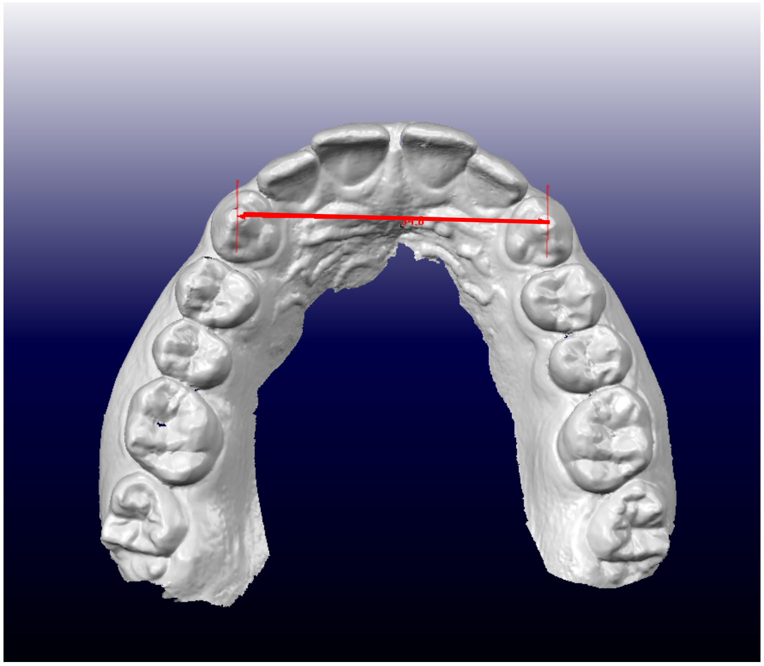

Figure 3: Intercanine width measurement landmarks

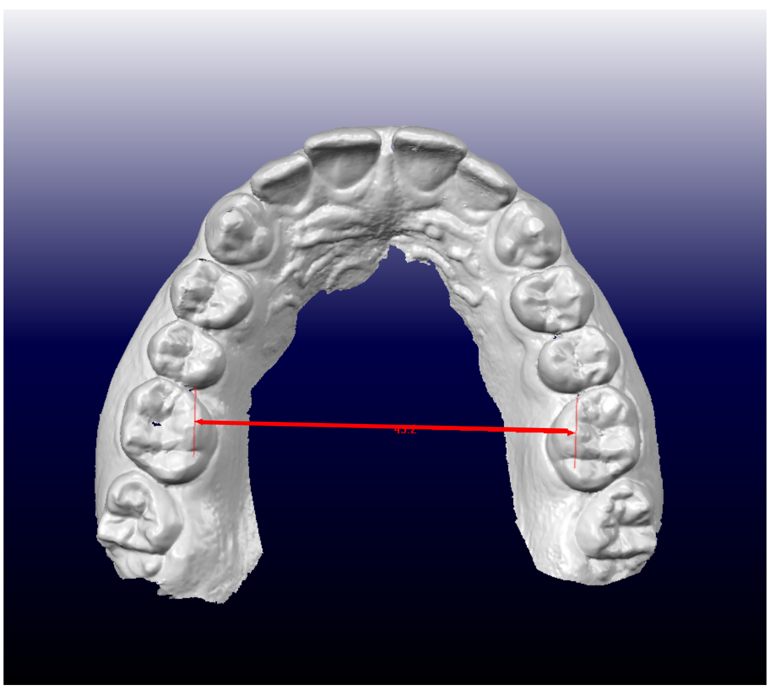

Figure 4: Intermolar width measurement landmarks

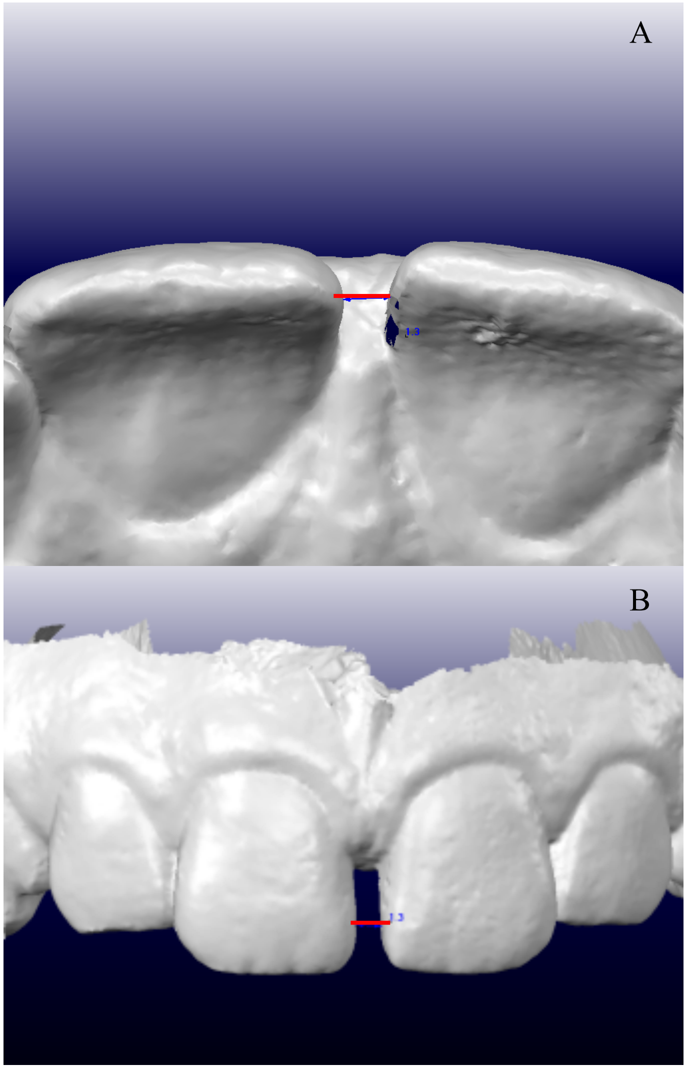

Figure 5: Diastema width measurements from the occlusal (A) and anterior (B) views

This study followed the ABO Objective Grading System (ABO-OGS) guidelines for determining molar inclination. First molar buccolingual inclination was measured using the ABO Phase III analysis feature on the OrthoCAD software. This compares the linear distance of a molar cusp to a pre-determined plane occlusal plane. The occlusal plane was created along the mesiolingual cusps of maxillary first molars (figure 6), and the distance from the mesiobuccal cusp of the first molar to the plane was measured (figure 7). An increase in this number post-treatment would show there was buccal crown tipping of the maxillary molar, while a decrease would show lingual crown tip. The ABO-OGS states that the buccal cusp of a maxillary molar should be within 1mm of the plane created by the lingual cusp tips in an acceptable finished orthodontic case [37].

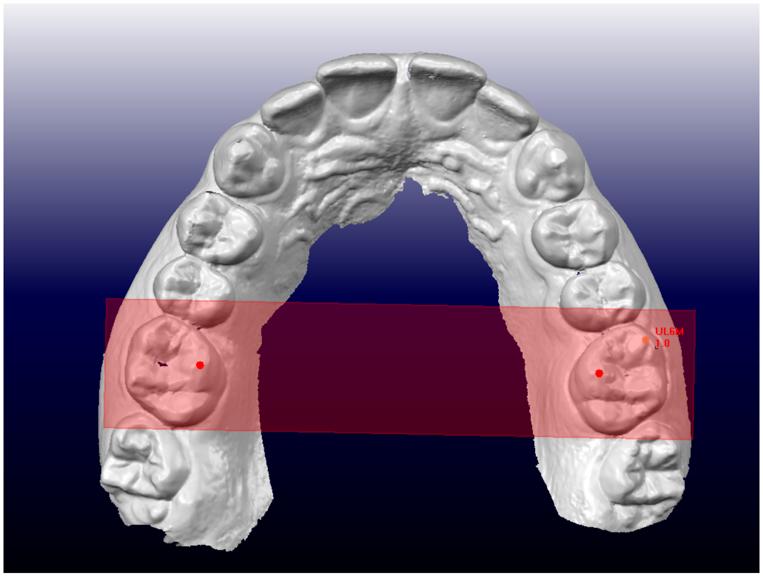

Figure 6: Occlusal plane created from the mesiolingual cusp tips of maxillary first molars

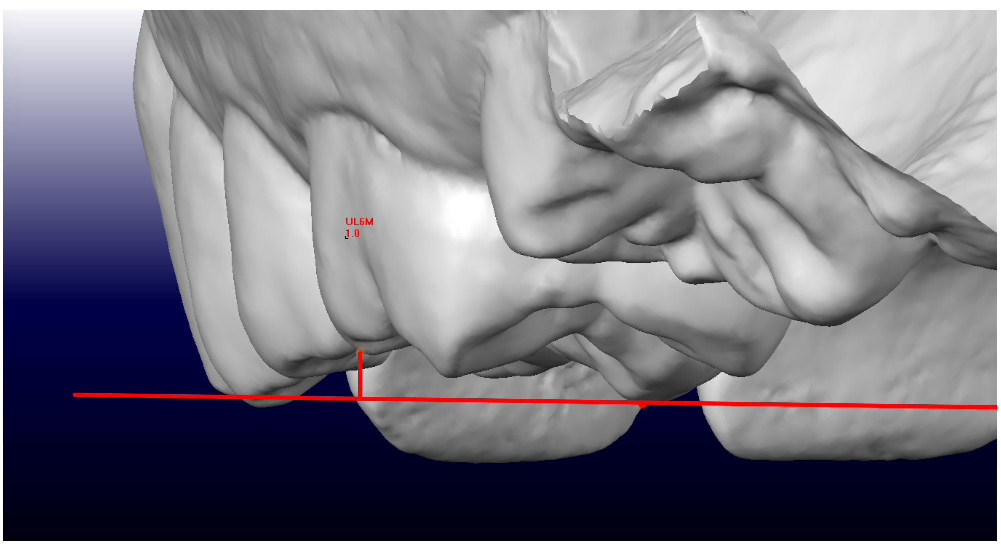

Figure 7: Molar inclination was quantified measuring the distance of the mesiobuccal cusp tip to the occlusal plane created in Figure 6

All measurements were taken on each patient's pre- and post-treatment models and data was compiled in an Excel spreadsheet for statistical analysis.

To check intra-rater reliability, 20% of cases were selected at random and re-measured by the primary investigator. A break of 4 weeks after the initial data collection period was taken to avoid memory bias. The same 20% of cases were re-measured by a second grader at the same time to check inter-rater reliability.

Data Comparison

Our data for intercanine and intermolar width was compared to a data set published in 2024 by Torbaty and colleagues[16]. This study compared non-expanded control patients to those treated with a Hyrax expander and the Invisalign First system and assessed the transverse dimension alongside other data points. Sample size was 40 patients in each treatment group, and digital models were analyzed on a similar virtual software.

Notable differences between this study and ours was the landmark for intermolar measurements. Torbaty used the central fossae of the maxillary permanent molars while this study used cusp tips as previously mentioned. Measurements for intercanine width were the same between the two studies. Furthermore, our study assessed cases in mixed and permanent dentition, while all cases in the Torbaty study had primary canines and molars.

Statistical Analysis

Data normality was assessed by a Shapiro-Wilk test.

Descriptive statistics of the pre- and post-treatment groups included mean, standard deviation, minimum and maximum values for all five data measurements. The binary measurement of diastema was described as a percentage of the total patient pool.

The intra- and inter-rater reliability was assessed by means of an intraclass correlation coefficient (ICC). Binary diastema (pre- and post-) showed perfect agreement and was not included in this analysis.

Changes from pre- to post-treatment were analyzed using a paired t-test for all measurements excluding diastema width. Normality issues were present with the distribution of diastema width measurements, so a Wilcoxon Signed Rank Test was used instead of a paired t-test.

Comparison to the Torbaty et al. study was completed using a One-Way ANOVA to compare all groups, followed by a post hoc Tukey HSD to further analyze any significant findings from the ANOVA test.

RESULTS

Reliability

The ICC test used to assess intra-rater reliability showed excellent reliability for most measurements, and intercanine and intermolar post-treatment measurements showed good reliability[38] (Table 2). Wide confidence intervals were seen for diastema, intermolar and intercanine post-treatment despite having good to excellent ICC values. Inter-rater agreement showed excellent reliability for all values except pre-treatment diastema, which showed good reliability[38] (Table 3). Again, diastema showed a wide confidence interval despite having a good ICC value. The wide confidence intervals are likely due to the small sample size of the intra- and inter-rater reliability checks that were done. Binary diastema (pre and post) showed perfect agreement and are not included in Tables 2 or 3.

INTRA-RATER CHECKS

Pre-Treatment	ICC	95% CI
Intermolar (mm)	.996	.906, .998
Intercanine (mm)	.993	.952, .999
RHS Molar Tip (mm)	.970	.821, .996
LHS Molar Tip (mm)	.968	.775, .996
Diastema (mm)	.950	.645, .993

Post-Treatment	ICC	95% CI
Intermolar (mm)	.832	.029, .976
Intercanine (mm)	.782	-.300, .969
RHS Molar Tip (mm)	.961	.750, .994
LHS Molar Tip (mm)	.977	.834, .997
Diastema (mm)	.908	.395, .987

Table 2: Inter-rater reliability checks

INTER-RATER CHECKS

Pre-Treatment	ICC	95% CI
Intermolar (mm)	.997	.997, 1.0
Intercanine (mm)	.987	.915, .998
RHS Molar Tip (mm)	.998	.987, 1.0
LHS Molar Tip (mm)	.986	.914, .998
Diastema (mm)	.880	.168, .983

Post-Treatment	ICC	95% CI
Intermolar (mm)	.995	.962, .999
Intercanine (mm)	.997	.980, 1.0
RHS Molar Tip (mm)	.989	.925, .999
LHS Molar Tip (mm)	.998	.985, 1.0
Diastema (mm)	.990	.930, .999

Table 3: Inter-rater reliability checks

Pre-Treatment and Post-Treatment Descriptives

The mean, standard deviation, and range of each linear measurement - both pre- and post-treatment - can be seen in Table 4. The presence or absence of a diastema in each case is described as a percentage of the total sample size and can be seen in Table 5 for both pre-treatment and post-treatment cases. Intercanine and intermolar widths, diastema width and molar tip values all showed increases from pre- to post-treatment.

Pre-Post Descriptives

Pre-Treatment	Mean	SD	Min	Max
Intermolar (mm)	38.857	2.825	31.900	47.400
Intercanine (mm)	30.653	3.069	22.400	56.300
RHS Molar Tip (mm)	1.203	.538	.200	2.400
LHS Molar Tip (mm)	1.260	.627	.100	2.400
Diastema (mm)	.697	.887	0	2.800

Post-Treatment	Mean	SD	Min	Max
Intermolar (mm)	42.040	2.454	37.300	49.400
Intercanine (mm)	32.110	2.929	25.200	37.700
RHS Molar Tip (mm)	1.427	0.584	.200	2.400
LHS Molar Tip (mm)	1.473	0.656	.200	2.500
Diastema (mm)	1.420	0.978	0	3.000

Table 4: Mean, standard deviation, minimum and maximum values for pre- and post-treatment measurements

Diastema Change from Pre to Post				
	Pre-Treatment		Post-Treatment	
	Yes	%	Yes	%
Diastema	n=14	46.7%	n=22	73.3%

Table 5: Presence of a diastema for pre-treatment and post-treatment

Comparison Between Pre-Treatment and Post-Treatment

Pre-treatment interdental widths (intermolar, intercanine, diastema), and tips (maxillary first molar RHS and LHS) were compared to post-treatment widths and tips (Table 6). The paired t-test revealed statistically significant changes ($p<.001$) from pre-treatment to post-treatment measurements for intermolar width, intercanine width and tip of maxillary first molar. The mean change in intermolar and intercanine width was 3.18mm (8.18%) and 1.46mm (4.76%) respectively. Changes in maxillary molar cusp position (tip) was comparable from the RHS to LHS, showing changes of 0.23mm (19.17%) and 0.21mm (16.67%) respectively.

The diastema width measurement showed normality issues with the distributions – likely from the presence of outliers - so a Wilcoxon Signed Rank Test was used instead of a paired t-test. This test also showed statistically significant changes in pre- and post-treatment diastema width with an average increase of 1.42mm in diastema width from pre- to post-treatment. That represents a 102.86% increase in mean diastema from pre- to post-treatment.

Change from Pre to Post				
	Mean Pre-Treatment	**Mean Post-Treatment**	**Change (%)**	**Sig (p)**
Intermolar (mm)	38.857	42.040	3.18 (8.18%)	<.001
Intercanine (mm)	30.653	32.110	1.46 (4.76%)	<.001
RHS Molar Tip (mm)	1.203	1.427	0.23 (19.17%)	<.001
LHS Molar Tip (mm)	1.260	1.473	0.21 (16.67%)	<.001
Diastema (mm)	.697	1.420	0.72 (102.86%)	<.001

Table 6: Changes in linear measurements from pre- to post-treatment

Comparison to Torbaty et al. 2024

The One-Way ANOVA test comparing all groups (control, Hyrax, Invisalign First and IPE) showed statistically significant ($p<.001$) differences for both intermolar and intercanine width changes (Table 7). To further explore these differences, post hoc comparisons were completed.

T1 to T2 Change Comparison to Torbaty et al, 2024									
	Torbaty et al.						Bailey et al.		
	Control (n=41)		**Hyrax (n=40)**		**Invisalign First (n=40)**		**IPE (n=30)**		
	Change	**SD**	**Change**	**SD**	**Change**	**SD**	**Change**	**SD**	**Stat (p)**
Intermolar (mm)	0.53	0.68	4.40	1.38	2.47	1.17	3.18	1.72	63.81 (<.001)
Intercanine (mm)	0.27	1.21	3.70	1.89	3.69	1.24	1.46	0.85	70.51 (<.001)

Table 7: Comparison of pre- and post-treatment interarch widths between modalities tested in this study and Torbaty et al, 2024

The intercanine post hoc tests comparing the IPE to the Torbaty treatment modalities can be seen in Table 8. The changes in intercanine width were statistically significant between the IPE and controls, Hyrax and Invisalign First ($p = 0.01$, $p < .001$ and $p < .001$ respectively). The IPE showed a greater change in intercanine width than the control (1.46mm and 0.27mm respectively), but less change than what was reported in the in the Hyrax and Invisalign First conditions (3.7mm and 3.69mm respectively).

Intercanine Post Hoc Comparisons	
Comparison	**Sig (p)**
IPE vs Control	0.01
IPE vs Hyrax	<.001
IPE vs Invisalign First	<.001

Table 8: Intercanine post hoc comparisons of IPE to treatment modalities used by Torbaty et al, 2024

The intermolar post hoc tests comparing the IPE to the Torbaty treatment modalities can be seen in Table 9. The intermolar changes were statistically significant between the IPE and control ($p < 0.001$), and IPE and Hyrax ($p < 0.001$). Specifically, IPE showed a greater change than the cited control group (3.18mm and 0.53mm respectively), and less change than the cited Hyrax group (4.4mm). The IPE showed greater intermolar changes than Invisalign First (2.47mm), however these changes were not statistically significant ($p = 0.52$).

Figure 8 illustrates the intercanine and intermolar post hoc testing for the IPE compared to the cited control, Hyrax and Invisalign First groups.

Intermolar Post Hoc Comparisons	
Comparison	**Sig (p)**
IPE vs Control	<.001
IPE vs Hyrax	<.001
IPE vs Invisalign First	0.52

Table 9: Intermolar post hoc comparisons of IPE to treatment modalities used by Torbaty et al, 2024

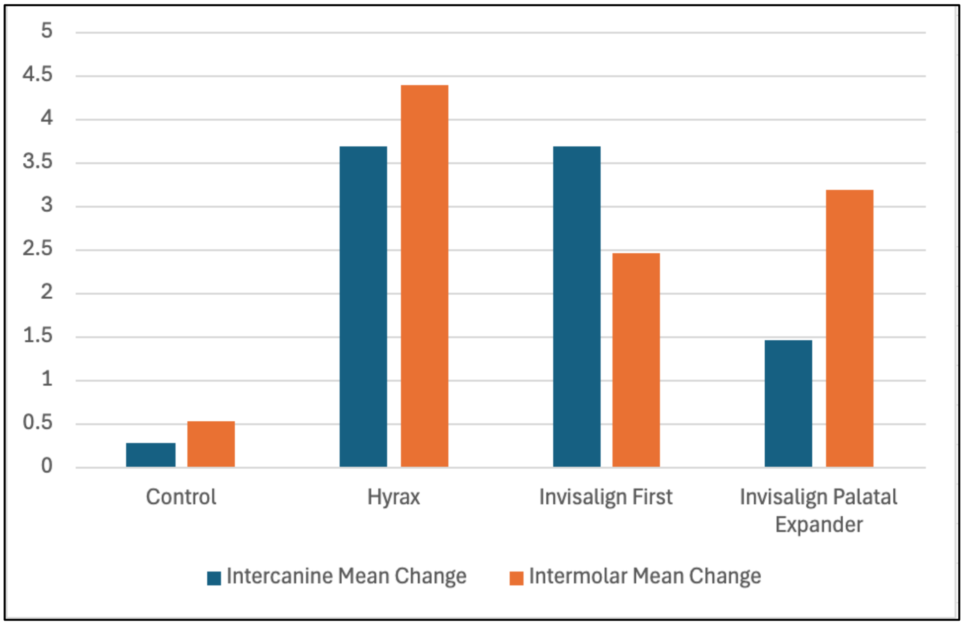

Figure 8: Intercanine and intermolar post hoc testing for the IPE compared to modalities used by Torbaty et al, 2024

DISCUSSION

The consequences of a narrow maxilla in children and adolescents are more apparent than ever. With the use of removable, custom appliances on the rise, the Invisalign Palatal Expander System appears to fill a void in the market – skeletal expansion with ease of use and improved oral hygiene. However, before clinicians can swap out their traditional appliances, supporting data is required. The purpose of this study was to assess the clinical effectiveness of the Invisalign Palatal Expander (IPE) System as a means of maxillary skeletal expansion in children and adolescents.

A benchmark for successful maxillary expansion is an increase in inter-dental widths. On average, both intermolar and intercanine widths increased after treatment with the IPE, confirming that it is an effective method to expand the dental arch. The IPE produced significant levels of expansion for both inter-arch landmarks, however the percent change of intermolar width was almost double that of the intercanine (8.18% and 4.76%, respectively). Compared to previous studies that analyzed expansion modalities, the IPE intermolar increase of 3.18mm was higher than expansion measured from the same landmarks with Invisalign First (1.08mm) and a removable acrylic expansion appliance (3.04mm) in a 2024 study by Pamukcu et al[12]. However, the IPE performed poorly when comparing intercanine width changes to the modalities used by Pamukcu and colleagues. The average increase of 1.46mm when treated with the IPE is less than the reported 2024 findings of 2.14mm from Invisalign First and 3.49mm from a removable acrylic expander. Similar findings were found when comparing to Torbaty et al, highlighting the underperformance of the IPE at increasing intercanine widths. The current IPE design provides complete coronal coverage of the maxillary permanent molars and either the second primary molar or premolar, and partial coverage on the first primary molar or premolar [39]. This setup enforces no anchorage on the canines, possibly explaining the decreased expansion when compared to modalities that actively place forces on canine teeth.

To assess whether the expansion occurring is skeletal or dental is challenging, with true confirmation requiring radiographic assessment. A simple clinical sign that practitioners often look for during skeletal expansion is the occurrence of a midline diastema. The presence of the diastema is an indicator that the midpalatal suture has split, but the size of diastema should not be used to quantify the amount of sutural expansion[9]. In 2022 Salmoria and colleagues used both CBCT imaging, and diastema width to evaluate sutural opening after MARPE expansion. They found that all subjects who showed a midline diastema also had CBCT sutural opening, and concluded that a maxillary incisor diastema was positively associated with anterior and posterior suture opening for all subjects studied ($p<0.05$) [40]. When comparing the amounts of sutural expansion to diastema width increase, various studies have been completed with similar results. Alves and colleagues (2022) measured diastema width and radiographic suture opening with the Hyrax appliance and found average suture expansion (3.18mm) to be greater than the average increase in diastema width (2.53mm)[41]. Similar findings were found in 2021 from Yoon et al. finding an average sutural opening of 3.05mm was associated with a mean diastema change of 1.60mm ($p < 0.0001$)[42], suggesting sutural opening could be greater than diastema width increases and strengthening the correlation between increased diastema width and radiographic sutural expansion. The results of this study showed that 70% of patients treated with the IPE saw an increase in diastema width. The average 1.42mm increase in central diastema is both statistically and clinically significant, indicating a high likelihood that the IPE is successful at opening the midpalatal suture, and that true skeletal expansion is possible with this removable appliance.

An undesirable outcome that occurs with maxillary expansion is buccal crown torque of the posterior teeth. During skeletal expansion, accompanying dental expansion occurs at the same time, with previous studies recording up to 65% of arch width changes coming from dental tipping[43]. This side effect is more common in adolescent patients where the midpalatal suture is more fused. Buccal crown torque leads to plunging lingual cusps, bite opening and decreased buccal bone thickness[44]. This study assessed dental torque produced from IPE expansion by measuring the linear distance of the buccal cusp tip to the occlusal plane, the same method used for assessing finished Orthodontic cases with the ABO Objective Grading System (ABO-)OGS. The ABO-OGS states that the buccal cusp of a maxillary molar should be within 1mm of the plane created by the lingual cusp tips in an acceptable finished orthodontic case[37]. On average, the buccal cusps of patients treated with the IPE moved apically 0.22mm. In clinical biomechanics, the amount of vertical displacement of a cusp tip from torque is a function of the distance from the centre of rotation to the cusp tip. With an average distance of 7mm from the cusp tip to the centre of resistance on a maxillary first molar, a 0.22mm vertical change would equate to an estimated 6 degrees of torque change from treatment with the IPE[44,45]. Despite the 0.22mm change in cusp height being statistically significant, the amount of change in torque lacks clinical significance, as a 6-degree torque can easily be corrected with subsequent fixed or clear aligner treatment. Control of torque likely comes from the full plastic coverage of maxillary molars on the IPE, a feature that typical rapid palatal expanders often lack. These torque changes could be controlled further if future updates to the IPE setup allowed active movement on the anchor teeth, and clinicians would be able to add counteracting torque while expanding.

Comparison to Torbaty et al, 2024[16]

The 2024 study by Torbaty and colleagues provided data to compare the IPE to non-treated controls, Hyrax skeletal expansion and Invisalign First dental expansion. When comparing the IPE to controls, IPE widened intercanine and intermolar widths significantly more than what occurs naturally during pubertal growth. While these findings are not shocking, they re-emphasize that maxillary transverse deficiencies do not self-resolve and highlights the need for Orthodontic intervention in children of young ages.

In contrast, the Hyrax expander outperformed the IPE statistically significantly in both intermolar (4.40 mm and 3.18mm respectively) and intercanine width changes (3.70mm and 1.46mm respectively). This is likely a consequence of the removable nature of the IPE, with fixed appliances typically showing higher efficacy for maxillary expansion[36]. The continuous force system of the Hyrax provides more consistent, high forces on the suture, and avoids issues with compliance and wear time. While the patients selected for the IPE all demonstrated adequate compliance, the intermittent force system naturally will be less effective at distracting bony sutures.

Comparing the outcomes of Invisalign First and IPE shows more variation. Invisalign First statistically significantly exceeded the IPE for intercanine widths (3.69mm and 1.46mm respectively). As previously mentioned, this could be accounted for by the lack of attachments and anchorage on the canines with the IPE. IPE resulted in larger intermolar widths than Invisalign First (3.18mm and 2.47mm respectively), but the comparison was not statistically significant, with less than 1mm difference in mean post-treatment widths.

Ultimately the decision to use Invisalign First versus the IPE should be determined by treatment goals, not comparing efficacy. Treating maxillary transverse deficiency requires proper identification of the etiology before creating a treatment plan. While both IPE and Invisalign First increase interdental widths, they do so with different methods – with and without a skeletal component. Invisalign First shows no signs of sutural opening and will increase the dental arch width by dental tipping. In a case where maxillary molars show compensated lingually tipped crowns, the palate is wide and well formed, and side effects such as bite opening are beneficial, dental expansion is the ideal treatment choice. Placing an IPE on this hypothetical patient would increase their interdental widths, but would not address the underlying cause of their transverse deficiency. Similarly, this study shows that skeletal expansion with minimal dental tipping is possible with the IPE, suggesting it is an acceptable treatment option for buccally or well inclined teeth with a tapered maxilla and deep palate, signaling a skeletal cause to the transverse deficiency.

The comparison to Torbaty et al. allows a clinician to globally assess the different modalities for expansion. For a provider to move away from appliances they have habitually used for years, the IPE needs to show strong and significant efficacy compared to what is currently used in their office. While the IPE has shown to provide expansion, it is up to each individual clinician to decide whether the results show effectiveness worthy of ousting an existing appliance in their clinical toolbox.

Study Limitations

This study has potential limitations. Due to the newness of the IPE technology at the time of data collection, our sample size was limited by the number of completed patients that showed good compliance and fit the inclusion criteria. Increasing sample size in a future study could prevent random error and increase the statistical power.

This study was a single-center study with all patients being treated by the same clinician (RD). This had its benefits, as all cases were treatment planned similarly, and expanded consistently. However, collecting data over multiple centres including multiple clinicians would provide more diverse patient pools, larger sample sizes and strengthen generalizability.

This is the first known study to look at the effectiveness of expansion using the IPE. Sample patients included those without dental crossbites and those with crossbites of one or more teeth. It is unknown if a dental crossbite could affect the expected expansion.

This study did not use radiographic intervention to confirm skeletal expansion at the midpalatal suture due to its retrospective nature. Doing so could verify the presence of skeletal expansion, discern what expansion was skeletal versus dental, and strengthen these results.

This study used only linear measurements to assess the performance of the Invisalign Palatal Expander System. Future studies could look at utilizing 3-Dimensional data collection, which could improve accuracy and allow a more comprehensive understanding of the results of the appliance.

The comparison to Torbaty et al. has limitations as each data set was collected with unique methodology and guidelines. Neither study had a predetermined expansion amount, meaning each patient was expanded to their own individual needs. This creates the potential for bias based on the patient pool selected. A group that presents with more severe maxillary constriction may produce higher mean changes in arch widths, not because the treatment modality was more successful, but because the overall expansion required was more. Furthermore, patient pools varied slightly between the two studies. Torbaty et al. patients were all in the mixed dentition stage with primary canines present, compared to our study which included adolescents in permanent dentition with permanent canines. With longer roots, permanent teeth – especially canines – may be more resistant to movement from an expander and could vary results derived from dental landmarks.

CONCLUSIONS

From the results obtained in this study we can conclude that:

- IPE increases intermolar and intercanine widths
- Skeletal expansion with IPE is possible based on diastema development in 70% of subjects
- IPE is less effective at increasing intercanine width than alternative expansion modalities
- IPE is less effective than traditional rapid palatal expanders (e.g. Hyrax) at increasing interdental widths

Revisiting Null Hypothesis

<u>Null Hypothesis #1:</u>

Maxillary expansion completed with the Invisalign Palatal Expander System will not statistically significantly increase interdental widths, diastema width or tip of molars

- Statistically significant increases were observed in intermolar, intercanine, diastema width, and molar tip ($p<.001$); therefore, the null hypothesis is rejected

<u>Null Hypothesis #2:</u>

There is no statistically significant difference between intermolar and intercanine width outcomes when comparing the Invisalign Palatal Expander to expansion modalities used by Torbay et al. (2024)

- Compared to the controls, there were statistically significant differences in intercanine ($p=.01$) and intermolar ($p<.001$) width changes using the IPE. Therefore, we reject the null hypothesis.

- Compared to the Hyrax, there were statistically significant differences in intercanine ($p<.001$) and intermolar ($p<.001$) width changes using the IPE. Therefore, we reject the null hypothesis.
- Compared to Invisalign First, there were statistically significant differences in intercanine width changes using the IPE ($p<.001$), but changes in intermolar width were not statistically significant ($p=0.52$). Therefore, we partially reject the null hypothesis.

RECOMMENDATIONS

- Align has made claims about the IPE beyond tooth movement including decreased chair time, fewer emergencies, and increased patient comfort. Comparing these details of patients treated with IPE versus a traditional expander would test these claims.
- Assessing the same data points as this study using a multi-centered approach could provide different results.
- Each IPE is programmed to expand the arch 0.25mm. If you compared the number of expanders used to the changes in interdental widths (actual versus expected expansion) you could view the product efficacy in a new perspective.

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ANNEXURES

Ethics Approval

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

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. Nicole Bailey	University of Manitoba/Preventive Dental Sciences	HS26817 (H2025:046)

APPROVAL DATE:	EXPIRY DATE:
March 7, 2025	March 7, 2026

STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable):
Dr. William Wiltshire

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE:
	Preliminary Clinical Findings Using the Invisalign Palatal Expander System

SPONSORING AGENCIES, FUNDING AGENCIES AND/OR COORDINATING GROUPS:
PI funded

Submission Date of Investigator Documents:	HREB Receipt Date of Documents:
January 29, 2025 and March 3, 2025	January 29, 2025 and March 3, 2025

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version (if applicable)	Date
Protocol: Proposal as outlined in the revised University of Manitoba Bannatyne Campus Research Ethics Board Submission Form for Retrospective Chart or Records Review		February 24, 2025
Consent and Assent Form(s):		
Other: Data Capture Sheet (undated)		submitted March 3, 2025)
Master List (undated)		submitted March 3, 2025)

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.

QUALITY ASSURANCE
The University of Manitoba Research Quality Management Office may request to review research documentation from this research study/project to demonstrate compliance with this approved protocol and the University of Manitoba Policy on the Ethics of Research Involving Humans.

1

A unit of the office of the Vice-President (Research and International)
https://umanitoba.ca/research/opportunities-support/ethics-compliance/ethics/bannatyne

CONFLICT OF INTEREST

Any Principal or Co-Investigators of this study who are members of the UMHREB did not participate in the review or voting of this study.

CONDITIONS OF APPROVAL:

1. The study is acceptable on scientific and ethical grounds for the ethics of human use only. ***For logistics of performing the study, approval must be sought from the relevant institution(s).***
2. This research study/project is to be conducted by the local principal investigator listed on this certificate of approval.
3. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to the research study/project, and for ensuring that the authorized research is carried out according to governing law.
4. **This approval is valid until the expiry date noted on this certificate of approval.** **A Bannatyne Campus Annual Study Status Report** must be submitted to the HREB within 15-30 days of this expiry date.
5. Any changes of the protocol (including recruitment procedures, etc.), informed consent form(s) or documents must be reported to the HREB for consideration in advance of implementation of such changes on the **Bannatyne Campus Research Amendment Form.**
6. Adverse events and unanticipated problems must be reported to the HREB as per Bannatyne Campus Research Boards Standard Operating procedures.
7. The UM HREB must be notified regarding discontinuation or study/project closure on the **Bannatyne Campus Final Study Status Report**.

Please quote the above Human Ethics Number on all correspondence.

Inquiries should be directed to the REB Secretary Telephone: (204) 789-3255/ Fax: (204) 789-3414

Ethics Project Renewal

Research Improvements Through
Harmonization in Manitoba
400-500 Portage Avenue
Winnipeg, MB R3C 3X1

CHIPER PROJECT RENEWAL

Harmony Project ID: 3756
Project Title: Preliminary Clinical Findings Using the Invisalign Palatal Expander System
Sponsor Protocol ID/Number: N/A
Principal Investigator: Nicole Bailey
Advisor: N/A

Submission date: 03/Mar/2026 12:19

Submission Type: Project Renewal

Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER)
Board: HREB
Review Type: Delegated
Approval Date: 03/Mar/2026
Renewal Date: 07/Mar/2027

The application was approved.

Signed:

Ms. Shelly Rempel-Rossum 03/Mar/2026 20:53

CHIPER HREB Vice-Chair

CHIPER has reviewed the above-named research project and has found it to be acceptable on ethical grounds for research involving human participants. CHIPER is constituted and operates in accordance with the current Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and the applicable laws and regulations of Manitoba.

Renewal approval implies that the most recent approved versions of the Protocol, Investigator Brochures, consent forms, advertisements, letters of initial contact or questionnaires, recruitment methods, etc. are approved.

In respect to clinical trials, CHIPER complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, and the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

OHRP IRB Registration: IRB00012696

CONDITIONS OF APPROVAL

-Any modification to the application, protocol or research materials must be submitted for approval prior to implementation.

-A Renewal or Project Completion Form must be submitted prior to the above expiry date. Research cannot be conducted without a current ethics approval. Submit 4-6 weeks ahead of the expiry date.

-If participants have a negative experience (either physical, psychological or emotional) you are required to submit the adverse event in accordance with RITHIM reporting guidelines.

-If there is a deviation from the approved project, you are required to submit a the deviation in accordance with RITHIM reporting guidelines.

-Any new information that may affect the welfare or consent of participants must be submitted in accordance with RITHIM reporting guidelines.

-Any suspension or cancellation imposed by a funding agency or regulatory body that is related to this research project must be submitted in accordance with RITHIM reporting guidelines.

-Any findings that may have ethical implications or may affect the decision of the CHIPER ethics board must be submitted in accordance with RITHIM reporting guidelines.

-When a project has been completed or terminated, a Project Completion Form must be submitted.

**This correspondence includes electronic signature(s) (validation and approval via an online system).*

JOURNAL ARTICLE

TITLE: Clinical Outcomes Using the Invisalign Palatal Expander (IPE) System

ABSTRACT

Objective: Assess the clinical outcomes of patients who have received expansion through the Invisalign Palatal Expander System.

Methods and Materials: This study assessed 30 patients who met the inclusion criteria and were treated with an IPE. Pre- and post-expansion digital models were acquired and measurements for maxillary permanent intermolar width, intercanine width, tipping of the maxillary molar, presence of diastema and diastema width were collected. Data for intercanine and molar widths were compared to an existing data set (Torbaty et al., 2024) to assess how the IPE compared to controls, Hyrax expansion and Invisalign First.

Results: Statistically significant ($p<.001$) increases occurred for all measurements after treatment with IPE. Intermolar and intercanine widths increased on average by 3.18mm (8.18%) and 1.46mm (4.76%) respectively. Diastema width increased an average 1.42mm, for 70% of patients. Compared to Torbaty et al., IPE performed better than Invisalign First for intermolar changes, but worse for intercanine changes. Hyrax expansion outperformed IPE for both intermolar and intercanine widths.

Conclusions:

- IPE increases intermolar and intercanine widths
- Skeletal expansion with IPE is possible based on diastema development in 70% of subjects
- IPE is less effective at increasing intercanine width than alternative expansion modalities

- IPE is less effective than traditional rapid palatal expanders (e.g. Hyrax) at increasing interdental widths

INTRODUCTION

Orthodontic patients regularly present with maxillary transverse deficiency (MTD), with an average estimated 25% exhibiting a narrow maxilla[1,2]. If untreated during the childhood or adolescence, a narrow maxilla is unlikely to self-correct and can adversely affect the permanent dentition treatment options[3].

A narrow maxilla is normally corrected by expanding the intermaxillary suture, which can be done rapidly, slowly or with surgical intervention. A bonded rapid palatal expander (RPE) appliance is considered the Gold Standard for true non-surgical skeletal correction in adolescents[4], the objective being to separate the intermaxillary suture, not just widen the dental arch by tipping or moving teeth within the alveolus[4]. When assessing if skeletal distraction has occurred, clinicians often rely on the presence or increase of a maxillary central diastema as an easy and reliable indicator of success[5,6]. On the contrary, unsuccessful attempts at skeletal expansion often appears clinically with a buccally tipped maxillary posterior dentition.

Since its inception in the 1990's, Invisalign has become the largest manufacturer of clear aligners worldwide. Invisalign extended into the treatment of younger patients with early mixed dentitions with the announcement of Invisalign First clear aligners in 2018. The main solution for maxillary transverse deficiency with Invisalign First was dental expansion, and the product never claimed to be able to skeletally expand an arch [7].

In 2023, the Invisalign Palatal Expander (IPE) system was introduced as a series of custom printed, fully removable maxillary expanders. The expanders are designed to be changed daily with 0.25mm of expansion programmed with every subsequent appliance[8]. Align claims that their new palatal expanders decrease chair time, provides less patient discomfort and anxiety, and simplifies oral hygiene, all while creating skeletal expansion of the maxilla[9]. Currently there are no known, published independent research studies which investigate the claims made by Align, or to assess the clinical effectiveness of the IPE.

MATERIALS AND METHODS

Ethics approval was provided by the local Health Research Ethics Board, and patient records were obtained from a large orthodontic speciality practice from a single experienced Orthodontist implementing consistent protocols.

Sample size calculations were made based on a power of 0.8 and an alpha of 0.05 using different effect sizes. At a 1.0 effect size, the required sample was n=33 between two groups and n=30 was achieved

Pre- and post-treatment digital scans (.stl) were randomly selected for 30 patients meeting criteria of: non-extraction, fully erupted maxillary first molars, presence of canine teeth (primary or permanent), age 6–14 at treatment start, and good compliance per patient records. Exclusion criteria included additional IPE mechanics, auxiliaries beyond Invisalign attachments, prior orthodontic treatment, midcourse correction, supernumerary teeth, syndromes, and dental anomalies. The final sample included 13 males and 17 females (mean age 8.95 years, range 6–12).

Pre- and post-treatment digital models were created from an iTero digital scanner and uploaded to OrthoCad software. Arch and diastema width were measured by one evaluator using the software's arch measurement function.

Landmarks used were:

Intercanine Width (Figure 1): Canine cusp tip to canine cusp tip on the contralateral side (mm)

Intermolar Width (Figure 2): Mesiolingual cusp tip of maxillary first molar to mesiolingual cusp tip of maxillary first molar on the contralateral side (mm)

Diastema Width (Figure 3): Mesial point of maxillary central incisor to mesial point of maxillary central incisor on the contralateral side (mm)

A non-descriptive binary (present or absent) for each case was recorded for presence of a diastema.

This study followed the ABO Objective Grading System (ABO-OGS) guidelines for determining molar inclination, which compares the linear distance of a molar cusp to a pre-determined occlusal plane. The occlusal plane was created along the mesiolingual cusps of maxillary first molars (Figure 4), and the distance from the mesiobuccal cusp of the first molar to the plane was measured (Figure 5). An increase in this number post-treatment would show there was buccal crown tipping of the maxillary molar, while a decrease would show lingual crown tip.

For intra-rater reliability, 20% of cases were randomly remeasured 4 weeks after initial data collection to avoid memory bias. The same 20% of cases were re-measured by a blinded second evaluator to assess inter-rater reliability.

Intercanine and intermolar data was compared to data published by Torbaty et al. (2024) [10]. Their study compared non-expanded controls to those treated with a Hyrax expander and the Invisalign First system. Each group included 40 patients, with transverse dimensions assessed via similar virtual software.

Data normality was assessed using the Shapiro-Wilk test. Descriptive statistics for pre- and post-treatment groups included mean, standard deviation, and range for all five measurements. Diastema presence was reported as a percentage. Intra- and inter-rater reliability were evaluated using intraclass correlation coefficients (ICC). Binary diastema showed perfect agreement and was excluded from ICC testing. Pre–post changes were analyzed with paired t-tests, except for diastema width, which was non-parametric and assessed using the Wilcoxon signed-rank test.

Comparison with Torbaty et al. was performed using one-way ANOVA, followed by Tukey HSD for post hoc analysis of significant results.

Results

Average post-treatment width increases for intercanine (1.46mm, 4.76%), intermolar (3.18mm, 8.18%), and diastema (0.72mm, 102.86%) along with molar tip values (RHS: 0.23mm, 19.17% and LHS: 0.21mm, 16.67%) were statistically significant ($p<.001$, Table 1). The mean, standard deviation, and range of each linear measurement is shown in Table 2. The presence or absence of a diastema in each case is described as a percentage of the total sample size (Table 3).

ICC showed excellent intra-rater reliability for most measurements, with good reliability for post-treatment intercanine and intermolar values [11] (Table 4). Inter-rater reliability was excellent except for pre-treatment diastema, which was good [11] (Table 5). Binary diastema showed perfect agreement and was excluded.

Assesment of the study by Torbaty et al (2024), showed changes in both intermolar and intercanine widths between all their groups (Control, Hyrax, Invisalign First and IPE) which were highly statistically significant ($p<.001$, Table 6).

To further explore these differences, post hoc comparisons were completed. Intercanine post hoc tests, found that the IPE (1.46mm) showed greater change in intercanine width than the control (0.27mm), but less change than the Hyrax (3.7mm) and Invisalign First (3.69mm). These changes were statistically significant ($p = 0.01$, $p < .001$ and $p < .001$ respectively)(Table 7).

Intermolar post hoc tests, found that the IPE (3.18mm) showed greater change in intermolar width than the control (0.53mm), but less change than the Hyrax (4.4mm). Both changes were statistically significant ($p < 0.001$). The IPE (3.18mm) showed greater intermolar changes than

Invisalign First (2.47mm), however these changes were not statistically significant ($p = 0.52$)(Table 8).

Figure 6 illustrates the intercanine and intermolar post hoc testing for the IPE compared to the cited Control, Hyrax and Invisalign First groups.

Discussion

The Invisalign Palatal Expander (IPE) System offers alternatives to conventional skeletal expansion, potentially offering ease of use and improved oral hygiene.

A benchmark for successful maxillary expansion is an increase in inter-dental widths. On average, both intermolar and intercanine widths increased after treatment with the IPE, confirming it as an effective method to expand the dental arch. The IPE produced significant levels of expansion for both inter-arch landmarks, however the percentage change of intermolar width was almost double that of the intercanine width (8.18% and 4.76%, respectively). Similar findings were found when comparing our research to Torbaty et al, highlighting the underperformance of the IPE at increasing intercanine widths. The current IPE design provides complete coronal coverage of the maxillary permanent molars and either the second primary molar or premolar, and partial coverage on the first primary molar or premolar [12]. This setup produces no anchorage on the canines, possibly explaining the decreased expansion.

To assess whether the expansion occurring is skeletal or dental is challenging, with true confirmation requiring radiographic assessment. A simple clinical observation that clinicans often look for during skeletal expansion is the occurrence of a midline diastema. The presence of the diastema is an indicator that the midpalatal suture has split, but the size of diastema should not be used to quantify the amount of sutural expansion[5]. Salmoria and colleagues (2022) used both CBCT imaging, and diastema width to evaluate sutural opening after MARPE expansion and found that all subjects who developed a midline diastema, also had CBCT sutural opening. They concluded that a maxillary central incisor diastema was positively associated with anterior and posterior sutural opening for all subjects studied ($p<0.05$), strengthening the correlation between increased diastema width and radiographic sutural expansion[13]. The results of our study showed that only 70% of patients treated with the IPE developed an increase in diastema width. The average 1.42mm increase in central diastema is both statistically significant and clinically relevant, indicating a high likelihood that the IPE is successful at opening the midpalatal suture, and that true skeletal expansion is possible.

An undesirable outcome that occurs with maxillary expansion is buccal crown torque of the posterior teeth. This side effect is more common in adolescent and adult patients where the midpalatal suture is more fused. The present study assessed dental torque produced by IPE expansion. On average, the buccal cusps of patients treated with the IPE moved apically 0.22mm. In clinical biomechanics, the amount of vertical displacement of a cusp tip resulting from torque is a function of the distance from the centre of rotation to the cusp tip. With an average distance of 7mm from the cusp tip to the centre of resistance of a maxillary first molar, a 0.22mm vertical change would equate to an estimated 6 degrees of torque change from treatment with the IPE[14,15].

Despite the 0.22mm change in cusp height being statistically significant, the amount of change in torque likely lacks clinical relevance, as a 6-degree torque can easily be corrected with subsequent fixed or clear aligner treatment. Control of torque likely comes from the full plastic coverage of maxillary molars on the IPE, a feature that conventional rapid palatal expanders often lack and are absent with appliances such as a Quad-Helix, which in younger patients may also induce mid palatal sutural distraction[16].

The study by Torbaty and colleagues (2024)[10] provided data to compare the IPE to non-treated controls, Hyrax skeletal expansion and Invisalign First dental expansion. When comparing the IPE to controls, IPE widened intercanine and intermolar widths significantly more than what occurs naturally during pubertal growth. While these findings are expected, they re-emphasize that maxillary transverse deficiencies do not self-resolve and highlights the need for orthodontic intervention in children and adolescents.

In contrast, the Hyrax expander outperformed the IPE statistically significantly in both intermolar (4.40 mm and 3.18mm respectively) and intercanine width changes (3.70mm and 1.46mm respectively). This is likely a consequence of the removable nature of the IPE, with fixed appliances typically showing better compliance, higher forces and efficacy for maxillary expansion[17].

Comparing the outcomes of Invisalign First and IPE shows more variation. Surprisingly, Invisalign First statistically significantly exceeded the IPE for intercanine widths (3.69mm and 1.46mm respectively). As previously mentioned, this could be accounted for by the lack of attachments and anchorage on the canines with the IPE. IPE resulted in larger intermolar widths than Invisalign First (3.18mm and 2.47mm respectively), but the comparison was not statistically significant, with less than 1mm difference in mean post-treatment widths.

Ultimately the decision to use Invisalign First versus the IPE should be determined by treatment goals, not comparing efficacy. While both IPE and Invisalign First increase interdental widths, they do so with different methods – with and without a skeletal component. Deciding between these two modalities should be based on individual patient needs, palatal width and depth, pre-treatment torque of the posterior dentition, and deciding if their transverse deficiency is more dental or skeletal in origin.

For clinicians to move away from conventional expansion modalities, IPE must first demonstrate strong and significant efficacy relative to current options. While IPE achieves expansion, it is up to each clinician to determine whether its' results justify replacing existing tools in their practice in the various clinical scenarios and patient compliance and age are important considerations.

CONCLUSIONS

- IPE increases intermolar and intercanine widths
- Skeletal expansion with IPE is possible based on diastema development in 70% of subjects
- IPE is less effective at increasing intercanine width than alternative expansion modalities
- IPE is less effective than traditional rapid palatal expanders (e.g. Hyrax) at increasing interdental widths

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FIGURE LEGENDS

Figure 1: Intercanine width measurement landmarks

Figure 2: Intermolar width measurement landmarks

Figure 3: Diastema width measurements from the occlusal (A) and anterior (B) views

Figure 4: Occlusal plane created from the mesiolingual cusp tips of maxillary first molars

Figure 5: Molar inclination was quantified measuring the distance of the mesiobuccal cusp tip to the occlusal plane created in Figure 4

Figure 6: Intercanine and intermolar post hoc testing for the IPE compared to modalities used by Torbaty et al, 2024

Figure 1

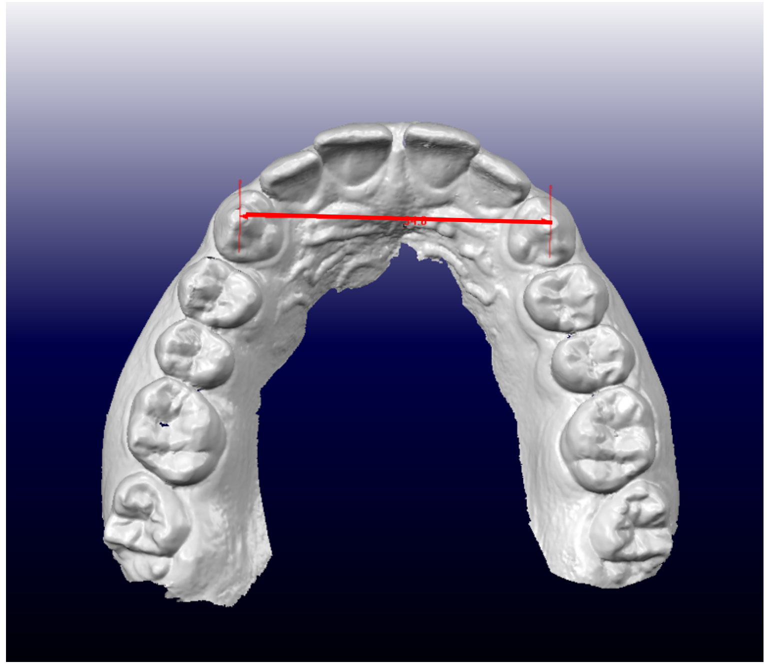


Figure 2

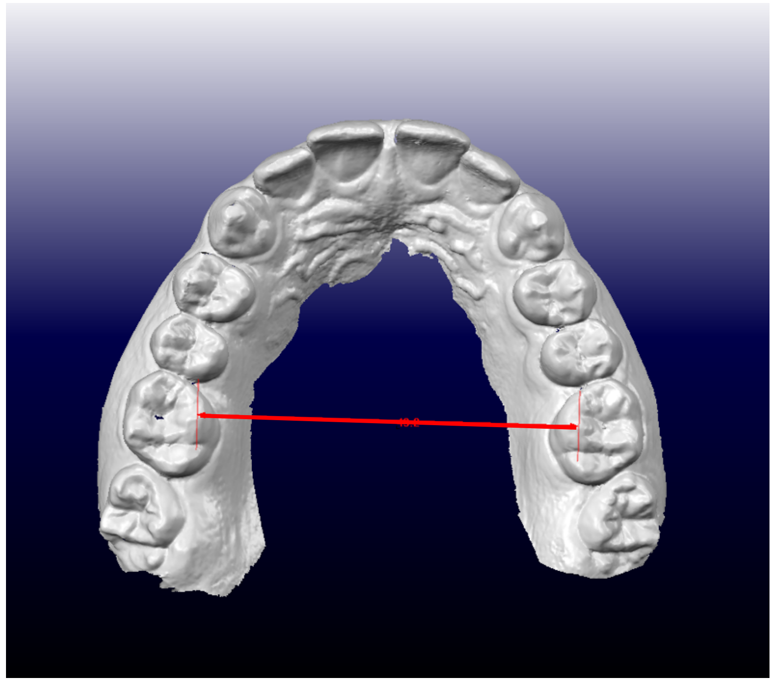


Figure 3

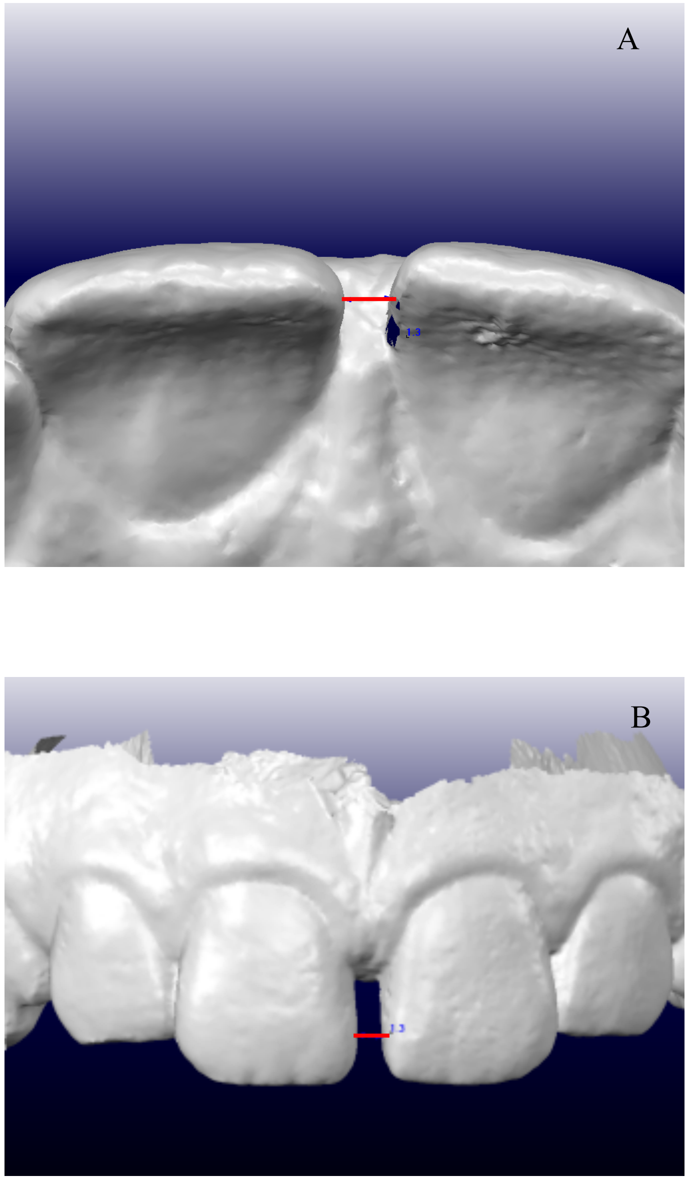


Figure 4

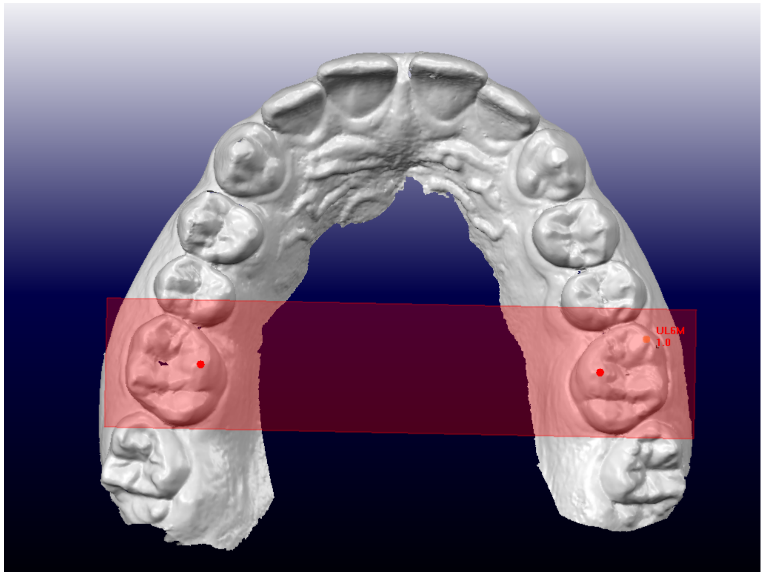


Figure 5

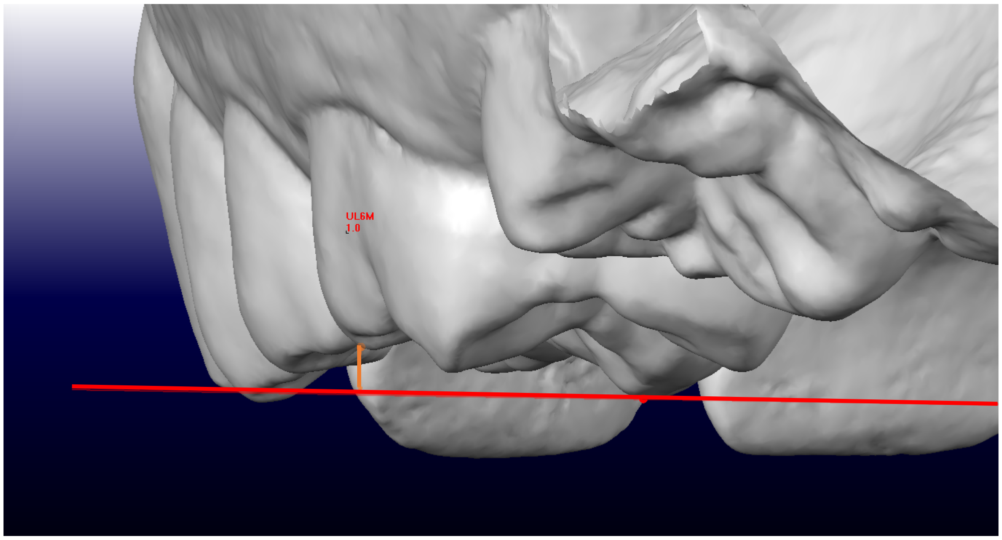
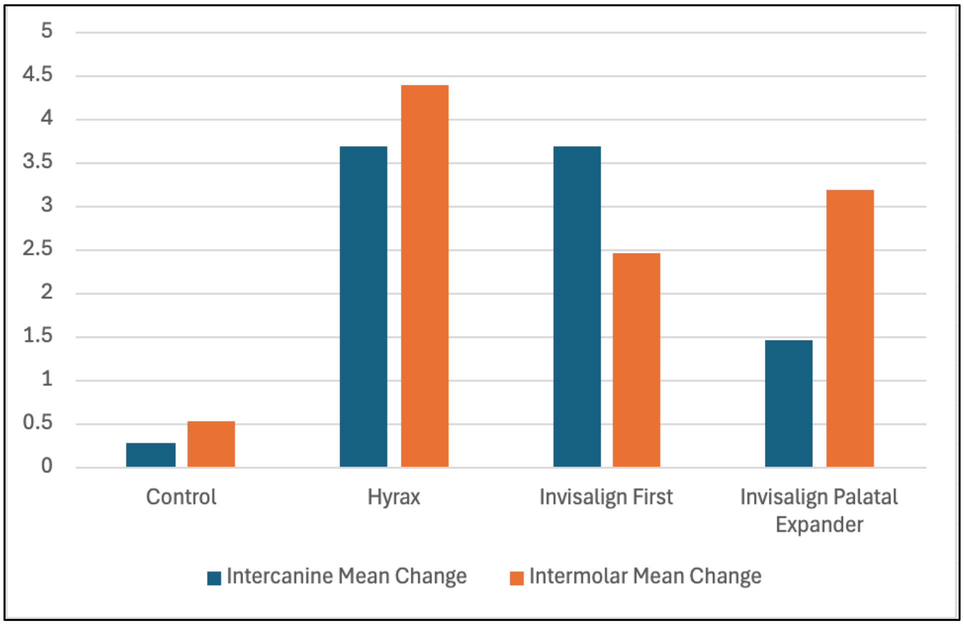


Figure 6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0
Control
Hyrax
Invisalign First
Invisalign Palatal Expander
Intercanine Mean Change
Intermolar Mean Change

Table 1: Changes in linear measurements from pre- to post-treatment

Change from Pre to Post				
	Mean Pre-Treatment	**Mean Post-Treatment**	**Change (%)**	**Sig (p)**
Intermolar (mm)	38.857	42.040	3.18 (8.18%)	<.001
Intercanine (mm)	30.653	32.110	1.46 (4.76%)	<.001
RHS Molar Tip (mm)	1.203	1.427	0.23 (19.17%)	<.001
LHS Molar Tip (mm)	1.260	1.473	0.21 (16.67%)	<.001
Diastema (mm)	.697	1.420	0.72 (102.86%)	<.001

Table 2: Mean, standard deviation, minimum and maximum values for pre- and post-treatment measurements

Pre-Post Descriptives

Pre-Treatment	**Mean**	**SD**	**Min**	**Max**
Intermolar (mm)	38.857	2.825	31.900	47.400
Intercanine (mm)	30.653	3.069	22.400	56.300
RHS Molar Tip (mm)	1.203	.538	.200	2.400
LHS Molar Tip (mm)	1.260	.627	.100	2.400
Diastema (mm)	.697	.887	0	2.800

Post-Treatment	**Mean**	**SD**	**Min**	**Max**
Intermolar (mm)	42.040	2.454	37.300	49.400
Intercanine (mm)	32.110	2.929	25.200	37.700
RHS Molar Tip (mm)	1.427	0.584	.200	2.400
LHS Molar Tip (mm)	1.473	0.656	.200	2.500
Diastema (mm)	1.420	0.978	0	3.000

Table 3: Presence of a diastema for pre-treatment and post-treatment

Diastema Change from Pre to Post				
	Pre-Treatment		**Post-Treatment**	
	Yes	**%**	**Yes**	**%**
Diastema	n=14	46.7%	n=22	73.3%

Table 4: Intra-rater reliability checks

INTRA-RATER CHECKS

Pre-Treatment	**ICC**	**95% CI**
Intermolar (mm)	.996	.906, .998
Intercanine (mm)	.993	.952, .999
RHS Molar Tip (mm)	.970	.821, .996
LHS Molar Tip (mm)	.968	.775, .996
Diastema (mm)	.950	.645, .993

Post-Treatment	**ICC**	**95% CI**
Intermolar (mm)	.832	.029, .976
Intercanine (mm)	.782	-.300, .969
RHS Molar Tip (mm)	.961	.750, .994
LHS Molar Tip (mm)	.977	.834, .997
Diastema (mm)	.908	.395, .987

Table 5: Inter-rater reliability checks

INTER-RATER CHECKS

Pre-Treatment	**ICC**	**95% CI**
Intermolar (mm)	.997	.997, 1.0
Intercanine (mm)	.987	.915, .998
RHS Molar Tip (mm)	.998	.987, 1.0
LHS Molar Tip (mm)	.986	.914, .998
Diastema (mm)	.880	.168, .983

Post-Treatment	**ICC**	**95% CI**
Intermolar (mm)	.995	.962, .999
Intercanine (mm)	.997	.980, 1.0
RHS Molar Tip (mm)	.989	.925, .999
LHS Molar Tip (mm)	.998	.985, 1.0
Diastema (mm)	.990	.930, .999

Table 6: Comparison of pre- and post-treatment interarch widths between modalities tested in this study and Torbaty et al, 2024

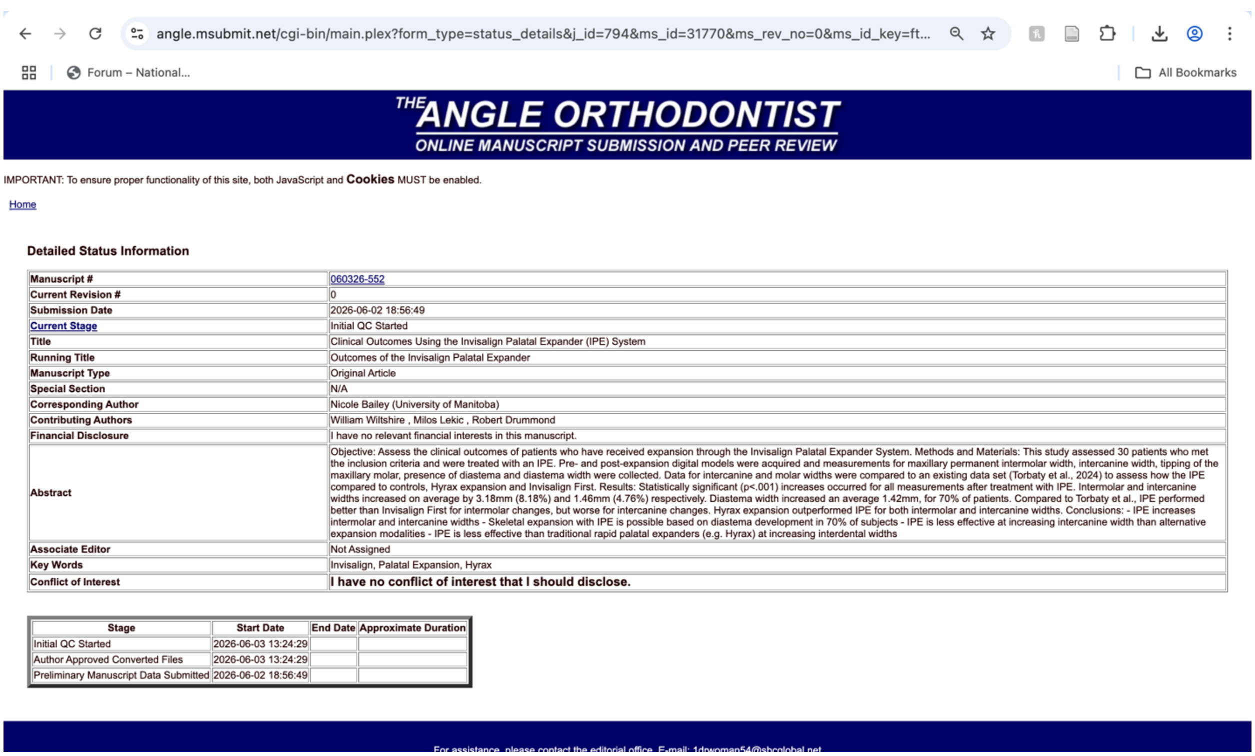
T1 to T2 Change Comparison to Torbaty et al, 2024									
	Torbaty et al.						Bailey et al.		
	Control (n=41)		**Hyrax (n=40)**		**Invisalign First (n=40)**		**IPE (n=30)**		
	Change	**SD**	**Change**	**SD**	**Change**	**SD**	**Change**	**SD**	**Stat (p)**
Intermolar (mm)	0.53	0.68	4.40	1.38	2.47	1.17	3.18	1.72	63.81 (<.001)
Intercanine (mm)	0.27	1.21	3.70	1.89	3.69	1.24	1.46	0.85	70.51 (<.001)

Table 7: Intercanine post hoc comparisons of IPE to treatment modalities used by Torbaty et al, 2024

Intercanine Post Hoc Comparisons	
Comparison	**Sig (p)**
IPE vs Control	0.01
IPE vs Hyrax	<.001
IPE vs Invisalign First	<.001

Table 8: Intermolar post hoc comparisons of IPE to treatment modalities used by Torbaty et al, 2024

Intermolar Post Hoc Comparisons	
Comparison	**Sig (p)**
IPE vs Control	<.001
IPE vs Hyrax	<.001
IPE vs Invisalign First	0.52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Detailed Status Information

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Title	Clinical Outcomes Using the Invisalign Palatal Expander (IPE) System
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Corresponding Author	Nicole Bailey (University of Manitoba)
Contributing Authors	William Wiltshire , Milos Lekic , Robert Drummond
Financial Disclosure	I have no relevant financial interests in this manuscript.
Abstract	Objective: Assess the clinical outcomes of patients who have received expansion through the Invisalign Palatal Expander System. Methods and Materials: This study assessed 30 patients who met the inclusion criteria and were treated with an IPE. Pre- and post-expansion digital models were acquired and measurements for maxillary permanent intermolar width, intercanine width, tipping of the maxillary molar, presence of diastema and diastema width were collected. Data for intercanine and molar widths were compared to an existing data set (Torbaty et al., 2024) to assess how the IPE compared to controls, Hyrax expansion and Invisalign First. Results: Statistically significant (p<.001) increases occurred for all measurements after treatment with IPE. Intermolar and intercanine widths increased on average by 3.18mm (8.18%) and 1.46mm (4.76%) respectively. Diastema width increased an average 1.42mm, for 70% of patients. Compared to Torbaty et al., IPE performed better than Invisalign First for intermolar changes, but worse for intercanine changes. Hyrax expansion outperformed IPE for both intermolar and intercanine widths. Conclusions: - IPE increases intermolar and intercanine widths - Skeletal expansion with IPE is possible based on diastema development in 70% of subjects - IPE is less effective at increasing intercanine width than alternative expansion modalities - IPE is less effective than traditional rapid palatal expanders (e.g. Hyrax) at increasing interdental widths
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