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Clear Aligner Therapy in the Mixed Dentition: Indications and Practitioner Perspectives

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A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

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Abstract

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By: Nicholas M. Lynch, DDS

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Introduction: This study evaluated current trends and perspectives among orthodontists regarding clear aligner therapy in the mixed dentition (CAMD), including insights into perceived indications, compliance, oral hygiene, and other factors.

Methods: An original, 22-item survey was mailed to both a randomized, nationally representative sample of practicing orthodontic specialists (n = 800) and to a specific, randomized sub-sample of high-aligner-prescribing orthodontists (n = 200). Questions assessed respondents' demographic information, experience with clear aligner therapy, and perceived advantages/disadvantages of CAMD compared to fixed appliance therapy (FA). Responses were compared using McNemar's chi-squared and paired t-tests to assess CAMD versus FA.

Results: 1,000 orthodontists were surveyed, and 181 (18.1%) responded during a 12-week period. Respondents were primarily solo private practice orthodontists. None of the demographic factors showed significant associations with CAMD use. CAMD use was less common than mixed dentition FA, but the majority of respondents predicted an increase in their future CAMD use (57.9%). Among respondents utilizing CAMD, the percentage of mixed dentition cases treated with clear aligners was significantly less than the overall percentage of clear aligner cases (23.7% vs 43.8%, $P < 0.0001$). Significantly fewer respondents considered skeletal expansion, growth modification, sagittal correction, and habit cessation to be feasible indications for CAMD compared to FA ($P < 0.0001$). Perceived compliance was similar for CAMD and FA ($P = 0.5841$), but perceived oral hygiene was significantly better with CAMD ($P < 0.0001$).

Conclusions: CAMD is emerging as an increasingly appealing treatment modality for children. The majority of surveyed orthodontists reported limited indications for CAMD compared to fixed appliances, but they perceived noticeable benefits for oral hygiene with CAMD.

Introduction

Clear aligners have now been used for adult orthodontic treatment for decades, and their popularity drastically increased after Align Technology released its "Invisalign" clear aligner product in 1997.[1] Initially, clear aligners were regarded as an option for treating mild or moderate malocclusions, but their applications have expanded along with new generations of software algorithms and plastic materials.[2,3] Numerous studies have subsequently explored practitioners' uses of clear aligner therapy for different treatment goals, case types, and case difficulty levels in adults with permanent dentition.[4–9]

Align introduced clear aligner therapy in the mixed dentition in 2008 with the release of their "Invisalign Teen" product.[1] The hallmark of this product was the inclusion of "eruption compensation wells" in the aligners that allowed for the eruption of permanent teeth by using algorithms to predict the size and shape of teeth.[1,10,11] However, this was mostly limited to mild malocclusions in the late mixed dentition, and the software required that numerous adult teeth already be present in order for the trays to perform more predictably.[1,12,13]

In 2019, Align Technology released its "Invisalign First" product, which included numerous new features: improved eruption compensation wells for canines, premolars, and incisors; terminal molar tabs; scalable attachments; pre-programmed arch expansion staging patterns; and other ClinCheck software changes, such as automatically maintaining primary tooth

spacing.[1] These revisions to both the software and the physical design of the trays were all intended to make aligner therapy more feasible in the mixed dentition by appropriately managing tooth exfoliation and eruption. Indeed, many preliminary studies and case reports have indicated that providers are interested in exploring the potential applications for mixed dentition aligner treatment, such as for anterior crossbite correction, eruption guidance, and other common early interventions.[14–17]

Orthodontists need to carefully weigh the possible advantages and disadvantages of utilizing clear aligners in the mixed dentition compared to fixed appliances. For example, some studies have shown better periodontal outcomes in child patients with aligners versus fixed appliances due to improved oral hygiene.[18,19] Additionally, compared to fixed appliances, these young patients might also experience less pain with aligner therapy.[20] Another study found that patients experienced less difficulty eating and chewing with clear aligners than with fixed appliances.[21,22] In terms of quality of life, a recent study found that aligners might offer easier adaptation to the appliance, fewer missed school days, and increased self-perception of attractiveness during treatment.[21] Finally, from both patient management and practice management standpoints, some studies have shown that aligner treatment might involve fewer appointments, fewer emergency visits, less chair time, and even reduced treatment time.[6,7]

Nevertheless, there is still a lack of high-level evidence on the effectiveness of clear aligners in children with mixed dentition, specifically when used for an early interceptive phase of treatment prior to comprehensive orthodontics in the permanent dentition. Additionally, some orthodontists have traditionally avoided clear aligner therapy in children due to presumed poor compliance.[10,23,24] However, given the possible benefits of this treatment modality, further investigation is warranted. Therefore, this study sought to assess orthodontists' current

preferences and perceived indications for aligners in the mixed dentition using an original survey. In this way, we can elucidate current trends among orthodontists, giving insight into the indications and exploring concerns over compliance. With this information, orthodontists can better evaluate the advantages and disadvantages of aligner therapy in the mixed dentition and re-assess their attitudes toward this treatment modality. Most importantly, this could potentially prompt orthodontists to provide a new treatment option to young and growing patients with beneficial effects on their oral health and wellbeing.

At present, there are few published studies regarding the use of clear aligner therapy in the mixed dentition (CAMD). This study sought to assess differences in orthodontists' experiences with clear aligner therapy versus fixed appliance therapy (FA) in the mixed dentition. Thus, all of the following aims were addressed: to quantitatively determine the frequency with which orthodontists prescribe CAMD; to qualitatively assess treatment indications for prescribing CAMD; and to qualitatively determine orthodontists' subjective perceptions of both compliance and oral hygiene with CAMD. The null hypothesis was that there would be no difference in reported prescribing frequency, indications, perceived compliance, or perceived hygiene between CAMD and FA.

Materials & Methods

Materials:

Approval to conduct this study was granted by the Virginia Commonwealth University Institutional Review Board (No. HM 20021335).

An original 22-question survey was sent via VCU Mail Services to both a randomized, nationally representative sample of practicing orthodontic specialists (n = 800) and to a specific, randomized sub-sample of high-aligner-prescribing orthodontists (n = 200). Thus, a total of 1,000 surveys were mailed. After six weeks, a second round of surveys was sent by mail to those providers who did not respond to the initial mailing. All practitioners were identified using either the American Association of Orthodontists (AAO) online database or Align Technology's Invisalign provider website. The primary sample was made to be geographically proportionate using a ZIP code randomization strategy to select practitioners from different ZIP codes on a weighted population basis by state. The secondary sample was also geographically proportionate by ZIP code and state, but only included orthodontists with the "Diamond Plus" designation on the Invisalign provider website. These two samples were intentionally designed to ensure sufficient survey participation of orthodontists with experience using clear aligners in the mixed dentition. Exclusion criteria included retired orthodontists, orthodontic students/residents, and any other non-orthodontic dental practitioners, such as general dentists or other dental specialists.

The survey questions were designed to acquire information on respondent demographics, current indications for clear aligner therapy in the mixed dentition, and respondents' preferences toward clear aligner therapy in the mixed dentition. Demographic questions assessed employment situation, practice geographical setting, years in practice, and experience with clear aligner treatment. Respondents were asked to report their practice statistics regarding the amount of aligner treatment versus fixed appliance treatment, the amount of Phase I treatment they perform, and their perceived indications for clear aligner therapy in the mixed dentition. Respondents' attitudes toward clear aligner therapy in the mixed dentition were also assessed, including questions on perceived compliance, perceived oral hygiene, and future trends. The complete survey document is included in the Appendix.

Data Collection:

All survey responses were collected by VCU Mail Services and de-identified prior to receipt by the research team. All study data from paper survey responses were then catalogued electronically and managed using REDCap electronic data capture tools hosted at Virginia Commonwealth University.[25,26] No personal identifying information was included in the results.

Statistical Analysis:

Survey responses were summarized using descriptive statistics, including counts and percentages for categorical variables and means with standard deviations for continuous variables. Respondents were categorized based on their self-reported use of clear aligners in the mixed dentition (CAMD). Respondents who reported that 0% of their cases in the mixed dentition were treated with clear aligners were categorized as "No Use"; those who reported 1-

49% of their cases were treated with clear aligners were categorized as “Low Use”; and those with 50% or more were categorized as “High Use.”

Paired t-tests were used to test for differences in clear aligner use for mixed dentition cases as compared to the overall practice rate. Associations between CAMD use and provider demographics (including practice type, practice setting, AAO constituency, years in practice, and time using clear aligners) were compared using chi-squared and Fisher’s exact tests as appropriate. Selections for the clinical indications for treatment were compared for fixed appliances versus clear aligners with McNemar’s chi-squared test, and indications for clear aligners were compared based on CAMD use categories with chi-squared tests. Perceived compliance and oral hygiene ratings were compared between clear aligners and fixed appliances with paired t-tests and among the categories of CAMD use with ANOVA. Post hoc pairwise comparisons were adjusted using Tukey’s adjustment. Significance level was preset at $P = 0.05$. SAS EG v.8.2 (SAS Institute, Cary, NC) was used for all analyses.

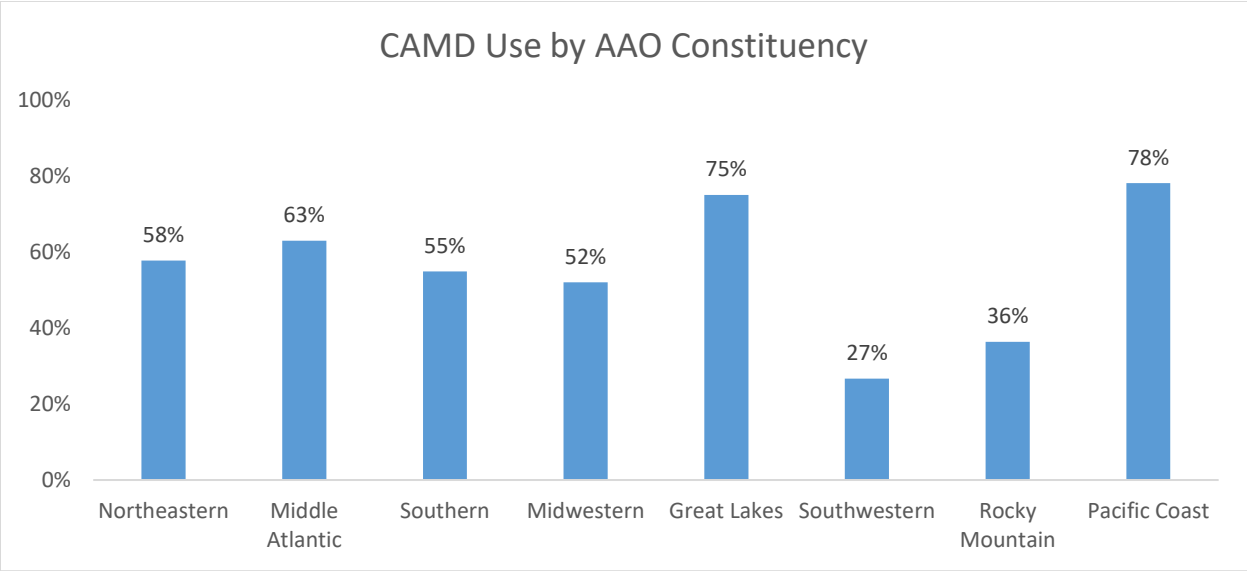
Results

A total of 181 surveys were returned, with 149 responses from the primary sample (82.3%) and 32 responses from the secondary sample (17.7%). Thus, the overall response rate was 18.1%, the primary sample response rate was 18.6%, and the secondary sample response rate was 16.0%. The majority of respondents were solo private orthodontic practitioners (n = 136, 76%). Most respondents practiced in a suburban or urban setting (74%). There was a roughly proportional distribution of respondents across the various AAO constituencies and a normal distribution in terms of years in practice. Only 8% of respondents reported using clear aligners for less than 5 years, whereas 92% had at least 5 years of experience and 43% had over 15 years of experience. A complete summary of respondent characteristics is provided in Table 1. When correlating these demographic factors to the level of CAMD use, AAO constituency was the only category demonstrating statistical significance (P = 0.0282), with increased CAMD usage in the Pacific Coast and Great Lakes constituencies (See Figure 1).

Table 1: Respondent and Practice Demographics

	n	%
Practice Type		
Solo private orthodontic practice	136	76%
Group private orthodontic practice	36	20%
Corporate orthodontic practice	3	2%
Academic institution	3	2%
Practice Setting		
Rural	3	2%
Small town	44	25%
Large town / Suburban	103	58%
Urban / Metropolitan	29	16%
AAO Constituency		
Northeastern	26	15%
Middle Atlantic	27	15%
Southern	31	17%
Midwestern	25	14%
Great Lakes	12	7%
Southwestern	15	8%
Rocky Mountain	11	6%
Pacific Coast	32	18%
Years in Practice		
< 5 years	9	5%
5 - 10 years	27	15%
11 - 20 years	42	23%
21 - 30 years	54	30%
31 - 40 years	35	20%
> 40 years	12	7%
Time Using Clear Aligners		
< 5 years	14	8%
5 - 10 years	45	25%
11 - 15 years	43	24%
> 15 years	77	43%

Figure 1: CAMD Use by AAO Constituency



On average, respondents reported that 31% (SD = 24.8) of their cases were treated with clear aligners and 69% (SD = 24.7) were treated with fixed appliances. They also reported that about 21% (SD = 12.8) of their total cases involved Phase 1 or early treatment in the mixed dentition. The average percentage of mixed dentition cases treated with clear aligners was reported to be 13.6% (SD = 24.5%), versus 85.4% (SD = 25.6%) that were treated with fixed appliances. Among the respondents who reported treating patients in the mixed dentition with clear aligners, the average percentage of CAMD was significantly less than their average overall use of clear aligners in their practice (23.7% vs 43.8%, $P < 0.0001$). A summary is provided in Table 2.

Table 2: Self-Reported Clear Aligner Utilization

	Mean	SD
What percentage of your overall practice consists of clear aligner cases?	31.3%	24.8
What percentage of your overall practice consists of fixed appliance cases?	68.8%	24.7
In a typical year, what percentage of your total cases involve some form of Phase I or early treatment in the mixed dentition?	21.2%	12.8
When treating children in the mixed dentition, what percentage of your cases consists of clear aligners?	13.6%	24.5
When treating children in the mixed dentition, what percentage of your cases consists of fixed appliances?	85.4%	25.6
On a scale of 1 to 10 (with 1 being highly unfavorable and 10 being highly favorable), what is your current attitude toward the use of clear aligner therapy for children with mixed dentition?	5.0	3.4
On a scale of 1 to 10 (with 1 being highly unlikely and 10 being highly likely), what is the likelihood that you will prescribe clear aligner therapy for children with mixed dentition in the future?	5.3	3.6
Percentage of Clear Aligners (among those who use clear aligners in the mixed dentition)	**Mean**	**SD**
Overall Percentage of Clear Aligners	43.8%	24.1
Percentage of Clear Aligners in the Mixed Dentition	23.7%	28.4
Paired Difference (*P* < 0.0001)	**20.2%**	**21.2**

Respondents were categorized into three groups based on their level of CAMD use: no use (0% of cases), low use (1-49% of cases), and high use (50% or more of cases). These categories were not significantly associated with any of the respondent or practice demographics. Among these three categories, there was also no difference in the average percentage of cases that included some form of early mixed dentition treatment ($P = 0.5091$). A summary is provided in Table 3.

Table 3: Association Between Use of Clear Aligners in the Mixed Dentition (CAMD) and Respondent and Practice Characteristics

	No Use (*n* = 75)	Low Use (*n* = 76)	High Use (*n* = 25)	*P*-value
Practice Type (*n*, %)				0.3043
Solo private orthodontic practice	60, 45%	54, 40%	20, 15%	
Group private orthodontic practice	12, 33%	21, 58%	3, 8%	
Corporate orthodontic practice	1, 33%	1, 33%	1, 33%	
Practice Setting (*n*, %)				0.1495
Rural/Small town	21, 46%	19, 41%	6, 13%	
Large town/Suburban	47, 46%	42, 41%	13, 13%	
Urban/Metropolitan	5, 19%	15, 58%	6, 23%	
AAO Constituency (*n*, %)				0.1927
Northeastern	11, 44%	11, 44%	3, 12%	
Middle Atlantic	9, 35%	13, 50%	4, 15%	
Southern	14, 45%	14, 45%	3, 10%	
Midwestern	11, 46%	10, 42%	3, 13%	
Great Lakes	3, 27%	7, 64%	1, 9%	
Southwestern	11, 73%	3, 20%	1, 7%	
Rocky Mountain	7, 64%	2, 18%	2, 18%	
Pacific Coast	7, 23%	16, 52%	8, 26%	
Years in Practice (*n*, %)				0.9929
< 5 years	3, 33%	5, 56%	1, 11%	
5 - 10 years	11, 42%	12, 46%	3, 12%	
11 - 20 years	18, 45%	16, 40%	6, 15%	
21 - 30 years	22, 41%	24, 44%	8, 15%	
31 - 40 years	15, 45%	14, 42%	4, 12%	
> 40 years	4, 33%	5, 42%	3, 25%	
Time Using Clear Aligners (*n*, %)				0.1536
< 5 years	8, 57%	4, 29%	2, 14%	
5 - 10 years	21, 49%	19, 44%	3, 7%	
11 - 15 years	17, 43%	20, 50%	3, 8%	
> 15 years	27, 35%	33, 43%	17, 22%	
Percentage of Cases in the Mixed Dentition (Mean, SD)	20.4%, 2.09	21.1%, 1.46	23.8%, 2.57	0.5091

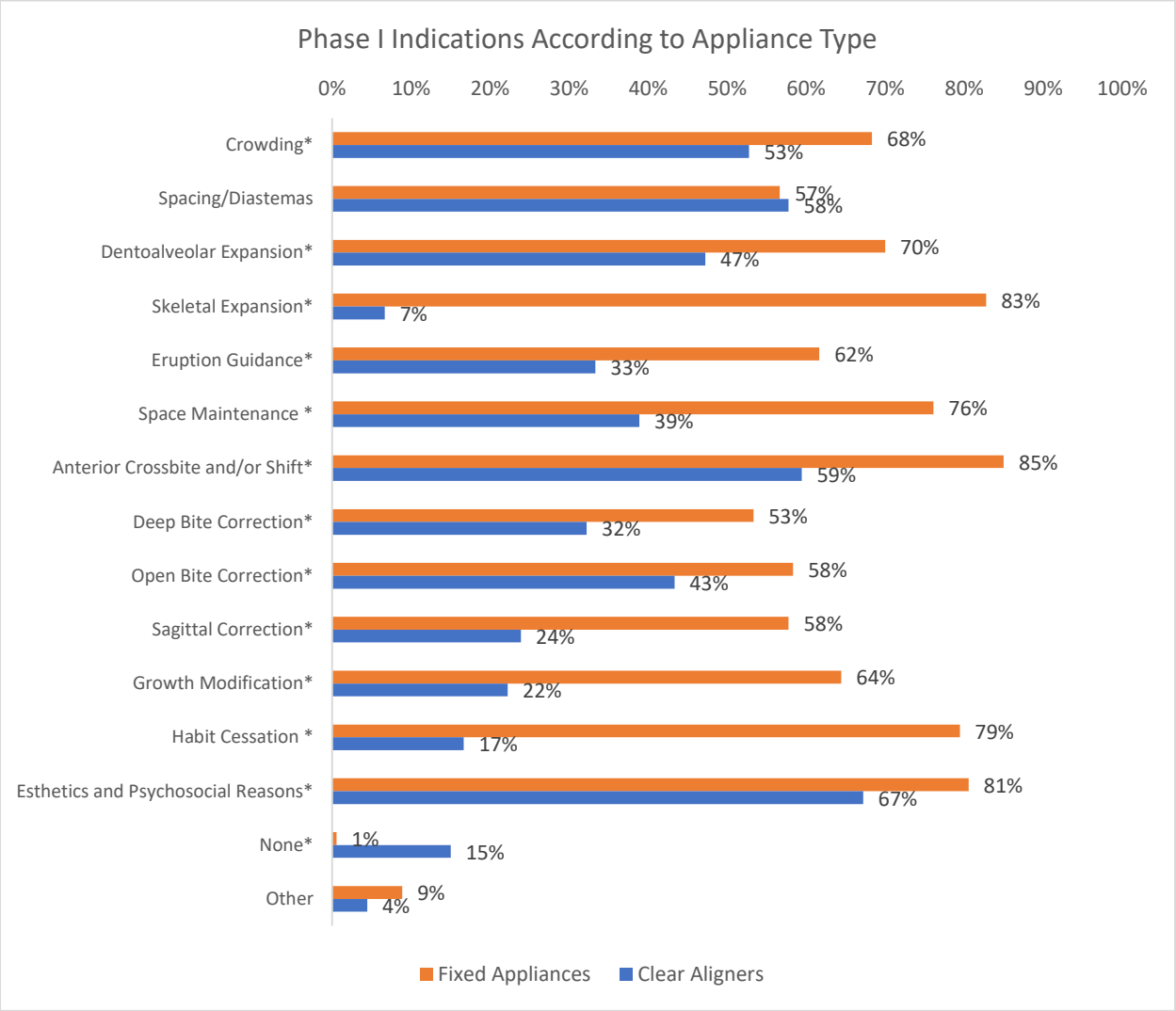
Respondents were asked to select all of the clinical orthodontic scenarios and indications for which they felt it could be appropriate to utilize clear aligner therapy and/or fixed appliance therapy (see survey questions #15-16). Respondents were significantly more likely to select fixed appliances than clear aligners for all of the clinical indications except for spacing/diastemas (57% vs 58%, $P = 0.7815$). There were significantly more respondents who stated that there were no clinical indications for CAMD (15%), compared to those who selected no clinical indications for mixed dentition FA (1%) ($P < 0.0001$). The largest difference was seen for skeletal expansion, which was considered an indication for mixed dentition FA by 83% of respondents, compared to only 7% with CAMD ($P < 0.0001$). A complete summary of the clinical indications are given in Table 4.

Table 4: Clinical Indications for Treatment with Clear Aligners and Fixed Appliances

Indications	**Fixed Appliances**	**Clear Aligners**	***P*-value**
Crowding*	123 (68%)	95 (53%)	0.0006
Spacing/Diastemas	102 (57%)	104 (58%)	0.7815
Dentoalveolar Expansion*	126 (70%)	85 (47%)	<0.0001
Skeletal Expansion*	149 (83%)	12 (7%)	<0.0001
Eruption Guidance*	111 (62%)	60 (33%)	<0.0001
Space Maintenance*	137 (76%)	70 (39%)	<0.0001
Anterior Crossbite and/or Shift*	153 (85%)	107 (59%)	<0.0001
Deep Bite Correction*	96 (53%)	58 (32%)	<0.0001
Open Bite Correction*	105 (58%)	78 (43%)	0.0016
Sagittal Correction*	104 (58%)	43 (24%)	<0.0001
Growth Modification*	116 (64%)	40 (22%)	<0.0001
Habit Cessation *	143 (79%)	30 (17%)	<0.0001
Esthetics and Psychosocial Reasons*	145 (81%)	121 (67%)	0.0023
None*	1 (1%)	27 (15%)	<0.0001

**Indicates statistically significant differences with McNemar's Chi-squared test*

Figure 2: Phase I Indications According to Appliance Type



Indications for clear aligners were also significantly associated with the level of CAMD use for all clinical indications presented in the survey (Table 5, Figure 3). Respondents in the high-use group reported the greatest frequency and variety of CAMD usage, with statistically significant differences for all indications ($P < 0.0001$). The no-use group reported significantly

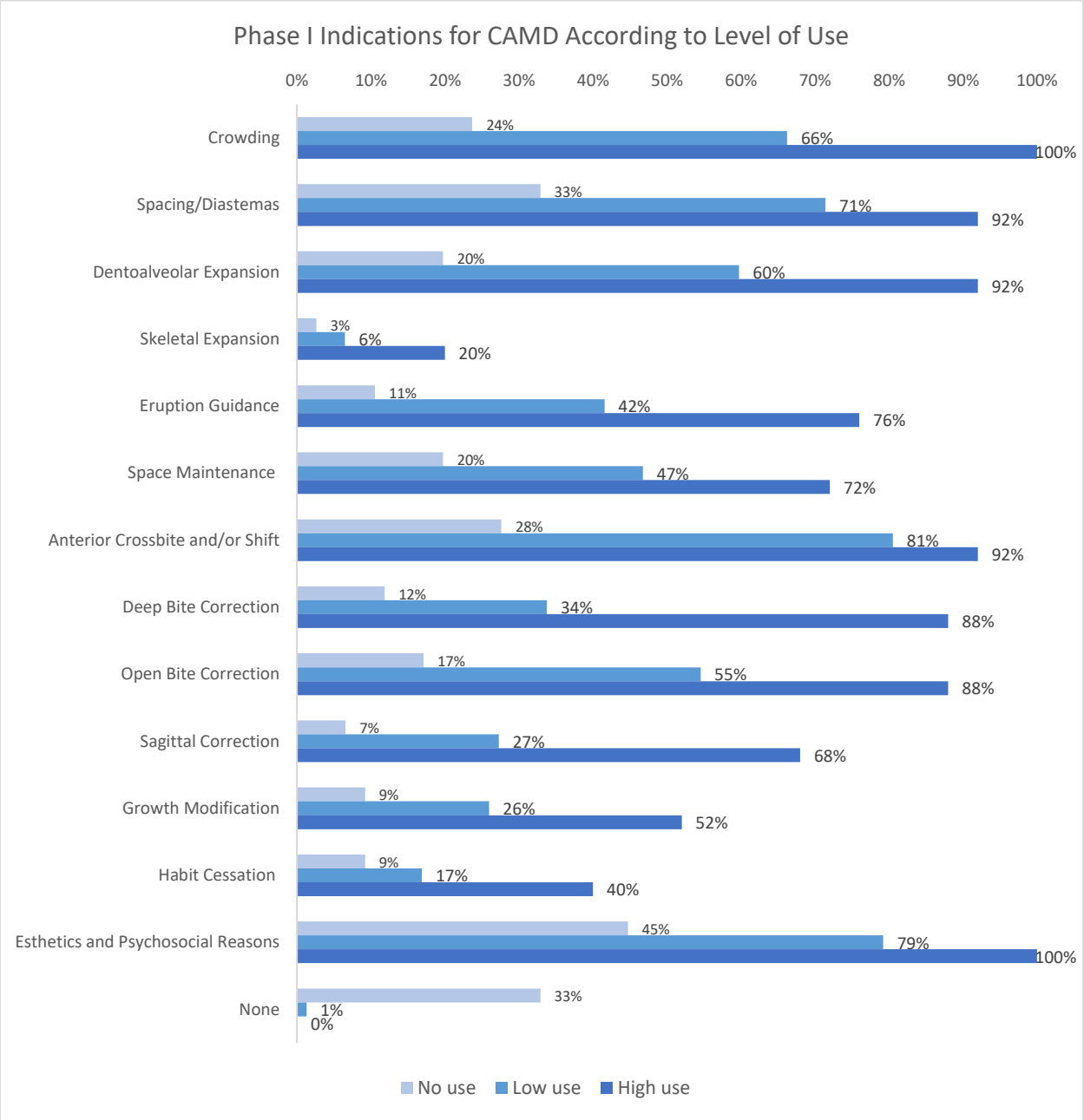
fewer perceived indications by a large margin compared to both the low-use and high-use groups. For example, all of the respondents in the high-use group selected crowding as an indication for CAMD, compared to only 66% and 24% of respondents in the low-use and no-use groups, respectively ($P < 0.0001$). Among the no-use group, 33% answered that there were no feasible clinical indications for CAMD compared to only 1% in the low-use group and 0% in the high-use group ($P < 0.0001$).

Table 5: Clinical Indications for Treatment with Clear Aligners by Level of Clear Aligner Use for Mixed Dentition Cases

Indications	**No Use (*n* = 75)**	**Low Use (*n* = 76)**	**High Use (*n* = 25)**	***P*-value***
Crowding*	24%	66%	100%	<0.0001
Spacing/Diastemas*	33%	71%	92%	<0.0001
Dentoalveolar Expansion*	20%	60%	92%	<0.0001
Skeletal Expansion	3%	6%	20%	0.0109
Eruption Guidance*	11%	42%	76%	<0.0001
Space Maintenance *	20%	47%	72%	<0.0001
Anterior Crossbite and/or Shift*	28%	81%	92%	<0.0001
Deep Bite Correction*	12%	34%	88%	<0.0001
Open Bite Correction*	17%	55%	88%	<0.0001
Sagittal Correction*	7%	27%	68%	<0.0001
Growth Modification*	9%	26%	52%	<0.0001
Habit Cessation *	9%	17%	40%	0.0017
Esthetics and Psychosocial Reasons*	45%	79%	100%	<0.0001
None*	33%	1%	0%	<0.0001

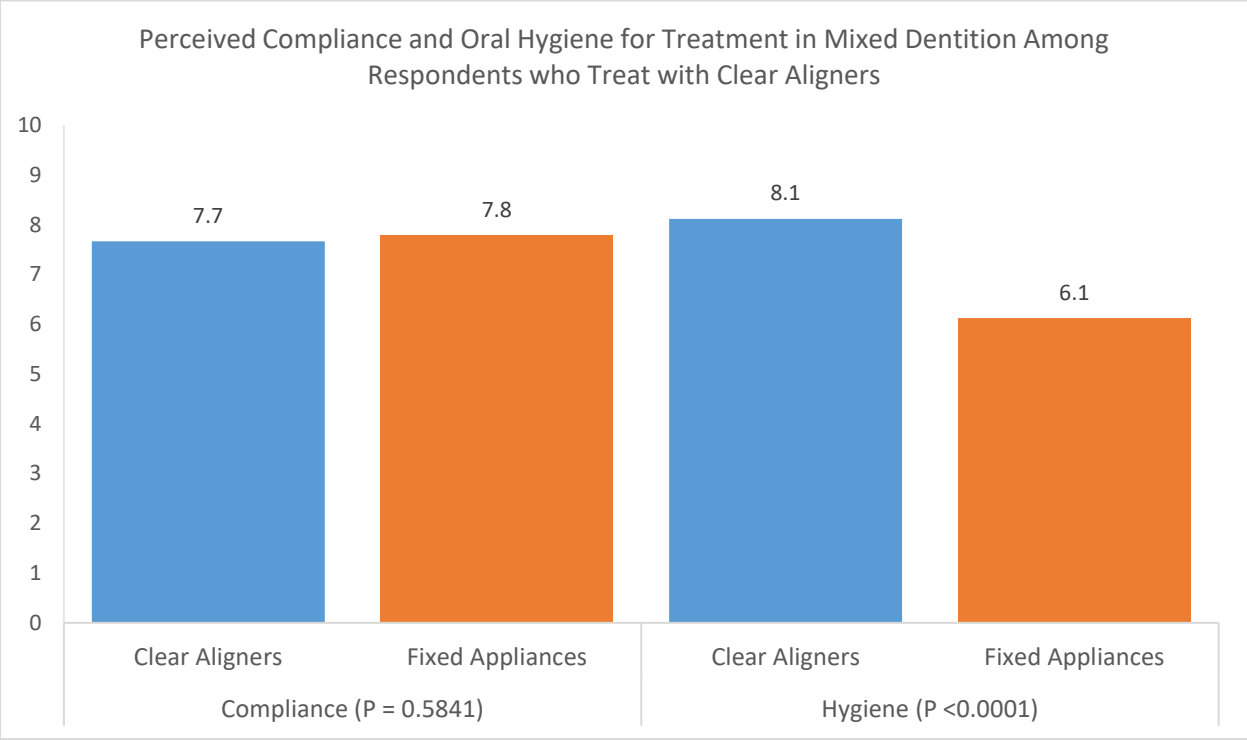
**P-value from Chi-squared test*

Figure 3: Phase I Indications for CAMD According to Level of Use



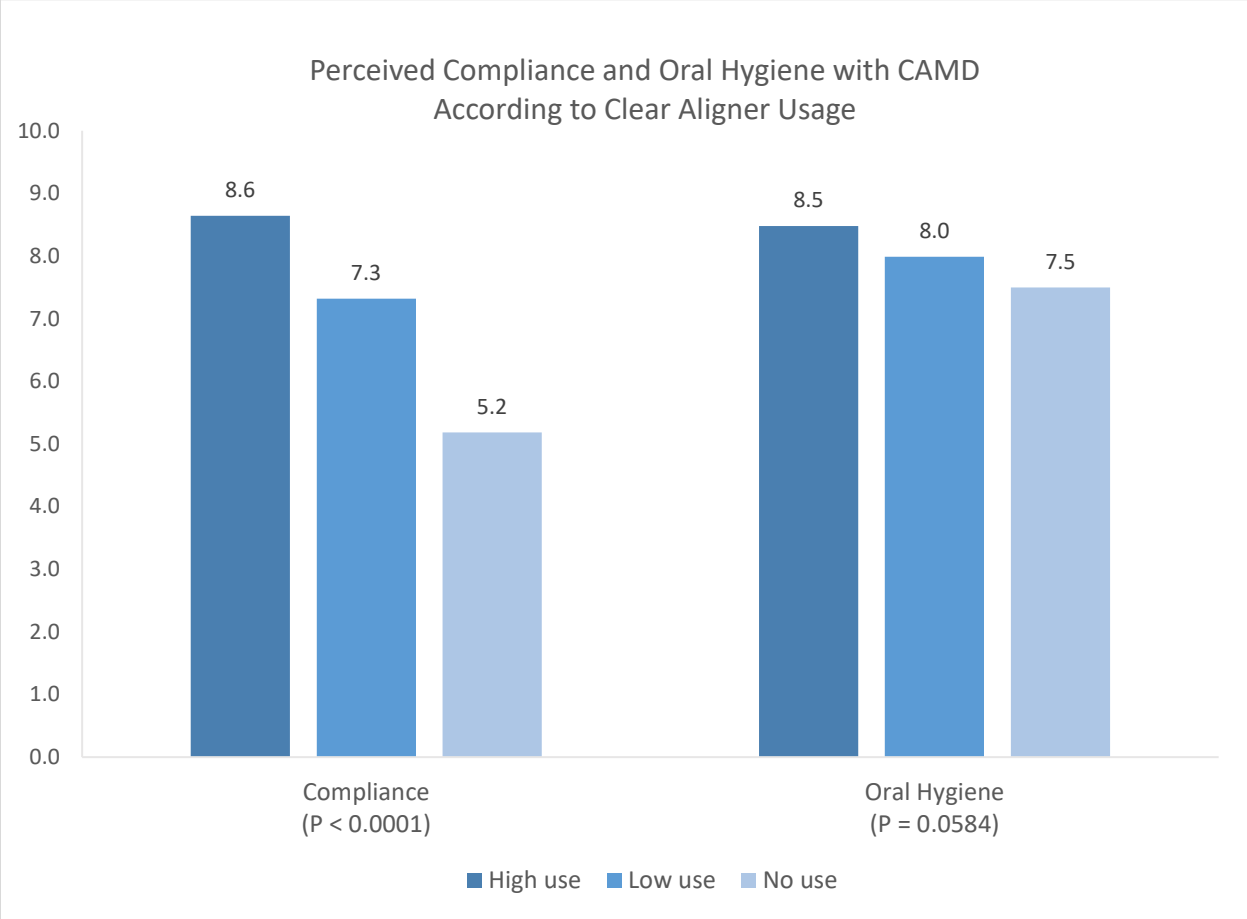
The average perceived compliance with mixed dentition fixed appliances was not significantly different from that of clear aligners (7.8 vs 7.7, *P*- = 0.5841). However, perceived oral hygiene was rated significantly higher on average for clear aligners than with fixed appliances (8.1 vs 6.1, $P < 0.0001$). See Figure 4.

Figure 4: Perceived Compliance and Oral Hygiene with CAMD Usage



The ratings of perceived compliance were also significantly associated with the amount of CAMD use ($P < 0.0001$). Respondents in the high-use group rated compliance with clear aligners to be on average 8.6 out of 10, which was significantly higher than the low-use group (7.3, $P = 0.0046$) and the no-use group (5.2, $P < 0.0001$). Perceived compliance for the low-use group was also significantly higher than the no-use group ($P = 0.0008$). Perceived hygiene showed only a marginally significant association with CAMD use ($P = 0.0584$). Respondents in the high-use group rated perceived hygiene to be on average 8.5 out of 10, which was not significantly different from the low-use group average of 8.0 ($P = 0.1646$) nor the no-use group average of 7.5 ($P = 0.0684$).

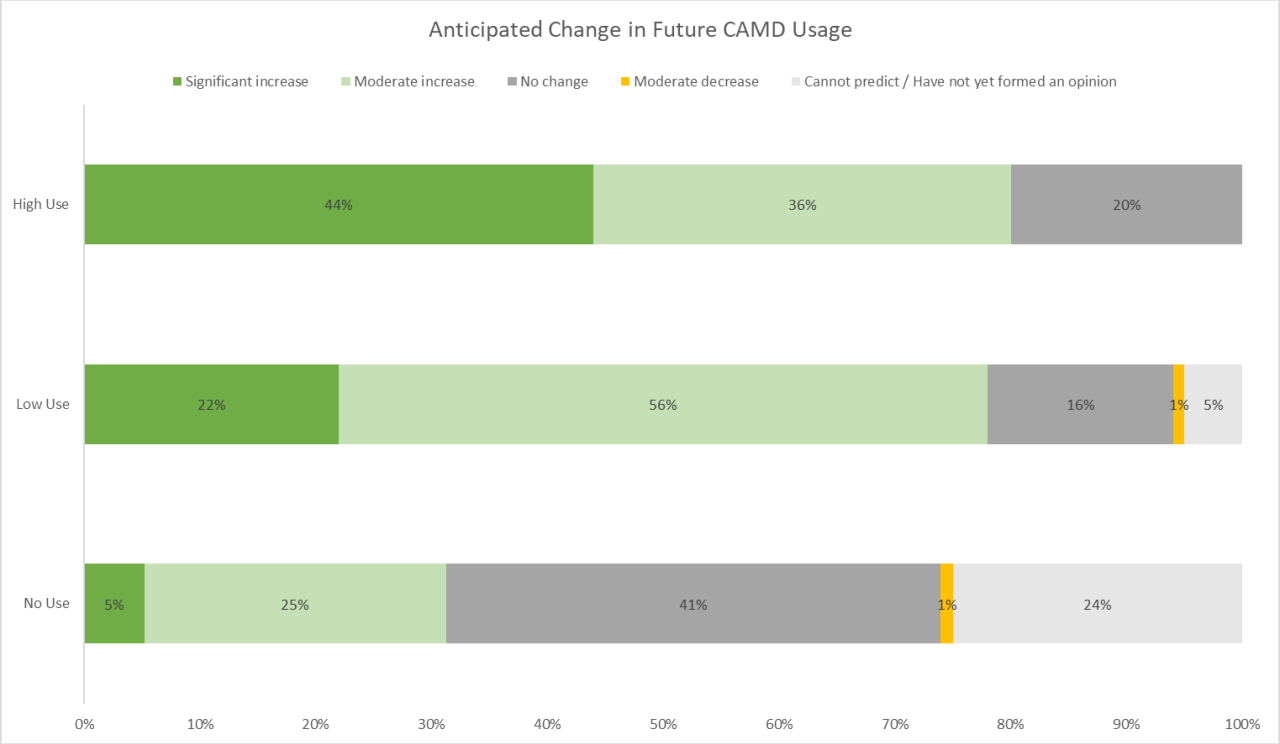
Figure 5: Perceived Compliance and Oral Hygiene for CAMD According to Level of Clear Aligner Usage



When asked about their anticipated use of CAMD in the next 5 years, 18% of respondents (n = 32) indicated a significant increase in use and 40% (n = 71) indicated a moderate increase. Only 2 respondents indicated an anticipated decrease in CAMD use. As shown in Figure 6, anticipated change was significantly associated with the current use of CAMD (P < 0.0001). Respondents in the high-use and low-use groups were more likely to indicate moderate or significant increases in CAMD (80% and 78%, respectively) compared to only 30% in the no-use group. Respondents in the no-use group were most likely to either predict

no change (41%) or that they could not predict (24%). Overall, the answers from all respondents indicated a collective future increase in CAMD usage, with the minority of respondents predicting no change in their level of CAMD use, and only very few respondents predicting a decrease in their level of CAMD use.

Figure 6: Anticipated Change in Future CAMD Usage



Discussion

This study assessed current preferences among orthodontists regarding clear aligner therapy in the mixed dentition (CAMD), including insights into respondent demographics, practice statistics, indications, compliance, oral hygiene, and various patient factors related to appliance selection. Based on previous studies assessing dental professional response rates to mailed paper surveys, the achieved response rate of 18.1% is acceptable.[27,28] As such, the data give a representative picture of the current state of CAMD use among U.S. orthodontists.

It is important to note that our sample comprises two different subgroups: one is nationally representative and generalizable, while the other specifically targeted high-aligner-using practitioners. This was done intentionally to ensure that the survey data included enough responses from orthodontists who have experience with a sufficiently large volume of CAMD in order to provide meaningful responses on their observations of this treatment modality (instead of simply receiving an inordinate number of responses from those who do not use CAMD and thus might have less input to offer regarding its effectiveness). To account for this, the aggregate data was analyzed using the following group breakdown: "No Use", "Low Use", and "High Use." Given that there were 32 respondents included in the secondary sample that was identified via the Invisalign database, these respondents roughly constitute the high-use group (n = 25). By contrast, the remaining orthodontists in the low-use and no-use groups can be considered more

representative of the average orthodontist. As such, the way that the data were analyzed allows for comparison of responses from typical orthodontists against the responses from orthodontists who self-reported a significantly higher level of clear aligner usage. Thus, in this way, we sought to reduce bias in the results and demonstrate how CAMD trends differ in relation to respondent usage levels

Despite this two-pronged approach to the survey strategy, the respondent demographic data still appear to exhibit fairly typical AAO orthodontist demographic characteristics. The vast majority of respondents were solo private practitioners (76%), and 20% were in a group private practice. This agrees well with the 2018 AAO membership data showing that 93% of member orthodontists belonged to either a solo or group private orthodontic practice owned by a dental practitioner. The majority of respondents practiced in suburban settings (58%), which also agrees somewhat well with the AAO data showing that 43% of member orthodontists practice in suburban areas.[29] The number of years in practice followed a normal distribution, with a plurality (30%) indicating that they had been practicing for 21-30 years; this was similar to the median of 19 years in practice found in the 2019 JCO Orthodontic Practice Study.[30] AAO constituencies also appeared to have a relatively proportional distribution of respondents in agreement with the constituencies' respective populations, as well as being comparable to the same JCO survey.[30] Additionally, across all groups, the high overall percentage of respondents with several years of experience using clear aligners further demonstrates that this sample of respondents represents valid candidates to offer information about their experiences using clear aligner therapy. Taken together, these comparisons of demographic and practice data indicate that the sample in this study is acceptably representative of US orthodontists.

As a general summary, our data indicate that orthodontists still predominantly use fixed appliances more often than clear aligners, both for their overall cases (mean 68.8%, median 75%) and for mixed dentition cases (mean 85.4%, median 98%). This is somewhat similar to a 2019 published survey of orthodontic practice data which found that aligners comprised only 15% of average total cases started.[31] The somewhat large difference between the mean and median values can be explained by two factors: a small number of outlier respondents with very high aligner usage, and the tendency for respondents to give simple round-number responses (such as 75% vs 25%, and 50% vs 50%). Even among the respondents who reported performing any CAMD treatment (excluding non-users), CAMD usage was still significantly less than overall aligner usage (43.8% vs 23.7%, $P < 0.0001$). If anything, given that the combined sample specifically included a high-use group, the numbers in this study might even represent an overestimate of the level of CAMD usage in the overall orthodontist population. The average percentage of total cases that involve some form of mixed dentition or Phase I treatment was 21.2%; this appears to roughly agree with another Phase I-related survey study which found that, on average, 9.5% of active orthodontic patients were aged 6-8 and 26.6% were aged 8-11.[32]

The advantages and disadvantages of Phase I treatment have been investigated extensively in the literature. Some practitioners consider many types of mixed dentition orthodontic treatment to be unnecessary or to be a form of over-treatment. In fact, Gianelly asserted that nearly all treatment goals are achievable with single-phase treatment in the late mixed dentition for over 90% of patients.[33] Therefore, it is a valid question to ask whether or not increased CAMD use might merely represent Phase I treatments that are either too early or unnecessary. However, our data indicate that those respondents with the highest level of CAMD use do not perform a significantly greater overall amount of mixed dentition treatment than those

in the low-use and no-use groups in this survey (respectively, 23.8% vs. 21.1% and 20.4%; P = 0.5091). These values are similar to those of another survey study which showed that orthodontists reported treating 15% of their patients with two phases in 2020, and 20% in an earlier 2002 version of the same survey.[34] In sum, the anecdotal notion of an association between more frequent CAMD treatment and overall Phase I treatment frequency is not supported by these data. Instead, this would seem to indicate that the average practitioner still relies on their diagnosis and perception of treatment needs when deciding whether or not to intervene early.

Regarding the specific indications for Phase I orthodontic intervention, there is arguably still debate in the literature regarding which specific conditions require early treatment. In fact, scientific reviews have concluded that early interceptive orthodontic treatment (particularly when performed in two phases) rarely offers improved outcomes over single-phase orthodontic treatment performed in the permanent dentition; furthermore, even when early treatment is effective, the benefits often do not outweigh the additional cost and burden to the patient, family, and provider.[35,36] Nonetheless, this survey included a variety of potential indications for early treatment to broadly assess how and when respondents prefer to intervene.

Sagittal correction was among the least commonly selected indications for mixed dentition treatment with aligners, despite being an objective that many practitioners prefer to address earlier in treatment (such as through the use of various Class II correction appliances). However, this is arguably not surprising, given that there is significant evidence showing that early Class II correction is generally not indicated. Specifically, early Class II correction as part of a two-phase treatment is typically more relapse-prone, more costly, more time-consuming, and no more successful than single-phase treatment later in life.[37,38] On a related note, it is often claimed that early sagittal correction is nonetheless beneficial with regard to overjet reduction

protecting against trauma to prominent upper incisors. However, research has also cast doubt on this purported benefit, showing that early orthodontic treatment did not reduce the incidence of incisor trauma, despite decreased overjet.[39]

The presence of an anterior crossbite and/or shift was most frequently rated as an appropriate mixed dentition treatment indication, both for CAMD and FA. This agrees well with another study on orthodontic treatment timing, where anterior crossbite was the most frequently selected indication for early mixed dentition orthodontic treatment.[32] A recent cases series also advocated for CAMD therapy as an esthetic and comfortable strategy for treating mixed dentition anterior crossbites, citing the benefit of aligner thickness for vertical bite clearance.[40]

While anterior crossbite was the most frequently selected indication overall, when analyzing responses by level of aligner use, the presence of crowding was the most frequently selected indication among the high-use group. Interestingly, crowding has been rated as one of the most common indications for which orthodontists prescribe clear aligners in the permanent dentition.[34] However, it is debatable whether or not this indication is warranted in the early mixed dentition. In particular, Gianelly argued that early treatment of crowding is not necessary in the mixed dentition.[33,41] Tied with crowding as a highly rated indication were esthetics and psychosocial concerns; even across all levels of aligners, respondents frequently agreed that, not only is this an appropriate situation to initiate early treatment, but also that CAMD therapy would be well-suited to address it. This agrees with the findings of another study comparing quality of life in adolescent patients treated with aligners versus those treated with fixed appliances; the aligner patients reported greater comfort and faster adaptation to treatment, missed less school, and had greater feelings of attractiveness and self-confidence.[21] All of these

purported benefits would likely contribute to any esthetic and/or psychosocial benefits of orthodontic treatment.

One concept that is commonly discussed in connection with clear aligners for children is that of transverse maxillary arch development. Importantly, a considerable amount of scientific evidence indicates that maxillary expansion for the resolution of posterior crossbites, especially when any occlusal shifts are present, is often more beneficial and more successful at earlier ages.[42] Among all of the potential indications included in this survey, maxillary skeletal expansion was deemed the least appropriate indication for CAMD, with only 7% of overall respondents selecting it. This agrees with conventional orthodontic wisdom that some form of fixed appliance (whether a rapid maxillary expander, quad helix, or other related appliances) are necessary to achieve true skeletal expansion at the mid-palatal suture. Indeed, studies on attempted maxillary expansion with clear aligner therapy in adults have demonstrated inaccurate virtual predictions and overestimated amounts of bodily movement, with primarily buccal tipping of posterior teeth occurring instead.[43–46] Clinical research on the use of clear aligners for maxillary expansion in mixed dentition patients is still limited. Two recent studies claim that CAMD is effective for treating mild maxillary transverse deficiencies, with one even claiming that clear aligners might be a feasible substitute for traditional fixed maxillary expanders. However, the expansion noted in these studies was only mild (ranging from approximately 1 to 3 mm), largely due to mesial-out rotations of upper molars, and likely only dentoalveolar in nature (given the lack of CBCT data to provide evidence of true skeletal expansion).[47,48]

Overall, more respondents selected FA more often that CAMD as an appropriate choice for every single indication listed. This suggests that FA therapy is generally still perceived as the most suitable appliance for all early treatment indications. Additionally, for all indications

surveyed, there were statistically significant differences between the no-use, low-use, and high-use groups. There was a clear pattern, with significantly fewer respondents selecting any given indication as an appropriate situation to use CAMD therapy when comparing the low-use and high-use groups. Very few respondents from the no-use group rated any indications as appropriate for CAMD. This seems to demonstrate that there is no consensus among respondents on CAMD indications, and that the perceived appropriateness of CAMD therapy is closely tied to the respondents' respective levels of clear aligner usage.

Compliance is arguably even more important to clear aligner therapy than fixed appliance therapy, since removable appliances can only work when worn. As such, concerns over poor compliance are often cited as a challenge with CAMD therapy, with children being considered less dependable wearers than adolescent or adult patients. Attempts to increase and measure aligner compliance in younger patients, such as built-in compliance indicators, demonstrate just how important this aspect is to orthodontists.[24] Several studies in the literature have found that increasing age was negatively correlated with daily wear time, with younger patients wearing various removable appliances for a greater amount of time per day.[49,50] More specifically, a recent study found that poor cooperation with aligner treatment was most common among teenage (14-17 years old) and young adult (20-29 years old) patients, whereas there was significantly better cooperation in child patients (less than 12 years old).[23] Similarly, this study found that there was no overall difference in perceived compliance between CAMD and mixed dentition FA, which would indicate that aligner cooperation might be acceptably high among young patients. However, when compliance ratings were compared between the respondent groups based on level of aligner use, the results clearly showed that compliance ratings positively correlated with the frequency of aligner therapy. The direction of this relationship is

unclear, though, as it cannot be determined whether high-aligner-prescribing orthodontists prescribe more aligners because they have high compliance, or if they achieve increased compliance because of their greater experience with aligners. Alternatively, it is also possible that the ratings of higher compliance among the respondents in the high-use group merely represent an overall positive bias in favor of aligner treatment. Conversely, it can likely be inferred that the significantly lower level of perceived compliance in the no-use group is an important factor in their appliance selection.

During any type of orthodontic treatment, adequate oral hygiene is essential for maintaining oral health, and fixed appliances present physical obstacles to proper brushing and flossing. As such, some practitioners assert that removable clear aligners permit superior oral hygiene, and this notion appears to be supported by several studies. One prospective clinical trial in adults found that clear aligners were associated with improved periodontal status compared to fixed appliances, including decreases in plaque, gingival inflammation, bleeding on probing, probing depths, and periodontal pathogen levels.[51] A subsequent study with patients ranging in age from 11 to 62 years found similarly improved gingival health in clear aligner patients compared to fixed appliance patients.[18] More specific to adolescent patients, another clinical trial involving patients aged 10-18 years also found decreased plaque scores, decreased bleeding on probing, and decreased probing depths in clear aligner patients versus fixed appliance patients.[19] On a broader level, both a recent systematic review and a recent meta-analysis also found improved periodontal health with decreases in periodontal indices for clear aligner patients compared to fixed appliance patients; however, both studies cautioned that the current level of evidence is only of moderate quality due to heterogeneity and risk of bias, thereby necessitating future RCTs of higher quality.[52,53] Overall, the respondents in the present study appeared to agree

that young patients tend to have superior perceived oral hygiene with clear aligner therapy. Thus, it may be beneficial for orthodontists to consider utilizing CAMD instead of FA with child patients for whom they anticipate oral hygiene difficulties.

When asked about their intentions to increase, maintain, or decrease their current level of CAMD usage, the vast majority of respondents predicted either a significant or moderate increase (see Figure 6). Granted, this predicted increase was much more frequent among current CAMD users, especially the high-use group. Therefore, it is reasonable to assume that any future growth in this treatment modality will likely be attributable to those who already use CAMD or have a favorable opinion regarding its applications. However, even though the majority of respondents in the no-use group expected no change, many of them still stated that they expected either a significant or moderate increase in their CAMD usage. Thus, there still appears to be much appeal to at least try this modality, even among current non-users. As previously mentioned, possible benefits of CAMD such as improved oral hygiene are likely factors that are prompting providers to consider this appliance. With that being said, future clinical studies will be needed to assess the efficacy of CAMD more closely.

Open-ended feedback from the final question of the survey generated highly varied and subjective answers, but several similar comments seemed to represent certain trends. These comments focused on controversial indications, compliance, hygiene, the necessity of early treatment, and financial factors. Many respondents endorsed negative views of what they called "Phase I" treatment, arguing that it often represents unnecessary treatment that is performed primarily due to the pressure felt by practitioners to produce. Furthermore, some respondents insisted that aligner companies' marketing aggravates these pressures. However, the results of this study do not seem to confirm this worry; instead, it appears that early mixed dentition

treatment rates are low overall and similar between no-, low-, and high-use groups. Several respondents specifically mentioned skeletal expansion, which is a widely accepted Phase I indication; they stated that they do not believe it is possible with clear aligners. Therefore, they reported either avoiding clear aligners entirely, or using a fixed maxillary expander prior to or concurrent with aligner therapy. The results of this study confirm that this anecdotal view is widely shared among respondents, with very few respondents selecting skeletal expansion as an appropriate indication for CAMD therapy. Regarding compliance, the comments fit into two opposing categories: half of the compliance-related responses argued that compliance will always be the biggest barrier to CAMD success, while the other half reported surprisingly successful compliance levels. Some respondents even claimed that they observe better compliance in younger children than in teenagers and adults. It was clear that respondents' early experiences with aligner compliance impacted whether or not they continued to utilize CAMD with confidence. Finally, while several open responses asserted that they will categorically avoid ever using aligners in the mixed dentition, a greater number of open responses expressed enthusiasm & satisfaction with the results of their mixed dentition clear aligner therapy. In sum, it is clear that this treatment modality is still relatively new and that there is a large variation in the extent to which orthodontists are willing to utilize it.

Conclusion

Overall, the results of this survey study indicate that clear aligner therapy is emerging as an increasingly popular orthodontic treatment modality for children in the mixed dentition. Specifically, the following main conclusions were elucidated:

- CAMD usage is still significantly less than both mixed dentition FA and adult clear aligners, but it is predicted to grow.
- The majority of respondents perceived CAMD to be less suitable than FA for skeletal expansion, growth modification, sagittal correction, and habit cessation.
- Perceived compliance is similar between CAMD and FA.
- Perceived oral hygiene is superior with CAMD compared to FA.
- Respondents with high CAMD use do not report a greater amount of early mixed dentition treatment than the average orthodontist, but they do report significantly greater indications, oral hygiene, compliance, and predicted future usage with respect to CAMD.

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Appendix

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Survey

Clear Aligner Therapy in the Mixed Dentition: Indications and Practitioner Preferences

You are invited to participate in a research study investigating the current practitioner preferences and perceived indications for aligners in the mixed dentition. All responses are anonymous, and no personal identifiers will be collected. Your participation in this study is voluntary. You may stop answering questions at any point and withdraw from the study. The survey should take 5 – 10 minutes to complete. If you elect to participate, please read and follow the instructions before, and throughout, the survey.

We thank you for your willingness to participate in this study.

Should you have any further questions, you may contact the research team at:

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This survey contains questions about your attitudes and experiences regarding clear aligner therapy for patients in the mixed dentition. For the purposes of this study, we ask that you answer all questions based on your current perceptions of this specific clinical modality, ***regardless of whether or not you personally have provided this type of treatment.*** *For any questions regarding terminology, please refer to the following working definitions:*

- Phase I treatment = interceptive orthodontic treatment for child patients in the mixed dentition (e.g., correction of anterior or posterior crossbites, growth modification, space maintenance, etc.)
- Clear aligner therapy = any type of clear thermoplastic used in a series to perform orthodontic tooth movement; not limited to any particular company, brand, or product
- Fixed appliances = refers to the bands, brackets, and wires used as part of the standard edgewise straight-wire technique
    - Can be considered to include other traditional appliances or orthopedic devices, such as headgear, palatal expanders, habit appliances, etc.
- Permanent dentition = characterized by the presence of only permanent teeth, but not necessarily all permanent teeth; no primary teeth present
- Mixed dentition = characterized by the presence of both permanent and primary teeth

Please select one answer for each question, unless otherwise instructed. For paired questions involving percentages, your summed answers should add up to 100 percent*. Thank you for your participation.*

1. Which of the following best describes your practice situation?

- ☐ Private solo orthodontic practice
- ☐ Private group orthodontic practice
- ☐ Corporate orthodontic practice
- ☐ Academic institution

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2. Which of the following best describes the geographical setting of your practice?

- ☐ Rural
- ☐ Small town
- ☐ Large town / Suburban
- ☐ Urban / Metropolitan

3. In which region of the United States do you practice (based on AAO districts)?

- ☐ Northeastern
- ☐ Middle Atlantic
- ☐ Southern
- ☐ Midwestern
- ☐ Great Lakes
- ☐ Southwestern
- ☐ Rocky Mountain
- ☐ Pacific Coast
- ☐ Southern

4. How many years have you been practicing as an orthodontist?

- ☐ < 5 years
- ☐ 5 – 10 years
- ☐ 11 – 20 years
- ☐ 21 – 30 years
- ☐ 31 – 40 years
- ☐ > 40 years

5. How long have you been using clear aligners in your practice?

- ☐ < 5 years
- ☐ 5 – 10 years
- ☐ 11 – 15 years
- ☐ > 15 years

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6. Please indicate your current Invisalign provider level:

- ☐ Bronze
- ☐ Bronze Plus
- ☐ Silver
- ☐ Silver Plus
- ☐ Gold
- ☐ Gold Plus
- ☐ Platinum
- ☐ Platinum Plus
- ☐ Diamond
- ☐ Diamond Plus
- ☐ Not applicable

****For questions #7 and #8, your answers should combine to equal 100%.*

7. What percentage of your overall practice consists of ***fixed appliance*** cases?

_____ **%**

8. What percentage of your overall practice consists of ***clear aligner*** cases?

_____ **%**

****For questions #9 and #10, your answers should combine to equal 100%.*

9. When treating children in the mixed dentition, what percentage of your cases consists of ***fixed appliances***?

_____ **%**

10. When treating children in the mixed dentition, what percentage of your cases consists of ***clear aligners***?

_____ **%**

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11. In a typical year, what percentage of your total cases involve some form of Phase I or early treatment in the mixed dentition? (*Does NOT need to add up to 100% with another answer*)

_____ **%**

12. On a scale of 1 to 10 (with 1 being highly unfavorable and 10 being highly favorable), what is your current attitude toward the use of clear aligner therapy for children with mixed dentition?

	1	2	3	4	5	6	7	8	9	10	
Unfavorable	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Favorable

13. On a scale of 1 to 10 (with 1 being highly unlikely and 10 being highly likely), what is the likelihood that you will prescribe clear aligner therapy for children with mixed dentition in the future?

	1	2	3	4	5	6	7	8	9	10	
Unlikely	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Likely

14. How do you anticipate your use of clear aligners in the mixed dentition will change over the next five years?

- ☐ Significant increase
- ☐ Moderate increase
- ☐ No change
- ☐ Moderate decrease
- ☐ Significant decrease
- ☐ Cannot predict / Have not yet formed an opinion
- ☐ Not applicable

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15. For which of the following ***clinical scenarios or indications*** do you feel it could be appropriate to prescribe ***fixed appliances*** for interceptive Phase I therapy in the mixed dentition [select all that apply]:

- ☐ Crowding
- ☐ Spacing/diastemas
- ☐ Dentoalveolar expansion
- ☐ Skeletal expansion
- ☐ Eruption guidance
- ☐ Space maintenance
- ☐ Anterior crossbite and/or shift
- ☐ Deep bite correction
- ☐ Open bite correction
- ☐ Sagittal correction
- ☐ Growth modification
- ☐ Habit cessation
- ☐ Esthetics & psychosocial reasons
- ☐ None
- ☐ Other: _____

16. For which of the following ***clinical scenarios or indications*** do you feel it could be appropriate to prescribe ***clear aligners*** for interceptive Phase I therapy in the mixed dentition [select all that apply]:

- ☐ Crowding
- ☐ Spacing/diastemas
- ☐ Dentoalveolar expansion
- ☐ Skeletal expansion
- ☐ Eruption guidance
- ☐ Space maintenance
- ☐ Anterior crossbite and/or shift
- ☐ Deep bite correction
- ☐ Open bite correction
- ☐ Sagittal correction
- ☐ Growth modification
- ☐ Habit cessation
- ☐ Esthetics & psychosocial reasons
- ☐ None
- ☐ Other: _____

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17. Aside from the specific clinical indications assessed in Questions #15, which of the following additional reasons explains your ***rationale for selecting fixed appliances*** over clear aligners for children in the mixed dentition? [Select all that apply]

- ☐ Poor compliance with clear aligners (lost/broken trays, lack of wear, etc.)
- ☐ Poor oral hygiene with clear aligners
- ☐ Patient esthetic preferences (O-tie colors, bracket shapes, etc.)
- ☐ Patient social reasons/peer pressure
- ☐ Appliance biomechanics (modifications, adaptability, etc.)
- ☐ Environmental concerns (recycling)
- ☐ None/Not applicable
- ☐ Other: _____

18. Aside from the specific clinical indications assessed in Questions #16, which of the following additional reasons explain your ***rationale for selecting clear aligner therapy*** over fixed appliances for children in the mixed dentition? [Select all that apply]

- ☐ Poor compliance with fixed appliances (broken brackets, poor elastic wear, etc.)
- ☐ Poor oral hygiene with fixed appliances
- ☐ Patient esthetic preferences (clear trays, colored attachments, stickers, etc.)
- ☐ Patient social reasons/peer pressure
- ☐ Appliance biomechanics (modifications, adaptability, etc.)
- ☐ Environmental concerns (recycling)
- ☐ None/Not applicable
- ☐ Other: _____

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19. If you currently prescribe ***fixed appliances*** in the mixed dentition, or have prescribed them previously, how would you rate the overall ***compliance*** of these child patients on a scale of 1 to 10? (With "1" being a total lack of compliance and "10" being perfect compliance)

	1	2	3	4	5	6	7	8	9	10		N/A
Non-compliant	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Compliant	☐

20. If you currently prescribe ***clear aligner*** therapy in the mixed dentition, or have prescribed it previously, how would you rate the overall ***compliance*** of these child patients on a scale of 1 to 10? (With "1" being a total lack of compliance and "10" being perfect compliance)

	1	2	3	4	5	6	7	8	9	10		N/A
Non-compliant	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Compliant	☐

21. If you currently prescribe ***fixed appliances*** in the mixed dentition, or have prescribed them previously, how would you rate the overall ***oral hygiene*** of these child patients on a scale of 1 to 10? (With "1" being to a total lack of oral hygiene and "10" being perfect oral hygiene

	1	2	3	4	5	6	7	8	9	10		N/A
Poor OH	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Excellent OH	☐

22. If you currently prescribe ***clear aligner*** therapy in the mixed dentition, or have prescribed it previously, how would you rate the overall ***oral hygiene*** of these child patients on a scale of 1 to 10? (With "1" being to a total lack of oral hygiene and "10" being perfect oral hygiene)

	1	2	3	4	5	6	7	8	9	10		N/A
Poor OH	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Excellent OH	☐

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23. Comments:

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