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| **Republic of Iraq****Ministry of Higher Education and Scientific Research****University of Baghdad****College of Dentistry**  |
| **Invisalign: Clear aligners** |
| (A Review on the development of clear aligners and their increased use in orthodontic) |
| **A project submitted to the council of the College of Dentistry, Department of orthodontics at University of Baghdad for partial fulfillment of the requirement of B.D.S degree.** |
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**بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ**

**(يُؤْتِي الْحِكْمَةَ مَنْ يَشَاءُ وَمَنْ يُؤْتَ الْحِكْمَةَ فَقَدْ أُوتِيَ خَيْراً كَثِيراً وَمَا يَذَّكَّرُ إِلاَّ أُولُو الأَلْبَابِ)**

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**CHAPTER ONE**

Introduction

# CHAPTER ONE

## Introduction

The world is developing at a quick pace now more than ever, and the esthetic demands of our society are increasing especially with the wide use of social media which opened the eyes of the community to new cosmetic dentistry treatment options worldwide. The use of removable clear aligners in treatment for adults has grown tremendously in the last few years especially with the technological advancements in 3D printing technology, and for patients who are no longer growing significantly, this form of therapy now can be used for quite complex problems.

"You have a choice: You can get with this new technology or remain stuck in the past" **Crouse, (2017)**

Invisalign takes a modern approach to straightening teeth, using a custom-made series of aligners, these aligner trays are made of smooth, comfortable, thin (typically less than 1 mm) and virtually invisible plastic that simply worn over the teeth. Wearing the aligners will gradually and gently shift the teeth into place, based on the exact movements the orthodontist plans out for patients.

There are no metal brackets to attach and no wires to tighten. The patient simply pops in a new set of aligners approximately every two weeks, until treatment is completed and the patient achieve the confident smile that they've always wanted. The best part about the whole process is that most people won't even know that the patients are straightening their teeth.

One thing should be kept in mind that invisalign is a removable orthodontic appliance after all, so excellent compliance of the patient is mandatory to deliver the desired results.

 The appliance have to be worn a minimum of 20 to 22 hours a day and each aligner should be worn for approximately 400 hours in order to be effective. **Xiem, (2007)**.

**CHAPTER TWO**

Review of Literature

# CHAPTER TWO

## 2.1. History

The concept on which the Invisalign system is based on has been around since the 1940s. In **1945, Kesling** published the first article on the use of elastic positioners to move teeth that had been realigned in a wax setup.

He realized that the lab requirements would be significant, and did not envision this as a practical means of more extensive treatment.

Some years later, **Nahoum, (1964)** described a method to change tooth contours using thermoformed plastic.

In **1971, Pontiz** introduced a thermoformed plastic appliance called the “invisible retainer” made on a master model that prepositioned teeth with base-plate wax. He claimed that this appliance could produce limited tooth movement. **McNamara, (1984).** and others also described using invisible retainers to achieve minor tooth movement. **Sheridan, (1993)** later developed a technique involving interproximal tooth reduction and progressive alignment using clear Essix appliances, and those techniques were further developed by Hilliard and Sheridan with a series of special thermoforming pliers designed to enhance specific movements.

**Zia Chishti** and **Kelsey Wirth** started Align Technologies in April **1997**, a new company with no ties to previous suppliers of dental and orthodontic materials and with the help of a handful of forward thinking orthodontists, they applied 3-D computer imaging graphics and created the Invisalign method. This appliance was the first orthodontic treatment method to be based solely on three-dimensional (3D) digital technology. Align Technologies received FDA clearance to market Invisalign in August 1998, and began commercial operations in July 1999. **Raghunath, (2011),** By late 2001, Align had manufactured one million aligners.

In 2002, Invisalign was made available to GP Dentists and, in mid-2003; dental schools began adding Invisalign to their curriculum.

In 2007, Align added distribution partners in the Asia Pacific and Latin America regions, and introduced Vivera retainers.

In 2008, Align launched two new treatment options – Invisalign Teen and Invisalign Assist – adding features that range from specially-engineered aligners and aligner wear indicators to help doctors treat teen-aged patients, to streamlined treatment planning and case monitoring support to help newly trained Invisalign doctors.

In 2010, Align added a new distribution partner for the smaller country markets in Europe, the Middle East, and Africa region. Align also introduced Invisalign **G3**, a set of innovations engineered to deliver even better clinical results, including new Precision Cuts designed to make it easier to treat Class II & III patients with Invisalign, new SmartForce features for more predictable tooth movements, and new ClinCheck 3.0 software designed to reduce ClinCheck treatment plan revisions. Finally, in late 2010, Align received regulatory approval to market and sell Invisalign in China and announced that it expects commercial availability to begin in the second half of 2011.

In October 7, 2011, Align technology introduces invisalign **G4** New smartforce(r) features help doctors treat more complex cases engineered to help doctors achieve even better clinical results for open bite treatments, more predictable movement of upper laterals, and improved root control for canines and central incisors.

In October 17, 2012Align Technology Introduces Next Generation of Invisalign(R) Aligner Material; SmartTrack(TM) Material Delivers Improved Control of Tooth Movement and Patient Comfort.

In January 7, 2013 Align Technology Introduces New iTero(R) Imaging System for Restorative or Orthodontic Procedures.

In January 18, 2013 Align Technology Announces January 21st Availability of SmartTrack(TM) Invisalign® Aligner Material.

In December 3, 2013, Align technology announces invisalign**G5** innovations for treatment of deep bite Including: new smartforce attachments and pressure areas designed to level the curve of spee by improving control of premolar extrusion and anterior intrusion for more predictable deep bite treatments. Also Precision aligner bite ramps were designed to disocclude the posterior teeth for improved efficiency in deep bite treatments.

In the first half of 2015, the evolution continues with Invisalign **G6** which includes the launch of ClinCheck Pro with 3D Controls and the first premolar extraction solution engineered to improve clinical outcomes of severe crowding or bimaxillary protrusion treatments that require first premolar extraction and are planned for maximum anchorage. The Invisalign**G6**first premolar extraction solution combines new SmartStage technology and SmartForce features and is designed to provide vertical control and root parallelism.

On October 11, 2016 Align technology announces next series of innovation with invisalign**G7** and clincheck pro 5.0 software which enables greater control and fine-tuning of the treatment outcomes.

Over the years, Invisalign has developed into a successful brand with a number of products in its portfolio.

## 2.2. Pretreatment consideration

Patients frequently arrive in an orthodontic office with the request to be treated with an invisible appliance. In this situation, they can be offered lingual appliances or Invisalign therapy. Principally, Invisalign therapy is orthodontics with just a different appliance system. Therefore, consultation, record collection, documentation of existing problems and treatment goals should follow standard orthodontic operational procedures, A candidate for orthodontic treatment with the Invisalign System should have fully erupted permanent teeth, with growth completed. There is no age requirement, but the ability to comply with the treatment regimen of nearly fulltime wear is mandatory.

**Align Technology requests the following records:**

• Photographs (extraoral: frontal (at rest/smiling) and profile; intraoral: frontal, left/right lateral, maxillary/ mandibular occlusal)

• Radiographs (panoramic or periapical, optional: cephalogram)

• Vinyl polysiloxane impressions (maxillary, mandibular) plus bite registration

• Completed treatment form.

Other than the impressions, everything else can be submitted as high resolution records via email.

2.3. Selection of appropriate patients for Invisalign treatment

The chief complaint of patients choosing treatment with the Invisalign System includes crowding or spacing, flaring, supra or infraerupted teeth. **Boyd, (2000).** Spacing and flaring can generally be resolved without problems and intrusion of over erupted teeth is not a problem as long as the aligners are not dislodged occlusally from the anchor teeth. Retention can be easily improved by adding so-called attachments to the neighbouring teeth. Since extrusion of infraerupted teeth cannot be predictably accomplished with the Invisalign System alone it may require additional measures

Crowding can be treated by: interproximal enamel reduction (IER), expansion of the dental arch, moving posterior teeth distally or with extractions.

## 2.4. Space creation in Invisalign treatment

Crowding is most frequently resolved by IER, primarily because many Invisalign patients had orthodontic treatment previously, especially if the crowding is only moderate (Miethke and JostBrinkmann 2006). Extractions would create excessive space and IER is effective in avoiding open gingival embrasures (Atherton 1970; de Harfin 2000; Kurth and Kokich 2001; Zachrisson 2004), a problem which increases with age especially in patients with advanced periodontal diseases.

IER is also the treatment of choice in the case of a tooth size discrepancy between the two dental arches. Fundamentally, IER is an imitation of a physiological process because extensive attrition was a feature of the natural human dentition before civilization led to consumption of increasingly soft food.

An alternative to IER is transverse expansion of the dental arch. Although only 3–4 mm space can be generated and expansion may be unstable (Chenin et al. 2003). The mean accuracy of dentoalveolar expansion for the maxilla is

72.8%, while the lower arch presented an overall accuracy of 87.7%.

This applies especially to the mandible where crowding is most frequently seen. Still, expansion may be indicated as a wider dental arch avoids the appearance of dark buccal corridors while smiling **(Sarver 2001; Womack et al. 2002; Sarver and Ackerman 2003, Moore et al. 2005).**

Careful planning with overcorrection and other auxiliary methods of expansion may help reduce the rate of midcourse corrections and refinements, especially in the posterior region of the maxilla. **Houle, (2017)**.

It is worth mentioning that Clincheck prediction of expansion involves more bodily movement of the teeth than can be seen clinically. **Houle, (2017).**

Another alternative to IER is distalization of the molars to create space for the anterior segment. This approach too is limited to 3–4 mm space gain.

Invisalign aligners release an initial force of about **1 N** on distalizing a maxillary molar. This force delivery produces an increased concentration of bone modeling and remodeling mediators at both pressure sites and tension sites.These scenarios are compatible with previous in vivo and in vitro studies investigating the biological effects of orthodontic tooth movement. **Castroflorio, (2017).**

Distal movements can be enhanced by separating the posterior teeth before the vinyl polysiloxane impressions are taken. The preceding separation guarantees a much better fit of the aligners, especially in the interproximal spaces. The fit can be enhanced further by applying attachments on the teeth to be moved distally.

Since the laws of equilibrium cannot be overlooked, any retrusion of posterior teeth will produce some reciprocal protrusion of the anterior segments. Therefore, it is advisable to use appropriate interarch elastics simultaneously; also the orthodontist should take care that all distal movements are programmed sequentially.

Aligner therapy in association with composite attachments and class II elastics can distalize maxillary first molars by 2.25 mm without significant tipping and vertical movements of the crown. No changes to the facial height were revealed. [**Serena,**](https://www.ncbi.nlm.nih.gov/pubmed/?term=Ravera%20S%5BAuthor%5D&cauthor=true&cauthor_uid=27041551) **(2016).**

Besides the abovementioned limitation, a problem related to lengthening of the dental arch is that it is time consuming to gain the necessary space before the crowding of the anterior segment can be alleviated. This may adversely impact on the patient’s cooperation.

Another option is extraction, since basic orthodontic principles also apply to Invisalign, indications for extractions are no different for these treatments. When extractions of premolars are indicated, although such extraction spaces could be closed with aligners, paralleling the roots of all teeth would be difficult, especially in a mandibular arch with a deep curve of Spee.

 Extraction of mandibular incisors is only indicated if the lack of space exceeds 5.0 mm. It may be difficult to parallel the roots, and a midline discrepancy between the two dental arches will remain. The main objection to extractions, especially in adult patients with a certain degree of gingival recession, is that removal of teeth will almost inevitably lead to open gingival embrasures.

However, **Giancotti, (2015)** Stated that the Invisalign appliance, in correctly diagnosed cases, with careful 'ClinCheck' set-ups and good clinical monitoring, can routinely produce satisfactory outcomes in patients who require the removal of a lower incisor.

Extractions should be considered as the last choice for resolution of crowding during therapy with the Invisalign System, and such treatment may require the use of appropriate attachments and even specific adjuncts **(Miller et al. 2002)**.

2.5. Teeth movement in Invisalign system

Theoretically, aligners contact all tooth surfaces and thus they should allow all types of tooth movement, even root movements and rotations. **Bollen, (2003)** and others indicated that the Invisalign appliance yielded the most predictable results with tipping movements,

However, in more complex movements because the elasticity of the material is limited, premature contacts can occur between the aligner and the tooth to be moved. The consequence could be an unwanted movement, Therefore, such so-called less predictable tooth movements should at best be dealt with separately:

Examples of such movements are:

• Rotations of cylindrical teeth

• Extrusions

• Translations over larger distances e.g. after extractions of premolars

• Pure root movements.

The phrase ‘less predictable’ indicates that it is dubious that such movements can be generated

The two basic approaches are:

• Simultaneous movement of a group of teeth, called X-pattern due to its graphic representation

• Sequential movement of individual teeth as typically in a situation in which posterior teeth are distalized and where the movement of the second molars is followed by the first molars, the second premolars etc., named Y-pattern due to its graphic representation.

One study was to investigate the efficacy of orthodontic treatment using the Invisalign® system. Particularly, it analyzed the influence of auxiliaries (Attachment/Power Ridge) as well as the staging (movement per aligner) on treatment efficacy.

It reviewed the tooth movements of 30 consecutive patients who required orthodontic treatment with Invisalign®. In all patients, one of the following tooth movements was performed:

 (1) Incisor Torque >10°,

 (2) Premolar derotation >10°

 (3) Molar distalization >1.5 mm.

The groups (1)-(3) were subdivided: in the first subgroup (a) the movements were supported with the use of an attachment, while in the subgroup (b) no auxiliaries were used (except incisor torque, in which Power Ridges were used).

All tooth movements were performed in a split-mouth design. To analyze the clinical efficacy, pre-treatment and final plaster cast models were laser-scanned and the achieved tooth movement was determined by way of a surface/surface matching algorithm. The results were compared with the amount of tooth movement predicted by ClinCheck®.

The overall mean efficacy was 59% (SD = 0.2). The mean accuracy for upper incisor torque was 42% (SD = 0.2). Premolar derotation showed the lowest accuracy with approximately 40% (SD = 0.3). Distalization of an upper molar was the most effective movement, with efficacy approximately 87% (SD = 0.2).

2.6. Auxiliaries

### 2.6.1. Attachments

Aligner attachments are small custom-made composite additions, which are bonded onto selected teeth. There are two types of attachments: ellipsoid and rectangular.

Ellipsoid attachments are 3.00 mm long, 2.00 mm wide and 0.75 mm high, rectangular attachments are 2.00, 3.00 or 4.00 mm wide, 0.50 or 1.00 mm high and 0.30, 0.40 or 0.50 mm long. **Glaser, (2016).**

Both attachment types can be placed parallel to the long axis of the tooth or parallel to the occlusal plane. They can be attached to the buccal as well as to the palatal tooth surfaces. As a norm, the orthodontist should decide where which type of attachment should be placed.

placing 4 mm wide occlusally beveled rectangular attachments on the lower 4’s and 5’s provide “grip,” so that the aligners stay firmly on the posterior teeth, allowing for effective forces especially intrusion. **Glaser, (2016).**

For novices, it might appear difficult to decide about all these aspects. However, decision-making can be facilitated by comparing Invisalign treatment with fixed appliances therapy where it has to be decided whether a bracket on a specific tooth is needed. In general, appliance retention is enhanced significantly with the addition of attachments.

Too many attachments will, however, complicate aligner removal from the acrylic model during production as well as from the dentition later during treatment. Still, sufficient attachments should be included in the plan since they cannot be added later on. Not every virtual attachment has to be fabricated in the patient’s mouth, at least not initially. Because of the system’s versatility, it is possible to bond a programmed attachment at any stage of therapy.

The need for attachments is less for teeth with sufficient undercuts, for instance teeth with long crowns, whereas they are definitively needed in patients who have short clinical crowns and shallow undercuts.

### 2.6.2. Attachment fabrication

The actual fabrication is assisted by a so-called thin shell template, which is a 0.25 mm thick aligner with respective concavities. These are loaded with a strong light-curing micro-filled composite, preferably one that comes in various tooth colour shades. The tooth surface has to be prepared as for a typical acid etch bonding procedure. The loaded attachment template is carefully placed onto the teeth, the tray is firmly adapted with e. g. a ball end burnisher and finally all attachments are light cured. After polymerization, the template is carefully removed and the excess composite material is ground off with an appropriate finishing bur. After this clean-up, the attachment should be well defined.

 Attachment bonding is facilitated when it is done after the first aligner has been worn intensively for about 1 week. Then, all teeth will be slightly mobile, which enhances the adaptation of the bonding template. Further, the patient is by now sufficiently adept at handling his/her aligner effortlessly and so the risk of damaging an attachment or an aligner is minimized. If an attachment is lost or damaged during treatment, it can be refitted. This can be accomplished with either the current aligner or the respective part (tooth) of the original thin shell template. If the respective area is cut out, the attachment can be bonded to a specific tooth. The same course of action should be followed if an attachment was not fabricated initially but seems to be needed later on. In addition, if many attachments have to be placed, it might be practical to cut the thin shell template into segments to facilitate the bonding.

### 2.6.3. Power Ridges

A power ridge is a feature on the aligners that delivers force on a tooth at a specified position. Can be used to accomplish incisor torque, they appear at the gingival margin on the outside and at the tooth edge on the inside of the upper and lower front teeth, as the power ridge applies force to the tooth, it allows the correction of the inclination of the teeth.

### 2.6.4. Bite ramps

Precision bite ramps are prominences on the lingual surface of upper aligners (not filled with composite).

The depth of bite ramps are up to 3.0mm to accommodate overjet.

Precision bite ramps are automatically. customized for each patient and each position is adjusted to maintain anterior contact throughout all stages of movement.

## 2.7. Indications:

• Fully erupted permanent teeth.

• Growth has minimal or no effect on treatment (i.e., late adolescents and adults).

• Mild spacing (1-3 mm).

• Moderate spacing (4-6 mm).

• Mild crowding (1-3 mm).

• Moderate crowding (4-6 mm).

• Narrow arches that are dental in origin (4-6 mm).

• Treated cases with relapse.

• Space closure.

• Tooth movement following interproximal reduction.

• Dental (not skeletal) expansion.

• Flaring.

• Distalization.

• Space closure following the extraction of a lower incisor.

## 2.8. Contraindications. Boyd, (2000)

Certain malocclusion more difficult to treat:

• Crowding and spacing over 5mm.

• Skeletal antero-posterior discrepancies.

• Centric relation and centric occlusion discrepancies.

• Severely rotated teeth (more than 20 degrees).

• Open bites (anterior and posterior).

• Extrusion of teeth.

• Severely tipped teeth (more than 45 degrees).

• Teeth with short clinical crowns.

• Arches with multiple missing teeth.

• Closure of bicuspid extraction spaces.

## 2.9. Laboratory

### 2.9.1. Polyvinyl Siloxane (PVS) impressions

There are different impression techniques:

Polyvinyl siloxane is the impression material of choice because it yields highly accurate impressions that remain stable for as long as three weeks and allows for multiple pours. **Boyd, (2000)**.

A. It's the easiest but most likely to result in defective impressions involves a one-step impression using a suitable “medium body” PVS material in the proprietary Invisalign impression trays. Many orthodontists prefer this method because of the potential for reduced chair time and expenses. The problem with this one step technique is that there is a higher probability of missing the critical anatomy of one or more teeth, especially the areas distal to the second molars which are required for proper fit of the aligners.

B. The second impression technique that can be used is a combination technique where impressions of the second molars are first captured using a PVS putty material to create a posterior dam. The medium body material is used over the putty to gain a more detailed impression of the second molars, as well as to capture the rest of dentition.

Although this technique takes more chair time, the advantage is that it reduces the probability of having an unacceptable impression.

The first step involves making custom trays and Essix-type retainers that we later describe to the patient as “training aligners.” When the patient elects to start treatment, an alginate impression is taken of both arches. The patient is then scheduled to return for final impressions. The rest of the first step is completed in the laboratory. The impressions are poured up in the office using standard dental stone and trimmed as though they were to be used to make Essix-style retainers.

Then the thermoformed plastic material is formed over the models but not trimmed. While the full sheet of thermoformed plastic material is still on the stone model, a plastic impression tray is sized and then filled with the heavy body or putty PVS material of your choice, and the model with untrimmed thermoformed plastic material is inverted and pressed down into the impression material, It is important to make sure the distal of the second molars are captured in the custom tray.

Once the custom tray is made, the thermoformed plastic material is trimmed in a typical manner and will be used as the patient’s “training aligner.” The next step involves the final impression when the patient returns to the office for the final PVS impressions, which are made by placing a minimal amount of a fast set light body wash inside the custom tray.

Once the impressions are made, the patient receives the training aligners and, if he or she is interested in bleaching the teeth, the training aligners may be used while awaiting the arrival of aligners from Align.

### 2.9.2. The Digitalization Process

The patient's polyvinyl siloxane (PVS) impressions and bite registration must first be converted into dimensionally accurate 3- dimensional electronic study models by means of a Computer Aided Tomography (CAT) scan.

To create a virtual dental model directly from the impression with CT scanning, the impression is mounted on a platform that rotates in front of an amorphous silicon x-ray sensor .Hundreds of digital radiograph of the impression are captured as it rotate at 360°. These radiographs are converted to images called sinograms, which represent the data from a horizontal line of the detector as the part rotates. **Raghunath, (2011).**

2.9.3. Direct Digital Manufacturing

Currently, there are two promising technologies:

● cone beam CT (CBCT)

● Intraoral light scanners.

Both of these technologies have the potential of producing an image that would be of a sufficiently high quality that the orthodontist would be able to capture the image directly in their office and then electronically transmit that image to Align Technology to have the appliances made. **Xubair, (2014).**

The advantage of direct digital capture of the dentition would be: **Xubair, (2014).**

 (1) The elimination of the need for PVS impressions and their inherent potential for clinical errors.

 (2) Reducing the time needed to produce appliances because the image would be transmitted instantly to Align Technology via the Internet.

### 2.9.4. 3D Virtual models

These slices are stacked electronically and inverted, and the resulting surface is smoothed to yield a raw electronic study model.

When the impressions arrive at Align Technology in Santa Clara, California, they are scanned using an industrial CT scan to produce a 3D virtual model. The technician uses a best-fit occlusion based on wear facets and virtual contacts along with the intraoral photographs provided in the submission kit to articulate the models. **Raghunath, (2011).**

### 2.9.5. The Virtual Setup

Once the virtual models are produced they are then sent electronically to Align's facility in Costa Rica where the raw electronic models are "detailed" by using software that simulates standard dental laboratory procedures, such as bubble removal, void filling, and gingival-line definition.

Then the 3D image is accessed by technician who transforms the raw data into a plan for the manufacture of custom aligners. **Raghunath, (2011).**

Once the virtual models are produced, they are segmented using boundary recognition software to define individual teeth. It is important to remember that the impression generally does not capture the interproximal surfaces of the teeth, so the software must interpolate that information and estimate the location of interproximal surfaces and contact areas. Once that is accomplished, virtual “roots” are placed.

\*The technicians re-create the virtual gingival margins using morphing-type software to mimic the gingival conditions seen on the clinical photographs.

The preparation work is finished at this point, and the virtual model is forwarded electronically to the TREAT (Align Technology, Inc.) operator to perform the final setup and staging. TREAT is the proprietary software that Align Technology uses to simulate treatment and setup the virtual model to allow the manufacture of the aligners. It is a sophisticated 3D graphics program that gives the operator great control of tooth position and rate of tooth movement. It is not the software that the orthodontist uses to view the virtual model, which is called ClinCheck.

Once the virtual setup is completed and approved by the orthodontist, a series of plastic models is fabricated using stereolithography on which the aligners are then made by a thermoforming process.

### 2.9.6. Thermoforming process

The process is comprised of 3phases:

A. Cutting Process: Virtual tools in the form of planar and curved cutters that are part of the Treat software are used to isolate data for each tooth within the arch into separate geometric units. **Raghunath, (2011).**

B. Creating the Final Setup: Each crown is painted to distinguish between the tooth anatomy and gingival tissue. Landmarks such as the facial axis of the clinical crown of each tooth are identified. Now the separated teeth can be moved as individual units into arch form. The technician moves the specific teeth into alignment creating a final setup which precisely matches the doctor’s prescription. **Raghunath, (2011).**

C. Staging process: The next step in the process is to determine the number of intermediate stages (and thus the number of aligners) between the original malocclusion and the final treatment result. An important aspect of controlling tooth movement with aligners is staging. **Raghunath, (2011).**

-The two factors:

● Path of tooth movement.

● Velocity at which the teeth are to be moved with aligners.

The maximum velocity of tooth movement currently is 0.20-0.25 mm per tooth per stage. The greater the distance that the teeth need to be moved or rotated and the more complicated the movement path, the greater the number of aligners needed to treat the patient. The number of aligners varies from ten or less for relatively simple problems to fifty aligners or more in complicated malocclusions.

The basis for simultaneous movement is that all the teeth within each arch are moved together from the initial stage through the final stage.

The tooth that moves the most dictates the overall number of stages based on the maximum allowable tooth velocity. Moving the other teeth simultaneously from the first to the last stage reduces the velocity for all the other movements and increases their predictability without increasing the overall number of aligners. **Xubair, (2014).**

It is important to understand that although significant amounts of clinical testing have gone into the development of staging patterns, the orthodontist can always request custom staging when he or she feels it is necessary to improve treatment outcomes.

Although not recommended by Align Technology, there are some orthodontists who, for complex movements, greatly reduce the amount of linear movement per stage to about 0.1 mm per stage and then deliver fresh aligners on a weekly basis in order to have the aligners maintain greater aligner rigidity. Although this results in twice as many aligners, the total treatment time remains the same.

## 2.10. ClinChecksoftware

After the forecast model and treatment sequence have been generated, this information is sent over the Internet to the orthodontist, who reviews the forecast model and sequence by way of the ClinCheck® soft-ware program.

ClinCheck allows the orthodontist to view the treatment in all aspects as well as superimpose one stage of treatment over another to visualize individual tooth movements so as to gauge the probability of accomplishing the desired movement that will be biologically feasible. **Raghunath, (2011).**

The ClinCheck set-up can be used: **Raghunath, (2011), Xubair, (2014).**

The single greatest benefit of ClinCheck is its usefulness as a tool for therapeutic diagnosis. One can prescribe a given treatment plan, such as a non-extraction approach with some expansion and proclination if crowding is present. The outcome may be visualized and compared with treatment using either extractions or interproximal reduction. Although the treatment outcomes cannot be superimposed on each other, they each can be superimposed on the pretreatment virtual model for evaluation.

1. For Diagnosis and treatment planning, evaluate the need for IPR, expansion, extraction, distalization, or proclination.

2. Control the anchorage and available space necessary for the planned movements.

3. For verifying that technician has performed modifications.

4. As a consultation device to show treatment limits to patient.

5. For verifying if aligner is tracking.

6. Control the velocity and direction of tooth movements.

7. Control the amount and frequency of force to be applied to these movements.

**● The clinician's role in ClinCheck**

With experience, doctors tend to be more specific in their initial prescription of what they want, but the sequence of steps and the amount of movement between steps is specified by the technician if this is not spelled out in detail in the prescription.

In essence, when the ClinCheck is posted for the doctor to examine, the computer technician has sent a draft treatment plan for review. The software used by the computer technicians has default scenarios for different types of malocclusions and default rates of tooth movement (0.25 mm/aligner or anterior teeth, 0.33 mm/aligner for posterior teeth). These defaults are satisfactory for simpler cases but not for the more complex ones. **Proffit, (2007).**

For complex treatment, the doctor must customize the plan in terms of the amount of interproximal reduction of teeth (if any) is to be done, the sequence of tooth movement steps, the rate of tooth movement with each subsequent aligner (often reducing the amount of movement at critical points), the extent to which bonded shapes are to be used to increase the aligner's grip on the teeth. **Proffit, (2007).**

## 2.11. ClinAdvisor. Raghunath, (2011).

On October 17, 2006, Align also announced the rollout of ClinAdvisor(TM), a new suite of software tools designed to make Invisalign case selection, submission and review processes more efficient for doctors.

ClinAdvisor simplifies case selection by helping doctors identify the skills necessary for a specific case. A complexity rating system categorizes treatment plans as "Easy," "Moderate" or "Advanced" and lists expected treatment characteristics and potentially challenging movements for each option.

Doctors have the option of choosing from four separate treatment goals for more efficient treatment planning:

1. Pre-Restorative: helps prepare teeth for restorative procedures

2. Esthetic: aligns the upper and lower anterior teeth

3. Anterior Function Improvement: improves the canine relationship in addition to esthetic alignment

4. Optimal Setup: addresses all aspects of malocclusion.

2.12. Aligners production

An orthodontic product like Invisalign requires from 6 to 40 sequential appliances per arch; manual fabrication of this many appliances would be prohibitively expensive, and it would be difficult to maintain the required accuracy, **Raghunath, (2011).**

Instead, Align Technology uses stereo lithography technology to create its reference models Stereo lithography (SLA) is a rapid prototyping process by which a product is created using a Ultra-violet (UV) curable liquid resin polymer and advanced laser technology.

These SLA resin models are loaded into an automated aligner-forming system that heats, forms, and laser-marks sheet plastic over each model. **Raghunath, (2011).**

These parts are transported on a conveyor belt to a robotic arm that loads each part into an automated cutting machine for trimming where they are trimmed to within ½ mm of gingival margin for patient's optimal comfort and minimal visibility. Automation enables aligner trimming to be completed in less than 30 seconds.

Once trimmed, the part is ejected, and the aligner is separated, laser-etched with the patient's initials, case number, aligner number, and arch (upper or lower) then polished, disinfected, and packaged for shipment to the customer.

## 2.13. Aligner Material

Invisalign appliances are composed of polyurethane with added methylene diphenyldiisocyanate and 1, 6 hexanediol. Polyurethane, the basic constituent polymeric component of Invisalign aligners, is not an inert material and is affected by heat, moisture, and prolonged contact with enzymes.

What this really means is that it's a medical grade polymer or plastic with some additives that change the properties of the material making it clear, strong, thin, flexible, and an ideal material to use in the oral cavity as it is hypo-allergic, inert and biologically stable.

Invisalign in January 18, 2013 introduced the new SmartTrack aligner material, which delivers a gentle, more constant force over the two-week aligner wear period to improve tracking. With higher elasticity than the standard aligner material with its flexible material makes aligners more comfortable and easier to insert and remove.

In addition, patients have found that Smart Track still provides the same clarity and aesthetics as previous aligner material. The result is a more predictable aligner, more comfortable and almost invisible treatment from day one.

## 2.14. Invisalign treatment protocol

2.14.1. Protocol for changing aligners. **Boyd, (2005).**

1. Recently Align developed a more rigid standard for magnitude of tooth movement which now requires TWO WEEKS for each Aligner.

2. May be more than *two weeks* per aligner in extraction cases with bodily movement, for patients who wear Aligners less than 22hrs/day, or if problems occur with Aligner seating completely.

3. Patients should keep the last 3 to 4 Aligners in order to go back to a stage that fits if seating problems occur.

2.14.2. Concept and protocol**. Graber, (2000)**

In the treatment with Invisalign, the clinician forms a diagnosis, plans the treatment, and communicates this desired plan through the Internet to laboratory technicians who refine these communications via the computerized *ClinCheck*® until the clinician is satisfied with the plan. Aligners are then fabricated and shipped to the treating clinician.

Patient compliance can be superior to other removable appliances because the use of highly accurate impression materials leads to an excellent fit, and the patient is more willing to wear an appliance that can't be seen. The skill set required for this system by the clinician is unique in comparison to other fixed and Removable orthodontic techniques.

Clinicians generally do not make continual midcourse changes as treatment progresses. These skills are learned in certification courses and seminars available through Align Technology. One of the advantages of Invisalign is the ability to perform even complex tooth movements with a clear and removable system. Complex tooth movements are possible once the clinician has reached a level of training and experience appropriate to the

more challenging tooth movements. It is always advisable to master simple cases before progressing to the most complex movements.

2.14.3. Collection of Records**. Graber, (2000)**

1. Pretreatment study models, photographs, OPG, Cephalogram and other diagnostic records for the orthodontic diagnosis and treatment planning.

2. In addition, it is pertinent that high precision impressions are made of polyvinyl material. The bite is also recorded, and the impressions are sent to the Invisalign office.

3. Highly sophisticated softwares are used, which through a 3D scan technology create a virtual patient. Other specific softwares include ‘Tooth shaper’ & ‘Auto bite tool’ which identify the shape of the teeth and occlude them in centric relation.

2.14.4. New Treatment Protocol

In 2003, Align Technology formed a Clinical Advisory Board (CAB) consisting of 13 orthodontists who had used Invisalign treatment extensively in their practices. This group decided to adopt a new protocol already being used by several of its members. The success experienced by the CAB members with this protocol prompted Align Technology to adopt most of its elements in a “Best Practices Protocol”, which would be recommended for all treatment performed after Jan. 1, 2007.

● The principles of this new protocol are as follows: **Boyd, (2006)**

1. Simultaneous movement of all involved teeth. Similar to the use of light arch wires and low-friction brackets for leveling and alignment, this creates the space needed for tooth movement and slows down the movement of all teeth except the one requiring the greatest number of stages to be corrected at a given velocity (the “determining tooth”).

2. Use of beveled 1mm (buccolingual dimension) horizontal rectangular premolar attachments for retention of aligners during intrusive movements such as leveling the lower curve of Spee in cases of deep overbite, for extrusion, and for control of a tooth's long axis during torquing movements.

3. The use of pressure areas on the lingual surface of aligners is designed to re-direct the intrusive force through the long axis of anterior teeth.

4. Use of 1mm vertical rectangular attachments for rotation of round teeth or canines, as well as translation of teeth adjacent to an extraction site.

5. Slowing down certain types of tooth movement, including rotation, extrusion, torquing, and bodily movement, below the previous standard velocity of 0 .25mm per stage.

6. Maintaining visible space (approximately 1mm) between teeth during movement of one tooth paste another.

7. Using expansion instead of interproximal reduction as a primary method of increasing the space available for correction of crowding.

8. Delaying any interproximal reduction that may be needed to correct Bolton discrepancies and other tooth-size issues until the teeth is aligned, to avoid removing enamel at an angle.

2.15. Aligner fit. **Raghunath, (2011)**

The Aligner must fully "cup" the tooth crown at all times to prevent the occurrence of aligner length/arch length discrepancy. Thus, it should be understood that poor vertical fit of the aligner promotes mesiodistal problems. The aligner can fully seated with the help of Chewies made of polyurethane foam.

The presence of saliva bubbles between the tooth and the inner aligner surface indicates an inadequate aligner fit. Other indications are: void spaces predominantly occlusally/incisally and – after attachment bonding – discrepancies between these composite shapes and the respective aligner concavities. Such incongruities become evident especially to the patient if the attachment is marked before the aligner is replaced. In case of poor aligner fit, the cause must be detected. Most likely, it will be lack of patient cooperation or lack of tooth movement.

## 2.16. Invisalign Retainer

2.16.1. Invisalign retention protocol. **Boyd, (2000)**

1. Full-time wear 5-6 months (can do additional minor treatment or over-correction).

2. To close posterior bite (>85% of patients have this).

● Cut aligners distal to occlusal contacts (usually 1st or 2nd premolars) and let settle 2-4 week.

● Then wear while sleeping only (usually indefinitely).

This retainer is composed of either polypropylene or polyvinylchloride (PVC) material. It is made by using a mould of the teeth and gums and fits over the entire arch of the teeth.

The Clear Retainer is often compared to Invisalign trays. However, they differ in that the Invisalign system more likely to be used to move the teeth and to remedy an orthodontic problem. **Libron, (2010).**

2.16.2. Advantages & Disadvantages of Clear Retainers. **Libron, (2010).**

**The Advantages:**

1) Because they are custom-made to fit over the teeth, they help hold teeth in their new locations.

2) They tend to be more comfortable to wear than the metal braces.

3) Patients may be able to comply better with wearing them for the required period of time per day since they are less noticeable (better aesthetics).

**The Disadvantages:**

1) They are made of plastic and are therefore delicate and if mishandled, could easily break.

2) Since they cover the entire teeth, they may not be recommended if you tend to clench or grind your teeth because this may produce cracks or small holes.

3) They are less bulky, and because they are made of translucent plastic, might be easier to lose or forget.

4) If the gums are puffy or inflamed, impressions may not be possible to take, as it would lead to loose-fitting retainers.

## 2.17. Aligner Cleaning

1. Brush with toothbrush (powered better).

2. Soak 5 minutes with new Align dissolving tablets or 3-4 drops of Clorox (both sodium hypochlorite).

3. sonic vibrating cleaning unit

2.18. The advantages of Invisalign:

1. Esthetic-rarely noticed even at close distance - attracts additional patients.

2. Better cooperation than fixed.

3. Better hygiene than fixed.

4. Possible to treat “brittle” perio problems.

5. No decalcification.

6. 3D control of tooth movement.

7. Shorter appointments.

8. Decreased doctor & auxiliary time - emergencies rare.

9. Decreased allergic response (no metal or latex) - aligners are made from polyvinyl material approved as an internal implant material.

10. Controlled overcorrection possible.

11. Can close anterior open bite.

12. Less damage to existing restorative dentistry (especially porcelain) and tooth structure than fixed appliance.

13. Retention facilitated (does not require a new patient experience).

14. Ideal for re-treatment.

15. Decreased occlusal abrasion from Para-functional habits during treatment.

16. Technically much easier than lingual or clear appliances.

17. Ability to present case to patient with final result prior to treatment.

18. Ability to review treatment progress during treatment to increase compliance.

19. Provides a record of projected results which enables future review.

20. Disappearing patients have very minimal potential for periodontal or caries damage.

21. Ability to take a pause in treatment - better management of delinquent accounts.

2.19. The disadvantages of Invisalign: **Joffe, (2003)**

1. They are largely dependent on a patient's habits and their cooperation. The success of the Invisalign aligners is based on a patient's commitment to wear the aligners for a minimum of 20–22 hours per day, only removing them when they are eating, drinking, or brushing their teeth.

2. The system is somewhat expensive, as conceded by the Align Company. And can be more expensive than traditional wire and bracket systems.

3. The aligners must be removed before eating, an advantage and disadvantage depending upon the person. They and the teeth should be cleaned before re-inserting them afterwards.

4. Because the aligners are removed for eating, they could be lost. Invisalign recommends that the patient keep the previous aligners in case this happens.

5. The orthodontically induced inflammatory root resorption (OIIRR) phenomena can unpredictably appear with this treatment modality, just as it does with all other orthodontic treatment modalities. **Brezniak, (2008)**

6. Certain teeth are slightly problematic for Invisalign aligners to rotate. Some lower premolars with their rounded shape can be difficult for the aligners to grasp and apply a rotational force to.

7. Invisalign treatment is not perfectly suitable for teeth that require vertical movement, such as teeth that are higher in the gum line than other teeth. The aligners work by applying pressure on teeth, whereas teeth that are too low or too high require pulling to be moved into place. Recent studies collected from 3 practitioners concluded The Invisalign appliance appears to manage the vertical dimension relatively well, and the primary mechanism is via incisor movements. **Khosravi, (2017)**.

8. Invisalign becomes less accurate going from the anterior to the posterior region. **Houle, (2017)**

9. If a patient grinds or clenches her or his teeth during the day or while sleeping, the aligners can become damaged.

10. Aligners may cause a slight lisp at the beginning of treatment. This usually disappears as the patient becomes used to the treatment.

## 2.20. Comparison between Invisalign and fixed Appliance

❖ Many patients who request Invisalign treatment have previously undergone orthodontic treatment with fixed appliances and do not want to repeat the experience. **Boyd, (2006).**

❖ Esthetic concerns are often a significant factor for adult patients, many of whom are unwilling to wear braces, but teenagers also request Invisalign nowadays because they do not want the look of fixed appliances. **Boyd, (2006).**

❖There was no difference in the amount of mandibular incisor proclination produced by clear aligners and fixed labial appliances in mild crowding cases. **Hennessy, (2016)**

❖ **Spear, (2004)** reported that patients who require minor restorative dentistry or bleaching tend to prefer the combination of orthodontic treatment with less invasive restorative dentistry to extensive full coronal restorations and no orthodontic treatment. **Spear, (2004).**

❖ Patients with short dental roots may be better candidates for clear aligners than for fixed appliances. A recent longitudinal study of 100 consecutive Invisalign patients showed no measurable root resorption. In contrast, an average 10% of patients treated with fixed appliances have clinically significant root resorption of at least 3mm. **Baumrind, (1996), Vlaskalic, (1998).**

❖ Clear aligners may also be a good choice for patients with mild anterior open bite. **Boyd, (2006).** The double thickness of the clear plastic appliances on the occlusal surfaces, in combination with the patient's own force of mastication, exerts an intrusive force on the posterior teeth, slightly closing the bite. **Iscan, (1997), Dellinger, (1986).**

❖ Treatment with fixed appliances may also extrude the teeth, further opening the bite, especially when interarch elastics are used on the anterior teeth. **Pearson, (1986), Arat, (1992).** Clear aligners may be more effective than fixed appliances in correcting deep overbite because of their more predictable intrusion mechanics.

❖ In addition, the disclusion of the teeth avoids the occlusal interferences of fixed Appliances: **Joffe, (2003), Pearson, (1986), Boyd, (2001).**

❖ Anterior and posterior dental cross bites are also effectively treated with clear aligners, probably because of their disclusion effect. **Joffe, (2003).** Skeletal cross bite, on the other hand, should be treated with orthopedic or surgical methods. It has recently been shown that presurgical treatment involving clear aligners in combination with fixed appliances can be effective in patients requiring complex orthognathic surgery with corrections in all three planes of space. **Miller, (2002).**

❖ Patients with bruxism may also be good candidates for treatment with aligners, which prevent occlusal wear. After treatment, clear retainers are generally worn at night indefinitely, extending their protective benefits. Studies by **Nedwed, (2005)** and **Miller and colleagues, (2007)** have shown that clear aligner treatment reduces myofascial discomfort from clenching and grinding, presumably because of the disarticulation of the teeth by the appliances.

❖ clear aligner treatment has been found to cause much less patient discomfort than treatment with fixed appliances, which are often associated with mucosal irritation, tooth soreness, and other problems. **Nedwed, (2005)**.

❖ Clear aligner treatment is especially appropriate for patients with extensive porcelain or metal restorations. These artificial surfaces do not allow as secure a bond with a fixed appliance as a natural tooth surface does, and the restorations may also be damaged in debonding.

❖ The Invisalign ClinCheck® computer plan can be used as a virtual diagnostic setup, allowing decisions to be made on appropriate treatment strategies such as extractions, distalization, interarch elastics, interproximal reduction, or expansion. **Miller,(2007).** Anchorage can be evaluated with the superimposition tool or surgical (interarch movement) simulation tool.

❖ The software can be used to demonstrate the limits of treatment to the patient, to create an abbreviated version of the virtual treatment plan that can be e-mailed to patients and referring doctors, and to verify proper tracking of the aligners. The program can also help the orthodontist determine the biomechanical and biological feasibility of a particular treatment plan and analyze the pathways of tooth movement. **Joffe, (2003).**

**CHAPTER THREE**

References

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