# TREATMENT EFFECTIVENESS OF THE INVISALIGN® SYSTEM:

# A SYSTEMATIC REVIEW

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## ABSTRACT

The aim of the investigation was to search the current literature (from April 2005 to December 2012) and determine the effectiveness of orthodontic tooth movement using the Invisalign system. With changes in attachments implemented within the past few years, a more recent appraisal of the available literature is of value. It is expected that this systematic review will provide a more up-to-date understanding of the treatment effects (efficacy in tooth movement and stability) of the Invisalign system. Additionally, an evaluation of the indications and case selection using Invisalign will be conducted

A computerized search was conducted using PubMed, Evidence Based Medicine (EBM) Reviews Database (Cochrane Database of Systematic Reviews), Database of Abstracts of Reviews of Effects and Cochrane Central Register of Controlled Trials, Science Direct, and Thomsen's ISI Web of Science.

Inclusion criteria that were to be satisfied by the literature search results were publications in English and human clinical trials. Studies not pertaining to the question of clinical effectiveness of Invisalign were selected for exclusion.

Case reports, book chapters, and review papers were considered separately for analysis and contribution to the general information gathering in the systematic review. Book chapters were excluded.

Quality assessment was performed on the studies that fulfilled the inclusion criteria. The quality and design of the study was considered. Of the studies that passed the quality assessment stage, a thorough evaluation was completed. Summaries of the included articles were prepared and information regarding study design, subjects, treatment times, and outcomes were organized

in tabulated form. Appraisal of the included studies was performed using the 2010 CONSORT statement and 2009 ADA Clinical Recommendations Handbook.

Overall, of the 271 studies reviewed (Stage I), 23 were selected for further review (Stage II). Ultimately, 10 studies were included in the systematic review (Stage III).

In summary, after thorough analysis of the studies, it has been shown that Invisalign is an effective appliance for minor space closure, lingual constriction, and correction of anterior rotations and marginal ridge height discrepancies. However, Invisalign lacks the ability to correct anteroposterior discrepancies, occlusal contacts, extrusion, and rotations greater than 15 degrees. While the achieved and predicted tooth movement discrepancy was very minimal, it was found that overbite must be overcorrected.

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## TABLE OF CONTENTS

Page

## LIST OF FIGURES

FIGURES Page



## LIST OF TABLES

TABLE

# CHAPTER 1

# INTRODUCTION

The field of orthodontics advances with hypothesis testing and innovative product development. Orthodontists must think about how to advance themselves as expert clinicians to accompany the advancing field. Innovation aided by technology will allow for more communication-enhancing, effective, and accurate treatment. Orthodontists must not only think about the patient in the present, but they must also be able to utilize the innovative tools at their disposal to achieve the most stable, health-supporting, and esthetic outcomes. The ultimate goal of the orthodontist is to improve the patient's overall quality of life.

The public perception of quality of life has changed over the past few decades. Quality of life in modern times has taken on a new form: one emphasizing beauty and youth more than ever before. Plastic surgery and elective esthetic procedures have increased dramatically.

Similarly, orthodontic treatment in the adult population has been on the rise in recent times. In contemporary society, an emphasis on facial and dental esthetics has motivated adults to seek orthodontic treatment. With the development of new esthetic appliances, such as Invisalign®, adult patients are able to experience not only an esthetic treatment process but also achieve an esthetic treatment result. With esthetics in high demand, there has been an overwhelming rise in the number of Invisalign cases (Invisalign 2012).

Since the establishment of traditional fixed orthodontic appliances, many new alternative orthodontic appliances have been engineered to achieve the dental, alveolar, and skeletal goals set out by orthodontists. With the advent of any new appliance comes the difficult task of evaluating its clinical performance and efficacy. Evaluation of an appliance's clinical performance and effects depends profoundly on the clinician's skill and experience as well. To date, there have not been many publications in the literature that evaluate the treatment outcomes and effects of cases treated with Invisalign. The lack of research in case-controlled settings has made it quite difficult for clinicians to determine efficacy of the appliance. Controversy also exists about the indications for aligner treatment. Align Technology has claimed that 90% of orthodontic patients are candidates for Invisalign. Of these patients are those with mild to moderate crowding (1-6 mm), nonskeletal constricted arches, and those who have had relapse after fixed appliance therapy (Boyd 2001). Evidence-based health care seeks to provide the best possible treatment that is based on a collection of sound evidence. A recent systematic review of the Invisalign System was performed and found no strong conclusions could be made about the indications, treatment effects, and limitations of the appliance (Lagravere 2005). Since this systematic review was conducted, changes to the appliance have been implemented along with an urging for randomized clinical trials that follow the CONSORT statement.

The purpose of this study is designed to determine the treatment effects of the Invisalign System using more recent studies. These treatment effects are inclusive of indications, limitations, and treatment outcomes of Invisalign.

# CHAPTER 2

# LITERATURE REVIEW

## 2.1 Treatment Planning Process

The treatment planning process is one of the most fundamental aspects of a patient's orthodontic management. It may be further divided into the treatment aims and treatment plan. The plan is a goal-centered approach that considers the appliance system that will be implemented. It is the plan, however, that must be preceded by achievable aims that will bring about a healthy and esthetic treatment outcome. Some of these aims include: improving dental health, relieving crowding, correcting the buccal occlusion, reducing overbite and overjet, and aligning the teeth. Based on these aims, the plan is constructed with consideration for the mandibular arch, maxillary arch, buccal occlusion, and choice of appliance (Roberts-Harry 2003).

### *2.1.1 Different Treatment Modalities*

In order to achieve the most favorable treatment outcome, correct appliance selection is crucial. Orthodontic appliances conveniently fall into four categories: removable, fixed, functional, and extra-oral. It has been believed for some time that removable appliances are capable of only limited tooth movements, while the preferred fixed appliances are said to more accurately position the teeth.

Removable appliances have received much criticism in the past, because prior studies had shown poor treatment outcomes. Richmond and Shaw demonstrated that fifty percent of cases treated with removable appliances had either not improved or actually

worsened. It has thus been highly recommended that removable appliances be only considered in tipping, block movements, overbite reduction, space maintenance, and retention.

Fixed appliances tend to be the appliance of choice for most orthodontists, because it is believed that teeth may be more fully controlled in three dimensions of space. Multiple teeth may be translated simultaneously and a more precise treatment outcome may be established.

Functional appliances are a modality of orthodontic treatment surrounded by controversy, due to disagreeing views on the exact physiologic mechanism of action, be it dento-alveolar or skeletal. While these appliances may allow for considerable tooth movement, precision in tooth placement, rotation correction, and effective bodily tooth translation may not be possible. Extra-oral appliances, including headgear and facemask devices, may provide an external source of anchorage and restrain skeletal growth (Roberts-Harry 2006).

### *2.1.2 Decision-Making Process of Selection of Orthodontic Treatment Modality*

The decision-making process in clinical orthodontics consists of a model that involves interactions between patient input, appearance and psychosocial needs, functional needs, risks of treatment, and doctor input. Upon establishment of a diagnostic problem list, the clinician must rank each problem in priority of its therapeutic modifiability and importance to the patient's esthetic, functional, and psychosocial needs. "Therapeutic modifiability" refers to the clinician's ability to predict the "achievable optimum" when utilizing a given treatment modality in consideration of the treatment

goals for a patient (Ackerman 2004). Therapeutic modifiability must be weighed against the problems on the diagnostic problem list in order to establish a final treatment plan.

## 2.2 Adult Orthodontic Treatment

During the past few decades, adult orthodontic treatment has become more commonplace. In 1970, the percentage of adults receiving orthodontic treatment was 5%. By 1990, the percentage increased to 25%. Recent studies have demonstrated that the prevalence of adult malocclusion is similar to or greater than malocclusion rates in children and adolescents (McLain 1985). Searcy and Chisick determined that 77 percent of U.S. Army recruits exhibited a malocclusion warranting need of orthodontic treatment (Searcy 1994). According to the Third National Health and Nutrition Examination Survey, about 50 percent of adults exhibit severe overjet, 47.7 percent have a deep bite, and 6 percent possess an anterior crossbite. The main intra-arch problem in adults in the United States and Western Europe is crowding, followed by spacing, crossbites, and rotated teeth. (Proffit 1998). The prevalence of malocclusion in Western European adults is between 40 and 76 percent (Salonen 1992, Burgersdijk 1991).

Adult orthodontic treatment may either be classified as adjunctive or comprehensive. Adjunctive orthodontic treatment can be done in concert with or prior to other dental procedures that are necessary to control disease and restore function. Treatment may involve de-rotating malaligned teeth or alleviating crowding in order to facilitate proper cleaning and plaque control and improve periodontal health. Treatment may also be needed to align adjacent teeth, consolidate space, and establish proper dimensions prior to implant placement (Tulloch 1993). Comprehensive orthodontic

treatment aims to combine dental and facial esthetics, ideal occlusal relationships, and dentoalveolar stability. Comprehensive orthodontic treatment usually warrants at least 18 months of treatment and addresses nearly all teeth in the dental arches.

### *2.2.1 Indications for Comprehensive Orthodontic Treatment*

Indications for comprehensive orthodontic treatment include unacceptable esthetics, decreased masticatory function, and trauma predisposing a patient to caries or periodontal disease. Many studies have shown that almost 50% of adults seeking orthodontic treatment are motivated by a desire to improve their dental and facial esthetics. Other factors include psychosocial factors, dental/periodontal health, occlusal function, and general health and speech (Nattrass 1995, Sergl 1997, Breece 1986, Lew 1993).

### *2.2.2 Discomfort with Orthodontic Treatment*

The most common feelings of discomfort that patients undergoing orthodontic treatment sense are tension, pressure, soreness of teeth, and pain (Ngan 1989). Individual psychologic states have great bearing on the discomfort experienced and reported by patients. Studies in psychology have shown that pain is dependent on personal values and expectations such as self-efficacy and treatment outcome (Bandura 1977, Rotter 1966). With progression of treatment, patients adapt to the discomfort experienced as the feelings of pain either diminish or disappear from their focus. One study shows that it takes about 14 days for this pain adaptation to occur for patients undergoing orthodontic treatment (Brown 1991). The type of orthodontic appliance must also be considered

when evaluating pain experienced by patients. It has been asserted that both fixed and removable orthodontic appliances cause an equal amount of discomfort to the patient (Oliver 1985). On the contrary, Sergl and Stewart both found that fixed and functional appliances produce greater pain responses when compared to removable appliances (Sergl 1998, Stewart 1997).

*2.2.3 Periodontal Concerns*

Bragger and Lang have defined periodontal disease as "an inflammatory disease triggered by bacteria that supragingivally affect the gingiva (gingivitis) and subgingivally affect the supporting connective tissue and alveolar bone (periodontitis)" (Bragger 1996, Sanders 1999). Adults have an increased prevalence of periodontal disease when compared to children and adolescents. Localized bone loss will not necessarily prevent orthodontic treatment from successfully achieving goals; however, it is necessary to control periodontal disease prior to initiating orthodontic treatment.

One systematic review suggested that patients with an existing malocclusion had worse periodontal health than patients without a malocclusion. Recommendations to patients for orthodontics, however, could not be given as treatment for prevention of periodontal problems (Bollen 2008).

In patients that exhibit good periodontal health and proper oral hygiene care, properly sequenced orthodontic treatment does not cause significant long-term effects on periodontal attachment and bone levels. On the other hand, in patients that exhibit active periodontitis, orthodontic tooth movement may accelerate the disease process, despite good oral hygiene. Orthodontic bodily tooth movement into a plaque-induced infrabony

defect can be successfully done, however, if the patient's diseased lesion is eliminated prior to orthodontic tooth movement with maintenance of good oral hygiene. (Artun 1987, Thilander 1996).

Fixed orthodontic appliances can hinder plaque control (Buttke 1999). If the patient is unable to maintain proper plaque control, fixed orthodontic appliances can lead to moderate to severe gingival hyperplasia. This is reversible with proper oral hygiene and removal of the orthodontic appliances.

### *2.2.4 Root Resorption and Adverse Effects of Treatment*

Orthodontically-induced inflammatory root resorption can compromise the success of orthodontic treatment and reduce longevity of the teeth. It has been asserted that the main risk factors for root resorption are conical roots with pointed apices, dilacerations, and a history of trauma (Proffit 2007). The amount of orthodontic tooth movement has been positively correlated with the extent of root resorption (Deshields 1969, Sharpe 1987, Parker 1998). In one study, it was determined that after six months of orthodontic treatment, clinically significant resorption (greater than 2 mm) was diagnosed in 4% of the patients. It was also found that predisposing risk factors for root resorption did not have any bearing on the actual amount of resorption after those six months (Makedonas 2012).

### *2.2.5 Patient Satisfaction and Expectations*

Treatment concerns of adult patients must be taken into consideration prior to commencing treatment. It has been found that nearly half of adult subjects questioned

cited embarrassment associated with wearing appliances as the primary reason for not seeking orthodontic treatment (Breece 1986, Lew 1993). Among the adults who actually initiated orthodontic treatment, however, only 20% reported an adverse social effect. Other concerns expressed by adults included high cost, duration of treatment, and fear of pain (Lew 1993).

When treatment outcomes are considered, successful orthodontic treatment can be defined as treatment that achieves the objective and subjective goals that were outlined at the beginning of treatment. Objective goals are treatment goals that the orthodontist would like to achieve. On the other hand, subjective goals are patient-driven goals, such as facial attractiveness. In the majority of cases, there is good correlation between objective and subjective goals (Proffit 1998). One study found that almost 100 percent of treated adults stated that they would undergo orthodontic treatment if they had to do it over again. Many studies have been able to show that after completion of orthodontic treatment, adults develop a more positive self-image and self-confidence, better body image, and improved career opportunities and social life (Lew 1993, Varela 1995).

Adults who complete orthodontic treatment also place an added value on their dentition. They tend to be highly motivated when it comes to maintaining oral hygiene and regularly seeking professional dental care. Seeking orthodontic treatment can ultimately benefit both patient and the general dentist (Buttke 1999).

### *2.2.6 Patient Compliance*

Compliance has been defined as "the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides

with medical or health advice" (Haynes 1979). Studies have shown that there is no association between patient compliance and socioeconomic status, quality of life, and education level (Horsley 2007, Dickens 2008, Mandall 2008). Generally, females tend to be more compliant than males (Cucalon 1990). It has been suggested that self-motivation and the rapport between the orthodontist and patient are more significant determinants for patient compliance (Mehra 1998, Brattstrom 1991). Treatment outcome depends greatly upon patient compliance and cooperation.

When removable appliances are considered, patient compliance becomes an even more paramount factor in determining success of treatment. Align Technology developed a compliance indicator, composed of the food dye Erioglaucine disodium salt encapsulated in the aligner for use on patients using Invisalign Teen. In the presence of saliva and oral fluids, the polymer is released and the amount of dye loss will coincide with the amount of time the patient has been wearing the aligner (Abolfathi 2009, Tuncay 2009). Some of the shortcomings of the compliance indicator are the difficulty in ruling out other factors that may cause the dye to fade: drinking with the aligners in the mouth, storing the aligners in water, and cleaning the trays using tablets with oxidizing agents (Schott 2011).

### 2.3 History of Esthetic Removable Appliances

Esthetic, removable appliances have existed since the 1950s as thermoforming was introduced. Since then, the material of choice has evolved from rubber-based and thermo-formed substances to Invisalign's EX30 plastic material.

### *2.3.1 Positioners*

In 1926, Remensnyder had developed the Flex-O-Tite gum-massaging appliance, which was able to bring about minor tooth movements (Remensnyder 1926). Overlay appliances for tooth movement became popularized in 1945 by Kesling's establishment of a simple "tooth positioning appliance" that would allow teeth to move into their ideal positions as well as effectively retain them (Kesling 1945). Nahoum used vacuum-formed dental contour appliances to achieve tooth movement to treat malocclusions, adjunctively utilizing tooth attachments and elastics (Nahoum 1964). Sheridan subsequently introduced Essix clear aligners for tooth movement in 1993.

These clear plastic tooth-moving appliances can be an excellent option for compliant adults and adolescents with mild to moderate alignment issues. The success of achieving treatment goals depends on three factors: force, space, and time (Tuncay 2006).

### *2.3.2 Essix*

The Essix System is based on a single-appliance aligner, which can be adjusted at subsequent appointments to the treatment goals initially outlined. Essix appliances may be fabricated in the office laboratory, thus reducing the cost of fabrication. In order to accomplish tooth movement with this appliance, space within the appliance and space within the dentition must be appropriately created. Space within the appliance can be achieved either by blocking out the working cast or creating a window in the aligner. Creation of space within the dentition may include expansion, extraction, or interproximal reduction. The complexities that arise with expansion and extraction

include failure to coordinate the arches and difficulty in uprighting roots, respectively. In crowded cases, the best approach is interproximal reduction of enamel.

The Essix appliance permits force application on any point on the surface of the clinical crown. A more incisal point of application will allow for more tipping, and a more gingival point will allow for more bodily movement. Two systems utilized in achieving tooth movement with an Essix appliance involve the Hilliard thermoforming pliers and mounding. The first system uses thermopliers to change the appliance through spot-thermoforming. The projections or bumps formed are made toward the tooth surface and heated to approximately 200 degrees Fahrenheit. These projections can help to induce additional force as the treatment progresses. The second system involves adding sequential mounds of composite to the surface of the tooth to enhance tooth movement. Both systems involve the same biomechanical principle, in that force is being applied to the tooth via interference of the plastic returning to it resting state (Tuncay 2006).

**2.4 Align Technology, Inc.**

Align Technology, Inc. was founded in 1997 to create an innovative esthetic appliance. It was engineered to take after principles originally formulated by Remensnyder, Kesling, Nahoum, and Sheridan, while also integrating CAD/CAM (computer-aided-design/computer/aided-manufacture) technology. Align Technology, Inc. was formed by two MBA students, two orthodontists, and a computer engineer. The company is based out of Santa Clara, California and has over 800 employees with divisions in Europe, Mexico, and Costa Rica (Tuncay 2006).

### *2.4.1 Invisalign System*

While the concept of moving teeth with plastic aligners has been present since 1926, the Invisalign System is the first system to incorporate modern technology in a way that makes this concept more efficient and feasible. The Invisalign process requires several steps: acquisition of complete patient records, impression scanning and case setup, ClinCheck review for the clinician, aligner processing, and tray delivery. Each aligner is designed for a maximum of 0.25 to 0.4 mm of tooth movement over a two-week period (Ling 2007). Since 1997, the Invisalign System has improved and has been adapting to meet the needs of clinicians and patients.

#### *2.4.1.1 Clinical Studies*

There was much controversy from the beginning over the limitations of Invisalign in treating moderate to difficult cases. Earlier studies had shown limitations, while more recent studies have shown successfully treated moderate to difficult cases. The main reason for this discrepancy is that the earlier studies were performed within the first four years of the Invisalign system's development. During this stage, there were issues in achieving bodily movement, torquing of roots, extrusions, and rotations of premolars and canines (Boyd 2008).

Among the initial clinical studies investigating Invisalign were two longitudinal clinical trials and one cross-sectional study. These studies established that Invisalign was successful in achieving certain types of tooth movements: tipping, rotations of incisors, and closure of naturally occurring spaces. Intrusion was also found to be a successful

tooth movement (Taylor 2003). The studies evaluated different appliance materials and also established that the protocol of changing aligners every two weeks was more effective than weekly (Bollen 2003, Clements 2003).

*2.4.1.2 Indications and Contraindications for Invisalign*

The Invisalign appliance is most successful in treating malocclusions with mild malalignment (1 to 5 mm of crowding or spacing), deep overbite, non-skeletally constricted arches that can be expanded with limited tipping of the teeth, and mild relapse after previous fixed-appliance treatment. There are, however, cases that are contraindicated or difficult to treat. These cases include: crowding and spacing greater than 5 mm, skeletal anterior-posterior discrepancies of more than 2 mm as measured in cuspid relationships, centric relation and centric occlusion discrepancies, severely rotated teeth greater than 20 degrees, extrusion of teeth, severely tipped teeth more than 45 degrees, teeth with short clinical crowns, and arches with multiple missing teeth (Joffe 2003).

2.4.1.3 *Treat*® Software

Treat Software is utilized by an Invisalign virtual orthodontic technician to "cut" the virtual models and separate the teeth. This allows for individual movement of the teeth to sequence treatment. Originally, in 1997, the cutting process took about 48 hours per case due to software limitations. During this time, there was no virtual gingiva and the process required a lot of time and input from the clinician. The clinician was required to send numerous detailed forms to the company in addition to deciding the proper

sequencing of the teeth based on the treatment plan. Today, aligner staging is performed by Align Technology. Clinicians still take part in the treatment staging process through ClinCheck (Tuncay 2006).

*2.4.1.4 ClinCheck Software*

Once a diagnosis and treatment plan are established, treatment sequencing and mechanics are designed through the Invisalign system software called ClinCheck. ClinChecks are created by technicians from patient records (impressions, bite registration, photographs, and radiographs) and the clinician's treatment form. The ClinCheck is then sent electronically to the clinician for review for potential modifications or acceptance. The three-dimensional virtual representation in ClinCheck allows for diagnostic setups, treatment planning, and evaluations for the clinician. Staging of treatment is displayed, and the clinician is able to examine virtual tooth movement at each stage through navigation tools. The two main components to ClinCheck are a series of computerized images of the patient's teeth from the initial to final stages of movement and pressure-formed clear plastic appliances made from stereolithographic (SLA) models of the images in the first component. Acceptance of the ClinCheck will then initiate creation of the SLA models for final manufacture of the aligners (Tuncay 2006).

*2.4.1.5 Tooth Movement*

Tooth movement using the Invisalign system is planned through staging. Staging is a collection of procedures used to achieve the final projected positions of teeth using

the Treat software. Staging takes into consideration the biologic limitations of tooth movement and the biomechanical principles involved in tooth movement.

With the novel introduction of attachments, forces could be delivered in directions that the plastic aligner itself could not provide. In an analogous manner, attachments served as brackets and the plastic aligner served as the wire (Tuncay 2011). Attachments are geometric composite shapes that are bonded to the facial or lingual surfaces of teeth for the purpose of increasing aligner retention through maximal adaptation to the teeth.

When intrusion is planned, attachments are programmed to be placed on the posterior teeth in order to help anchor the aligner. Extrusive movements are least predictable because the aligner by design must be able to pull away from the teeth. Derotation of cylindrical teeth also poses challenges because of the minimal interproximal surface and undercuts present along the horizontal occlusal plane to the aligner. Buccal and lingual attachments are placed in order to create purchase points for better tracking during rotation movements. Root translation requires that the orthodontic force be applied at the gingival area of the tooth (Kuo 2006).

With the development of the optimized attachments, the system was able to yield desired force vectors, avoid interferences, encourage extrusive movements, and minimize friction for ease of aligner removal.

Planning tooth movement with the Invisalign System may require for overcorrection to achieve the desired outcome. While overcorrection with fixed appliances is done in anticipation of relapse once the appliances are removed, overcorrection with aligners is done to overcome any problems along the way and to achieve the goals of tooth movement. The most common indications for overcorrection

are minor incisor rotations, minor in-and-out discrepancies, minor residual spaces, and minor anterior deep bite. However, due to the inability to determine which teeth may need overcorrection, it is thought to be most effective to add overcorrection stages during and not at the beginning of treatment (Kuo 2006).

An alternative to overcorrection is the use of detail pliers. Additional forces can be applied to the teeth in the aligners. Some common problems that the detail pliers can correct are minor rotations, in-and-out discrepancies, and light interproximal contacts through the placement of dimples in the appropriate positions on the aligners (Kuo 2006).

*2.4.1.6 Advantages and Disadvantages*

The main attraction of Invisalign has been the esthetic appeal of the appliance. However, there are many other advantages that the Invisalign system can offer. Patients who may require minor restorative dental treatment and bleaching have shown to be great candidates for orthodontic treatment (Spears 2004). In comparison to fixed appliances, patients with clear aligners have also reported less discomfort, mucosal irritation, and soreness of the teeth (Miller 2007). Patients who have short roots may also be good candidates for clear aligners. One recent longitudinal study showed no measurable root resorption in 100 consecutively treated Invisalign patients (Boyd 2008, Boyd 2009). Invisalign may also be a great option for patients who have parafunctional habits such as bruxing and grinding. The aligners serve as a thin night guard to prevent further occlusal wear. Recent studies found that in patients with a history of parafunctional habits and pain, clear aligner treatment was able to decrease myofascial discomfort (Nedwed 2005, Miller 2007). Clear aligners have also proven useful in correcting a mild anterior open-

bite. The intrusive effect on posterior teeth due to increased interocclusal distance from the double thickness appliance material can help to close a dental open-bite (Boyd 2006). Similarly, correction of a deep overbite is a major advantage with the Invisalign appliance, because there is more predictability with intrusion mechanics and disclusion of teeth (Boyd 2001, Miller 2002).

One of the greatest disadvantages to the Invisalign appliance is patient compliance. In any removable system, patient self-motivation is fundamental to the success of treatment. Another disadvantage to the appliance is the limitation with extraction cases. Premolar extraction treatment is difficult to manage with the appliance, because it is difficult to maintain the roots and teeth in an upright manner. Bollen found that excessive tipping occurs around premolar extraction sites and that only 29% of patients with two or more premolar extractions had complete space closure with the aligners (Bollen 2003). Other disadvantages to the appliance are the limitations in correcting buccal malocclusions.

Recent improvements to the Invisalign protocol have been established. There have been changes to anterior/posterior corrections, staging for interproximal reduction, attachments, and staging of tooth movements (Boyd 2008). In considering anterior/posterior corrections, it is not being recommended to institute elastic wear from the beginning of treatment. Fewer aligners are required when simultaneous staging is utilized in conjunction with elastics as opposed to distalization. When staging for interproximal reduction, it is important to plan for it when there is little overlap between teeth and thus better access to interproximal contacts. Tooth movements are now staged to occur simultaneously, and the tooth that needs the most movement determines the

minimum amount of stages required. Simultaneous tooth movement is analogous to the leveling and alignment in low friction brackets with a light wire. Attachments are now placed in the middle of the crown instead of 2 mm from the gingival margin (Boyd 2008).

*2.4.1.7 Aligner Material*

The chemical and physical properties of the aligners are what impart the forces to achieve projected treatment goals. Currently, the Invisalign aligner is made of Ex30, a polyurethane plastic of 0.030 mil thickness. The plastic is flexible enough for patient comfort and wear while stiff and durable enough for the required forces and tooth movement. Initial use of this Ex30 material resulted in a yellow discoloration of the aligners, which was then resolved with modifications to the plastic crystalline property (Tricca 2006).

Align conducted experiments with a thicker aligner, Ex40, in order to increase efficacy of tooth movement and reduce the case-refinement rate. Results showed that the use of Ex40 did improve anterior alignment; however, the material did not prevent the need for additional aligners in detailing and finishing cases (Duong 2006).

*2.4.2 Three-Dimensional Imaging*

The Invisalign system would not be possible without the use of 3-D technology. Physical models are able to be converted into virtual three-dimensional models, and polyvinylsiloxane impressions are able to be converted into three-dimensional models via scanning (Lee 2002).

The 3-D virtual model carries several advantages when compared to orthodontic plaster models. The 3-D model is easily stored digitally, accessible at all times, and manipulated and analyzed instantaneously (Redmond 2001).

Image acquisition is crucial for modeling the teeth and planning movements and manipulations. There are different modes of image acquisition: laser scanning, destructive scanning, white-light scanning, and computerized tomography. Laser scanning consists of a laser beam projected on the object of interest, and the reflection of the beam is subsequently recorded. While laser scanning was the first scanning technology utilized by the Invisalign System, there were problems in the speed of acquisition and the ability to capture undercuts and small interproximal spaces. Invisalign then turned to destructive scanning, which captures cross-sectional information and constructs a 3-D image. It was found to successfully capture intricate geometries and undercuts. The process to prepare plaster casts for scanning, however, is time-consuming and expensive. White-light scanning uses a white-light pattern to capture images of the scanned object. It provides high accuracy and resolution; however, the detail in capturing deep undercuts and interproximal gaps is not sufficient. Invisalign thus transitioned into utilizing computerized tomography technology.

### *2.4.3 Computerized Tomography (CT) Scan*

Technological advancements have brought in a new era of 3-D digital models. Using a CT scan with the Invisalign System, a set of impressions can translate easily into a 3-dimensional image without the intermediate step of pouring a plaster cast. A set of

impressions is mounted on a rotary table in the scanner, and x-rays pass through the impressions as a detector captures images at different angles (Kaza 2006).

### 2.8 Statement of Thesis

This study is designed to determine the treatment effects of the Invisalign System. This systematic review is a continuation of the review performed by Lagravere and Flores-Mir. The objectives are:

1. To determine the treatment effects of the Invisalign system
2. To determine the indications for orthodontic treatment utilizing the Invisalign system

# CHAPTER 3

## AIMS OF THE INVESTIGATION

The aims of our investigation were to search the current literature from April 2005 to December 2012 and determine the effectiveness of orthodontic tooth movement using Invisalign. With changes to Invisalign implemented within the past few years, a more recent appraisal of the available literature is of value. The prior existing systematic review on Invisalign does not take into account the new changes that were applied to improve the appliance's efficacy. It is our hope that this systematic review will provide a more current understanding of the treatment effects, indications for, and stability of the Invisalign system.

# CHAPTER 4

# MATERIALS AND METHODS

## 4.1 Inclusion and Exclusion Criteria

Inclusion criteria that were to be satisfied by the literature search results were publications in English and human clinical trials. Any studies not pertaining to the question of clinical effectiveness of Invisalign were selected for exclusion.

Case reports and review papers were considered separately for analysis and contribution to the general information gathering in the systematic review. Book chapters were excluded.

## 4.2 Study Design

Stage I

A computerized search was conducted using PubMed (from April 2005-December 2012), Evidence Based Medicine (EBM) Reviews Database (Cochrane Database of Systematic Reviews), Database of Abstracts of Reviews of Effects and Cochrane Central Register of Controlled Trials (to the fourth quarter of 2012), Science Direct (from April 2005 to December 2012), and Thomsen's ISI Web of Science (from April 2005-December 2012).

The literature was searched using the term "Invisalign". Any studies not published in English were excluded from the study. Of the accessible studies, titles and abstracts were read to identify selection for inclusion in the systematic review. If the study did not meet the inclusion criteria, exclusion was indicated. However, if the article

was deemed borderline by the reviewer, additional review by a second reviewer was utilized.

Stage II

Quality assessment was performed on the studies that fulfilled the inclusion criteria. The quality and design of the study was considered.

Stage III

Of the studies that passed the quality assessment stage, a thorough evaluation was completed. Summaries of the included articles were prepared and information regarding study design, subjects, treatment time, and outcomes were organized in tabulated form. Using the 2010 CONSORT statement and the 2009 ADA Clinical Recommendations Handbook, critical appraisal of all included studies were performed.

# CHAPTER 5

# RESULTS

## 5.1 Stage I: Database Results

Overall, of the 271 articles reviewed, twenty-three were selected for inclusion in the systematic review (Stage II).

PubMed was searched for the term "Invisalign". Seventy-one articles were found. Twelve articles were applicable for further analysis.

Evidence Based Medicine (EBM) Reviews Database (Cochrane Database of Systematic Reviews was searched for the term "Invisalign". There were zero systematic reviews found in the search.

Database of Abstracts of Reviews of Effects and Cochrane Central Register of Controlled Trials was searched for the term "Invisalign". Three articles were found. One article was selected for further review.

Science Direct was searched for the term "Invisalign". One hundred fifty-seven articles met the initial criteria. After review, one was selected for further review.

Thomsen's ISI Web of Science was searched for the term "Invisalign". Forty articles were found. Nine were selected for further analysis.

**Table 1: Database Search Results**

| DATABASE | KEY WORD | RESULTS |
|---|---|---|
| PubMed | Invisalign | 71 |
| EBM Reviews Database | Invisalign | 3 |
| Database of Abstracts (Cochrane Central Register of Controlled Trials) | Invisalign | 0 |
| Science Direct | Invisalign | 157 |
| Thomsen's ISI Web of Science | Invisalign | 40 |

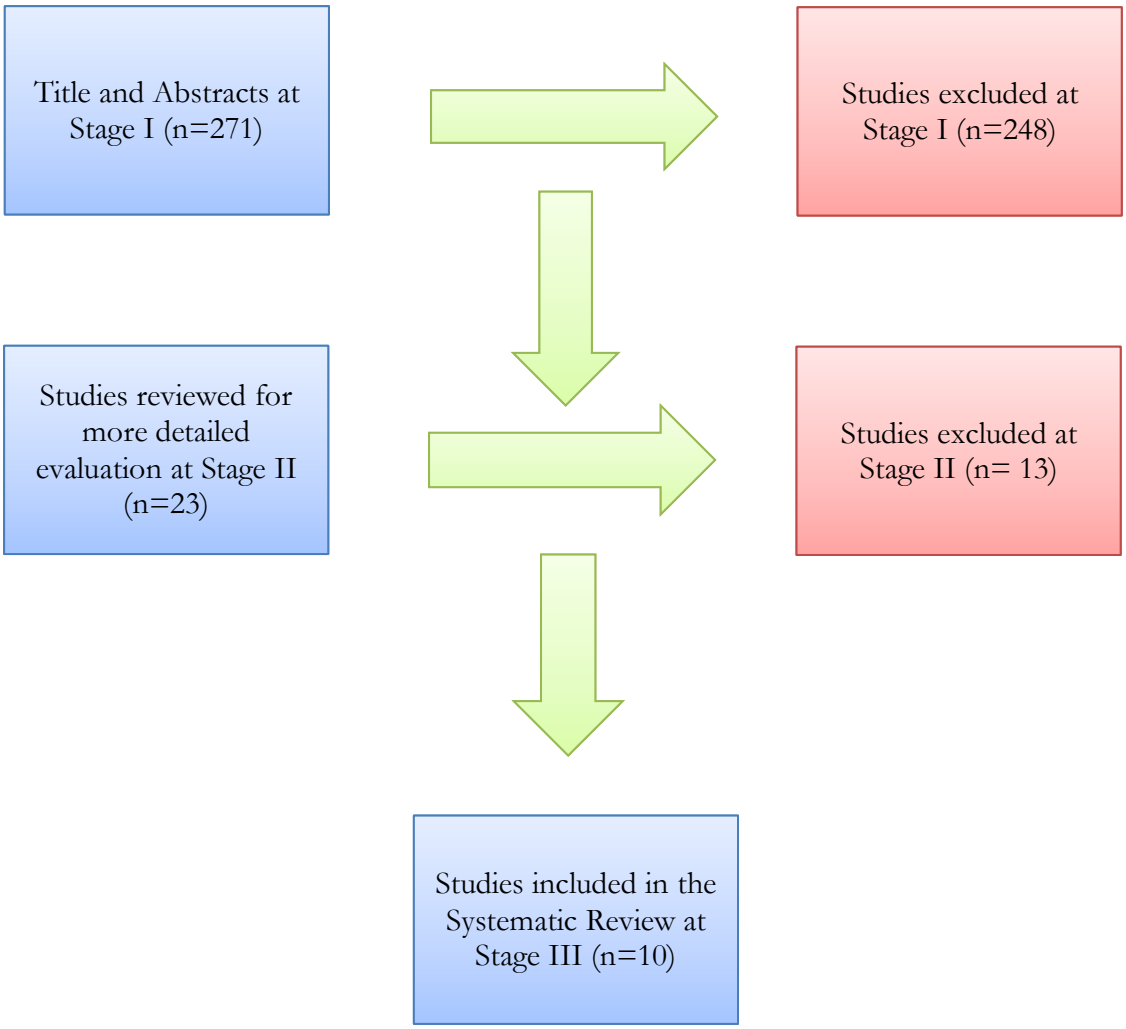


**Figure 1: Study Flow Diagram**

### 5.2 Stage II: Article Review

At stage II, twenty-three articles were reviewed for study quality and design. A detailed evaluation of each of the articles to be excluded is presented in the following paragraphs. One article was deemed borderline. Discussion with the second reviewer, P.L., established that the article was not appropriate for inclusion in the systematic review.

The article "A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment" by Miller et al was excluded because it evaluated the differences in quality of life impacts between subjects treated with Invisalign vs. those with fixed appliances during the first week of orthodontic treatment. The study did not answer the important question of treatment effectiveness of Invisalign. However, the study did find that patients in the Invisalign group experienced less pain and had fewer negative impacts on their lives than those with fixed appliances.

The remaining articles were case reports, which were additionally not included in the review. Several of the following case reports that were excluded are explained in detail below.

The article "Halitosis, Oral Health and Quality of Life during Treatment with Invisalign and the Effect of a Low-dose Chlorhexidine Solution" by Schaefer and Braumann was excluded, because the study did not examine treatment effectiveness of Invisalign. Instead, they found that neither halitosis, oral dryness, nor high plaque or gingival index measurements were observed. Thus, it is unnecessary to recommend the general adjunctive use of a low-dose chlorhexidine mouthwash during Invisalign treatment.

The article "Adult patients' adjustability to orthodontic appliances. Part I: a comparison between labial, lingual, and Invisalign" by Shalish et al was excluded, because this study also did not examine treatment effectiveness of Invisalign. This prospective study evaluated the 68 patients' perception of pain and recovery to lingual, buccal, and Invisalign orthodontic appliances. The lingual appliance was associated with more severe pain and analgesic use, the greatest oral and general dysfunction, and the

longest recovery. Invisalign patients complained of severe pain in the initial days after insertion. Overall, the Invisalign group had the lowest level of oral symptoms and a similar general activity disturbance and oral dysfunction when compared to the buccal appliance group.

The article "A Comparison of the Periodontal Health of Patients during treatment with the Invisalign System and with Fixed lingual appliances" by Miethke and Brauner was excluded, because the study evaluated periodontal health of patients and not the effectiveness of treatment. The study determined that Invisalign patients had significant better periodontal indices and less periodontal risk as compared to patients with lingual appliance. Sulcus probing, however, was similar among both groups.

### 5.3 Stage III: Articles for Inclusion

The articles that were selected for inclusion in the systematic review are tabulated in Table 2.

The 2009 ADA Clinical Recommendations Handbook will be used to evaluate systematic reviews, case-control studies, randomized-controlled trials, and cohort studies. Additionally, the 2010 CONSORT Statement will be used to evaluate randomized-controlled trials.

The article "Outcome assessment of Invisalign and traditional orthodontic treatment compared with the American Board of Orthodontics objective grading system" by Djeu et al is a retrospective cohort analysis that compared two groups of 48 patients (Invisalign and fixed braces groups) using the objective grading system to evaluate posttreatment records according to guidelines set by the ABO Phase III examination.

Patients were collected from an ABO board-certified orthodontist in New York City. Control for initial severity of malocclusion was carried out through the discrepancy index of each case. They found that the Invisalign group lost an average of 13 OGS points more than the fixed braces group. Invisalign scores were much lower than the braces scores for buccolingual inclination, occlusal contacts, occlusal relationships, and overjet. Invisalign patients finished 4 months sooner than the fixed braces patients, and the appliance was shown to be successful at closing spaces and correcting anterior rotations and marginal ridge heights. However, Invisalign was found to be lacking in its ability to correct large anteroposterior discrepancies and occlusal contacts. Using the 2009 ADA Clinical Recommendations Handbook for cohort study appraisal, the quality of the study was evaluated as good. Comparable groups were assembled from initial records, and it was a case-controlled study that used the ABO discrepancy index to control for case complexity differences between the two groups. Reliable and valid instruments (ABO gauge) for measuring the eight ABO OGS criteria were used in assessing the post-treatment records. Examiner reliability was high, and appropriate attention to confounders (age, compliance, and experience level of the orthodontist) was given in the analysis. The study quality was good overall. There was selection bias as the orthodontist could select which cases in both groups would be selected for inclusion in the study. This may have distorted the statistical analysis resulting from the method by which subjects were collected. Also, in analyzing the success of rotation of posterior teeth, the OGS criteria only evaluate marginal ridges and not rotations specifically. No information was provided regarding which teeth had received interproximal reduction or attachments.

The article "The treatment effects of Invisalign orthodontic aligners: A systematic review" by Lagravere et al is a systematic review that reviewed two articles from and before 2005. The authors found that no strong conclusions could be made regarding the treatment effects of Invisalign appliances. It was suggested that future prospective randomized clinical trials be carried out to substantiate the claims about Invisalign's treatment effects. According to the 2009 ADA Clinical Recommendations Handbook for systematic reviews, the study quality was evaluated as good. It is a fairly recent review with comprehensive sources and search strategies with a standard appraisal on included studies and valid conclusions.

In the article "Invisalign and Traditional Orthodontic Treatment Postretention Outcomes Compared Using the American Board of Orthodontics Objective Grading System" by Kuncio et al, a comparative cohort study was performed to evaluate the postretention dental changes between patients treated with Invisalign and those treated with fixed braces by an ABO board-certified orthodontist in New York City. Both groups consisted of eleven subjects, based on recall from subjects of the Djeu study. In the Invisalign group, retention consisted of full-time wear of the final aligners for six months and nightly wear for another six months. In the braces group, retention consisted of the same protocol with an Essix retainer. In the Invisalign group, total alignment and maxillary anterior alignment worsened postretention compared to the braces group. Using the 2009 ADA Clinical Recommendations Handbook for cohort studies, the quality of the study was deemed good. The measurement instruments were equally applied to both groups and interventions were spelled out clearly. The study used the OGS criteria along with four subcategories of the OGS alignment criterion to examine

post-retention changes. Although the Invisalign group showed a larger decrease in the alignment score, the differences between the Invisalign and fixed braces groups were not statistically significant. While the Invisalign group may have relapsed more in the maxillary anterior teeth, both groups had similar overall alignment scores.

Kravitz's article, "How well does Invisalign work? A prospective clinical study evaluating the efficacy of tooth movement with Invisalign", superimposed the predicted positions of four hundred and one anterior teeth (198 maxillary and 203 mandibular) from 37 patients over the virtual Treat model of the achieved tooth positions using the ToothMeasure software. As treatment only involved correction of the anterior teeth, the DI was only scored on overjet, overbite, anterior open bite, and crowding. Kravitz found that the mean accuracy of tooth movement with Invisalign was 41%. The most accurate movement was lingual constriction, while the least accurate movement was extrusion, specifically of the maxillary and mandibular central incisors. At rotational movements greater than 15 degrees, accuracy of rotation for the maxillary canines was low. Lingual crown tip was more accurate than labial crown tip. The study can be qualified as good, following the 2009 ADA Clinical Recommendations Handbook. Reliable and valid measurement instruments and software were used; however, all tooth movements exhibited large standard deviations. Thus, mean accuracy for each tooth movement may not be completely valid. Appropriate attention to possible confounders was given. While many clinicians in the study requested overcorrection, the final predicted tooth position was the measurement used. Thus, even movements with low accuracy may have indeed achieved their desired tooth position.

The article "Accuracy of Invisalign treatments in the anterior tooth region" by Krieger et al analyzed to what extent the pre-treatment model corresponded to the initial position in the ClinCheck and to what extent the predicted treatment result corresponded to the actual treatment outcome in regards to overjet, overbite, and dental midline shift. Initial and final ClinCheck images were compared to the pre-treatment and post-treatment models of 35 patients. Crowding was resolved in the maxilla most frequently by IPR and in the mandible by a combination of IPR and protrusion. Invisalign technology showed only minimal deviations from computer transfer into 3-dimensional digital images in ClinCheck. Tooth corrections in the vertical were the most difficult to obtain. The concordance between the predicted and actual treatment results was 14.3%. It is suggested that clinicians carry out a case refinement toward the end of treatment or horizontally beveled attachments of 1 mm buccal-lingual thickness in the premolar region for aligner retention and elastics for vertical overcorrection. Fixed appliances additionally may become needed in complex cases. According to the 2009 ADA Clinical Recommendations Handbook, the study level can be qualified as fair. Comparable groups were assembled initially; however, there was variation among the subjects in initial presentation and in treatment mechanics. It would be advisable to group different treatment mechanics in order to compare the different modalities implemented. In addition, some but not all important outcomes were considered.

An extended version of the study was performed by Krieger et al in "Invisalign treatment in the anterior region: Were the predicted tooth movements achieved?" to compare the pre-treatment and post-treatment casts to initial and final ClinCheck images of 50 patients. The parameters evaluated were upper/lower anterior arch length,

intercanine distance, overjet, overbite, dental midline shift, and the irregularity index. The difference between the achieved and the predicted tooth movement was mostly minimal. All parameters were shown to be significantly equivalent except for the overbite. A similar conclusion to the pilot study was made in that special attention must be paid to correction of deep bite. The higher number of subjects and more outcomes considered in this study show a higher level of quality as compared to the previous pilot study. However, it may be more advisable to compare groups by case complexity (mild vs. moderate vs. severe crowding) or severity of malocclusion to better understand the limitations in outcome.

The article "Influence of Attachments and Interproximal Reduction on the Accuracy of Canine Rotation with Invisalign" by Kravitz et al evaluated the effect of attachments and interproximal reduction on the rotation of canines. The study found that the mean accuracy of canine rotation with Invisalign was 35.8%. While the most commonly utilized attachment for canine rotation was the vertical-ellipsoid (0.75 mm thick), the attachments and interproximal reduction were not found to improve the accuracy of canine rotation using Invisalign. According to the 2009 ADA Clinical Recommendations Handbook, comparable groups were assembled well and maintained throughout the study. The attachment only, IPR only, and neither attachment nor IPR groups had similar distributions in gender, age, ethnicity, and number of treatment aligners. However, one crucial area requiring consideration was the amount of canine rotation needed among the patients. There was a large range in the amount of canine rotation needed and different groups had varying numbers of subjects with discrepant amounts of canine rotation needed (in degrees), thus affecting the outcomes. The N

group had only 2 of 18 canines with attempted rotations greater than 5 degrees, while the IO and AO groups had 12 of 18 canines and 15 of 17 canines, respectively, attempting rotations greater than 5 degrees. Moreover, there were not enough subjects to study canine rotations with both attachments and IPR implemented. The amount of IPR was also not evaluated in the study. Overcorrections, which are an important component of the ClinCheck stage for clinicians in treatment planning, were also not accounted for. Teeth with a reported low accuracy may have indeed achieved the desired rotation needed. Consequently, the level of quality can be deemed fair according to the ADA guidelines and no accurate conclusions can be made regarding the factors contributing to successful canine rotation using Invisalign.

The article "Activation time and material stiffness of sequential removable orthodontic appliances. Part 3: Premolar extraction patients" by Baldwin et al investigated teeth adjacent to premolar extraction spaces during space closure with Invisalign followed by fixed appliances. Twenty-four subjects with at least one premolar extraction were included in the study. With aligners alone, severe tipping was noted among the teeth adjacent to the extraction sites, with more tipping observed in the mandibular arch. When followed by fixed appliances, significant uprighting of the tipped teeth was achieved. Comparisons of soft versus hard tray material and the 1-week versus 2-week tray change schedule showed no differences in interdental angle change. 50% of the subjects required a reboot, and the average treatment time for dual modality therapy was 40 months. According to the 2009 ADA Clinical Recommendations Handbook for randomized-controlled trials, the study can be evaluated as fair quality design. The small sample size of each group did not provide adequate power to the study to draw

conclusions about hard vs. soft and 1 vs. 2 week protocols. The design and size of attachments used in the study were also not revealed. Due to the lack of control group, it was impossible to determine how aligner therapy compared to fixed appliance therapy. Additionally, only 1 of 24 patients completed the initial set of Invisalign. Thus, any possible correction of tipping that would have been implemented during the later stages of aligner treatment was not detectable. According to the CONSORT statement, there were several criteria that were not reported in the methods and results sections.

In the article, "Self-ligating versus Invisalign: analysis of dento-alveolar effects", by Pavoni et al, 20 subjects received self-ligating appliances (TIME 3) and 20 subjects received Invisalign in order to compare the changes in the transverse dimension and perimeter of the maxillary arch. Statistically significant differences between the self-ligating group and Invisalign group were found for the following measurements, with larger values shown for the self-ligating group: intercanine width (cusp), first interpremolar width (lingual), first interpremolar width (fossa), second interpremolar width (lingual), second interpremolar width (fossa), and arch perimeter measurements. There was no statistically significant difference between the groups with respect to overall treatment time. Utilizing the 2009 ADA Clinical Recommendations Handbook, the study can be evaluated as poor. The desire to compare the transverse dimension of the subjects after treatment was not justified by the initial presentation of the patients. The groups that were assembled for the study presented with Class I malocclusion and mild crowding in the mandibular arch. There was no indication in the study of patients with a transverse deficiency. Thus, a treatment goal may not have been expansion in the transverse and the findings would not be relevant to the indicated treatment for patients.

Key confounders are also given little or no attention. A control group was deemed unnecessary by the investigators.

The article "Finishing with Invisalign" by Duong and Kuo is a prospective clinical study that was conducted in order to explore the process for finishing and the optimal material for finishing. Another goal of the study was to obtain data regarding the different types of tooth movement that require overcorrection and how much overcorrection would be needed. Patients wore a duplicate last aligner in a thicker material (Ex40) for the last 2 weeks. The thicker material is approximately one third stiffer than the usual EX30 material. Wearing the Ex40 aligners at the end of treatment showed that there can be slight improvement in anterior alignment. However, it still did not completely eliminate the need for additional aligners or a refinement stage. Evaluation using the 2009 ADA Clinical Recommendations Handbook shows the study to be of poor quality. The assembled group of patients was not successfully maintained throughout the study. A 30% dropout rate of subjects occurred. Additionally, it is not clear what methodology was used to determine if cases post-EX40 needed further treatment using refinement aligners.

**Table 2: Included Studies**

| Author, Year | Type of Study | # in Tx (Sex, Age) | Control | Time in Invisalign Tx | Outcomes | Quality of Study |
|---|---|---|---|---|---|---|
| **Kuncio et al, 2007** | Retrospective Cohort Study | Invisalign: 11 pts (10 females, 1 | No control | Tx time not given | Changes in total alignment were worse | Good |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | male)<br><br>Fixed braces: 11 pts (10 females, 1 male) | | | postretention in pts treated with Invisalign; Maxillary anterior alignment worsened postretention in the Invisalign group | |
| **Lagravere, Manuel and Carlos Flores-Mir, 2005** | Systematic Review | 2 articles reviewed<br>Study 1: 38 pts<br>Study 2: 51 pts | No control | Study 1: 20-32 months<br>Study 2: Tx time not given | Neither article successfully quantified the treatment effects of Invisalign. Randomization only used in one study w/ high dropout rate in both studies | Good |
| **Kravitz et al, 2009** | Prospective Clinical Study | 37 pts treated w/ Anterior Invisalign | No control | Tx time not given | Mean accuracy of tooth movement was 41%; the most | Good |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | (198 maxillary, 203 mandibular teeth) (23 females, 14 males, mean age 31 yrs) | | | accurate movement was lingual constriction (47.1%) and the least accurate movement was extrusion (29.6%) – specifically extrusion of maxillary (18.3%) and mandibular central incisors (24.5%), followed by mesiodistal tipping of the mandibular canines (26.9%); low accuracy for canine rotation; lingual crown tip more | |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | accurate than labial crown tip; no difference in accuracy between maxillary and mandibular tooth movement | |
| **Krieger et al, 2011** | Retrospective Cohort Study | 35 pts (24 females, 11 males, mean age 33 yrs) | No control | Mean duration: 10 months | Minimal deviations with computer-aided transfer and conversion of clinical tooth malalignments into a 3-D digital representation in ClinCheck; tooth corrections in the vertical plane most difficult to | Fair |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | achieve, in comparison to overjet and midline shift | |
| **Krieger et al, 2012** | Retrospective Cohort Study | 50 pts (34 female, 15 male, mean age 33 yrs) | No control | Tx time not given | Moderate to severe anterior crowding successfully corrected using; accurate 3-D ClinCheck predictions; overbite demonstrated greatest deviations between predicted and achieved tooth movements | Good |
| **Kravitz et al, 2008** | Prospective Clinical Study | 31 pts (33 maxillary and 20 mandibular canines) (18 females, 13 males, mean age | Control: Neither attachments nor IPR | Mean duration: 7.2 months | Mean accuracy of canine rotation 35.8%; no significant difference between groups with | Fair |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | 29.4 yrs) | | | attachments only, interproximal reduction only, and neither attachments nor interproximal reduction for canine rotation accuracy; highest accuracy w/ interproximal reduction grp; most commonly prescribed attachment shape was vertical-ellipsoid (70.5%) | |
| **Baldwin et al, 2008** | Sample from Randomized Clinical Trial | 24 pts (at least one premolar ext) (18 women, | No control | Mean duration: 40 months (16.9 months in | Trend for more tipping of mandibular teeth compared with | Fair |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | 6 men, mean age 32.8 yrs) | | aligners, 23.3 months in fixed appliances) | maxillary teeth during space closure following 2nd premolar ext; Tx premolar ext w/ Invisalign followed by fixed tx may not be faster; no difference in use of hard vs. soft aligners or changing weekly vs every other week in the amount of dental tipping around ext spaces; fixed appliances can correct tipping found in aligner tx | |
| **Pavoni et** | Prospective | Invisalign: | No control | Mean | Invisalign tx | Poor |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| **al, 2011** | Clinical Study | 20 pts (12 females, 8 males, mean age 18 yrs)<br><br>Self-ligating fixed appliances: 20 pts (9 females, 11 males, mean age 15 yrs) | | duration: 18 months for both groups | successfully aligned arches through derotation of teeth and leveling of arches; Invisalign can tip crowns but cannot tip roots bc of lack of control of tooth movement | |
| **Djeu et al, 2005** | Retrospective Cohort Study | Invisalign: 48 pts (pre-tx age of 33.6 yrs)<br><br>Fixed braces: 48 pts (pre-tx age of 23.7 yrs) | No control | Mean duration: 1.7 years for braces group, 1.4 years for Invisalign group | The Invisalign group lost 13 more OGS points than the braces group; OGS passing rate was 27% lower than that for braces; Invisalign scores lower than braces scores for buccolingual | Good |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | inclination, occlusal contacts, occlusal relationships, and overjet; strengths of Invisalign – closing spaces and correcting anterior rotations and marginal ridge heights; Invisalign pts finished 4 mo sooner than fixed braces pts; Invisalign OGS scores were most significantly correlated to initial overjet and occlusion | |
| **Duong and Kuo, 2006** | Prospective Clinical Study | 20 pts | No control | Tx time not given | Wearing Ex40 (thicker) aligners at the | Poor |

**Table 2 Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | end of tx can slightly improve anterior alignment; pts who use Ex40 aligners as retainers at the end of tx can expect to achieve slight improvement in alignment during the retention phase; however this did not eliminate the need for refinements | |

# CHAPTER 6

# DISCUSSION

For the past fourteen year, Invisalign has been a popular treatment choice among patients and clinicians for its esthetics, comfort, and improved oral hygiene. Indications for Invisalign cases are mild to moderate crowding (1-6 mm), mild to moderate spacing (1-6 mm), nonskeletal constricted arches, and relapse after fixed appliance therapy. Many claims were made by the manufacturer about its success in space closure, alignment, dental expansion, flaring, and distalization (McNamara 2001). While these claims are mere guidelines, it is the clinician's responsibility to make the correct diagnosis and provide the most appropriate treatment plan to the patient. There is still controversy about the extension of some of these indications that are purported by the manufacturer. Questions continue to remain about the efficacy with which Invisalign can move teeth. While Align Technology purports that 20-30% of patients will require a mid-course correction or refinement in order to achieve the treatment goals, orthodontists report that 70-80% of patients actually require a midcourse correction, refinement, or placement of fixed appliances in order to achieve those goals (Align Technology 2002; Boyd 2005 lecture; Sheridan 2004).

In order to offer the appropriate treatment plan, the clinician should be able to refer to scientific evidence to support his/her decisions. There has been an unfortunate lack of published clinical research in the past involving the Invisalign system in case-controlled settings. A previous systematic review in 2005 attempted to analyze the treatment effects of Invisalign. Only 2 published articles were suitable for inclusion in

the analysis. No conclusions could be made about the indications for, limitations of, and outcomes of use of the Invisalign system. It was recommended that randomized clinical trials be conducted for better evaluation of the treatment effects of Invisalign.

This present study is a continuation of the prior systematic review. Since 2005, there have been advances and modifications to the Invisalign system, with the advent of optimized attachments. Most recently in 2013, there has been a further modification to the system, with the introduction of the SmartTrack aligner material (EX15). Thus, with changes to the system comes an accompanying need for clinical studies to examine its treatment effects.

In this systematic review, a more contemporary search for new literature was conducted to determine if the call for randomized clinical trials was met. While the search yielded 271 studies, many of those studies tended to be case reports and descriptions of the use of the system. Ten published studies were included for analysis and subsequent appraisal. Of the ten studies, half of the studies were evaluated as good quality studies according to the 2009 ADA Clinical Recommendations Handbook and CONSORT statement. One of those studies was the prior systematic review, which unfortunately could not come to any conclusions regarding the treatment effects of the Invisalign system.

In the 2005 study by Djeu et al, it was determined that the Invisalign group lost an average of 13 OGS points more than the fixed braces group. Invisalign scores were much lower than the braces scores for buccolingual inclination, occlusal contacts, occlusal relationships, and overjet. Invisalign patients finished 4 months sooner than braces patients, and the appliance was shown to be successful at closing spaces and correcting

anterior rotations and marginal ridge heights. However, Invisalign was found to be lacking in its ability to correct large anteroposterior discrepancies and occlusal contacts. Thus, while Invisalign claims to be excellent at distalization, Djeu found anteroposterior correction to be quite difficult with the aligner system.

In another clinical study in 2009, Kravitz found that the mean accuracy of tooth movement with Invisalign was 41%. The most accurate movement was lingual constriction, while the least accurate movement was extrusion, specifically of the maxillary and mandibular central incisors. At rotational movements greater than 15 degrees, accuracy of rotation for the maxillary canines was low. Lingual crown tip was more accurate than labial crown tip.

In the 2012 Krieger study, it was found that the difference between the achieved and the predicted tooth movement was mostly minimal. All parameters, inclusive of upper/lower anterior arch length, intercanine distance, overjet, dental midline shift, and the irregularity index, were shown to be significantly equivalent except for the overbite. A similar conclusion to the pilot study was made in that special attention must be paid to correction of deep bite.

It is still imperative that more randomized clinical trials that judiciously follow the CONSORT statement be conducted in the field of orthodontics, specifically regarding the treatment effects of the Invisalign system. The less scientific evidence clinicians have at their disposal, the more anecdotal information plays a key role in making treatment decisions. Invisalign aligners will continually evolve, and treatment effects will be more difficult to study unless future studies are conducted to measure the changes that are implemented by the system.

# CHAPTER 7

# CONCLUSIONS

In summary, after thorough analysis of the studies, it has been shown that Invisalign is an effective appliance for minor space closure, lingual constriction, and correction of anterior rotations and marginal ridge height discrepancies. However, Invisalign lacks in its ability to correct anteroposterior discrepancies, occlusal contacts, extrusion, and rotations greater than 15 degrees.

While the achieved and predicted tooth movement discrepancy was very minimal, it was found that overbite must be overcorrected.

Clinicians must rely on scientific evidence as well as their clinical experience in order to make appropriate decisions regarding treatment with the Invisalign appliance.

Conclusions cannot be made from several studies, however, due to the lower level quality of these studies. It is recommended that as the Invisalign appliance continues to change, the need for randomized controlled becomes met. Sound scientific evidence is needed to support or deny the claims made by Invisalign.

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# APPENDICES

## APPENDIX A

### List of Excluded Studies

1. Miller K, McGorray S, Womack R, Quintero J, Perelmuter M, Gibson J, Dolan T, Wheeler T. A Comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment. Am J Orthod Dentofacial Orthop 2007; 131:302.e1-302.e9.

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## APPENDIX B

### List of Included Studies


1. Djeu G, Shelton C, Maganzini A. Outcome assessment of Invisalign and traditional orthodontic treatment compared with the American Board of Orthodontics objective grading system. American Journal of Orthodontics and Dentofacial Orthopedics 2005; 128 (3): 292-298.

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