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History, Present and Future of Aligners

1.1 History of Clear Aligners

1.1.1 Early Beginning

Recent advances in technology have allowed many inventions that were previously only thought of to become a reality. Such is the case with clear aligners whose history began at the start of the 20th century.

These early retainers were developed by Hawley and others and made from Vulcanite and gold.

Rubber was first used in 1924, when Orrin Remensnyder developed the 'Flex-o-Tite',¹ a device that was meant to stimulate gums through home use combined with toothpaste, and was therefore convenient for periodontally compromised patients.

1 Remensnyder, O. A gum-massaging appliance in the treatment of pyorrhea. *Dent Cosmos*. 1926; **48**: 381–384.

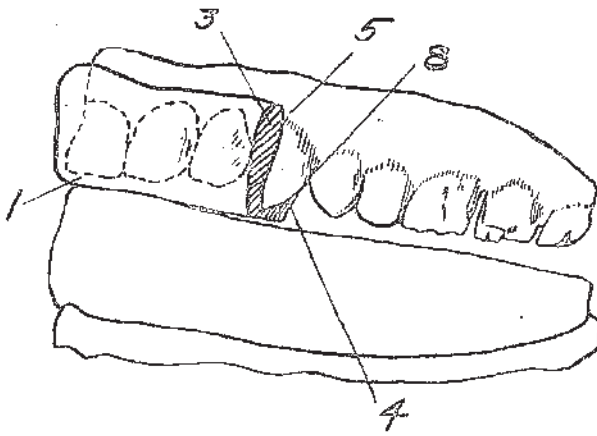


FIG. 1.

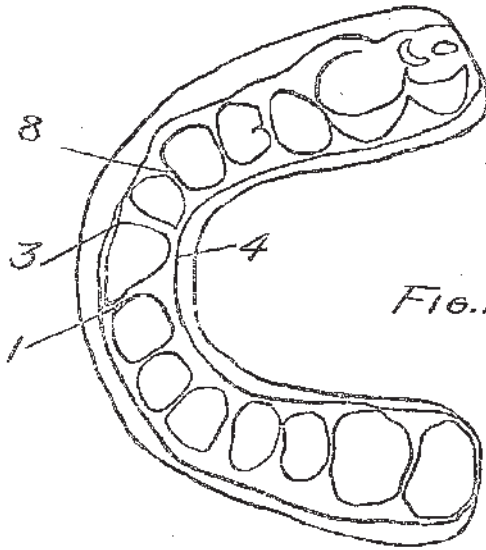


FIG. 2.

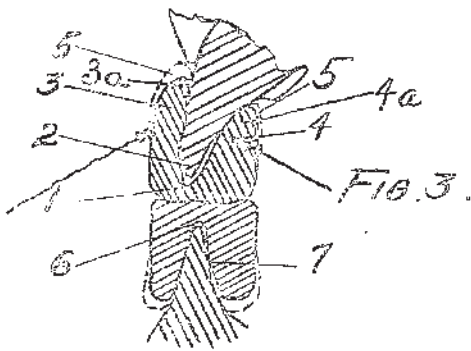


FIG. 3.

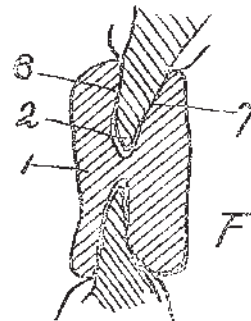


FIG. 4.

Fig. 1.1 Remensnyder patent file.

On approval the patent, Remensnyder described that the device might cause small teeth movements, using the expression 'orthodontic appliance' to describe it on his second patent for the device.²

Twenty years later, in 1946, Harold Kesling was responsible for developing what he called the 'Tooth Positioner', a device made from Vulcanite meant to prevent relapse after orthodontic treatment.

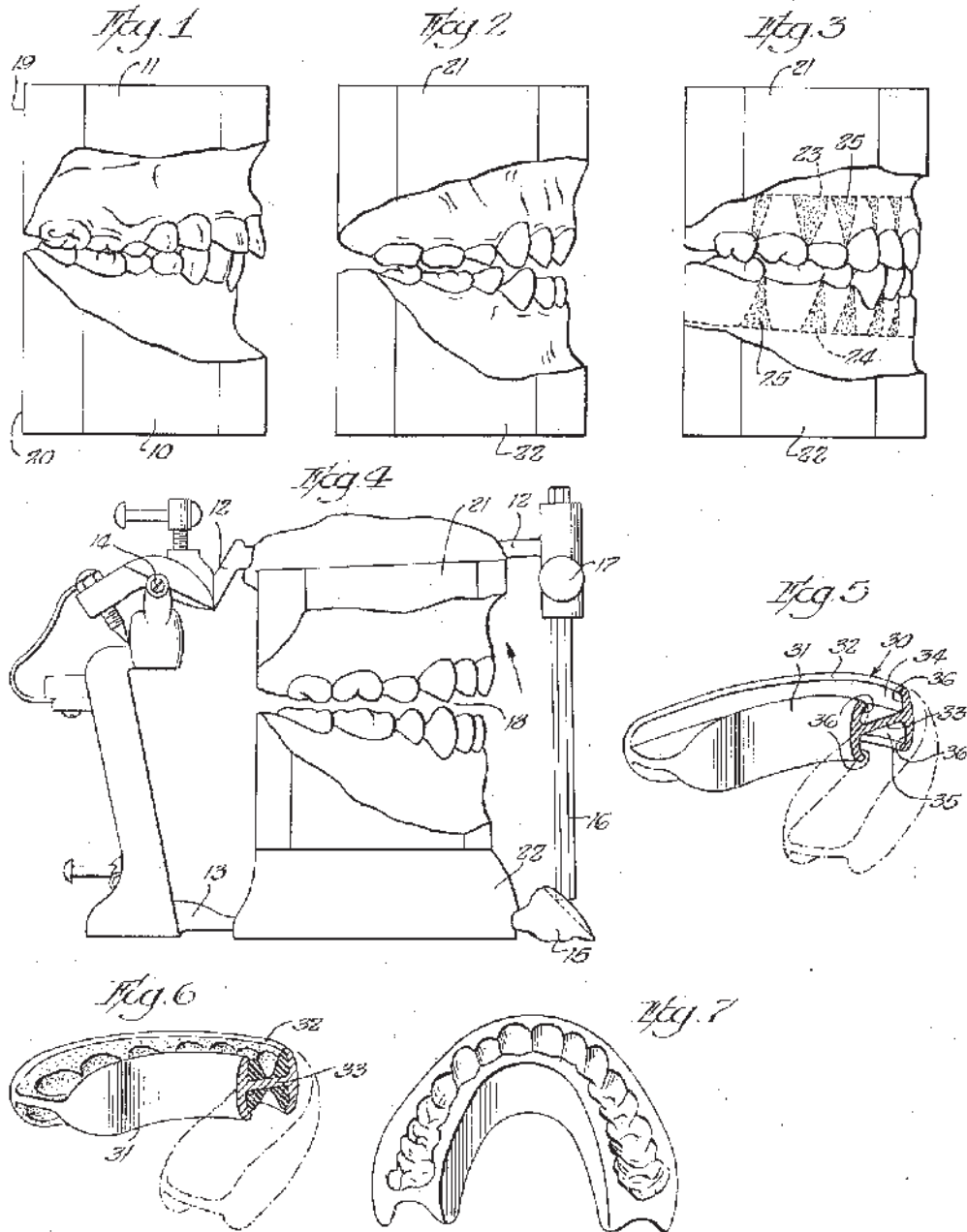


Fig. 1.2 Kesling patent file.

² Remonsnyder, O. United States Patent 2,479,780, Orthodontic Appliance, Aug. 23, 1949.

This, alongside variations from other orthodontists, was considered a gold standard for several years, in which black vulcanite was the preferred option.

By using the tooth positioner, Kesling suggested ‘major tooth movements could be accomplished with a series of positioners by changing the teeth on the setup slightly as treatment progresses. At present this type of treatment does not seem to be practical. It remains a possibility, however, and the technique for its practical application might be developed in the future’.

In 1963 when Shanks developed a technique for producing mouth guard style transparent retainers, with a machine capable of producing them. In 1964 Nahoum patented his ‘vacuum formed dental contour appliance’, while other orthodontists such as Ponitz³ faced problems in different designs such as heating capability or plastic needs.

Up to this time these devices were used to stabilize the results of previous orthodontic treatment but were also used for minor corrections to the position of the teeth.

At the end of the 1980s, Elasto devices were developed that were made from highly flexible silicon that could be used for either one or two teeth quadrants.⁴ Tooth movements were possible thanks to several set-ups that were built in different plastics, depending on the clinician’s needs, after fixed appliances.

In 1994, Sheridan developed an aligner system,⁵ which he called ESSIX, using clear, polymeric shell appliances with thermoplastic divots to reposition teeth, which was meant to solve minor anterior malpositions. In 1997, together with Schwartz, they standardized this by patenting a system that would be implemented in many dental offices until now, an ‘in-office’ vacuum system.

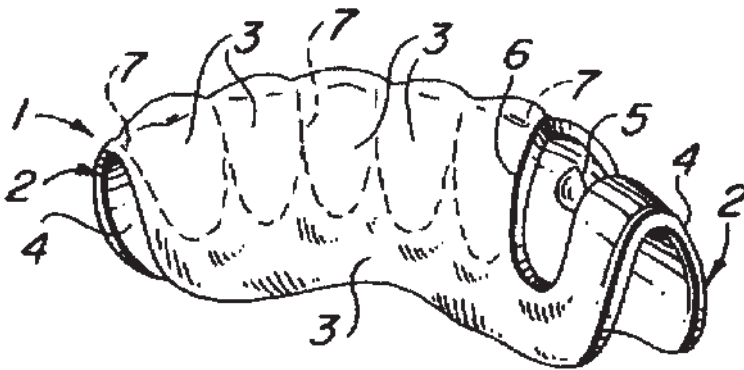


Fig. 1.3 Schwartz and Sheridan patent file.

3 Ponitz, R. Invisible retainers. *Am J Orthod.* 1971 59(3): 266–272.

4 Hinz R. Elasto-orthodontic system – a development of the positioner. *Prakt Kieferorthop.* 1991;5(3):179-88.

5 Sheridan JJ, McMinn R, LeDoux W. Essix thermosealed appliances: various orthodontic uses. *J Clin Orthod.* 1995;29(2):108–13.

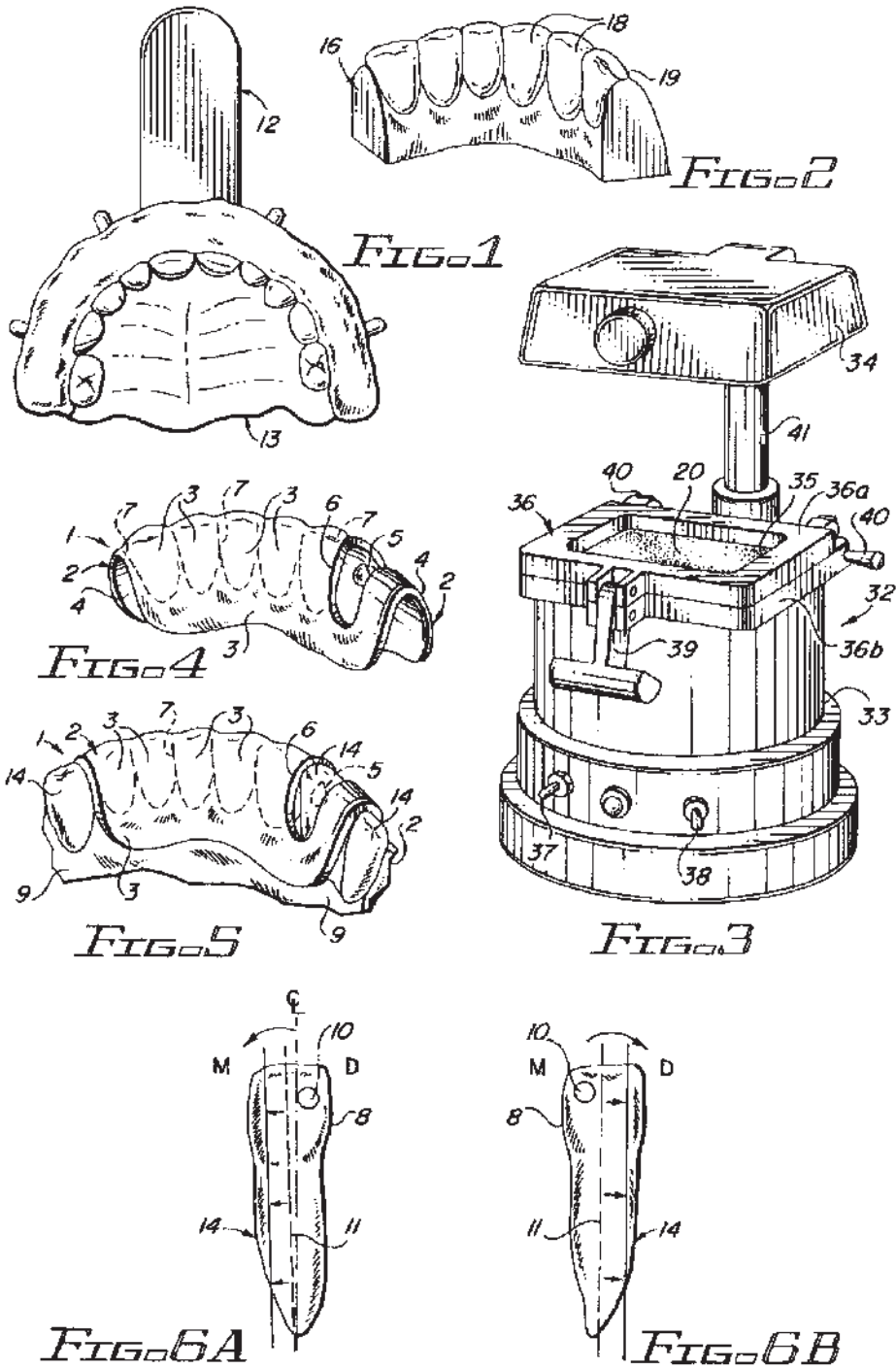


Fig. 1.3 (Cont'd)

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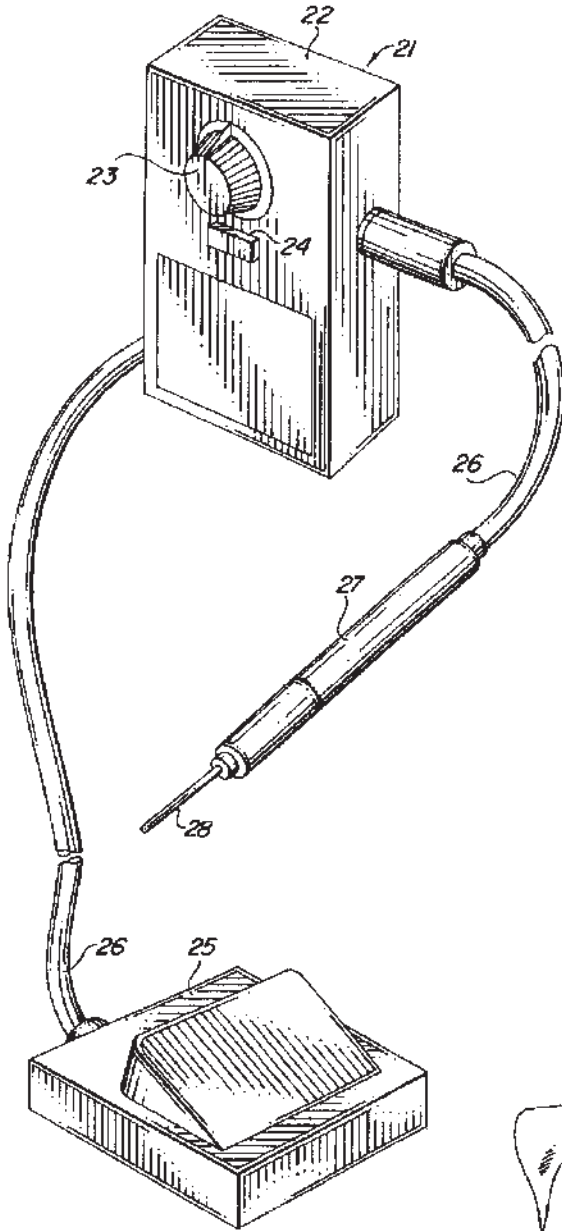


FIG. 8

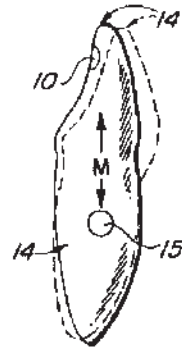


FIG. 7

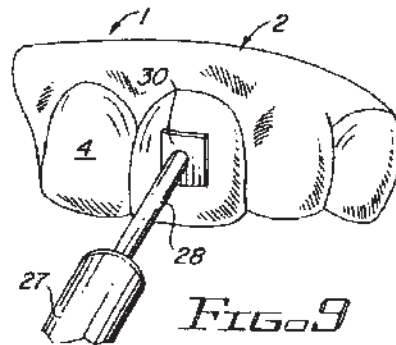


FIG. 9

Fig. 1.3 (Cont'd)

1.2 Origins of Align Technology

At the end of the 1990s a computerized aligner system was developed in the USA with promising features: namely, Invisalign, created by two Stanford students, Zia Chishti and Kelsey Wirth.

Zia Chishti was an orthodontic patient that found out that his own clear retainer might be applicable to the whole orthodontic treatment, as it might be able also to move teeth and avoid metal braces. This reasoning led to why they both started the Company, partnered with some other students in their campus, Apostolos Leros and Brian Freyburger, who were responsible for the Computer Aid Design part of this start-up.

They then developed a software to design incremental stages of retainers to straighten teeth in a campus laboratory. In 1998, they got Food and Drug Administration (FDA) approval, and were then able to sell their product to the orthodontic community, which was resistant to this radical change, mostly owing to the lack of orthodontic experience of its founders.

In 2000, they raised \$140M from venture capital companies and this allowed them to start a \$31 million TV campaign that same year. In 2001, the Company went public, raising an additional \$128M on NASDAQ.⁶

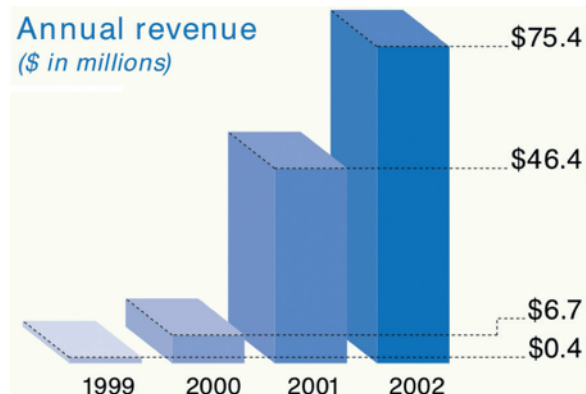
During this time, consumers drove more than 70% of the American Orthodontists to be trained in the system.⁷ That same year, Align Technology made Invisalign available to general dental practitioners, arguing that offering it only to orthodontists would be considered unfair competition by dentists.

By then, Align Technology was spending most of its revenues on advertising, and losing about \$18 million per year,⁸ which led cofounders Wirth and Chishti to resign from Align Technology before 2003.



Fig. 1.4 Align Technology logo.

Fig. 1.5 Align Technology annual revenue.



6 Feder, BJ. 'Orthodontics Via Silicon Valley; A Start-Up Uses Computer Modeling And Venture Capital to Reach Patients'. The New York Times, 18 August 2000: p. 1.

7 Bush, J. 'Stealth Braces'. YT Regional Newspapers (August 14, 2001). Retrieved January 9, 2013.

8 Lau, G. 'It has a bracing impact on patients; Align Technology' May 3; 2004.

After a cut in advertising to one-third of the original, the company grew from 80,000 patients treated in 2002 to 175,000 in 2004, while receiving awards for its stereolithography techniques, medical design and fast growth. In addition, the company finally achieved a profit for the first time in 2003.

In 2004 the FDA cleared expanded labelling for Invisalign and removed the permanent dentition requirement, making possible the launching of Invisalign TEEN and widening clinical applicability to include more complex cases and increase the age band for treatment.



Fig. 1.6 Align Technology stereolithographic has been heavily awarded.

In 2005, the Harvard School of Dental Medicine required for the first time that its orthodontic graduate students complete Invisalign certification before they graduated.⁹

1.3 Early Clear Aligner Manufacturers

Although most patented innovations have been developed by Align Technology, other companies have been working on new functionalities since the beginning of the century.

Orthoclear

- Founded in 2005 by Zia Chishti, one of the Invisalign system founders, based in Pakistan, ended its operations in 2006 after a corporate agreement with Align Technology that followed litigations related to trademark.

ClearCorrect

- Founded in 2006 in Texas, it was developed by one of the practitioners using Orthoclear, after it ended its operations, to be able to finish his patient treatments not using the Invisalign system, offered to old Orthoclear customers.
- This was made in collaboration with a technician working with plaster models. In 2008 they digitalized the process and were able to produce larger series of aligners, which they sent to the orthodontists together with the plastic models made for every movement.
- The Company was acquired in 2008 by Straumann group, together with some other companies with previous experience in the field to build an aligner system driven by this international holding.

⁹ Antelman G. *International Directory of Company Histories*. St James Press. 2008; **94**: pp. 15–18.

Fig. 1.7 Models and aligners by Clear Correct.



Orthocaps

- Founded in 2006 in Germany by Khan, this system has a ‘method of combining two different soft aligners for day and night time use’. These two types differ from one another in both their composition and the amount of pressure they exert. This innovation is called the TwinAligner system.

Inman aligner

- Developed by a dental technician, Donal P. Inman in 2000 in Florida, it was initially for minor alignments and finally widely used by general practitioners for veneer preparation in a simple and more affordable way than other aligner brands.

1.4 Align Technology Development

Align Technology claims an investment over \$1000M, which has made them a leader the clear aligner market over 20 last years, with more than 900 patents currently issued at the time of writing.

This progress has been possible thanks to an increasing clinical and engineering team that has been involved with many innovations over the years, such as:

- Invisalign 1.5: this included initial SmartForces and attachments, which are attachments combined with three dimensional (3D) activations on the aligner material (by then, EX30) that help creating counterforces to achieve desired movement.
- Invisalign G3: this included passive aligners on the arch with less movement to allow class II and III elastics on patients with A-P correction needed, as well as laser cut precision cuts or hooks.
- Invisalign G4: Optimized attachments for root control movements, open bite, and pressure points on aligners on teeth with small clinical crowns that could not accommodate double attachments.

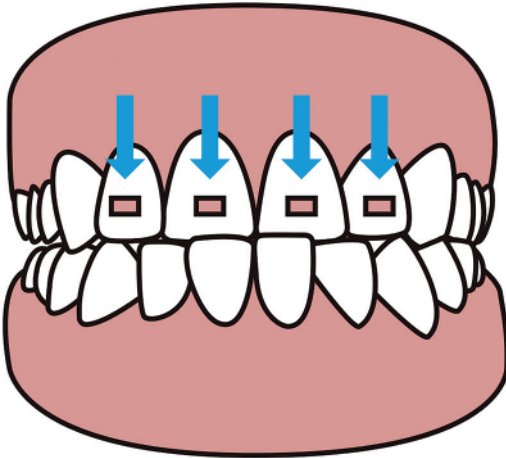


Fig. 1.8 Optimized attachments for anterior open bite.

- SmartTrack: Align Technology’s proprietary material for aligners, launched for its increased fitting and elasticity.
- Invisalign G5: mostly for vertical malocclusions treatment, including specific protocols for Spee curve intrusion, passive attachments or precision ramps to help disoccluding posterior sectors.

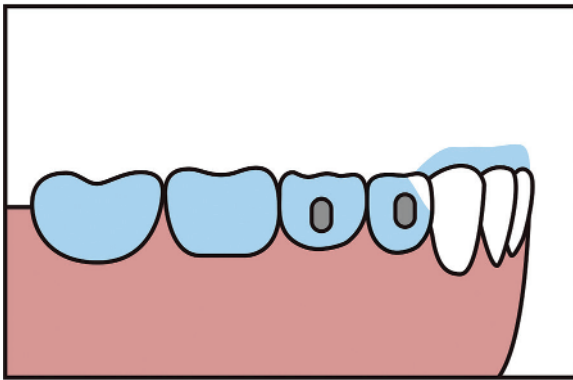


Fig. 1.9 Passive attachments for anterior intrusion.

- Invisalign G6: specific movement protocol for premolars extraction as well as exclusive attachments group designed to fulfil the best outcome in these cases.
- Invisalign G7: designed for improved finishing with functionalities such as specific lateral incisors attachments.
- One week wear: an aspect that helped to reduce the treatment length resulting from changing the aligners every 7 days instead of 14, as had previously been the case (after an internal clinical study).
- Mandibular advancement: this is one of the features that has further increased the range of cases treated, as it includes not just orthodontic treatments, but functional ones, substituting classical twin blocks or mandibular advancements for power wings.

These, together with further functionalities covered in this book can help the orthodontist to achieve the same results as with braces, and combined with auxiliary techniques such as TADs, intermaxillary elastics, buttons, surgery: any malocclusion can now be solved with aligners.

1.5 Current Situation and Future of Aligners

Since the beginning of the twentieth century there have been vast improvements in the field of orthodontics. These range from edgewise appliances to the latest straightwire ones and self-ligating braces.

If we were to search 'orthodontics' in PubMed, we would now find more than 70,000 entries, indicating that the profession is becoming more and more relevant for a global population that is demanding both health and aesthetics in their smile.

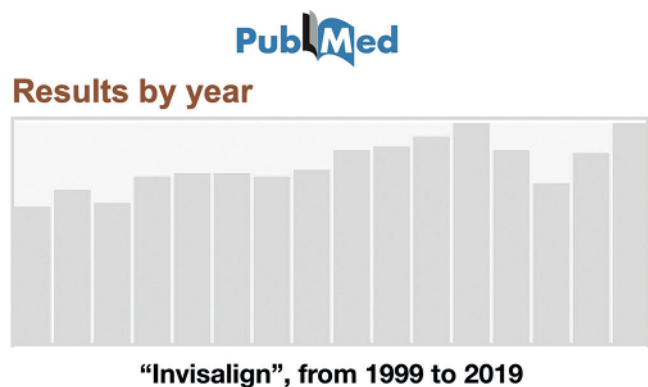
Fig. 1.10 Results in PubMed for 'orthodontics'.



As seen in the history of clear aligners, it is clear that the number of papers published on aligners is much lower than in the entire field of orthodontics, likely because of its relatively newness, with developments only coming in the last 5–10 years. The requirements for publishing a paper in a peer-reviewed journal can make it very difficult to fully appreciate their growth in the orthodontic community.

That being said, what we can see is that the popularity of aligners has been powered by Align Technology over the last 20 years, given that the majority of papers published have referred directly to the 'Invisalign' technique, and it has only been relatively recently that other brands have attempted to enter the market.

Fig. 1.11 Results in PubMed for 'invisalign' from 1999 to 2019.



It is for this reason that the patients mentioned in this book have been treated entirely using aligners produced by Align Technology; however, the biomechanical approach can be extended to any brand that, in the future, is able to develop a reliable product to treat any malocclusion using aligners and auxiliary techniques.

We constantly aim to analyse, study and understand what is happening within the field of orthodontics and strive to be on the edge of innovation, always one step ahead in order to provide our patients with the best solution for the situation that they face. We have focused on the most promising aligner brands available at this moment but we are aware that with technological advances everything may change very quickly.

1.6 Promising Aligner Initiatives

1.6.1 ClearCorrect by Straumann

Straumann is one of the larger dental companies in the world, and is known for dental implants. With the acquisition of ClearCorrect in 2019, a company founded in Texas in 2006, they entered the Aligner marketplace offering the following:

- Two aligner options: unlimited or individual (including just a single aligner), a flexible option to suit each practitioners needs.
- Free treatment setup (you do not pay for anything except the aligners).
- Polyurethane aligners, 0.3 inches (approx. 7.5 mm) thick, a very common material.

Unscaloped trim line extended past the gingival margin, intended to increase retention over scalped aligners, therefore reducing the need for attachments and improving aesthetics.

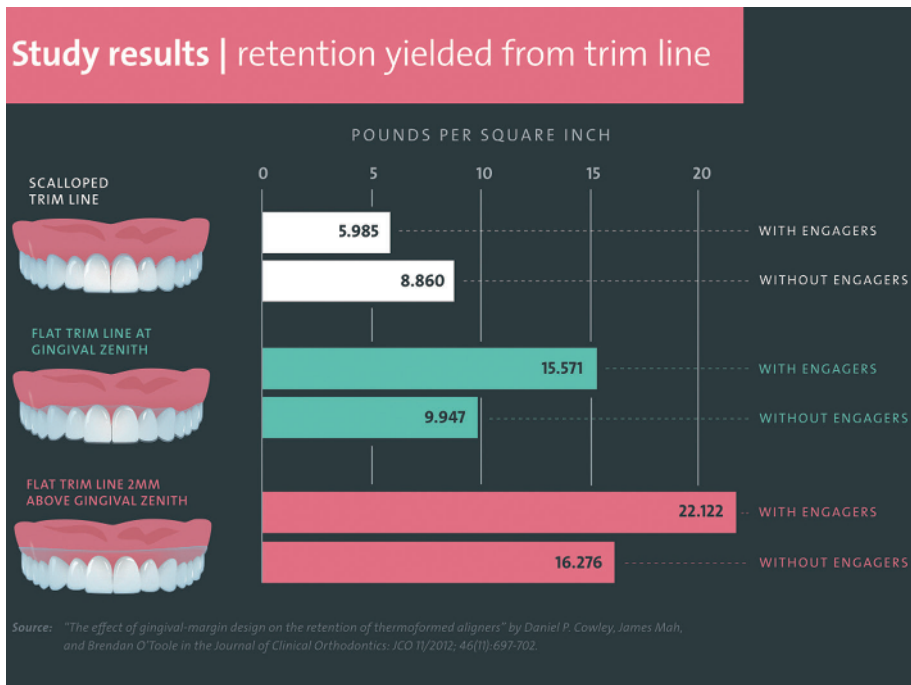


Fig. 1.12 ClearCorrect aligner retention chart. From: Cowley DP, Mah J, O'Toole B. The effect of gingival-margin design on the retention of thermoformed aligners. *J Clin Orthod* 2012; **46**(11): 697–702.

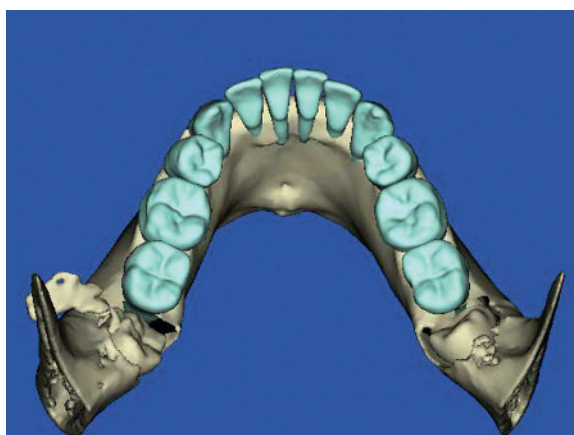
None of these aspects have been followed through a clinical study or published in a journal, so although this seems promising, we will have to wait to see how the system develops in the future.

1.6.2 SureSmile by Dentsply

Dentsply is the largest dental company in the world, with an extensive portfolio of dental products. Although initially focused on restorative dentistry they have recently incorporated dental implants and clear aligners. The acquisition of SureSmile from Orametrix in 2018 allowed them to enter the aligner market with a system displaying the following characteristics.

- The only aligner system linking cone beam computed tomography (CBCT) with cephalometric X-ray and virtual simulation of movement.
- Hybrid treatment, being able to mix braces and aligners.
- In-practice produced aligners, where the practitioner is sent the files to print three-dimensional models that are used to vacuum-form aligners with Essix plastics.

Fig. 1.13 SureSmile aligner software combined with CBCT.



1.6.3 F22 by Sweden and Martina

Sweden and Martina is a dental implant company from Italy that developed an aligner system alongside Prof. Siciliani from the University of Ferrara. The system has the following characteristics:

- Mentoring from a member of the University of Ferrara throughout the duration of the treatment.
- Chromatic stability, owing to less pigment retention from the plastic material used for the aligners, and proven through clinical study by the university.
- Optimal fitting, leaving a space smaller than 40 μm between the aligner and the teeth.
- 20% lighter force transmission than other aligner materials, according to one study by the university.
- Increased comfort, as a result of the university's trimming protocol.
- Increased retention, as a result of a design based on a paper published by Cowley¹⁰ suggesting higher values of retention are obtained when aligners are cut regularly and straight at the level of the gingival margin zenith.

¹⁰ Cowley, DP., Effect of Gingival Margin Design on Retention of Thermoformed Orthodontic Aligners (2012). UNLV Theses, Dissertations, Professional Papers, and Capstones. 1662. <https://digitalscholarship.unlv.edu/thesisdissertations/1662>.

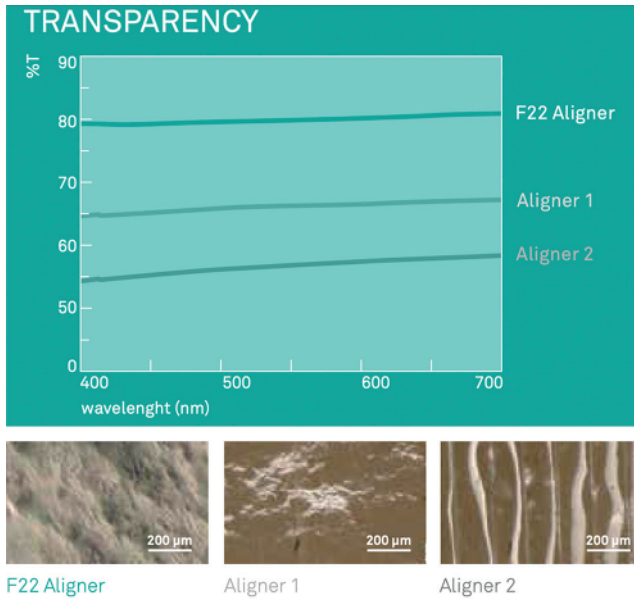


Fig. 1.14 F22 chromatic stability. From Lombardo *et al.* Optical properties of orthodontic aligners—spectrophotometry analysis of three types before and after aging. *Prog Orthod* 2015;16:41.

1.6.4 Clarity by 3M

The MBT prescription, developed by McLaughlin, Bennett and Trevisi, was successfully marketed by 3M, based in Germany, having developed many innovations in the orthodontic field and including the proprietary Incognito lingual braces system.

In 2018 they launched their Clarity aligners, with the same name they give to their aesthetic braces system, claiming:

- Advanced analytics and software planning tools.
- Open platform accessible with any scanner.
- 3M Treatment Tracking patient App.
- Accessibility from PC and MAC.

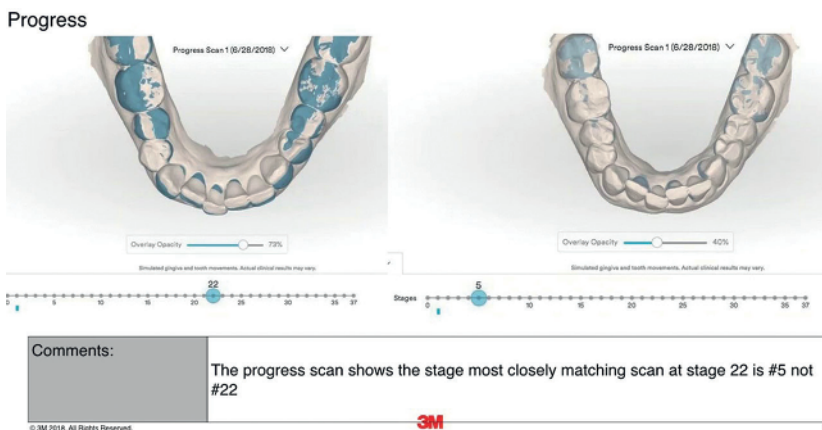


Fig. 1.15 3M superimposition for treatment evolution.

- From November 2019, the only information published in regard to this were two clinical cases published on their website, both for aligning anterior teeth, but with no A/P correction or vertical component in the treatment.

1.6.5 Spark, by Ormco

Ormco is one of the leading brackets and wires manufacturers in the world, which started offering its own aligners brand in 2019, claiming the following (data on file from the Company that we cannot access at this time):

- 1) TruGEN plastic aligner is clearer than the leading aligner (AKA Invisalign).
- 2) TruGEN plastic aligner produces higher sustained force retention in order to reach treatment goals faster than the leading aligner (AKA Invisalign).
- 3) Hand trimmed aligners, with scalloped edges that are meant to be more comfortable for the patient.

Apart from this, their product portfolio is similar to the one developed by Align Technology, with 3 treatment options (10, 20 or unlimited aligners), based on a 7 day wearing period of the aligners. They have as an advantage, the ability to perform single arch treatments using the unlimited aligners product, which is not available for Invisalign aligners.

In regards to their proprietary software, it has different functionalities than ClinCheck software, the most significant being the simulation of roots. None of this has been through a clinical study

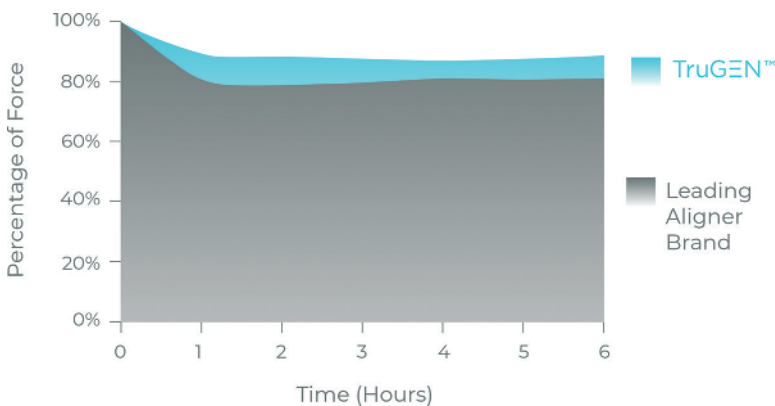


Fig. 1.16 Ormco results for their TruGEN plastic against SmartTrack (data on file).

or published in any journal so, even though these aspects are promising, we will have to wait to see how it develops in the future.

1.6.6 CA Clear Aligner by Scheu

This German aligner system enables clinicians to fully take control of aligner production, provided that there is a dental technician in the team responsible for developing models and manufacturing in-office vacuum aligners that offer several advantages:

- Integration of auxiliaries, such as expansion screws or distalizers
- Scheu biocompatible material
- Individual fabrication for each treatment step

- Three thicknesses available (0.5, 0.65 and 0.75 mm) to be changed selectively in order to exert certain forces



Fig. 1.17 Distalizer inserted in an in-practice aligner.

This is one of the segments that might grow in the near future when 3D printing allows direct aligner printing in the practice, thereby reducing the need for vacuum models, saving both time and money and making it cheaper to produce aligners. This will improve the affordability of the treatments for patients, as this option already provides a fit equal to that of any other aligner brand.¹¹

1.6.7 Irok

This US Company is focused on the printing of digital models for aligners design, but also for retainers, indirect braces bonding.

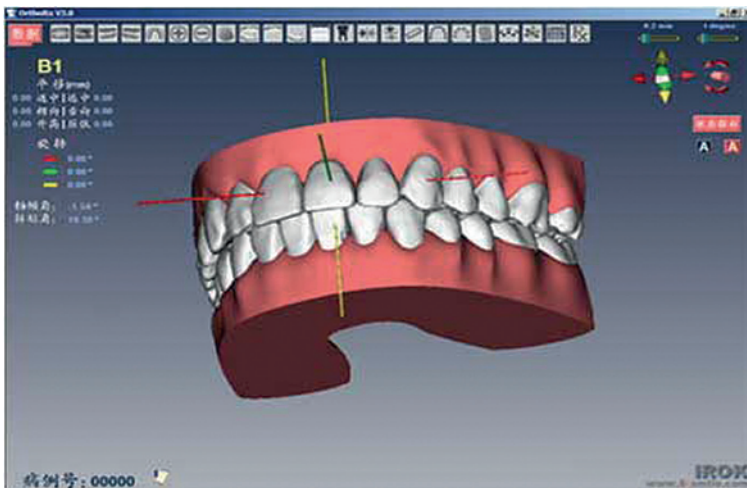


Fig. 1.18 Irok is focused on digital models that can serve different purposes.

11 Mantovani E *et al.* Scanning electron microscopy analysis of aligner fitting on anchorage attachments. *J Orofac Orthop.* 2019;**80**(2):79–87.

Its unique characteristic is that it provides the possibility of aligning in combination with dental implant software, based on the implant's final position, and it can be placed with a surgical 3D splint.

1.6.8 Angelalign

Founded in 2001 by Li Haumin in conjunction with Tsinghua University and Beijing Capital, Angelalign is the largest provider of transparent teeth aligners in China.

Since 2006 they have been granted 80 patents relating to processes, aligners, manufacturing and 3D technology and, for these reasons, they can offer a product with several technological advancements and functionalities through their iOrto platform:

- masterMulti, offering the opportunity to using different aligner thickness
- Mandibular advancement device, first launched globally, in 2015
- a7 extraction technology, tested over 15 years

Together with other Asian companies such as Smartee, for whom there is currently little information in Europe, Angelalign will probably become an important stakeholder in aligners development.



Fig. 1.19 A6 mandibular advancement launched in 2015.

1.6.9 Alineadent

This Spanish aligner Company has its origins in a dental laboratory specializing in orthodontic functional appliances, which led to the development of this aligner brand. Its characteristics are:

- Open system, compatible with any scanner brand
- Immediate validation from a dental technician
- Planning within 72 hours
- Production within 72 hours
- LineDock software for case management

Unfortunately, there is no evidence available with regard to its capability in the management of complex cases, as with some other dental companies manufacturing aligners. Their ability to improve this may rely on their approach to practitioners that may choose to use them in cases of minor tooth movements.

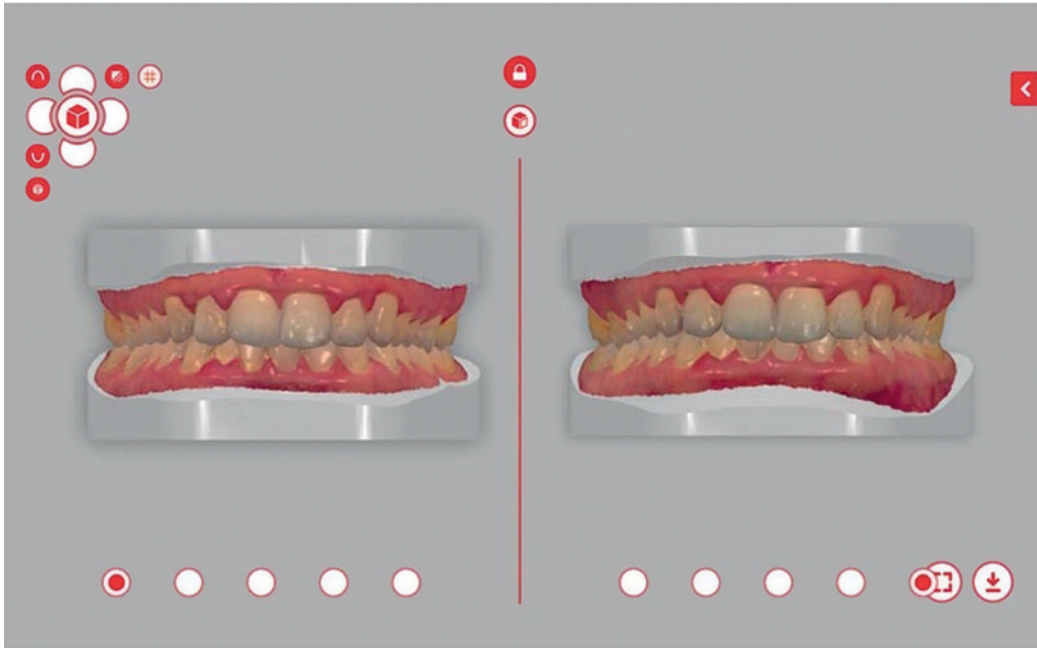


Fig. 1.20 LineDock software.

1.6.10 Remote Aligner Companies

It is important to mention direct to consumer aligners, or remote aligners initiatives, especially as Candid, one of these companies, has raised \$78.4M in venture capital funds, and SmileDirectClub already has more than 300 locations in the US, UK and Australia and has treated more than 650,000 patients since its foundation in 2014.



Fig. 1.21 SmileDirectClub self-polyvinyl siloxane (PVS) impression kit.

They all are based on the following workflow:

- Scanning in a company facility similar to a store or self-taking a polyvinyl siloxane (PVS) impression at home with a kit sent from a remote aligner company, and sending it back to its headquarters
- Validating the case at the company aligners production facility
- Patients receive the aligners

Step 1



Send us impressions of your teeth

Your \$95 starter kit gets you everything you need to send us impressions of your teeth; our orthodontists use them to design your treatment.

Step 2



Our orthodontists design your treatment

We show you a fully interactive v digital model of how your teeth will adjust over time. Treatment is customized by your assigned orthodontist.

Step 3



Get custom aligners delivered to your door

We'll deliver your complete set of aligners to your home, all in a single box. You'll also get out complimentary premium whitening system on us!

Fig. 1.22 CANDID aligners process.

In an era when people are used to a one-click-buy, particularly through their Smartphone, and when telemedicine is on the rise as a result of the growth of the internet and wearables that are part of our daily routines, this might sound ‘good’ for patients who want to have a cheaper treatment option, as they are usually three to four times cheaper than an average comprehensive treatment performed by an orthodontist.

There have been several blocks to the success of these companies: for, example SmileDirectClub were forced to pull out of the Spanish market after the Spanish Ministry of Health warned that their system was against Spanish Law, and the American Association of Orthodontists filed complaints with 36 state dental boards and attorney generals alleging specific statutory and regulatory violations.

These systems may lead to health problems in the future for some of their users owing to poor, improper treatment. This may lead to problems that need to be resolved in-house, resulting a further treatment cost on top of the impact on their health.



Fig. 1.23 CANDID aligners set.

1.7 Future of Clear Aligners

The future of clear aligners is, as with everything, unpredictable, but it likely that there will be a strong focus on:

- In-practice aligners, thanks to the development of 3D printing
- Integration of CBCT with treatment planning software
- Increasing number of laboratories and aligners companies
- Price reduction

What is clear is that, thanks to this, before 2030 100% of the orthodontic treatments will be performed with aligners in every practice in the world, as it is currently in ours.

We should aim to ensure that as orthodontists we are ahead of these changes and share our views and clinical experience with the orthodontic community as a whole so we may help to improve the smiles of everyone.