ORIGINAL SCIENTIFIC ARTICLE

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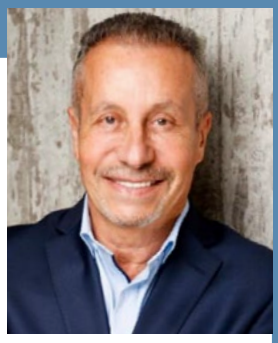
Clinical comparison of three aligner systems



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Key words *aligner, CA Clear Aligner, Invisalign, Orthocaps*

Objectives: *The object of this clinical study was to compare three different aligner systems. The aim was to help the orthodontist with choosing an adequate aligner philosophy/therapy system.*

Materials and methods: *This study included 60 randomly chosen patients. Mild to moderate cases were selected, and patients were assigned to three groups of 20 patients each. One group was treated with Invisalign (20 patients), the second group was treated with CA Clear Aligner and the third group of patients was treated with the Orthocaps aligner system. In all cases, attachments were used to additionally enhance the fitting and efficiency of the aligner.*

Results: *All investigated aligner systems achieved the predicted goal of the treatment, although with significant differences concerning accuracy, the predicted duration of treatment and the number of refinements. Significant differences were determined, especially regarding the efficiency, duration and cost of treatments.*

Conclusion: *Aligner orthodontics allow for handling difficult treatment cases despite different aligner philosophies, different materials and different durations of treatment. There were significant differences concerning the envisaged time of treatment. In moderate cases, a significant difference concerning duration and costs was determined.*

Introduction

There are many orthodontic systems on the market, and it can be difficult for clinicians to choose. The aim of this clinical study was to compare three different aligner systems. The main differences between the systems are described. The study combines a report of 60 treated patients, treated with three currently available systems. Comparisons were made based on factors useful to the clinician, including comfort, cost, and whether the intended treatment goal was reached.

Materials and methods

The study included a total of 60 patients who had refused treatment with fixed appliances, and did not accept buccal or lingual orthodontic applications, but accepted aligner treatment. Exclusion criteria were patients with a temporomandibular disorder, bruxism, poor oral hygiene and suspected lack of cooperation.

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The gender distribution was 37 female (62%) and 23 male (38%) patients. Mild to moderate cases were selected, and patients were assigned to three groups of 20 patients each. One group was treated with Invisalign (20 patients; Align Technology, San Jose, CA, USA), the second group was treated with CA Clear Aligner (Scheu-Dental, Iserlohn, Germany) and the third group of patients was treated with the Orthocaps aligner system (Rocky Mountain Orthodontics, Denver, CO, USA). Patients were assigned in order to each group (first patient CA Clear Aligner, second patient Invisalign, third patient Orthocaps, fourth patient CA Clear Aligner, etc.), until groups were full.

After intra- and extraoral examination (facial profile, malocclusion), all patients were informed about the diagnostics of their cases, the treatment options, the advantages and disadvantages of these options, and alternative treatment methods. Compliance, oral hygiene, suggested changes in their daily lives and nutrition habits were also discussed. All patients signed informed consent prior to treatment. The study was conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki.

Patients were presented with the workflow of the three aligner systems included in this study, and with the possible midcourse corrections and refinements. Further information was delivered, with illustrated information about attachments, stripping, corrections, and limitations of aligner treatment compared with fixed appliances[1]. The stability of achieved results and their retention, duration and the types of retention included were also discussed with the patients.

The average age of the included patients was 40 years. The oldest patient was a 69-year-old woman who was treated with Invisalign, and the youngest patient was a 15-year-old girl also treated with Invisalign. In the group of patients treated with Invisalign the average age was 42 years. The average age in the group of patients treated with CA Clear Aligner was 44 years. In the CA Clear Aligner group, the oldest patient was a 68-year-old woman, and the youngest patient was a 14-year-old boy. In the Orthocaps group the average age was 34 years, the youngest patient being a 10-year-old girl and the oldest patient being a 53-year-old woman.

The patients were treated using aligner therapy according to their group assignment. In all cases, attachments were used to additionally enhance the fitting and efficiency of the aligner. During and after the treatment, various data were collected. In order to perform the comparison as objectively and neutrally as possible, seven criteria for comparison were chosen:

- aligner specification
- manufacturing process
- comfort and invisibility
- precision of the envisaged goal of the treatment
- efficiency
- duration of treatment
- complications
- laboratory costs.

Aligner specifications (materials used)

The use of thermoplastic materials (polyethylene terephthalate glycol copolyester [PETG]) in aligner manufacturing has a long history[2-4]. Easy placement of aligners, a high degree of fitting as well as elasticity to allow for managing several tooth movements (such as extrusion, intrusion and torque) as well as minimising the loss of fixation are very important specifications of the materials used.

Furthermore, the thickness of the used aligner foils (0.50 mm, 0.62 mm, 0.75 mm and 1.00 mm; usually approximately 30% of the ordinary thickness are lost during the manufacturing process) and the frequency of changing these foils are crucial features of efficiency and a successful aligner treatment, thus increasing the comfort of orthodontics patients.

The specifications of the three compared aligner systems are shown in Table 1.

CA Clear Aligner

The CA system uses three foils with different thicknesses: soft 0.50 mm, medium 0.62 mm and hard 0.75 mm foil thermoplastic aligner[5]. Each treatment set includes three aligners of a different thickness. Increasing the foil thickness increase the magnitude of force delivered to move the teeth[6]. The frequency of set change is 1 week.

Invisalign system

One foil thickness (0.75 mm) is used and should be changed every 2 weeks, according to the treatment protocol of Align Technology.

Table 1 Specifications of the three aligner systems

System	Number of aligners/set	Set change (wk)	Foil thickness (mm)
CA Clear Aligner	3	3–4	Soft 0.50, medium 0.65, hard 0.75
Invisalign	1	2	0.75
Orthocaps	2	3	0.75–3.00

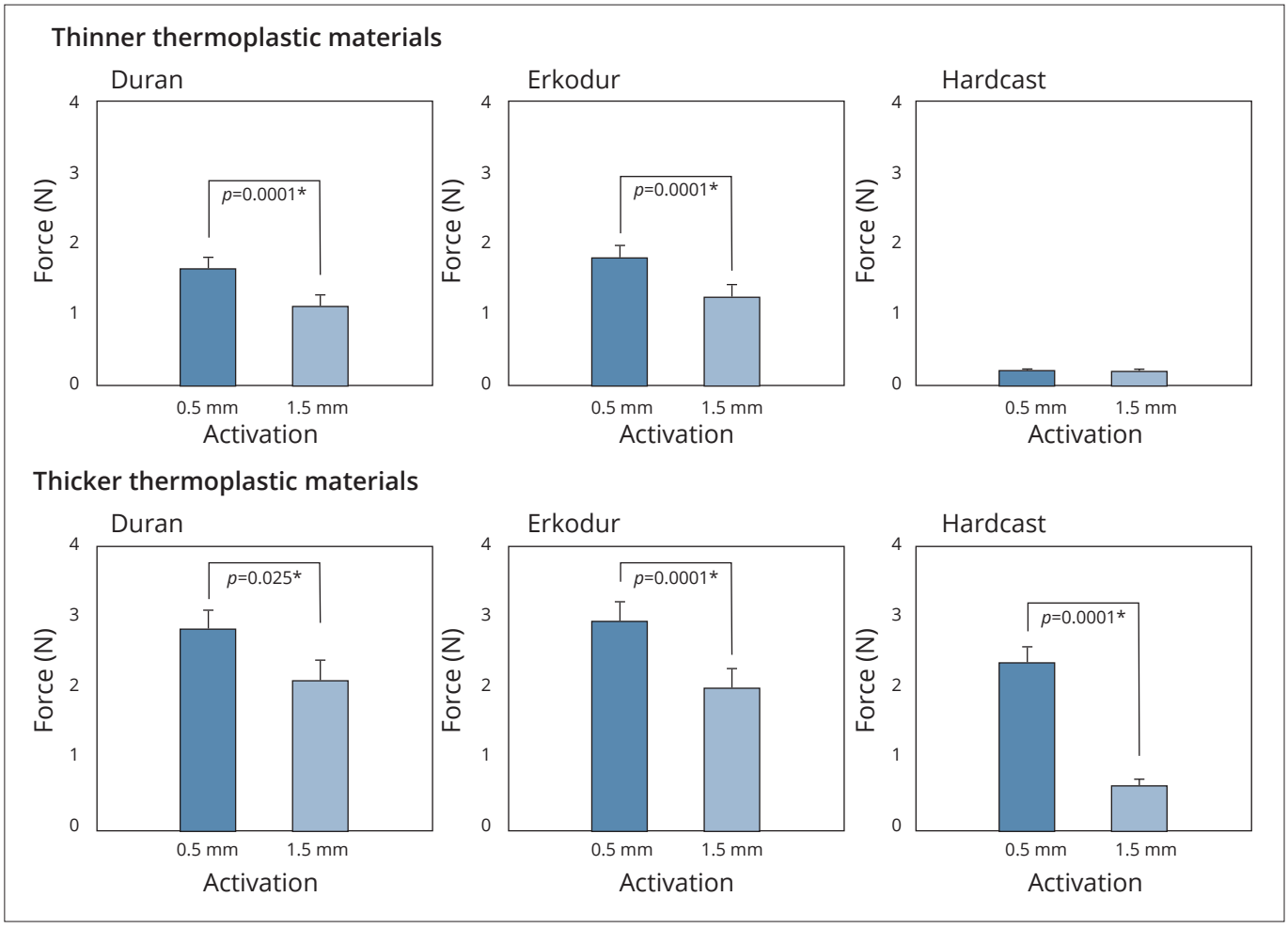

Fig 1 Foil thickness and increase in orthodontic forces. Reproduced from Kohda et al[7], with permission from Angle Orthod.

Orthocaps system

Two foils of different thickness (0.75 mm and 3 mm) are used. The thin aligner is worn in daytime and the thick foil at night. The change frequency is every 3 weeks (according to the Orthocaps treatment protocol).

Summary

As shown in Fig 1, and described by Kohda et al[7], "The thickness of the materials had a highly significant influence on the forces delivered by thermoplastic appliances, with appliances fabricated from thicker materials delivering greater forces".

Manufacturing process

CA Clear Aligner

The production method of dental pressure-/thermoforming splints is used for CA Clear Aligner production (three foils system). For this purpose, the Biostar appliance (Scheu-Dental) is used. The aligner can be manufactured in house (which can be considered an economic and practical advantage for the clinic) or at a commercial laboratory. Furthermore, the three-splint philosophy of CA allows a choice between the individual, monthly production of the aligner at an in-house laboratory[5] or serial aligner production using a three-dimensional (3D) workflow production (Scheu-Dental). With both methods, the Biostar appliance remains the main aligner manufacturing device. Note that only the CA manufacturing philosophy offers this 'dual' manufacturing option.

Invisalign

The serial production of aligners is the main and only manufacturing method used for the production of Invisalign aligners. With its own workflow, Invisalign follows exclusively the digital manufacturing philosophy, as shown in Table 2.

Orthocaps

Similar to the Invisalign manufacturing philosophy, Orthocaps integrates the serial production method for aligner manufacturing. Orthocaps has its own workflow and, like Invisalign, exclusively applies digital manufacturing methods. Manual or individual production at an in-house laboratory is not planned.

Table 2 Manufacturing process of the three aligner systems

System	Process		Type of process
	Manual	Digital	
CA Clear Aligner	Yes	Yes	Individual step-by-step
Invisalign	No	Yes	Serial production
Orthocaps	No	Yes	Serial production

Comfort and invisibility (in general)

The present study confirmed the present authors' experience, supported by the current literature, that the comfort and invisibility of aligners influences the patient's choice of orthodontic treatment. This is also in accordance with several published studies comparing buccal and lingual appliances.

Pain and pressure are part of orthodontic treatment, and in terms of intensity as well as duration and quality, are essential factors for the high levels of acceptance of aligner therapy among adult patients[8-12].

Factors that affect comfort and invisibility include:

- any decrease/increase in pressure
- foil thickness
- relation of the gingival margin to the aligner margin
- number of aligners/steps
- extent of tooth movements
- tooth movement overview (division of treatment steps).

According to the comparison of the three systems under analysis, the main factors that result in pain during aligner treatment are:

- foil thickness
- increase/decrease of pressure (forces) during aligner treatment.
- the number of aligners/sets, according to the present patients and the literature[13]
- the extent of tooth movements influences the quality and intensity of pain/pressure.

With the exception of the Clear Aligner treatment philosophy, almost all other systems use one foil thickness (0.75 mm foils, although Orthocaps uses thicker night foils). As mentioned above, Clear Aligner uses three different foils that are supposed to be changed weekly. Therefore, the tooth forces are gently increased, from 0.17 N with the first foil (0.5 mm), to 0.27 N with the 0.62-mm Duran foil, and finally to 0.35 N with 0.75-mm Duran foil[6,7]. This gentle increase of foil thickness meets the expectations of the patients and increases their motivation to enhance their compliance and acceptance of the orthodontic treatment as well.

This advantage of the CA aligner system, gently increasing the forces by increasing the Duran foil thicknesses,

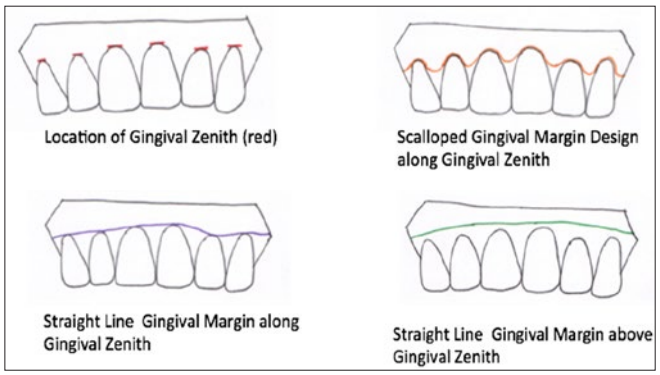

Fig 2 Relationship between the gingival margin and the aligner edge. Reproduced from Cowley et al[15] with permission from J Clin Orthod.

Table 3 Relationship between the gingival margin and aligner edge in the three aligner systems

System	Distance	Aesthetics	Anchorage
CA Clear Aligner	2–3 mm	Invisible	Sucking effect
Invisalign	Below	Visible	None
Orthocaps	Below	Visible	None

means a gentle increase in tooth sensitivity and a reduction of its duration, as well as increasing aligner efficiency with more comfort, compared to other aligner systems that use 0.75 foils from the beginning of treatment[14].

Regarding the visibility of the aligners, the main factor that influences the visibility of the aligner is the relationship between the edge of the aligner and the gingival margin (Fig 2 and Table 3). Depending on this relationship, the visibility of the aligner can be reduced or increased, which is important for the aesthetic expectations of the patient, as well as for the fit of the aligner, which improves its efficiency and therefore the duration of the treatment[15].

According to Cowley et al[15], there are three designs for aligners at the gingival margin:

- a scalloped gingival margin design, along the gingival zenith, which is used by Invisalign and Orthocaps
- a straight line gingival margin along the gingival zenith
- a straight line gingival margin above the gingival zenith (which is the used by CA Clear Aligner).

Aligners with attachments and scalloped margins show significantly less retention[16]. According to Cowley et al[15], "Aligners with attachments and scalloped margins had significantly less retention than aligners of the same material type with scalloped margins and no attachments. The 2 mm straight gingival margin design had the highest retentive forces when compared to aligners of the same material and attachment type." The straight line gingival margin shows additional physiological advantages compared to the other margin designs, as it is not in contact with the gingival zenith and therefore injuries in this area are avoided. The 2 mm straight gingival margin design is the Clear Aligner philosophy. According to the present study and the authors' experience, as well as published literature[17,18], this is an advantage of the Clear Aligner system compared with the other two systems.

Precision of envisaged treatment goal

Aligner orthodontics, regardless of the used system, has become more popular and accepted in recent years, increasing its proportion of orthodontics as a whole. This growth means more experience with this treatment technique, which also means extending the range of use. Certainly the proportion of limitations is getting smaller. Nevertheless, orthodontic treatment is connected to certain limitations that have to be taken into consideration[18-23]:

- extractions
- rotations of canines and premolars of more than 16 degrees (despite highly developed special attachments)
- deep bite, especially traumatic deep bite
- midline deviations of more than 2 mm.

Pretreatment

To simplify aligner treatment (or to make it possible at all), the orthodontics treatment was started with invisible fixed appliances, in the following cases:

- Rotations of the canines and/or premolars (more than 16 degrees). This range of rotations remains a challenge for all aligner systems. According to a study by Kravitz et al[1] including 37 patients/401 teeth in total, canines and

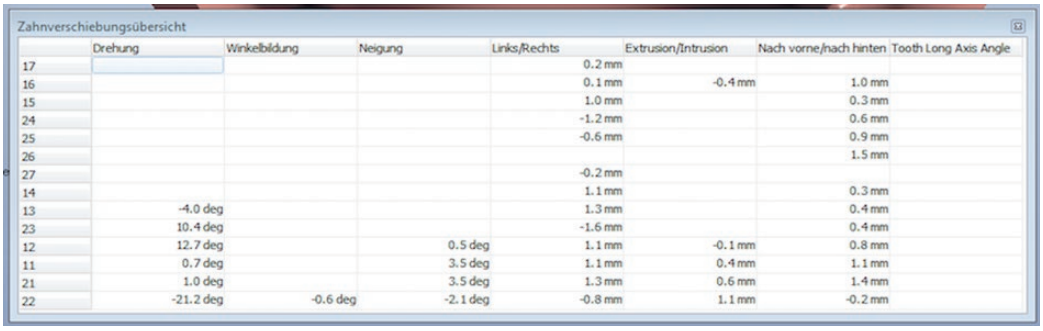

Fig 3 Tooth movement overview.

Table 4 The availability of a tooth movement overview in the three aligner systems

System	Movement overview
CA Clear Aligner	Available
Invisalign	Not available
Orthocaps	Not available

or premolars with a rotation of more than 20 degrees should be pretreated. Regarding stripping and involving special attachments to handle rotations during aligner treatment, Kravitz et al[24] state, "no statistically significant difference between the attachments only, IP [interproximal] reduction only and control in rotational accuracy" was found.

- Severe crowding (more than 6 mm). In these cases, the use of mini-implants was a big advantage to gain space, especially for the canines in the maxillary arch.

In the present study, a distalising Beneslider (PSM medical Solutions, Gunningen, Germany) was used successfully to enlarge the scope of aligner treatment and to avoid extraction. The Beneslider can be inserted before or during the aligner treatment.

Furthermore, the Carrière Motion Appliance distalizer (Henry Schein Orthodontics, Carlsbad, CA, USA) can be useful in cases when the distalisation of maxillary premolars and molars is needed to gain space or to manage distal occlusion.

The Aligner Rapid maxillary/mandible expansion (ARME), which is useful to gain space in both arches, is screwless and invisible. The present authors usually use this self-developed expansion method before starting the aligner treatment (patent pending).

Tooth moment overview

An overview of the tooth movement (Fig 3) is useful information for the doctor as well as the patient. In this way the planned tooth movement, extent and type of movement can be monitored and, if necessary, corrected or extended. Additionally, the tooth movement velocity can be adjusted and therefore the treatment duration can be influenced and determined.

Another advantage is that it can be used as an educational tool for patient communication and as a motivational instrument. The envisaged treatment goal can also be used to monitor and control the patient's compliance and individual reaction to the treatment.

CA digital and Invisalign do not offer a table in which the extent of tooth movement is included (Table 4).

Refinement

Refinement is the basis for controlling the precision of the envisaged treatment goal. The assessment of the precision of the predicted treatment goal and therefore the used aligner system was based on the frequency of needed refinement (number of aligner sets) to achieve the 'promised' treatment goal, i.e. the precision of the assumed duration of treatment[24].

Results

Regarding the results of the present study, the precision of the predicted treatment goal is presented in Fig 4 and Table 5. The highest precision of the predicted treatment goal was found in the CA Clear Aligner group (65%), whereas the lowest precision was presented in the Invisalign group, with

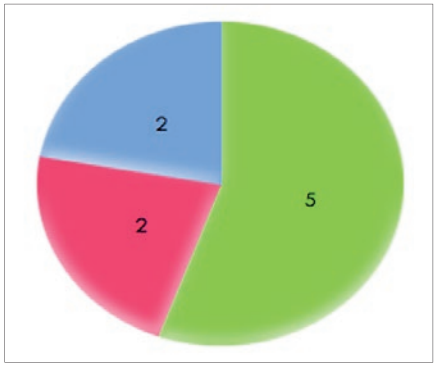

Fig 4 Frequency of change in treatment plan (number of cases). Red, CA Clear Aligner; blue, Invisalign; green, Orthocaps.

Table 5 Precision of the predicted treatment goal

System	Precision
CA Clear Aligner	65%
Invisalign	46%
Orthocaps	56%

Figs 5a to f Examples of adjustments to treatment plans. **(a to c)** Orthocaps treatment. **(a)** January 2013, at the start of treatment; 18 weeks of treatment predicted. **(b)** April 2014; changed to fixed orthodontic treatment. **(c)** June 2014, end of treatment. **(d to f)** Invisalign treatment. **(d)** Start of treatment; predicted 34 weeks (17 sets). **(e)** Midcourse correction after 1 year. **(f)** June 2014, after 34 sets of aligners.

46%. The Orthocap group presented an overall precision of 56%.

To define the predicted treatment goal, the treatment protocol of Kim and Echarri[25] was used. The leading tooth was used to determine the number of aligners that will be used as well as the treatment stages.

The OnyxCeph3 CA Smart 3D software (CA Digital, Hilden, Germany) was used for superimposition to compare the start and final position of the teeth as well as to determine the predicted treatment goal and the number of steps. For the evaluation, the model/space analysis was used according to Hasund et al[5,25,26].

Adjustments to treatment plan and technique

The present study showed that the frequency of adjusting the treatment technique was significantly higher in the Orthocap group, with five cases, when compared to the Invisalign and Clear Aligner group, each having two cases when the treatment technique had to be adjusted (Fig 4)

An additional comparison criterion was added to the study: Adjustments to treatment plan and technique. This was decided after the planned treatment time was over, and more than two refinements had been performed but the planned treatment goal had not been achieved. The additional criterion was applied to all three aligner systems. For all the adjusted cases, either the treatment approach was extensively changed, or the treatment technique was changed to fixed appliances (Fig 5).

Table 6 Overview of laboratory costs

System	Approx. cost (Euro)
CA Clear Aligner	40–69 per set
Invisalign	750–2300
Orthocaps	500–1500

Table 7 Wear time – frequency of changing aligner

System	Days/aligners
CA Clear Aligner	5–7
Invisalign	14
Orthocaps	21

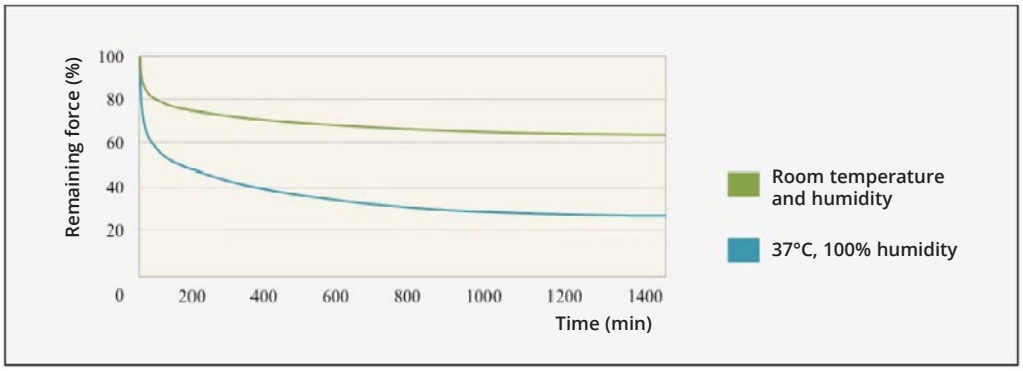

Fig 6 Decrease of pressure of the aligner material over time (in minutes); the remaining force was determined in percent. Reproduced from Tuncay[14] with permission from Quintessence Publishing.

Costs

There are large differences between the laboratory costs of the different systems (Table 6). The in-house CA manufacturing philosophy has much lower costs in comparison with Invisalign or Orthocaps. No additional external laboratory costs are required and the added value remains in the clinic, which is an important financial aspect for the clinic as well as for the patient.

Results

Increasing efficiency equals a reduction in the duration of the treatment. The main factors that affected the efficiency and duration of treatment in all 60 cases tested were:

- foil thickness/increasing the foil thickness (number of foils in each treatment set
- frequency of changing the foil (Table 7)
- the gingival margin design of the aligner
- individual biological reaction (advantage of manual production over serial production)
- compliance (in case of CA, no need for midcourse correction during aligner treatment, but more impressions are needed during treatment)
- case selection.

Side effects of aligner treatments

The potential side effects of aligner orthodontics treatment were investigated in the following fields:

- oral hygiene
- root resorption
- white spot lesions (WSL).

Oral hygiene

Many patients do not remove their aligners when drinking cold/soft drinks. This situation allows the liquids to accumulate beneath the aligner, on the enamel and at the gingival margin. Thus, a resource for infection, demineralisation, caries and gingival inflammation is created. The absence of the physiological oral cleaning process of saliva, lips, tongue and cheeks simplifies and accelerates this destructive process.

Before starting aligner treatment, all patients were informed and trained regarding the basic principles of oral hygiene that should be followed. For this purpose, a standard hygiene protocol was the basis of a training concerning teeth brushing and eating habits:

- Never eat or drink soft drinks when wearing an aligner.
- Brush your teeth and the aligner with tooth paste/fluoride and three times a day, for 3 minutes each time.

Make sure that the aligner does not show any white plaques.
- Support the brushing ritual by flossing.
- Ultrasonic cleaner is recommended.
- Pretreated patients with white spots or remarkable plaque scores need special attention, fluoride protection and hygiene training before starting aligner treatment.

In this regard, teenagers need special attention to complete a successful and caries, as well as demineralisation-free aligner treatment.

The consequent implementation of this hygiene protocol enabled the number of patients affected by gingivitis or decalcification to be kept very low in the present study. Of the 60 patients under analysis, there was only one case of severe gingivitis (Invisalign treated patient with poor oral hygiene).

White spot lesions

WSL, or white spots, on the enamel surface, mostly on the buccal surface are due to demineralisation of the enamel during orthodontic treatment, especially in case of buccal fixed appliance. Buschang et al[27] compared the occurrence of WSL among patients treated with aligner and fixed braces: 244 aligner patients and 206 with fixed braces were studied. Only 1.2% of aligner cases developed WSL, compared to 26% patients treated with brackets.

In the present study, no WSL were observed among the 60 aligner treated patients, despite using attachments in all investigated cases. This is in agreement with several studies in this field, which conclude that aligner treated patients have a significantly smaller risk of developing WSL[27].

Root resorption

The duration of orthodontics treatment is of great importance for the occurrence of root resorption. Furthermore, the range of applied forces has a great impact on root resorption[27].

In general, the duration of aligner treatment is shorter than traditional braces treatment. The forces used in aligner orthodontics are minimised, soft forces that are almost equal to the capillary pressure around the root apex (approximately 0.35 N) and similar to the forces applied in light orthodontics.

According to Makedonas et al[28], most of the root resorption occurs in the first 6 months of orthodontic treatment. No correlation was identified between duration of treatment and severity of root resorption. Other studies concluded that aligner treatment could lead to root resorption, but its scope is very similar to that occurring during orthodontics with light forces, with an average of < 10% of the original tooth length[29].

Root resorption was identified only in one of the present cases out of 60 patients (48-year-old woman, maxillary central incisors, treatment duration 6 months). No further root resorption was identified with all investigated systems, independently of treatment duration. For this purpose, panoramic radiographs were analysed.

Discussion

Ever more adults would like to start orthodontic treatment to improve their appearance. Many of these people are in social and professional situations which increase their aesthetic awareness, most of all when it comes to beautiful teeth.

According to a 2013 study, Align Technology estimated that Invisalign had a 31% share of the adult braces market[30]. The present authors' clinical experience is in agreement with this development, and that adult patients have increased their aesthetic awareness and expectations. They want invisible aesthetic solutions, distinct from ceramic or plastic brackets and lingual orthodontics.

In the majority of the present cases the envisaged treatment goal was achieved, although over different treatment durations, which also affected treatment duration, costs and patient comfort.

The use of different aligner thicknesses, gingival margin design (CA philosophy), frequency of changing the treatment sets, case selection and compliance were the main factors for achieving the successful treatment results in approximately the planned time.

The CA Clear Aligner is the ideal solution for this group of adult patients, and this corresponds with the present authors' daily clinical experiences. The present study offers practitioners and potential orthodontics patients a practical report to simplify their decision-making process when choosing the treatment method and aligner system.

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