Does Invisalign® Line Up with Evidence?

2nd Year DDS Community Dentistry
Critical Appraisal

Submitted to: Dr. J. Leake
Course: Community Dentistry

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ABSTRACT

This critical appraisal of the literature addressed Invisalign, a product that allows for a more aesthetically pleasing orthodontic treatment compared to traditional fixed orthodontic appliances (braces). The objective was to assess whether Invisalign is more efficacious compared to standard treatment of traditional fixed appliances. The appraisal was based on evidence from 2 main sources: a search of multiple electronic bibliographic databases and a manual search of the references of a previously published review on Invisalign. A total of 290 articles were reviewed. Of these, 3 were deemed relevant to our topic and of strong design. The validity of the final three articles was assessed by subjecting them to the "Checklist to Assess Evidence of Efficacy of Therapy", consisting of 16 points. The cut-off value was set as 70% and all three studies passed it, achieving a score of 77% each. The outcomes that were considered in the final papers were improvements of function and aesthetics, and the improvement of periodontal health of the patients undergoing orthodontic treatment. The evidence available does not supporrt using Invisalign as an alternative for traditional orthodontic treatment. Given the scarce amount of strong evidence, it is suggested that more studies are required to be able to draw any further conclusions. An evidence-based dental practice aims on providing the best treatment according to the sound scientific evidence, however one should also realize that scientific evidence should not automatically determine the selection of the treatment option. Other factors, such as aesthetic concerns of the patients and the cost of the treatment should be factored into the treatment considerations in order to provide comprehensive patient-centered evidence-based care.

INTRODUCTION

According to anthropological research, the prevalence of malocclusion has increased since ancient times (Evensen *et al*., 2007). Today, the prevalence of mild to severe malocclusion is estimated to be around 30%, with similar distribution between males and females (Peres *et al.*, 2008).

Fixed orthodontic appliances have been the backbone of orthodontic biomechanical technique, dating back to mid-18th century when the first interventions for correcting malocclusion were developed (The Dental HiWay, 2008). Since their introduction, many advancements have been made in their ability to correct malocclusion and they are now considered the standard treatment. A primary disadvantage of this treatment modality is poor aesthetics. This has been a driving force for the development of alternative treatment options for the adult population.

Invisalign, developed in 1999 (Align Technology, 2008), is a method of orthodontic therapy known as an "invisible" way of correcting malocclusions without using traditional braces. Instead it uses a series of clear custom-fabricated aligners designed to gradually, and sequentially move teeth to their desired positions. The aligners are synthesized from thin, transparent plastic that fits over the tooth crown. The aligners are worn for at least 20 hours each day but can be removed for eating and oral hygiene. The aligners are changed every two weeks until the treatment is complete (Bishop *et al*., 2002). Treatment length varies, depending on the case, however full program of treatment usually takes less than one year (Align Technology, 2008).

The Invisalign system is most successful for treating mild malocclusions (1 to 5 mm of crowding or spacing), deep overbite problems such as Class II division 2 malocclusions, overbite

that can be reduced by intrusion or advancement of incisors, non-skeletally constricted arches that can be expanded with limited tipping of the teeth, and mild relapse after fixed-appliance therapy (Joffe, 2003).

Past studies have concluded that "no treatment indications for, or limitations of Invisalign are supported with scientific evidence" (Mauel *et al*., 2005). On the contrary, another study concluded that the "Invisalign system of orthodontic tooth movement is a feasible alternative to traditional and removable appliance therapy in select cases" (Vlaskalic *et al*., 2002). A systematic review published in 2005 found no strong conclusions regarding Invisalign treatment (Lagravere *et al*., 2005). Thus, a new literature review was conducted to answer the following question: "Does Invisalign line up with the evidence?" In other words, does Invisalign provide the appropriate clinical results in addition to being more aesthetically pleasing compared to traditional metal braces? Currently, several studies exist but only few have assessed the effectiveness of this technique. A review of the literature was conducted in order to formulate an evidence-based conclusion on the efficacy of Invisalign compared to traditional orthodontic treatment. In essence, this report states the methods utilized for the literature review, a summary of the evidence gathered, as well as implications and conclusions derived based on the available evidence.

METHODOLOGY

A systematic method was used to search, identify and critically evaluate the relevant studies. In order to define search criteria it was decided that only the adult population (18 years old or more) was considered. The efficacy of treatment using the Invisalign system was compared to that of the traditional fixed orthodontic appliances. Traditional fixed orthodontic appliances were chosen as the control because this treatment modality is considered to be the

standard treatment in orthodontic therapy. Invisalign was considered the intervention in the studies examined, as it is the technique under investigation.

The following outcomes were considered in the search. The first outcome considered was the improvement in function and aesthetics as evaluated using the methods of the American Board of Orthodontics (ABO) Objective Grading System (OGS). The OGS criteria are used to objectively score improvements in all of the following: alignment, marginal ridges, buccolingual inclination, occlusal contacts, occlusal relations, overjet, interproximal contacts, and root angulation, resulting in the overall OGS score. A case is initially given a score of zero and points are subtracted according to the amount of discrepancy from the ideal (See Appendix A). Another outcome considered was the improvement in periodontal health of the subject undergoing orthodontic treatment as measured using the methods of Gingiva Index (GI), Papillary Bleeding Index (PBI), and Sulcular Probing Depth (SPD). GI was measured on a scale of 0 to 3, with 0 denoting healthy gingival tissue, and 3 denoting severe inflammation. PBI was also measured on the scale of 0 to 4, with 0 standing for no bleeding upon probing and 4 stranding for profuse bleeding. SPD was reported by measuring sulcus depth mesially, distally, lingually and buccally and calculating an average value per tooth in millimetres. The next outcome considered was the improvement of levels of supragingival plague as measured by the methods of Plaque Index (PI). PI was measured using the scale from 0 to 3, with 0 having the least amount of plaque and 3 having the most. Also, improvement in TMJ function was considered in terms of reduction of pain, mandible deviation, and crepitus. Maintenance of speech function during treatment was assessed in terms of the ability to pronounce sounds. Also the treatment duration was considered with shorter duration being favourable. Finally, monetary cost to the patient was also examined to determine which technique was more cost effective.

A detailed electronic search was performed using the following search engines: PubMed using “Invisalign” as the only search key word (41 articles), OVID Medline (from 1966 to January week 2 of 2008) using “Invisalign” , “orthodont$”, “esthetic$” and “invisible” as key word search terms (128 articles.), Cochrane Library of Systematic Review using “Invisalign“ as the only search term (2 articles), Web of Science using “Invisalign“ as the only search term (10 articles), Google Scholar using "Invisalign" and "Traditional" as keywords (114 articles). Also Proquest was used to search for dissertations using “Invisalign“ as the only search term (3 articles). The dentistry librarian at the University of Toronto was consulted about the most effective search technique. Additionally, a manual search was conducted using the reference list of the existing systematic review for Invisalign; two additional articles were added bringing the total number or articles selected to 290. (See Appendix F).

To further refine the search several steps were undertaken. Initially the eligibility of the selected studies was determined by reading the titles identified by the database searches and their relevance was assessed (Paper must have involved Invisalign treatment and must have been published in a peer-edited journal).

111 articles were further assessed at the level of the abstracts. The level of agreement was 92%. The relevant articles had to meet the following criteria:

- Must compare Invisalign to traditional fixed ortho appliance.
- Must be the primary study published in a peer-reviewed journal
- Must be a human *in vivo* study.
- Must be a RCT, prospective cohort, prospective clinical trial or retrospective case-control study.

- Must be available in English

- Must be published from 1996 to the second week of Jan, 2008

Several abstracts did not present enough information to make a decision, so the full articles were extracted and examined. Also several authors were attempted to be contacted for clarifications via email, however, no reply was received from any authors. The initial selection was done individually by two independent examiners and then any discrepancies were settled through discussion. Finally 3 articles were found to meet all the criteria and were included fro further analysis. At this stage the level of agreement was 100%.

The validity of the articles was assessed using Dr. Leake's modified version of the "Checklist to Assess Evidence of Efficacy of Therapy" and scores were reported as percentage (See Appendix D). The cut off value of 70% was chosen because there was a limited number of relevant articles available in the literature, thus, it was necessary to set the cut off at a low value in order to prevent exclusion of all the articles.

RESULTS

Based on the rigorous review of the current literature, three papers met or exceeded the minimum quality score of 70% on Dr. Leake's modified version of the "Checklist to Assess Evidence of Efficacy of Therapy".

Djeu *et al*. examined the differences in outcomes of patients treated for malocclusions using Invisalign and traditional fixed appliances. The study conducted was a retrospective clinical trial. The outcome measured in the study was the improvement of aesthetics and function

which was assessed using the ABO Objective Grading System (OGS). All measurements were performed by an ABO-certified orthodontist.

Initially, the Intervention (Invisalign, n=48) and Control (traditional fixed appliance, n=48) populations were assessed to ensure similarity of the two groups. There was a statistical difference (*P<0.0001*) between the average ages of the two populations.

Secondly, the Discrepancy Index (DI) was used pre-treatment to determine similarity between the populations based on ten objectively measurable criteria: overjet, overbite, anterior open bite, lateral open bite, crowding, occlusion, lingual posterior crossbite, buccal posterior crossbite, cephalometrics, other and the overall DI score. There was no statistically significant difference in overall DI score *(P=0.9066)* or any of the ten DI categories.

The Objective Grading System (OGS) was used post-treatment to determine the improvement in aesthetics and function and therefore the efficacy of the treatment. The OGS is based on eight objectively measurable criteria: alignment, marginal ridges, buccolingual inclination, occlusal contacts, occlusal relations, overjet, interproximal contacts, root angulation and the overall OGS score. The difference in overall OGS score of the Invisalign group and control group was statistically significant (*P<0.0001*). Contributing to this were statistically significant differences in scores for buccolingual inclination, occlusal contacts, occlusal relations and overjet, where the control group outperformed the Invisalign group.

There was a statistically significant negative correlation between the OGS score and three DI classifications (overjet (*P=0.0360*), occlusion (*P=0.0001*) and buccal posterior crossbite (*P=0.0497*)) for the Invisalign group. There was a statistically significant negative correlation between the OGS score and three DI classifications (overjet (*P=0.0400*), occlusion (*P=0.0013*) and other (*P=0.0415*)) for the control group.

Overall, 20.8% Invisalign cases and 47.9% of control cases had passing OGS scores. There was a statistically significant difference in passing rates between the two treatment modalities (*P=0.0052*).

Furthermore, there was a statistically significant difference in the length of treatment required to complete the case. The Invisalign treatment took an average of 1.4 years while the control group took an average of 1.7 years (*P=0.0138*). Overall, the paper was given a grade of D, according to the Canadian Task Force table of Recommendation Grades for Specific Clinical Preventive Actions. The paper scored 77% on the "Checklist to Assess Evidence of Efficacy of Therapy".

In the second paper, Kuncio *et al.* examined the post-retention dental changes of patients treated for malocclusions using Invisalign and traditional fixed appliances. This was a retrospective case-control study. Both groups had similar distributions of gender, age, ethnicity, retainer wear, treatment, and post-treatment length. Patients were treated solely with either tip-edge fixed appliances or removable Invisalign aligners. The inclusion criteria of the study were non-extraction cases, and malocclusions that fell within the treatment guidelines provided by Align Technology. This includes mild to moderate crowding (1-6mm), mild to moderate spacing (1-6mm), and non-skeletal constricted arches. The outcome examined was the improvement in aesthetics and function of the occlusion. This was measured objectively, using the measurement categories of the ABO OGS (See Appendix A).

Three statistical tests were used in this study. Fischer's exact tests were used to determine the similarity between control and test groups in terms of gender, age, and ethnicity. Unpaired t-tests were used for age, treatment length, post-treatment length, and differences from T1 to T2. Paired t-tests were used for changes within each group from T1 to T2.

Examiner reliability was assessed by having each patient's casts and panoramic radiographs randomly ordered, duplicated, masked and evaluated by two examiners. However, the paper does not mention whether the examiners were calibrated according to the ABO.

As a result of the study, both Invisalign (*P = 0.0039*) and Braces (*P = 0.0313*) groups showed significant decreases in mandibular anterior alignment in regard to changes from T1 (posttreatment) to T2 (postretention) as measured by the OGS. Only the Invisalign group showed a significant decrease in maxillary anterior alignment (*P = 0.0156*). Also, both Invisalign (*P = 0.002*) and Braces (*P = 0.0156*) groups showed significant decreases in total alignment, however, the decrease in Invisalign was significantly greater than that in the braces group (*P = 0.034*). Overall, the paper was given a grade of D, according to the Canadian Task Force table of Recommendation Grades for Specific Clinical Preventive Actions. The paper scored 77% on the "Checklist to Assess Evidence of Efficacy of Therapy".

In the third study, Miethke *et al.* conducted a prospective non-randomized clinical trial in order to assess gingival health and plaque accumulation between two groups of patients.

Improvements in periodontal health were measured objectively using GI, PBI, PI, and SPD tests in specific teeth (Please see Methodology for further details). Evaluation was conducted by a single examiner and his calibration status was not reported. Also no baseline measurements were performed in either group. The data were analysed and compared using Box-Whisker-Plots. It was found that the plaque accumulation significantly increased in the braces group as compared to Invisalign (*P<0.05*). Also study stated that GI, PBI, and SPD were not significantly different, however the power was not reported. The paper scored 77% on the "Checklist to Assess Evidence of Efficacy of Therapy". Due to the inconsistent data that was

presented, this paper was given a grade of I according to the Canadian Task Force Table of Recommendation Grades for Specific Clinical Preventive Actions.

DISCUSSION:

Invisalign was designed to be used in patients with Class I malocclusion and mild crowding/spacing. Literature available from the manufacturer claims that Invisalign can be used in most patients and "has been proven to be effective". However, based on the current literature available this critical appraisal suggests that Invisalign can be used only under specific conditions (please, refer to Methodology for the list of conditions) and is less effective compared to traditional orthodontic treatment. From the three papers that were selected to be of the highest level of evidence, two scored the grade of D, fair evidence to recommend against the use of Invisalign. The third study scored a grade of I, or insufficient evidence to make a recommendation.

The study performed by Djeu *et al*. showed that overall, Invisalign did not treat malocclusions as efficaciously as traditional fixed appliances. Although this study was a retrospective clinical trail, and therefore of fairly strong design, (II-2, as per the Canadian Task Force), it had some limitations. A primary area of concern was the population being examined. A selection bias was present because all the subjects were from a single office in New York; no individuals outside the New York-based practice were included. Therefore, the results of the study may only be applicable to the individuals in this particular practice but may not apply to people in the surrounding area outside of the practice. Furthermore, the study did not mention whether the subjects were matched for gender or ethnicity.

Another factor is that a significant difference existed between the average ages of the two samples. The article states however, that because the individuals in both samples were

adults who had stopped growing, the ability to move teeth with orthodontic forces was equal in both groups. Studies suggest that initially the rate of tooth movement is slower in adults, however once tooth movement has reached a "linear phase", rate are similar (R. Yen *et al*.). A future study would benefit from controlling this potential confounder.

Additionally, the subjects chosen for the Invisalign group were the first 48 cases that the orthodontist had performed. It would have been favourable to have used an operator with more experience to have a larger pool of cases from which to randomly draw a sample. Also, an operator with more experience would ensure that the cases were treated as effectively as possible because there may be a learning curve associated with the Invisalign technique.

Comparing the OGS scores of the Invisalign group to the control group revealed that Invisalign had significantly poorer OGS scores than fixed braces and that the passing rate (based on the OGS) score was also lower for Invisalign. Of the eight categories within the OGS, four categories were found to be significantly inferior in the Invisalign group; buccolingual inclination, occlusal contacts, occlusal relationships and overjet. The poor scores in occlusal relationships and overjet indicate that Invisalign is not as proficient at performing anterior-posterior corrections as traditional braces. Also, the significantly poorer scores in buccolingual inclination suggest that Invisalign may not correct crossbites as efficaciously as traditional orthodontics.

Furthermore, there was a statistically significant difference in the length of treatment required to complete the case. The Invisalign treatment took an average of 1.4 years while the control group took an average of 1.7 years. This was a benefit for the Invisalign group; aesthetically minded patients may be attracted to shorter treatment times as well as the "invisible" nature of the intervention. Although this was a positive outcome for the Invisalign

group, the end result as scored by the OGS, was inferior to a case completed with traditional orthodontics. This suggests that a shorter treatment time is not advantageous if the outcome of improved aesthetics and function is not satisfied by Invisalign as effectively as traditional methods.

However, patients may still prefer Invisalign treatment, regardless of treatment outcome, due to improved aesthetics, reduced treatment time and the ability to remove the appliance during meals and while performing oral hygiene (Align Technology, 2008).

In the next paper by Kuncio et al., Invisalign was shown to have more relapses than the braces group. Even though the mandibular anterior teeth relapsed significantly in both groups, the maxillary anterior teeth relapsed significantly only in the Invisalign group. This is significant both statistically and clinically since maxillary anterior tooth alignment is the most visually noticeable characteristic of one's mouth, and is the main reason why one would seek orthodontic treatment. The treatment effect was deemed to be beyond chance, precise, and large enough to be clinically important, however several drawbacks exist for this study.

Firstly, the examiners' calibration was not stated and the quality of the impression-taking was not investigated, thus the accuracy of the data may be questionable. Thirdly, a small sample size of only 22 patients was used. Because of these limitations, the results of this study may be not highly generalizable, and further investigation is warranted by the author.

Additionally, the sample used in this study was part of the same sample used by Djeu *et al*., 2005. Therefore the same factors apply this study, as in the previous study.

In the study by Miethke *et al.*, it was found that the plaque accumulation significantly increased in the braces group as compared to Invisalign, while GI, PBI, and SPD were not

significantly different in two groups. The first and the most important flaw was that no baseline measurements were done for any of the measurements rendering the results unreliable. Secondly, the examiners' calibration was not stated. Thirdly, the paper states that three appointments, during which the measurement were done, were spaced during 6 months, however the appointments were not taken at the same times for the patients, thus contributing to lower reliability of the results. Fourthly, the level of oral hygiene was not measured between two experimental groups. Finally, no power value was reported for the findings that were not reported significantly different, thus the risk of Type II error (false negative) is unknown. Due to a large number of flaws, the results of the study by Miethke *et al*. may not be considered reliable and thus were given a grade of I according to Canadian Task Force guidelines.

Some flaws that were inherent to all of the three studies include the short time span for the experiments to take place, lack of randomization for the patients, small sample size and sample selection bias, since all the patients in their respective studies were selected from only one practice.

The evidence from this report suggests that Invisalign scored inferior to the traditional Invisalign in terms of orthodontic tooth movement and ability to produce acceptable post-retention results. In addition, according to the current pricing for orthodontic treatment Invisalign costs about a thousand dollars more per treatment, as reported by Dr. Sunjay Suri, staff orthodontist at University of Toronto. Technology assessment table was created fro Invisalign, and one can see that evidence from both Kuncio *et al*. and Djeu *et al*. places Invisalgn in the least favourable category – both inferior results and higher price (See Appendix C)

Despite an increase in cost, based on the current appraisal the most current and available evidence suggests that the efficacy remains inferior to that of traditional braces.

However, the technology assessment table does not take into account other aspects that contribute to decision making. For instance, a patient may consider the superior aesthetics and shorter overall treatment time of Invisalign to be worth investing additional money.

Despite the higher price and inferior ability to cause orthodontic tooth movement as well as inferior ability to produce acceptable post-retention results, one needs to consider the fact that Invisalign may still be an acceptable treatment option for the patients seeking an aesthetic treatment if their condition fits the Invisalign criteria.

Although factors such as age, gender, and ethnicity were found similar in the studies, further studies should address such issues as the need for baseline measurements, random sampling methods, valid operator calibration, and should include a larger sample size.

Not all outcomes were examined, however, the selected studies have examined the outcomes most important to orthodontic treatment from the perspective of the practitioner. Ability to correct malocclusion was objectively measured by ABO examinations, a standardized and well-accepted measure. Periodontal health was objectively measured using PI, PBI, GI, and SPD, which are also standardized and well-accepted. Also, studies of stronger design would be preferred, such as clinical trials, as an RCT may be difficult to accomplish due to ethical reasons. Also, there is need to address other relevant outcomes such as costs, changes in aesthetics, and TMJ functioning while undergoing orthodontic treatment.

In addition, the future studies of Invisalign need to keep in mind that the aligners continue to evolve in terms of new material characteristics, thus making comparisons between future studies difficult.

CONCLUSION

Overall, the provided evidence is insufficient or opposed to the intervention (level I or D), which suggests using Invisalign is not as efficacious as traditional orthodontic treatment. Given the scarce amount of reliable evidence available, it is suggested that more studies are required to be able to draw further conclusion.

An evidence-based dental practice aims on providing the best treatment according to the strong scientific evidence, however, one should also realize that scientific evidence should not automatically determine the selection of the treatment option. Many factors should be evaluated to determine whether the intervention benefits are worth the associated costs. Such factors, such as cost of the treatment and the aesthetic concerns of the patients, should be factored into the treatment considerations in order to provide comprehensive patient-centered and evidence-based care.

APPENDIX A

Please refer to:

Cook DR *et al.* Comparison of university and private-practice orthodontic treatment outcomes with the American Board of Orthodontics objective grading system. Am J Orthod Dentofacial Orthop. 2005 Jun;127(6):707-712.

APPENDIX B

Data Abstraction Form

Abstracting the evidence for a proposed new treatment

Authors, (Title), Year of Publication

Population description (Location, age, sex, representative or special, disease status)

Intervention (Test treatment)

Control (Control treatment or placebo)

Outcome

Critical appraisal comments/score

Conclusion

Design strength and classification of recommendation

APPENDIX B Table of data abstractions

Article	Population	Intervention	Control	Outcome	Critical Appraisal/Checklist Score	Conclusion/Design Strength and Classification of Recommendation
Garret Djeu et al. (Outcome assessment of Invisalign and Traditional Orthodontic Treatment Compared with the American Board of Orthodontic Objective Grading Sysem), 2005. Data collected by Christopher Kirk, Feb 26th, 2008. Retrospective Case-Control	2 groups of 48 patients, NY, USA. -Average Age of Intervention Population: 33.6 years -Average age of Control Population: 23.7 years Inclusion Criteria 1.) Patient's malocclusion fell within the treatment guidelines provided by Align Technology 2.) Pretreatment Discrepancy Index (DI) scores had no statistical differences	N= 48 Intervention: Each patient completed orthodontic treatment solely using Invisalign.	N= 48 Control: Each patient completed orthodontic treatment solely using tip edged fixed appliances.	-Improvement in Aesthetics and Function of occlusion -Outcome objectively measured using the Objective Grading System (OGS) score -OGS consists of 8 categories and an overall score -Overall OGS score for Invisalign was –45.35 and –32.21 for Control, a statistically significant difference (P<0.0001) differences between groups. -20.8% Invisalign cases and 47.9% of control cases had passing OGS scores, a statistically significant difference (P=0.0052) -Treatment duration was shorter for Invisalign compared to Control (P=0.0138)	-Inter-examiner reliability was controlled, no significant differences (P<0.05) -Discrepancy Index (DI) was used to control for initial population -Practitioner was ABO certified. -selection bias, small sample size from one office -statistically significant difference in average age of samples (P<0.0001) -Practitioner had no previous experience with Invisalign -Periodontal condition, tobacco use, sex and other confounders were not considered Checklist Score: 11/13 (76.9%)	-The efficacy of Invisalign is less than traditional braces for the improvement of aesthetics and function as shown by the OGS values. -Further studies should be completed with improved samples Research Design Rating: II-2 Recommended Grade: D

APPENDIX B Table of data abstractions

Article	Population	Intervention	Control	Outcome	Critical Appraisal/Checklist Score	Conclusion/Design Strength and Classification of Recommendation
Kuncio et al., (Invisalign and Traditional Orthodontic Treatment Postretention Outcomes Using the American Board of Orthodontics Objective Grading System), 2007 Data Collected by Val Dabuleanu February 20, 2008. Retrospective Case Control Study	New York City, USA N = 22, 20 female, 2 male Patients treated solely with either tip-edge fixed appliances or removable Invisalign aligners. *All extraction cases were removed from the study	N = 11 treated by Invisalign only	N=11 treated by Tip-edge fixed appliances	Both groups showed significant decreases in total alignment (Invisalign = -2.1 +/- 1.64, P = 0.002) versus braces (-1.36 +/- 1.20, P = 0.0156) Invisalign alignment decreased more than braces (P = 0.034)	Group was similar in gender, age, ethnicity, retainer wear, treatment, and post-treatment lengths Inter-examiner reliability was assessed and no difference was found Quality of impression taking was not controlled for. Only successful Invisalign cases were considered Checklist Score = 11/13 (76.9%)	Post-retention of Invisalign was inferior to that of fixed appliances. Research Design Rating: II-2 Recommended Grade: D

APPENDIX B Table of data abstractions

Article	Population	Intervention	Control	Outcome	Critical Appraisal/Checklist Score	Conclusion/Design Strength and Classification of Recommendation
Rainer-Reginald Miethke and Silke Vogt. A Comparison of the Periodontal Health of Patients during Treatment with the Invisalign® System and with Fixed Orthodontic Appliances 2005 Data collected by Trent Sayers, February 25, 2008. Prospective Clinical Trial, Non-randomized.	Thirty consecutive patients each with fixed orthodontic appliance s with aligners were examined at three consecutive control visits for their periodontal condition. All individuals were part of the clientele of the Department of Orthodontics and Dentofacial Orthopedics of the Charite	N = 30 Intervention: Each patient fitted using Invisalign.	N = 30 Control: Each patient fitted with fixed orthodontic appliances.	Periodontal health was measured using 4 measurements: Gingival Index (GI), Papillary Bleeding Index (PBI), Sulcus Probing Depth (SPD). Plaque accumulation was measured using Plaque Index (PI). Central Incisor to 1st Molar were measured for GI, PI, and PBI. 1st molar and 1st premolar were measured for SPD, GI, PBI, and SPD were not significantly different (P = 0.05) PI was significantly different at P < 0.05	Failed to state at which point in the treatment the appointments took place. Failed to state whether the operator was calibrated. Level of oral hygiene was not assessed among patients. No baseline measurements were completed Power of the study was not stated for the results that were found not significantly different. Checklist Score: 11/13 (76.9%)	No significant difference was found etween Invisalign and Braces for GI, PBI, and SPD. Significant difference was found between Invisalign and braces for PI. Strength: Research Design Rating: II-2 Recommended Grade: I

APPENDIX C

Table 1.1 Technology Assessment Table

Compared to Traditional braces, Invisalign costs…	Compared to Traditional braces, Invisalign works…		
	BETTER	**SAME**	**WORSE**
LESS			
SAME			
MORE			Kuncio (II-2, D) Djeu (II-2, D)

APPENDIX D

University of Toronto
Community Dentistry

Checklist to Assess Evidence of Efficacy of Therapy or Prevention

Citation: _____

_____

1. Was the study ethical? ___
2. Was a strong design used to assess efficacy? ___
3. Were outcomes (benefits and harms) validly and reliably measured? ___
4. Were interventions validly and reliably measured? ___
5. What were the results?

   - Was the treatment effect large enough to be clinically important? ___
   - Was the estimate of the treatment effect beyond chance and relatively precise? ___
   - If the findings were "no difference" was the power of the study 80% or better ___

6. Are the results of the study valid?

   - Was the assignment of patients to treatments randomised? ___
   - Were all patients who entered the trial properly accounted for and attributed at its conclusion? e.g.,
     i) Was loss to follow-up less than 20% and balanced between test and controls or, if not, the effects of those losses satisfactorily accounted for ___
     ii) Were patients analysed in the groups to which they were randomised? ___
   - Was the study of sufficient duration? ___
   - Were patients, health workers, and study personnel "blind" to treatment? ___
   - Were the groups similar at the start of the trial? ___
   - Aside from the experimental intervention, were the groups treated equally? ___
   - Was care received outside the study identified and controlled for ___

7. Will the results help in caring for your patients?
   Were all clinically important outcomes considered? ___
   Are the likely benefits of treatment worth the potential harms and costs? ___

Adapted from: Fletcher, Fletcher and Wagner. Clinical epidemiology – the essentials. 3rd ed. 1996, and Sackett et al. Evidence-based medicine: how to practice and teach EBM. 1997

APPENDIX E

Table 1.2 Summary of Critical Appraisal Checklist Scores

Checklist criteria for assessing evidence of efficacy of therapy Modified by Dr. J. Leake of the Community Dentistry Department at the University of Toronto (Canada). Adapted from Fletcher *et al.* [30]	Djeu *et al.*	Kuncio *et al.*	Miethke *et al.*
The study was ethical.	Y	Y	Y
A strong design was used to assess efficacy.	Y	Y	Y
Outcomes were validly and reliably measured.	Y	Y	Y
Interventions were validly and reliably measured.	Y	Y	Y
Treatment effect was large enough to be clinically important.	Y	Y	Y
Estimate of the treatment effect was beyond chance and relatively precise.	Y	Y	Y
Power of study was better than 80% for "no difference" findings.	n/a	n/a	N
Assignment of patients to treatments were randomized.	N	N	N
Loss of follow-up was less than 20% and balanced between test and controls.	n/a	n/a	Y
Patients were analyzed in the groups to which they were randomized.	n/a	n/a	Y
The study was of sufficient duration.	Y	Y	Y
The patients, health workers, and study personnel were "blind" to treatment.	N	N	N
The groups were similar at the start of the trial.	Y	Y	N
Aside from the experimental intervention, the groups were treated equally.	Y	Y	Y
Care received outside the study was identified and controlled for.	n/a	n/a	n/a
All clinically important outcomes were considered.	Y	Y	N
The likely benefits of treatment are worth the potential harms and costs.	N	N	N
Raw score:	10/17	10/17	10/17
Adjusted Score: (eliminated non-applicable items)	10/13	10/13	10/16
Percentage Score:	76.9%	76.9%	62.5%

Y = Yes (1 point), N = No (zero point), n/a = Not Applicable (removed at adjusted score)

APPENDIX F

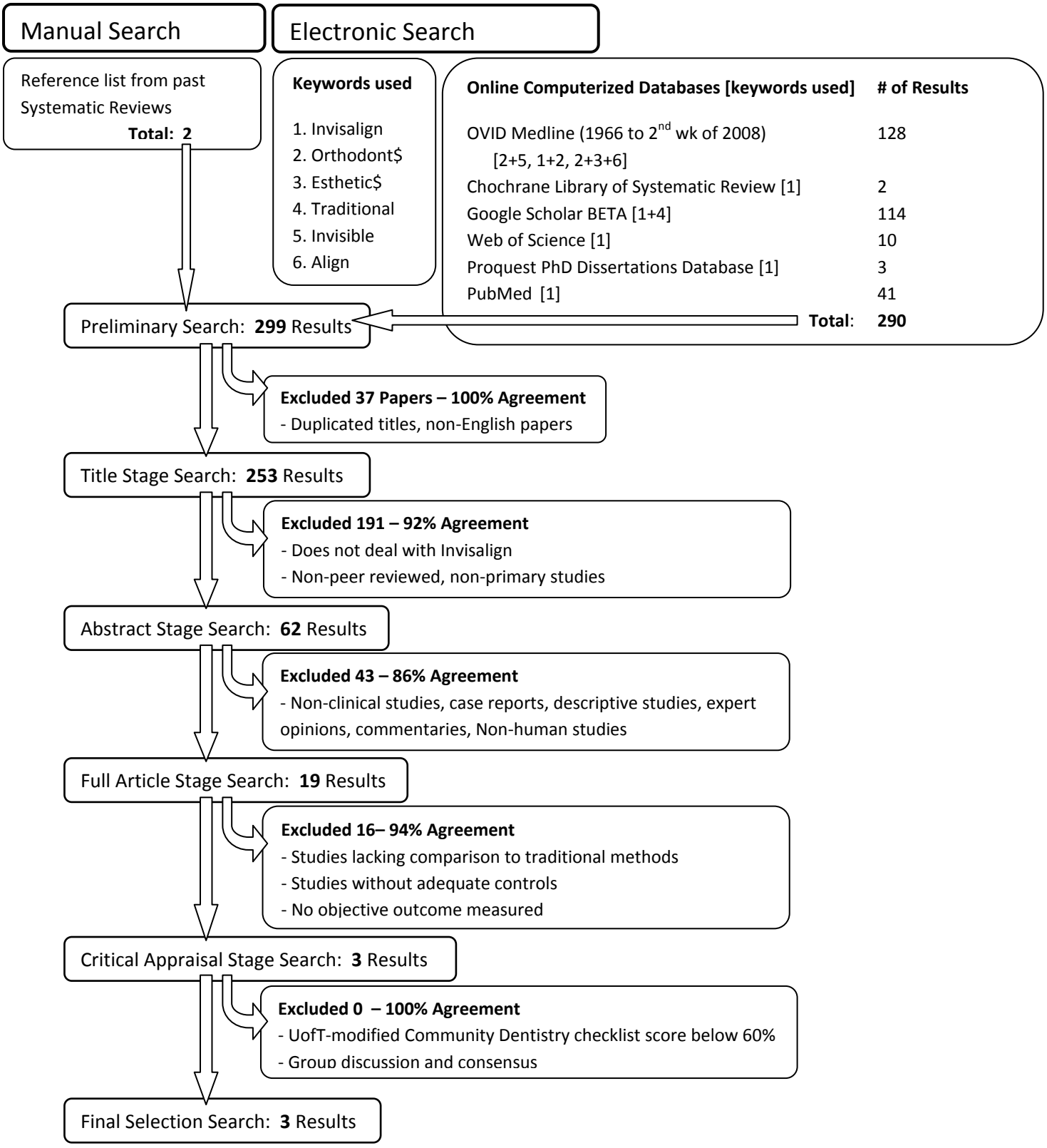

Figure 1.1 Flow diagram of literature search

APPENDIX G

TABLE 1.3 Table of Literature Selection at the Full Article Stage

No.	Name of Article	Type of Study
1	Akhlaghi A,Tufekci E, Lindauer SJ, Fowler C, Weiss B. Outcome of Invisalign and traditional orthodontic treatment using PAR index. Conference poster. Virginia Commonwealth University (USA), 2007. [11]	Cohort
2	Bollen AM, Huang G, King G, Hujoel P, Ma T. Activation time and material stiffness of sequential removable orthodontic appliances. Part 1: Ability to complete treatment. Am J Orthod Dentofacial Orthop. 2003 Nov;124(5):496-501. [12]	Randomized Control Trial
3	Clements KM, Bollen AM, Huang G, King G, Hujoel P, Ma T. Activation time and material stiffness of sequential removable orthodontic appliances. Part 2: Dental improvements. Am J Orthod Dentofacial Orthop. 2003 Nov;124(5):502-8. [13]	Randomized Control Trial
4	Clements KM, Bollen AM, Huang GJ, et al. Randomized trial on frequency of activation and stiffness of Invisalign appliances (abstract 2917). J Dent Res 2003;82(special issue B June):B-374. [14]	Randomized Control Trial
5*	Djeu G, Shelton C, Maganzini A. Outcome assessment of Invisalign and traditional orthodontic treatment compared with the American Board of Orthodontics objective grading system. Am J Orthod Dentofacial Orthop. 2005 Sep;128(3):292-8. [15]	Case-Control
6	Duong T, Kuo E. Finishing with invisalign. Prog Orthod. 2006;7(1):44-55.[16]	Commentary
7	Erdman-Spain SA. Evaluation of expected and actual Invisalign (reg) treatment outcomes. Dissertation. University of Illinois at Chicago, 2006, 66 pages. [17]	Case-control
8	O'Shaughnessy K, Taylor M, McGorray S, Dolce C, Wheeler T. Comparison of PAR Done on Stone and Invisalign® Digital Models. Conference poster. University of Florida (USA), 2004. [18]	Case-control
9	Kamatovic M. A retrospective evaluation of the effectiveness of the Invisalign appliance using the PAR and irregularity indices. Dissertation. University of Toronto (Canada), 2004, 117 pages. [19]	Case-Control
10	Kravitz ND. A prospective clinical study evaluating the efficacy of tooth movement with Invisalign. Dissertation. University of Illinois at Chicago(USA), 2007, 42 pages. [20]	Cohort Study
11*	Kuncio D, Maganzini A, Shelton C, Freeman K. Invisalign and traditional orthodontic treatment postretention outcomes compared using the American Board of Orthodontics objective grading system. Angle Orthod. 2007 Sep;77(5):864-9. [21]	Case-control
12	Lawton BT. Orthodontic Psychosocial Impacts. Dissertation. University of Florida (USA), 2003, 26 pages. [22]	Cohort
13	Meier B, Wiemer KB, Miethke RR. Invisalign--patient profiling. Analysis of a prospective survey. J Orofac Orthop. 2003 Sep;64(5):352-8. [23]	Cohort

14	Miethke RR, Brauner K. A comparison of the periodontal health of patients during treatment with the Invisalign system and with fixed orthodontic appliances. J Orofac Orthop. 2007 May;68(3):223-31. [24]	Randomized Clinical Trial
15*	Miethke RR, Vogt S. A comparison of the periodontal health of patients during treatment with the Invisalign system and with fixed orthodontic appliances. J Orofac Orthop. 2005 May;66(3):219-29. [25]	Non-randomized Clinical Trial
16	Miller KB, McGorray SP, Womack R, Quintero JC, Perelmuter M, Gibson J, Dolan TA, Wheeler TT. A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment. Am J Orthod Dentofacial Orthop. 2007 Mar;131(3):302.e1-9. [26]	Longitudinal Cohort
17	Nedwed V, Miethke RR. Motivation, acceptance and problems of invisalign patients. J Orofac Orthop. 2005 Mar;66(2):162-73. [27]	Cohort
18	Brown P, Bayirli B, Gaynier B, Vazquez D. Comparison Of Invisalign To Fixed Orthodontic Treatment Using ABO Indices. Conference poster. University of Detroit (USA), 2007. [28]	Case-Control
19	Phan X, Ling PH. Clinical limitations of Invisalign. J Can Dent Assoc. 2007 Apr;73(3):263-6. [29]	Commentary

*Studies that were ultimately selected for the current literature review

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