



# Clinical Protocol for Phase 1 Orthodontic Treatment of the Mixed Dentition with Invisalign First aligners

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Dr. Mark Garlington is a board-certified orthodontist in solo practice in Long Beach, CA. He has a Bachelor's Degree in biology from UCLA and received both his DDS and his orthodontic specialty training from the University of Southern California. Dr. Garlington is a member of the Angle Society and the AAO. He and his wife are involved with several community programs in Long Beach, including the YMCA, BLAST, LBCC Foundation, Rotary, and Rancho Los Amigos Hospital. Dr. Garlington was one of only twenty doctors in North America invited to participate in the Invisalign First limited market release and has started or finished over sixty Invisalign First cases in the past 12 months. Dr. Garlington is a Diamond Level Invisalign Provider.

## Summary

Efficient Phase 1 orthodontic treatment in our office means achieving our treatment goals in 6 to 9 months with no emergency visits, excellent oral hygiene maintained throughout treatment, and positive expectations generated in anticipation of Phase 2 treatment. Our practice consistently delivers efficient Phase 1 orthodontic treatment when we do the following: (1) use appliance systems that accomplish multiple tasks in parallel rather than in series, (2) streamline our appointment scheduling protocols into a consistent process, and (3) use digital dental technology to minimize chairtime. By using Invisalign First clear aligners and a digital workflow enabled through the iTero® intraoral scanner, our office is able to efficiently achieve excellent Phase 1 treatment results in mixed dentition patients with anterior spacing, anterior crowding, mesial drift from premature tooth loss, constricted dental arches, anterior dental crossbite, protruded incisors, and/or deep overbite.

## Background

We are strong advocates of Phase 1 orthodontic treatment, and around 30% of our case starts are Phase 1 treatments. The main goal of Phase 1 treatment in our office is to prevent serious problems from developing, in order to simplify the Phase 2 treatment later. For example, inadequate space for the permanent teeth can lead to ectopic eruption or impaction that requires surgical exposure. Patients with excessive incisor protraction may be prone to fractured teeth in the event of dental trauma. However, if the permanent teeth are able to erupt into a more normal position through Phase 1 arch development, we believe that the Phase 2 treatment time will be shorter than if the teeth are located in a more extreme position. Having the permanent teeth closer to a normal position also means that the gingival attachment supporting the teeth will be better, and the surrounding soft tissues will appear healthier and more balanced.

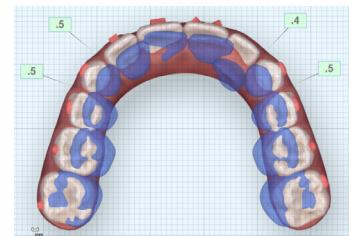
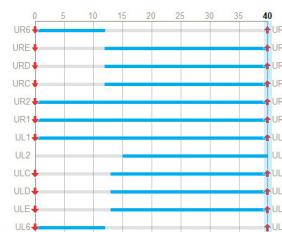
Early on, we used to promote serial extraction and enucleation of permanent premolars, but over the years, we have switched instead to expansion-based non-extraction treatments. Our typical Phase 1 treatment sequence used to consist of a fixed rapid maxillary expander and a lower Schwarz removable expander for arch development, followed by a 2x4 fixed appliance for dental alignment, and a lower lingual arch and upper bite plate as needed. For Class II patients, headgear and distalizing coil springs would also be added in order to reduce the severity of the Class II malocclusion for Phase 2. The main problem with this approach was that all the different appliances needed were often used sequentially, which increased the treatment time and made the patients and parents

much less enthusiastic about starting Phase 2 treatment afterwards.

Today, we still remove teeth for severe crowding cases, but our treatment efficiency has been significantly increased for mild to moderate Phase 1 treatments, by combining arch development and alignment into a single appliance system such as Invisalign First aligners. As a result, we no longer need to wait until after the arch development is completed to begin aligning the anterior teeth. We can accomplish both at the same time to avoid prolonging most Phase 1 treatments. This helps us reduce patient burnout, poor compliance, and negative feelings about Phase 2 treatment. We are also able to make the most out of the window of time when patients still respond well to their parents' guidance and to our treatment instructions. A single-phase orthodontic treatment once the patient becomes a teenager sometimes loses this advantage.

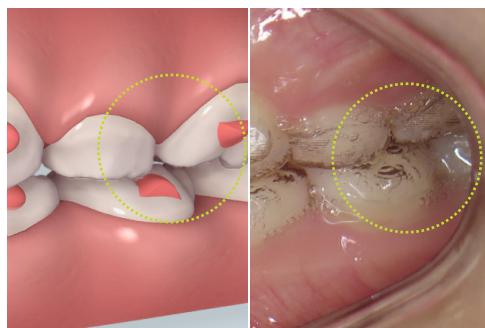
Several features of Invisalign First aligners for Phase 1 orthodontic treatment are unique to the product. First, the aligner staging pattern moves the molars first, followed by simultaneous expansion of the all the other teeth in the arch. Unlike traditional Phase 1 treatment where multiple appliances are used sequentially and the incisors are typically aligned later, Invisalign First aligners can align the incisors at the beginning of treatment, at the same time that the arches are widened. This distinction can lead to greater patient and parent satisfaction early on.

When applied to the posterior teeth, Invisalign's proprietary SmartStage™ technology produces the contacts and forces required for predictable dental arch expansion and good intercuspalation between the arches. This is accomplished by minimizing molar tipping and inclination during dental expansion. Compensatory buccal root torque is also automatically added whenever the arches are widened.



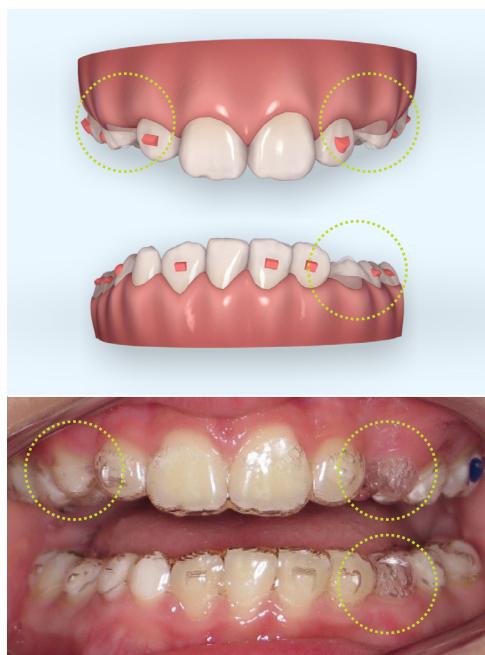
*Left: Staging pattern of the upper arch where the molars are moving first and expanding/rotating distally during aligners #1-12, followed by dental expansion of the C's, D's and E's during aligners #13-40. Incisor alignment starts at the very beginning of the aligner series. Buccal root torque compensation is also automatically added to the arch expansion. Right: The ClinCheck® set-up of the initial upper arch (in blue) superimposed over the treatment goal (in white).*

Second, optimized retention attachments help ensure adequate appliance retention on short clinical crowns in the mixed dentition. These attachments are automatically sized based on the height and shape of the crown. Optimized attachments for expansion support are also automatically placed whenever dental arch expansion is programmed. Like the optimized retention attachments, these are also automatically sized based on the height and shape of the clinical crown. The optimized expansion support attachments work in tandem with the SmartStage™ technology to achieve predictable dental arch expansion.



Left: Optimized retention attachments on the upper and lower left E's in the ClinCheck set-up. Right: The clinical appearance of the optimized retention attachments when the aligners are worn.

Finally, eruption compensations for incisors, canines, and bicuspids can be built into the areas of the aligners where the primary teeth have already been lost, so that any erupting permanent teeth can freely grow without vertical interferences from the aligner plastic.



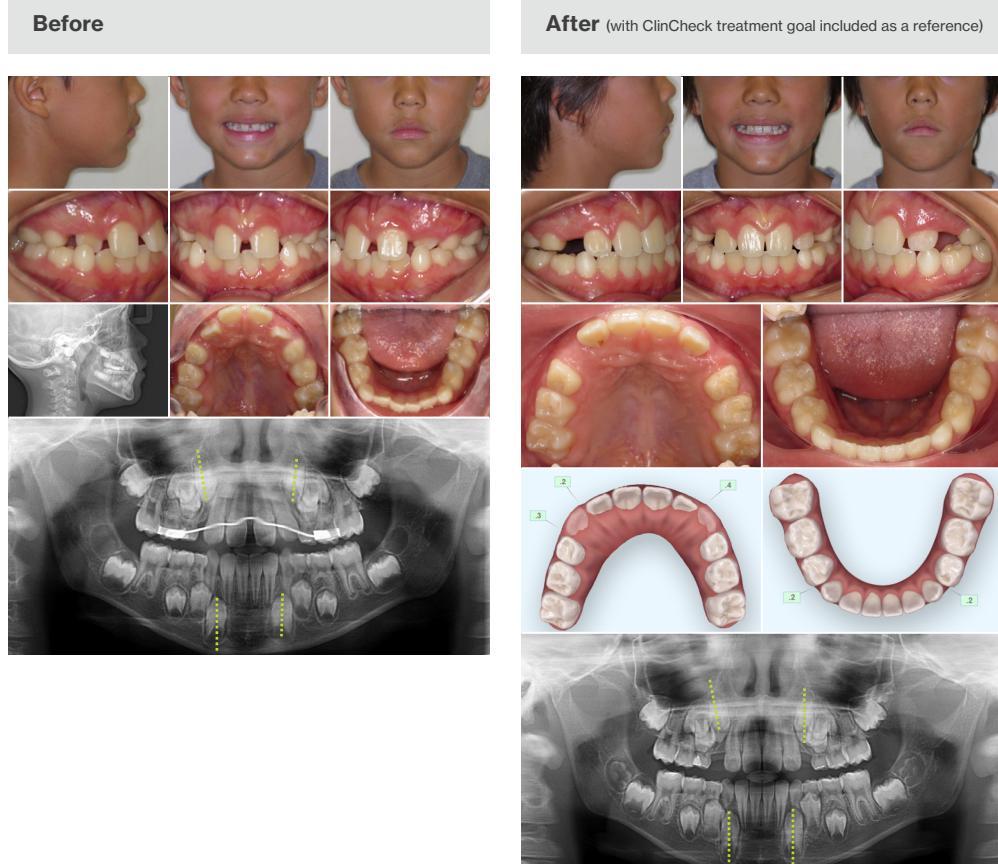
Upper image: Eruption compensation for the lower left and upper first premolars in the ClinCheck set-up. Lower image: The clinical appearance of the eruption compensation features. When this picture was taken, the upper right first premolar had already erupted into the eruption compensation space. The blue dot on the upper left molar is an optional wear-compliance indicator feature.

## Case Examples

### Patient #1

- 8 year, 1 month old male
- Chief Concern: Large gap between the upper front teeth.
- Diagnosis: Class I molar relationship, generalized upper spaces with inadequate space for the upper permanent canines, mild lower anterior crowding, and crossbite of the upper lateral incisors. A Nance appliance had been placed by the patient's pediatric dentist to prevent further mesial drift of the upper posterior teeth.
- Cephalometric analysis (refer to chart on the right)
- Treatment Plan: Consolidate spaces for the permanent canines, correct the anterior crossbite, and align the lower incisors.

Measurement	Patient	Norm (SD)
Skeletal pattern		Mesoecephalic
SNA	76.6	82 (3)
SNB	72.1	79 (3)
ANB	4.5	3 (2)
U1 - SN	95.4	103 (6)
IMPA	97.1	90 (5)
Interincisal angle	133.5	135 (11)



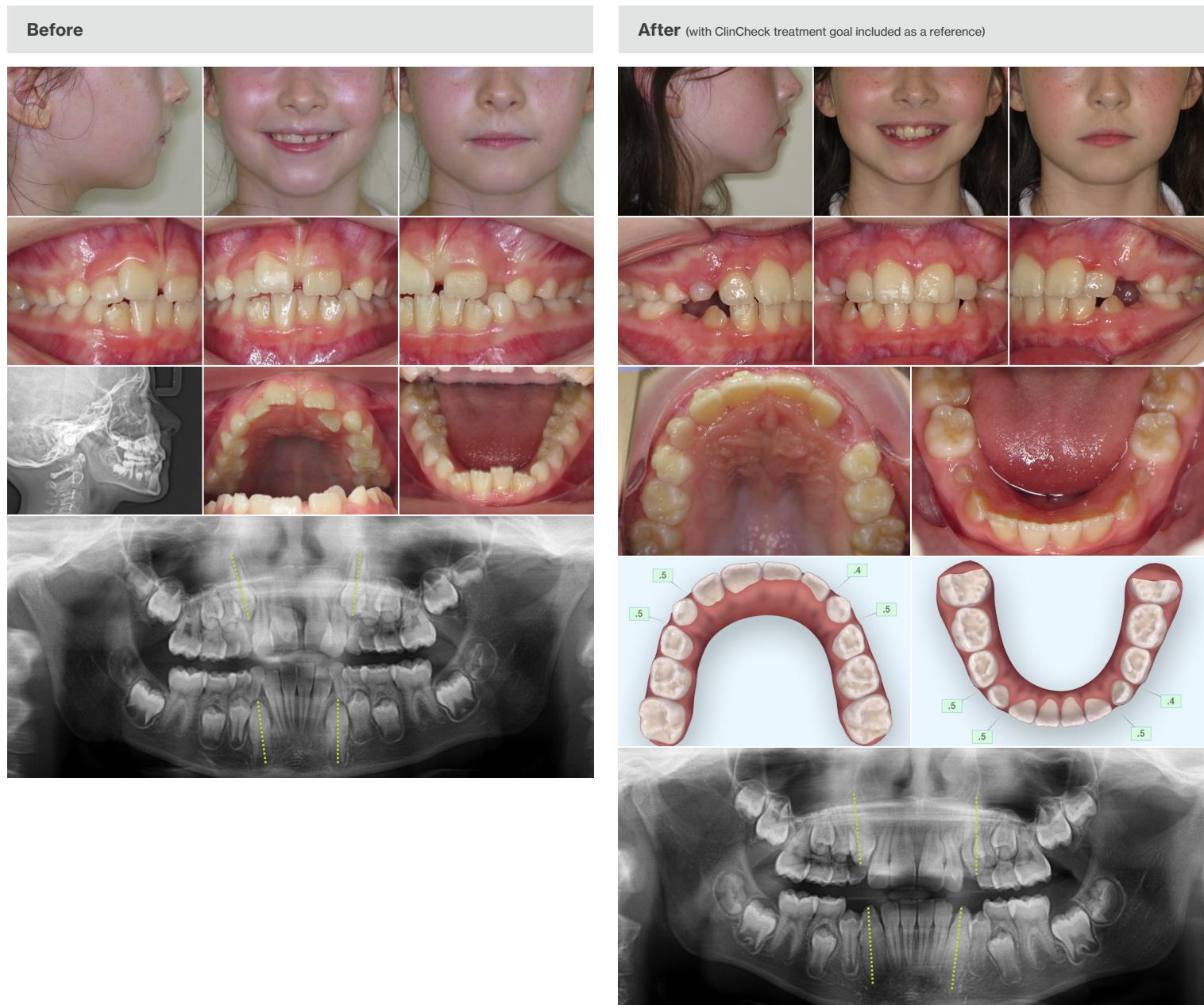
### Treatment Summary

26 + 15 + 16 upper aligners, 26 + 15 + 11 lower aligners; 10 months of treatment. Optimized retention attachments were used to enhance the aligner fit, and canine eruption compensations. Upper spaces were consolidated for the permanent canines. The crossbite of the upper lateral incisors was corrected with aligners only and did not require any bite ramps to temporarily open the bite. Retention: Clear invisible retainers for 12 hours a day until the canines erupt.

**Patient #2**

- 8 year, 10 month old female
- Chief Concern: Space between the two top front teeth and crooked bottom teeth.
- Diagnosis: Class II molar relationship (end-on) with constricted arches and mesially-rotated permanent upper first molars, a shallow overbite, crossbite of the upper left lateral incisor, midline diastema, low frenum attachment, and mild anterior crowding.
- Cephalometric analysis (refer to chart on the right)
- Treatment Plan: Expand both arches to make room for the permanent canines, correct the anterior crossbite, close the diastema, and refer the patient for a frenectomy, if needed.

Measurement	Patient	Norm (SD)
Skeletal pattern	Mesocephalic	
SNA	76.6	82 (3)
SNB	72.1	79 (3)
ANB	4.5	3 (2)
U1 - SN	95.4	103 (6)
IMPA	97.1	90 (5)
Interincisal angle	133.5	135 (11)

**Treatment Summary**

40+15 upper aligners, 19+15 lower aligners; 10 months of treatment. Optimized retention attachments were used to enhance the aligner fit. Eruption compensations were used in the additional aligners. The overbite was improved, the anterior teeth were aligned, and the crossbite corrected (without any bite ramps). The dental arches were widened to create space for normal eruption of the permanent canines. To help stabilize the diastema closure, a frenectomy was performed surgically during the time when the additional aligners were being manufactured. Retention: Clear invisible retainers for 12 hours a day until the lower canines erupt.

**Patient #3**

- 8 year old male
- Chief Concern: Lack of space for normal eruption of the permanent teeth.
- Diagnosis: Class II molar relationship (end-on) with constricted arches and rotated permanent first molars, moderate to severe deep bite (~80%), mild lower crowding, inadequate space for all the permanent canines except the lower right.
- Cephalometric analysis (refer to chart on the right)
- Treatment Plan: Widen the upper and lower arches to create space for the eruption of the permanent teeth (the lower left canine especially), distalize the upper molars to Class I, align and advance the incisors, and center the midline. Add Precision bite ramps to the lingual of the upper aligners to help open the bite (-3 mm upper incisor intrusion and ~1 mm lower incisor intrusion was programmed into the ClinCheck set-up).

Measurement	Patient	Norm (SD)
Skeletal pattern	Mesocephalic	
SNA	83.6	82 (3)
SNB	78.5	79 (3)
ANB	5.1	3 (2)
U1 - SN	98.4	103 (6)
IMPA	93.1	90 (5)
Interincisal angle	139.7	135 (11)

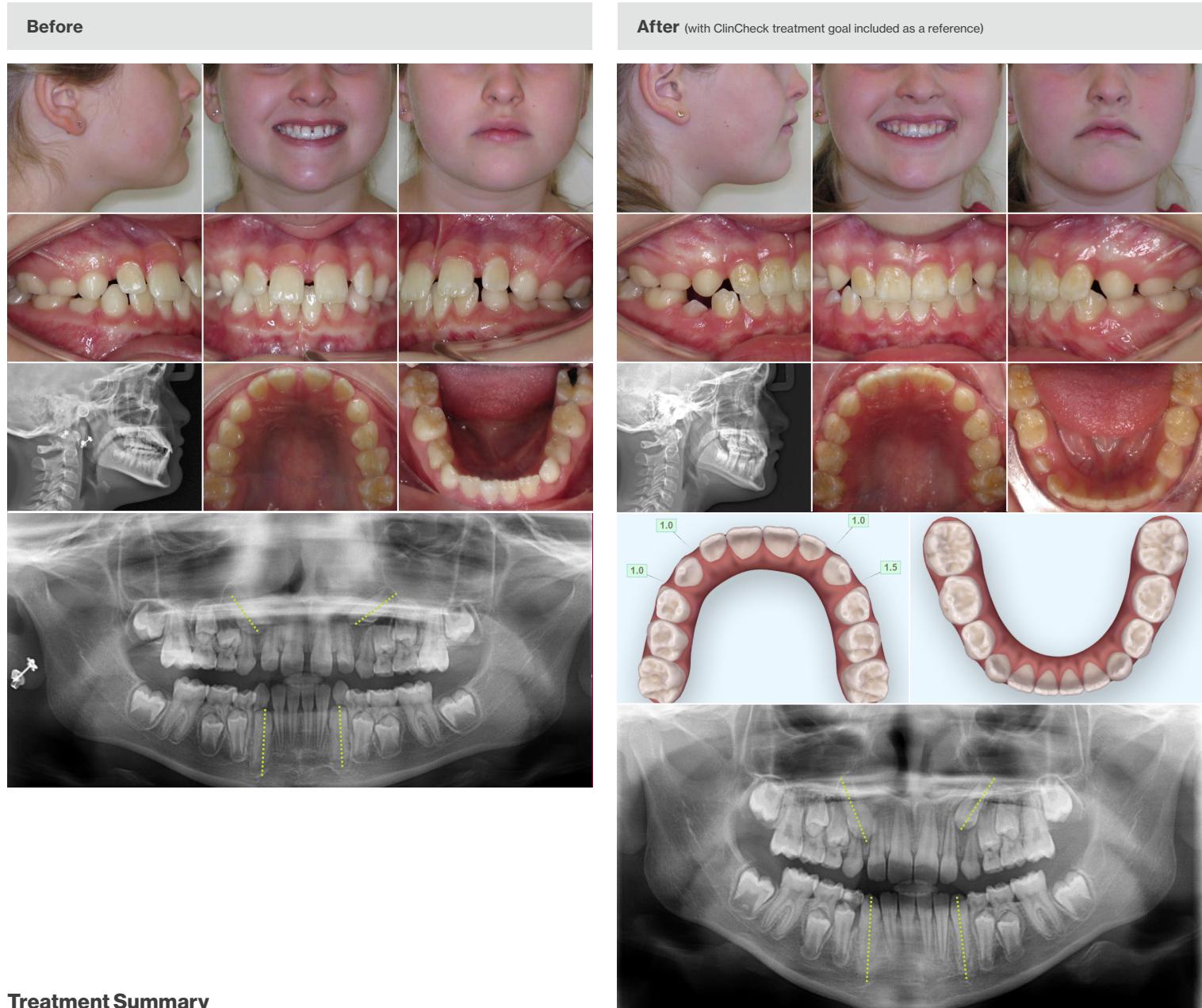
**Treatment Summary**

31 upper aligners, 31 lower aligners; 6 months of treatment. Optimized retention attachments were used to enhance the aligner fit, and canine and first premolar eruption compensations. A progress panoramic film shows that adequate space was created for the permanent canines to erupt. Overbite and incisor coupling are both excellent, and the molar relationship is now Class I. Retention: Clear invisible retainers for 12 hours a day until the permanent canines erupt.

**Patient #4**

- 9 year, 4 month old female
- Chief Concern: Spaces between the top teeth and suboptimal location of the permanent canines.
- Diagnosis: Class I molar (R); mild Class III molar (L), moderate deep bite (~50%), significantly flared upper incisors, moderate upper anterior spacing with high potential for impaction of the permanent upper canines, lower midline is shifted to the right.
- Cephalometric analysis (refer to chart on the right)
- Treatment Plan: Expand both arches, retract and upright the anterior teeth, distal-rotate the upper first molars, align the lower incisors, create space for the permanent canines, and center the midline.

Measurement	Patient	Norm (SD)
Skeletal pattern	Brachycephalic	
SNA	83.9	82 (3)
SNB	83.3	79 (3)
ANB	0.6	3 (2)
U1 - SN	113.1	103 (6)
IMPA	87.5	90 (5)
Interincisal angle	117.5	135 (11)

**Treatment Summary**

21 upper aligners, 29 lower aligners; 6 months of treatment. Precision bite ramps were used in the upper aligners to help open the bite to a normal overbite, and optimized retention attachments were used to enhance the aligner fit. The upper anterior spaces were consolidated and the severe proclination of the upper incisors was resolved. The final interincisal angle was 134.7 degrees, for a net change of +17.2°. A progress panoramic film shows a significant improvement to the position of the permanent upper canines, which are now erupting more normally. Retention: Clear invisible retainers for 12 hours a day until the permanent canines erupt.

## Discussion

We have been able to use Invisalign First aligners to treat a broad range of Phase 1 orthodontic problems. The clinical conditions we are now routinely treating with Invisalign First aligners include generalized anterior crowding and spacing (mild to moderate), arch length loss due to premature loss of primary teeth and mesial drift, constricted arches (up to edge-to-edge buccal overjet), anterior dental crossbites (1 or 2 teeth usually), midline diastemas, mild to moderate deep bite, and flared/protruded incisors. We can also treat patients with mild Class II or Class III molar relationships by rotating and distalizing the molars by ~1 mm. For mild sagittal corrections, interarch elastics are currently not being used, because the anterior segment appears to serve as an adequate anchor unit.

For arch development with Invisalign First aligners, we will set up 4 to 6 mm dental expansion per arch (the default clinical preference setting), and we do not add any extra width for overcorrection aligners, because the biological response seems to be better in mixed-dentition patients than in teens and adults. For more significant arch expansion (i.e., skeletal expansion), and for patients with airway issues, our Phase 1 treatment will begin with a fixed rapid maxillary expander followed by additional appliances as needed. For severe crowding patients, serial extraction is still our preferred treatment approach, and for moderate to severe Class II problems, we will still use headgear and fixed 2x4 appliances with open coil springs for molar distalization to begin the correction, and use a fixed functional appliance for mandibular advancement to finish the Class II correction in Phase 2. With the recent FDA clearance of Invisalign aligners with mandibular advancement, we may soon have an opportunity to give our moderate to severe Class II patients a better treatment experience as well.

The results we have achieved with Invisalign First aligners are excellent, and just as good as or better than what we typically achieve with fixed palatal expanders and/or removable Schwarz appliances followed by fixed appliances for Phase 1, but without any of the problems associated

with broken brackets, poking wires, and poor oral hygiene. Essentially gone are all the emergency appointments and appliance repair visits. Also, with aligner changes every 5 to 7 days for mixed-dentition patients, if a patient ever loses or breaks an aligner, they typically just advance to the next aligner in the series and wear it for a few days more to make up for the extra movement.

Particularly impressive to us has been the successful deep bite corrections and the successful uprighting of flared incisors with Invisalign First aligners. For deep bites, we believe that the combination of Precision bite ramps plus Optimized retention attachments results in an intrusion arch effect that gently moves the incisors apically while the posterior segments are widened. For patients with dental protrusion, we believe that the posterior teeth serve as an anchor unit against which the incisors can be retracted while the arch is being expanded to create adequate space.

Only a small percentage of our Invisalign First patients have had difficulties with aligner wear compliance (less than 10% of the 60 we have treated to date). For these patients, we switched them into fixed appliances at no additional charge, which is not difficult to do, and creates an opportunity to build goodwill. We would rather have the majority of our patients benefit from the advantages of clear aligners and manage the few exceptions with traditional fixed appliances, than deal with all of the inconveniences associated with fixed appliances in the majority of our Phase 1 treatments. Offering Invisalign First aligners for Phase 1 treatment has also been very positive for our practice reputation because the parents in our community are now aware that we only use fixed appliances if needed, and not as the default during the mixed dentition.

Another contributing factor to our efficiency with Invisalign First treatment has been our appointment scheduling protocol. Our goal is to finish the patient's Phase 1 aligner series in 5 delivery appointments, not counting the new patient exam, which includes initial records and an intraoral digital scan using the iTero Element. Our appointment scheduling protocol is the following:

Delivery Appointment #	# of Aligners Dispensed	Aligner Change Interval (days)	Doctor Time Scheduled (min.)	Appointment Time Scheduled (min.)
0	N/A (initial records and new patient exam)	N/A	15	60 min. for scan, records, and new patient exam
1	3	7 to 10	10	60
2	8	5 to 7	5	15
3	half of remaining	5 to 7	3	15
4	other half of remaining	5 to 7	3	15
5	retainer or refinement	5 to 7 (if additional aligners needed)	5	15

After the patient is scanned with the iTero Element intraoral scanner, the Invisalign First aligners are delivered to our office within 3 weeks, so we do not need to make any retainers to hold the teeth in place until then. The parents are very appreciative that their child's orthodontic records experience is completely digital and impression-free. They are impressed by the use of technology and how we have used technology to make their child's experience better. They also appreciate the time savings in not having to return for a separate records appointment.

Any composite attachments for Phase 1 aligner treatment are always bonded to the teeth on the same day that the first aligners are delivered. This is an important step to ensure adequate aligner fit from the onset, since the clinical crowns tend to be shorter in the mixed dentition. If the aligners are not seating well after the initial aligners are delivered, elastic aligner tray seaters (e.g., Chewies™) are used for a few days with each new aligner.

At the second aligner delivery appointment, 8 sets of aligners are delivered if the patient is doing well. These aligners are changed every 5-7 days. At the third aligner delivery appointment, half of the remaining aligners are delivered, and at the fourth delivery appointment, all the remaining aligners are delivered. If additional aligners are needed, the patient is re-scanned and instructed to wear the last best-fitting aligner while waiting for the new trays to be made. Using this protocol, completing Phase 1 treatment within our 6 to 9 month goal is quite reasonable. If additional aligners are needed, we usually do not have to place new or additional attachments and therefore can shorten the appointment time needed for delivery. At that appointment, we will usually give them all the remaining additional aligners to reduce the total number of appointments needed. In comparison, a traditional approach to Phase 1 treatment in our office often required 15 appointments (or more) and 12-15 months to complete.

Our retention protocol depends on whether the permanent canines are erupting soon. If the permanent canines are erupting soon or already erupting, a Hawley retainer is used for 12 hours a day (at home only, to minimize the risk of losing the appliances), and the acrylic is trimmed from time to time as the teeth erupt. If the canines will not erupt for a while, the last aligner or an Essix® retainer is used, also for 12 hours a day at home.

## Conclusion

The clinical protocols we have developed in our practice for Phase 1 treatment with Invisalign First aligners are designed give the patient and their parents a better treatment experience than Phase 1 treatment with traditional appliances. The results we have achieved with Invisalign First aligners have been excellent.

Invisalign First aligners can be used to treat a wide variety of orthodontic problems in the mixed dentition. Patients that can definitely benefit from Invisalign First aligner treatment include those with anterior crowding and spacing and/or blocked out permanent teeth due to constricted dentoalveolar arches and/or early loss of primary dentition. By creating more room for the permanent teeth to erupt, the second phase of orthodontic treatment can be significantly simplified. In mild Class II patients, expansion of the arches with slight distalization of the permanent first molars can reduce incisor protrusion and help prevent them from being damaged by traumatic impact.

Using Invisalign First aligners for Phase 1 treatment can also lead to increased efficiency in the delivery of orthodontic care and to an improved appointment scheduling protocol. This becomes a key element to streamlining the Phase 1 treatment experience for both the patient and the office.



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