Docusign Envelope ID: C1C1027A-561B-4CB0-925B-D688EFC7000E

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARCORRECT OPERATING LLC,
Petitioner,

v.

ALIGN TECHNOLOGY, INC.,
Patent Owner.

IPR2025-00818
IPR2025-00819
IPR2025-00820
IPR2025-00821
Patent Nos. 10,973,613,
11,154,384,
11,648,090,
11,648,091

DECLARATION OF YAN CHEN

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I, Yan Chen, declare as follows:

I. BACKGROUND

1. My name is Yan Chen. I am the Director of Materials Research Engineering at Align Technology, Inc. (Align). I have over 30 years of experience in polymer chemistry and materials science, including over 19 years designing, developing, and testing materials for dental and orthodontic use. I have worked at Align for the past 20 years.

2. I hold a Bachelor of Science degree in Chemistry and a Master of Science Degree in Polymer Chemistry & Physics from Jilin University in China. I also hold a Master of Science degree in Materials Science from the University of Cincinnati.

3. I began working at Align in June 2006 as a senior materials engineer. Before working at Align, I spent over a decade working in the fields of polymer and materials engineering. This included work as a polymer chemist at Ilypsa, Inc., a process development engineer at Caliper Life Sciences, a research associate at Aura Oncology Systems, a materials engineer at Lucent Technology and Avaya, Inc., (a Lucent technology spin-off), and as a research chemist at the Institute of Chemistry of the Chinese Academy of Science.

4. I have been listed as an inventor or co-inventor on over 50 issued US patents related to dental and orthodontic applications.

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II. OVERVIEW OF ALIGN'S DEVELOPMENT PROCESS FOR SMARTTRACK (ST30)

5. I am a co-inventor on U.S. Patent Nos. 10,973,613, 11,154,384, 11,648,090, and 11,648,091. These patents relate to technology developed by Align for manufacturing orthodontic appliances from multilayer polymer sheets. These patents claim priority to a patent application (U.S. App. No. 13/470,681 (the '681 application), now U.S. Patent No. 9,655,691) filed May 14, 2012.

6. Since the late 1990s, Align has been manufacturing clear plastic aligners that correct malocclusions and provide orthodontic treatment. These aligners are sold under the brand name Invisalign®. Patients wear clear plastic aligners over their teeth, and the aligners apply forces to cause the teeth to move. By wearing a sequence of aligners, a patient's teeth can be repositioned into a more orthodontically desirable arrangement.

7. Align's earliest aligners were made of a polycarbonate material called Proceed30, or PC30. These aligners were used for several years and widely adopted in the field.

8. In 2001, Align introduced a new aligner material called Exceed30, or EX30, which replaced PC30. EX30 was made of thermoplastic polyurethane. The EX30 material showed improved performance relative to PC30 aligners, with improved stress-strain curves and greater capacity to deliver force. The superior

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performance of polyurethane aligners relative to polycarbonate aligners led Align to shift away from polycarbonate for orthodontic aligners.

9. EX30 aligners were effective clear plastic aligner products for orthodontic treatment. Align's EX30 aligners became the top-selling clear plastic orthodontic appliances. EX30's composition saw widespread adoption and was used by both Align and competitors until Align's subsequent development of its next-generation aligner materials, which are described in the '681 application.

10. Years before the filing of the '681 application, Align began a development project with a goal of identifying materials for next-generation aligners that further improved over the performance of the EX30 material. Align began a design process in the mid 2000s to identify materials that would substantially improve over EX30 in orthodontic aligners. During a development process lasting more than five years, Align worked to develop a suitable appliance that would meet various criteria for improved orthodontic treatment relative to aligners made with EX30.

11. I joined Align in June 2006, and I was a member of a team developing these next-generation aligner materials. The team was led by Dr. Chunhua Li, a co-inventor on U.S. Patent Nos. 9,655,691 (which granted from the '681 application), 10,973,613, 11,154,384, 11,648,090, and 11,648,091. I understand Dr. Li

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submitted a declaration to the Patent Office describing details of this development process and its results.

12. My responsibilities as a key material engineer of this team included researching, identifying, obtaining and testing candidate polymeric materials to determine their suitability to produce an orthodontic appliance with improved performance relative to EX30, as well as recording the results of these tests. Our team engaged in a rigorous iterative process of ideation where we identified candidate materials and then performed rigorous tests on candidate materials from many different plastics companies to see if they met manufacturing and clinical standards for aligners. Through the process, Align conceptualized and then tested at least 269 different polymeric materials during this product feasibility and evaluation ideation and testing process. Testing included, among other things, performing tests of different materials' modulus of elasticity, elongation, polymer thermal-mechanical properties, stress-relaxation, durability, environmental stress cracking, transparency, thermoforming adaptation, and aligner thermoformability. Align's objectives in material development included improvement in stress-relaxation, as well as comparable or improved performance in other properties.

13. Our process of iterative ideation, testing, and refining selection of aligner materials aimed at identifying a top candidate material with well-balanced polymer properties to improve upon the overall performance of EX30. The at least

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269 polymeric materials that were tested during this process were compared to EX30 and to each other, and were narrowed down repeatedly under this process until a single material composition was identified for commercialization purposes. Our journey toward a candidate material lasted over five years.

III. THE ST30 MATERIAL

14. Through our ideation process, Align identified a thermoformable multilayer sheet formed of layers of different polymeric compositions. One type of layer in the multilayer material was a relatively hard layer of co-polyester. A second type of layer in the multilayer material was a relatively soft layer of thermoplastic polyurethane elastomer. The material identified by this process was subsequently adopted by Align as its material for production of almost all orthodontic aligners, and it was sold under the trade name "SmartTrack" and also referred to as "ST30."

15. An ST30 aligner is manufactured from a sheet of ST30 material and designed to be worn on a patient's teeth. When the patient wears an ST30 aligner, it applies forces to move the patient's teeth from a first configuration to a second configuration. This allows the patient's teeth to be re-positioned via the application of tooth-moving forces. In a commercial ST30 aligner, the aligner is formed from a sheet with three layers: two soft polymer layers and one hard polymer layer, with the hard layer located between the soft layers. The hard layer is formed of a hard

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co-polyester material, and the two soft layers are each formed of the same soft thermoplastic polyurethane elastomer material. In a commercial ST30 aligner, the hard layer's elastic modulus is greater than each soft layer's elastic modulus.

16. [redacted]

17. [redacted]

[redacted]

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18. ST30 material is formed into dental aligners for repositioning patients' teeth by thermoforming an ST30 sheet over a mold that is a positive model reflecting an arrangement of a patient's teeth. This thermoforming process molds the sheet into a multilayer aligner having layers matching those of the ST30 sheet. The aligner is fabricated as a negative model of the mold, which produces a shaped plastic aligner with multiple tooth-receiving cavities to receive the patient's teeth and resiliently reposition them from a first arrangement to a second arrangement by applying a resilient repositioning force to the teeth when the aligner is worn on the teeth of a patient.

19. ST30 aligners produce resilient repositioning forces due to mismatches between the shape of an aligner and a current position of a patient's teeth (e.g., the shape of an aligner can reflect a position toward which a patient's teeth are to be moved). ST30 aligner can also produce resilient repositioning forces due to areas where an aligner retains or anchors dentition, through implementation of rotational forces, and other displacements that are programmed into the geometry of a cavity. When worn, differences between aligner geometry and a current arrangement of dentition cause the apply a resilient force on the patient's teeth to urge them to reposition. After thermoforming, excess material is trimmed from the thermoformed multilayer sheet to produce an aligner.

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20. Typical treatment of a patient with ST30 aligners involves fabricating multiple aligners to move a patient's teeth in stages from an initial configuration (or arrangement) through a series of intermediate configurations toward a target configuration. A different aligner is made for each stage of a treatment plan: a mold is manufactured for each stage corresponding to how the patient's teeth should move in that stage and then using the thermoforming process described above to manufacture an aligner for that stage. Stages can correspond to intermediate configurations of a person's dentition. Typically, multiple ST30 aligners are made for a patient using thermoforming processes.

IV. ALIGN'S DEVELOPMENT PROCESS

21. As I discussed above, Align conducted an extensive iterative ideation process where we developed and tested many different polymeric materials as candidate aligner materials to replace EX30. Prior to the introduction of ST30, EX30 was the material Align used to make its commercial aligners.

22. As I further discussed above, Align identified and rigorously tested over 269 materials leading up to the development of ST30. Align compared measured properties of candidate polymeric materials to EX30 using material, mechanical, and other criteria including properties such as modulus of elasticity, elongation, polymer thermal-mechanical properties, stress-relaxation, durability, environmental stress cracking, transparency, thermoforming adaptation, and

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aligner thermoformability. The purpose of our ideation and testing processes were to identify materials whose performance showed they would be superior to EX30 and appropriate for commercialization. An orthodontic aligner is a Class II medical device, and accordingly, Align's development process identified polymeric materials for testing subject to the requirement of compatibility with use in such a device.

23. The top material identified for commercialization by this process was ST30. ST30 exhibited excellent properties, providing similar or superior properties to EX30 in each of the criteria of evaluation. For example, ST30 showed superior durability in conditions simulating intraoral use, as well as superior properties for delivery of tooth-moving forces under intraoral conditions, including stress-relaxation that showed greater than 50% improvement in retained force over time.

24. ST30 consistently showed excellent performance, including improved performance over single-layer materials in various tested parameters. For example, ST30 showed superior durability in intraoral conditions to multiple copolyesters, including Tritan copolyester.

25. In light of the excellent performance of ST30, it was selected by Align as the top material for further product development.

Docusign Envelope ID: C1C1027A-561B-4CB0-925B-D688EFC7000E

V. CLINICAL TRIAL RESULTS COMPARING ST30 TO EX30

26. As the test results I discussed above confirmed the superiority of ST30 to EX30 in *in vitro* testing, Align proceeded to *in vivo* testing in a clinical setting to assess the performance of ST30 aligners.

27. Align conducted a clinical study beginning May 16, 2011, comparing the performance of aligners made of ST30 to those made of EX30, which Align identified as the most relevant benchmark for performance, as EX30 was the dominant clear plastic aligner on the market at the time, and it represented the best known material for providing orthodontic tooth moving forces prior to ST30. I understand that details of this study were previously disclosed to the Patent Office.

28. In the study, referred to as the TREX Assist Pilot Study, orthodontic patients treated by participating doctors in the United States and Canada were divided into to two groups: an experimental group and a control group. The study followed a double-blind protocol in which neither patients nor treating doctors were informed of their group assignment. The experimental group had 1,015 patients that received ST30 appliances, consisting of all new Invisalign orthodontic patients for participating doctors over a one-month period. The control group included all patients of those doctors from the immediately preceding six-month period that received EX30 appliances. The patients in each group were tracked over a five-month period during which they wore their assigned aligners, which

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were made to produce target movements of teeth. These patients were classified into one of three categories. The “On-Track” group was patients whose measured tooth movement matched target tooth movement within predetermined variance. The “Off-Track” group was patients whose measured tooth movement fell outside allowable variance relative to target tooth movement. The “Cannot Match” group was patients whose measured tooth movement fell far outside allowable variance relative to target tooth movement.

29. During the study, patients in each group were assessed during the study using dental impressions to compare actual tooth movements to target tooth movements. The patients treated with ST30 aligners showed significantly superior outcomes to those treated with EX30 aligners, including a strongly significant increase in On-Track performance (a 26% improvement, $p < 0.001$), as well as strongly significant decreases in Off-Track (-17%, $p < 0.001$) and Cannot Match (-34%, $p < 0.001$) performance in patients treated with ST30 aligners compared to those treated with EX30 aligners.

30. The improved performance of ST30 shown in this clinical study showed that ST30 aligners were markedly superior to prior art aligners including aligners made with EX30. This significant improvement was surprising and unexpected even to Align, and in response, Align quickly replaced EX30 with ST30 as the material used to manufacture its aligners. This changeover occurred in

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2013, and constituted a near-total replacement in aligner materials. ST30 immediately became Align's top-performing material for clear plastic aligners, and since its introduction it has remained a market-leading material used for clear plastic orthodontic aligners.

31. Subsequently, to further assess the relative performance of ST30 to EX30, Align performed a large retrospective analysis. This analysis compared a total of 110,000 patients having both initial and secondary dental scans (that is, scans reflecting tooth positions before and after treatment) were assessed out of a population of over two million patients treated over a six-year period. The control group, patients treated with EX30, included 52,000 cases treated in 2008 and 2009, and the experimental group, treated with ST30, totaled 58,000 cases treated in 2013 and 2014. All of these cases were drawn randomly from the Invisalign patient database. I understand that analysis was also disclosed to the Patent Office.

32. In the study, measures of Tooth Movement Predictability were performed on each treated patient's teeth to assess how closely the movement of the teeth matched the movement that the aligners were designed to produce. The movements measured included rotation (turning of a tooth around its longitudinal axis), extrusion (elongation of a tooth or movement of a tooth in an occlusal or incisal direction), and root movement (movement of the root of a tooth in the direction of applied force while the crown is displaced at most a minimal amount),

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each of which were measured for multiple tooth categories to assess improvement in tooth movement predictability.

33. Improvement in Tooth Movement Predictability between groups was defined as: 100% x (Experimental Group Predictability - Control Group Predictability)/(Control Group Predictability). Predictability improvement was measured for a total of fourteen criteria based on type of movement (e.g., rotation, extrusion, and root tip movement) and type of tooth. Each measured movement type showed strongly significant improvement ($p<0.001$) for the Experimental Group (patients treated with ST30 aligners) over the Control Group (patients treated with EX30 aligners). As a weighted average, the Experimental Group (ST30) showed greater than 75% improvement in overall tooth movement predictability over the Control Group (EX30).

34. This figure showing over 75% improvement was published by Align in a flyer attached as Appendix A. As the flyer notes, the data showing an overall improvement in predictability of over 75% are held on file at Align, and the results are made available to the public on request. The flyer also reports other results of comparative testing between ST30 and other materials, including aligners made from single-layer polyurethane (EX30) as well as two types of copolyester aligners. ST30 showed significantly improved force retention over a two-week

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period, as well as exhibiting dramatically improved durability and better capacity to return to original shape after deformation.

35. The table below provides the measures of Tooth Movement Predictability and statistical significance values for each measured tooth movement.

Tooth Movement Type	Sample Size	Improvement	P-Value
Upper Canine Rotation	81,194	118%	<0.001
Upper Premolar Rotation	10,401	60%	<0.001
Lower Canine Rotation	56,100	88%	<0.001
Lower Premolar Rotation	14,472	79%	<0.001
Upper Canine Extrusion	8,515	33%	<0.001
Upper Incisor Extrusion	16,438	43%	<0.001
Lower Canine Extrusion	3,459	69%	<0.001
Lower Incisor Extrusion	8,958	123%	<0.001
Upper Canine Root Movement	26,688	80%	<0.001
Upper Premolar Root Movement	19,856	56%	<0.001
Lower Canine Root Movement	27,986	94%	<0.001
Lower Premolar Root Movement	12,439	88%	<0.001
Upper Central Root Movement	24,492	100%	<0.001
Upper Lateral Root Movement	25,994	88%	<0.001

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36. The relative performance of ST30 and EX30 was also separately analyzed and published in a study by Drs. Timothy Wheeler, Neha Patel, and Susan McGorray. The article reporting this study, titled "Effect of aligner materials on orthodontic tooth movement," was published in the peer-reviewed Journal of Aligner Orthodontics in 2017. A copy of the article is attached in Appendix B. The study was double-blinded, with patients randomly assigned to be treated with EX30 or ST30 aligners. Tooth movement was tracked over a 25-day period using scanning technology for a total of 33 patients. Patients tracked with ST30 showed significantly more tooth movement as a percentage of targeted movement (73.06% vs. 42.75%) during the first 14 days of treatment, and total movement over 25 days remained substantially greater for ST30 aligners (77.38% vs. 50.07%). Consistent with Align's testing, this study confirmed the substantial superiority of ST30 over EX30 at providing orthodontic tooth movement in patients.

37. These results confirmed the superior performance of ST30 aligners compared to aligners made of EX30, and in combination with the test results from Align's development process, the results also showed ST30's superiority to other prior materials, including the materials that Align evaluated during its development testing.

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VI. INDUSTRY ADOPTION OF ALIGN'S MULTILAYER TECHNOLOGY

38. As previously mentioned, before the launch of SmartTrack, Align used a single-layer material for its aligners. Align was not unique in using a single-layer material during that period. In 2012, all aligners, including those offered by ClearCorrect, were made with single-layer materials. After Align launched the first multi-layer-material aligner ever in 2012, other aligner companies rushed to use multi-layer materials, too. Multi-layer materials quickly became the industry standard. Some market participants use Bay Materials's Zendura FLX material, a three-layer material made of copolyester and thermoplastic polyurethane materials like those in ST30. These companies include:

a. ClearCorrect (Bay Materials/Zendura FLX)

b. Ormco Spark (on information and belief, Bay Materials/Zendura FLX)

c. Angel Align (on information and belief, Bay Materials/Zendura FLX)

d. 3M (now Solventum), which developed its own multi-layer material.

e. Shanghai MaxFlex (a Chinese company making multi-layer material for aligners)

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39. Additionally, ClearCorrect's sister company, Bay Materials, sells its multi-layer material to other dental labs and dentist offices that can manufacture their own aligners in-house with multi-layer aligner material. Conversely, there are very few aligner companies that only make single layer material aligners.

VII. MANNER OF JOINING LAYERS IN A MULTILAYER ALIGNER MATERIAL

40. As I discussed above, during the process that led to the development of the ST30 material, Align through our team subject hundreds of candidate aligner materials including numerous multilayered materials to rigorous mechanical and material tests. These materials had multiple layers of different polymer components, and those different polymer materials were joined together at an interface between layers. However, Align exclusively used materials joined by non-adhesive methods, such as coextrusion. Align did not use adhesive lamination, as it was known that adhesive lamination was a relatively poor choice for use in multilayer orthodontic aligners.

41. Adhesive lamination was known to have many drawbacks that made it undesirable for use in orthodontic aligners. For example, any adhesive used to join layers in an aligner must be biocompatible, capable of maintaining adhesion for long periods of time in the warm, wet environment of the human mouth, must not employ solvents that can be released into a patient wearing the aligner, and must be compatible with thermoforming. The adhesive must also be capable of joining both

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adjoining layers of polymer material, in order to serve its basic function as a glue. Satisfying all of these requirements simultaneously is very difficult, and it is typically not possible to identify adhesives meeting all of these criteria. Adhesive lamination also adds complexity to the process of joining layers of aligner material, as well as introducing additional cost.

42. Align was well aware of these considerations during the development process that led to the SmartTrack (ST30) material. Because of the downsides to using adhesive lamination, Align eliminated the use of adhesive lamination from its tested multilayer materials in favor of extrusive processes (e.g., coextrusion). In particular, Align's multilayer polymer products, including ST30, do not use multilayer sheets with adjacent polymer layers joined via adhesive lamination.

VIII. CONCLUDING STATEMENTS

43. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

Docusign Envelope ID: C1C1027A-561B-4CB0-925B-D688EFC7000E

44. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: February 20, 2026

By: DocuSigned by: Yan Chen 9463D2FFA5854F5...

Yan Chen

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APPENDIX A

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SmartTrack: Technology that's made to move

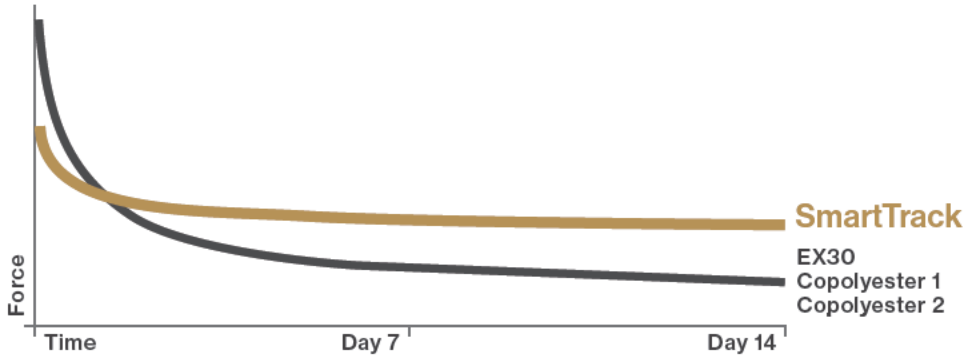
Exceptional control of tooth movement and tracking

SmartTrack material* delivers

75%

more predictability than off-the-shelf products

Forces measured in simulated oral environment



* Off-the-shelf, single layer .030 in material

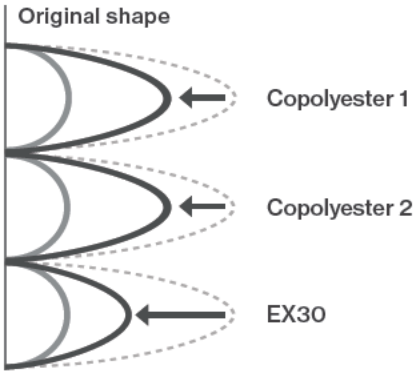
Quality of tooth tracking

SmartTrack material provides

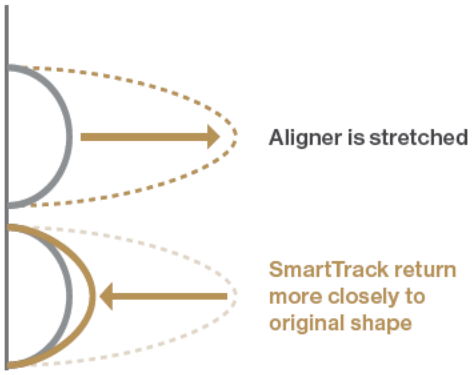
57%

improvement in tooth movement achieved compared to EX30*

Other aligner material



SmartTrack material



*As presented by Dr. Tim Wheeler at the 2014 AAO. Effect of Aligner Material, Duration, and Force Level on Tooth Movement. Master of Science thesis. Author: Patel, Neha Dipakkumar. Published: [Gainesville, Fla.]: University of Florida, 2014

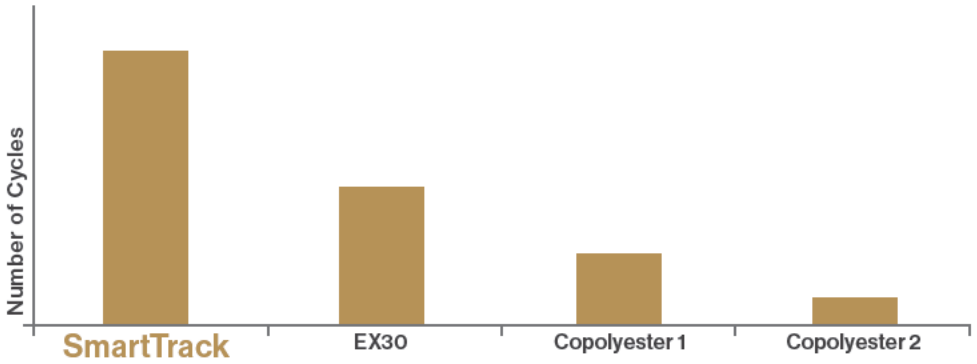
Superior durability

SmartTrack material is

4x

more durable than other aligner material*

Insertion/removal cycles before deformation



*compared to off-the-shelf, single layer copolyester material
*Data on file at Align Technology, as of June 11, 2018.

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APPENDIX B

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ORIGINAL SCIENTIFIC ARTICLE

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Timothy Wheeler

Timothy Wheeler, Neha Patel, Susan McGorray

Effect of aligner material on orthodontic tooth movement

Key words *aligners, orthodontics, plastic, polyurethane, thermoplasticl*

SmartTrack, created by Align Technologies, has a lower initial insertion force and a longer working range compared with the older EX30 material to aid orthodontic tooth movement (OTM).

Objectives: To investigate the effect of SmartTrack on OTM in vivo *over a 25-day period, compared with the EX30 material.*

Methods: Aligners made of one of the two materials and programmed for 0.25 mm of buccal movement of a maxillary incisor were used in 33 subjects (17 females and 16 males), between 18 and 40 years old, for 22 h per day for 25 days, in a randomised, blinded manner.

Results: SmartTrack achieved a significantly higher mean OTM (73.1% of planned tooth movement), compared with EX30 (42.8% of planned tooth movement) by day 14. No difference in OTM occurred from day 14 to 25.

Conclusion: SmartTrack achieved a higher mean OTM compared with the EX30 material over a 25-day period.

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Diplomate American Board of Orthodontics
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Introduction

Initially, treatment with clear aligners was limited to primarily tipping and minor rotations of anterior teeth. However, since the introduction of Invisalign by Align Technology in 1997, the development of clear aligners has been rapid over the past 20 years. More difficult movements, such as controlling root position and tooth rotations have been aided with various auxiliaries such as attachments or power ridges[1,2]. There are many different aligner products available on the market today and while there are some obvious differences between some, such as the use of attachments, one topic that is seldom mentioned is the possible differences between the aligner plastic. While we know that different orthodontic wires have different properties, we also need to understand that the same is true with aligner plastics.

Aligners today are fabricated from a thermoplastic polyurethane or copolyester. Because of the proprietary formulations of these materials, the practitioner is left with little information to judge the properties of the aligner plastic. These differences could impact on important clinician decisions, such as which attachments to use (if any), how much tooth movement to prescribe per aligner and how long each aligner should be worn. Since these are probably the main decisions practitioners make when treating patients, knowledge of the aligners' plastic properties becomes crucial.

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In 2013, Align Technology started fabricating aligners with a new material that they named SmartTrack. Up until that time, the plastic used was EX30. SmartTrack is a proprietary highly elastic material, which is a multi-layer aromatic thermoplastic polyurethane[3]. While it has been reported that the properties of the new material are important for improved performance of the aligner system, no actual tooth movement data on this performance has been reported. Therefore, the purpose of this study is to investigate the effect on total tooth movement between the original EX30 and SmartTrack materials utilising a human tooth movement model.

Materials and methods

Study design

The study was designed as a single-centre randomised clinical trial using methods similar to those previously reported[4,5]. IRB approval was obtained and the trial was conducted at the University of Florida Graduate Orthodontic Clinic.

Participants and eligibility criteria and enrolment

Full inclusion and exclusion criteria are included in Table 1. Participating subjects were between and including the ages of 18 and 40, had minor incisor misalignment, and would undergo orthodontic treatment at the conclusion of the trial.

Each subject was initially screened by telephone and then scheduled for the first of two preliminary visits. Preliminary visit 1 consisted of reviewing and signing the informed consent, reviewing the patient's medical history, performing an intraoral exam and reviewing inclusion and exclusion criteria. Preliminary visit 2 consisted of a digital intraoral scan using the Align Technology iTero HD2.9 system (San Jose, CA). This scan was used to fabricate the Invisalign aligners for the study. This visit also included full intraoral and extraoral photos and a full cone beam computed tomography scan (CBCT) (Imaging Sciences International, iCAT, Hatfield, PA, USA). All women were required to test negative for pregnancy prior to the CBCT.

Once a participant was accepted into the study, the target maxillary central incisor tooth was chosen. The criteria for choosing the target tooth consisted of the ability to achieve the desired movement with consideration to the initial position of both incisors. If both met this criterion, the principal investigator chose the target tooth randomly.

A total of 33 subjects were enrolled on the study after initial screening. If a subject missed more than two study visits, they were involuntarily dropped. One subject was dismissed midway through treatment due to the lack of follow-up with study visits. Data were utilised from the terminated subject through their last study visit. Subjects were required to wear the aligners at all times, except for when brushing their teeth, drinking, and eating. Compliance with aligner wear was documented through a daily diary distributed to study subjects at the initial delivery of the aligners. A complete medical and dental history was also taken at the initial visit and routinely checked, along with the daily diary at every visit, to monitor any excessive medication intake.

At the end of data collection, study subjects were given the opportunity to be treated for routine orthodontic treatment using the Invisalign appliances.

Data collection

A full overview of procedures carried out at each visit is detailed in Table 2. Subjects were randomised to each material group, EX30 or SmartTrack, in blocks of four using a computer-generated randomisation scheme. The maxilla was the only arch receiving an aligner and the target tooth was activated 0.25 mm in the antero-posterior (AP) direction. The single maxillary aligner was delivered and digital iTero scans were taken on days 1, 2, 3, 4, 7, 9, 11, 14, 16, 18, 21, 23, and 25 post-delivery. The study terminated at day 25. Participants and study clinicians were blinded to the aligner material.

Clinical tooth movement

The measurement of the AP movement of the target tooth was done using iTero™ digital impression scans and ToothMeasure, proprietary software developed by Align Technologies to superimpose scans as previously described[4-6]. The centroid of the clinical crown of the target tooth was established and the amount of AP tooth movement was then determined for each time point relative to either baseline or other time points.

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Table 1 Inclusion and exclusion criteria

Inclusion criteria	Males or females between and including the ages of 18 and 40 years old, desiring correction of minor incisor malalignment using the Invisalign appliance. Subjects may have had previous orthodontic treatment. Adult dentition with all upper anterior teeth present. At least one maxillary central incisor that has sufficient space between it and adjacent teeth to allow AP movement of 0.5 mm (crown tipping only). Normal pulp vitality and healthy periodontal tissues as determined by intraoral exam. Good health as determined by medical history. Willingness and ability to comply with study procedures, attend study visits, and complete the study. The ability to understand and sign a written informed consent form, which must be signed prior to initiation of the study procedures.
Exclusion criteria	Significant periodontal disease, (> 3 mm pocket depth or >1 mm of recession on maxillary anterior teeth). Active dental disease. Not under care of either a dentist or periodontist. Chronic daily use of any non-steroidal anti-inflammatory medication, oestrogen, calcitonin, or corticosteroids. History of use, or current use, of any bisphosphonate medication, or other medication for treatment of osteoporosis. Current smoker (must not have smoked in the past 6 months). Women must not be pregnant. Negative urine pregnancy tests prior to exposure to cone beam computed tomography (CBCT) imaging is require to verify pregnancy status. Any condition or use of medication which, in the opinion of the investigator, interferes with the biology of tooth movement. Any condition which, in the opinion of the investigator, results in increased risk to the subject.

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Table 2 Visit overview

	Prelim 1	Prelim 2	Day 0	Days 1, 2, 3, 4, 7, 9, 11, 14, 16, 18, 21, 23	Day 25
Informed consent	X				
Inclusion/exclusion	X	X			
Medical history	X				
Intraoral exam	X		X	X	X
Maxillary occlusal and frontal photos			X	X	X
Digital impression scan		X		X	X
Intraoral & extraoral photos		X			
Pregnancy test (women)		X			
CBCT		X			
Dispense aligner and daily diary			X		
Collect aligner and daily diary					X

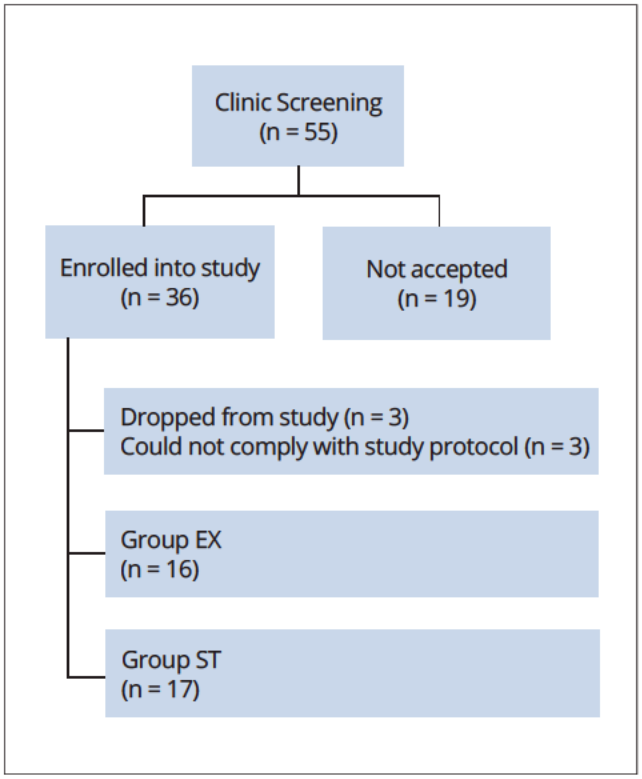

Fig 1 CONSORT flow chart of study sample.

Compliance

Self-reported compliance was recorded using a diary to record the times at which the aligner was inserted and removed, and was calculated as the percent of 24 h the subject wore the aligner.

Sample size calculation

The sample size required for this study was based on estimates from our previous tooth movement studies[4-6]. With 30 subjects (15 per group), we have 0.95 power to detect a difference of 75% of planned tooth movement for one material vs 55% of planned tooth movement for the second type of plastic, using a two-sided *t*-test, with level of significance set at 0.05. If the difference was smaller, 70% vs 55%, we had adequate power (0.78) to detect this difference.

Statistics

From our previous studies, the percentage of planned tooth movement appears normally distributed; hence two-sample *t*-tests were used to compare the percentage of planned tooth movement between the two material groups at days 14 and 25. Note that summary statistics

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Table 3 Demographics of subjects. SmartTrack material (ST), EX30 material (EX)

		N	Females	Males	*P*-value
Sex	Total	33	17	16	*P* = 0.87 (NS)
	Material ST	17	9	8	
	Material EX	16	8	8	

		N	Mean (yrs)	SD	Min (yrs)	Max (yrs)	*P*-value
Age	Total	33	26.95	5.31	20.06	40.07	*P* = 0.74 (NS)
	Material ST	17	26.65	5.44	22.05	40.07	
	Material EX	16	27.72	5.32	20.06	38.08	

Table 4 Percentage of total tooth movement achieved at day 14 and day 25 with each material. SmartTrack material (ST), EX30 material (EX)

	Day	N	Mean	SD	*P*-value
Material ST	14	16	73.06	37.98	Material 14 *P* = 0.02
	25	16	77.38	30.36	
	Diff	15	-0.47	19.96	
Material EX	14	16	42.75	30.93	Material 25 *P* = 0.02
	25	15	50.07	31.06	
	Diff	15	9.73	20.62	

and graphical methods will be used to characterise the data and confirm distributional assumptions. The relationships between age, gender, and compliance and tooth movement achieved would also be evaluated. Analyses would include two-sample *t*-tests and Pearson correlation coefficient estimation. A *P*-value less than 0.05 would be considered statistically significant.

Results

Participant flow

Figure 1 illustrates a CONSORT flow chart outlining the subject status through the study. In total, 36 subjects were initially enrolled in the study, three of whom dropped out prior to assignment. Sixteen subjects assigned EX30 material and 17 subjects assigned to the SmartTrack material completed the study.

Study subject demographic information is shown in Table 3. An equal number of males (48.48%) and females (51.52%) participated in this study, with an average age of 26.95 (± 5.31) years.

Tooth movement

As shown in Table 4, the SmartTrack material exhibited 73.06% of the tooth movement by day 14, which was significantly more than the 42.75% exhibited by the EX30 material (*P* = 0.02). There was no significant change in the amount of tooth movement between days 14 to 25 for either material. The average amount of tooth movement

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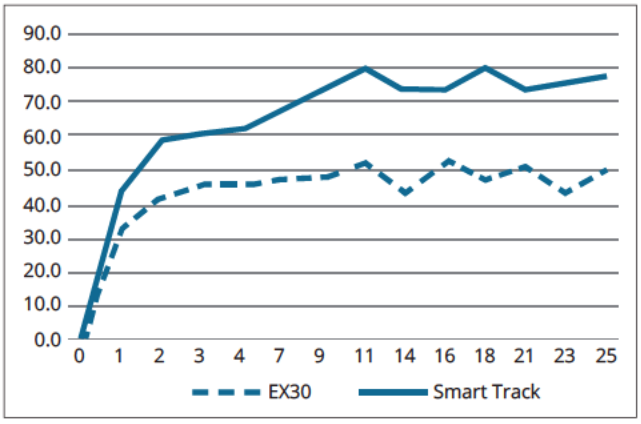

Fig 2 Percentage mean of tooth movement attempted by material over the 25-day study period.

for all subjects achieved at all time points for each material can be seen in Figure 2. There was no significant difference in tooth movement between sexes in either material group (Day 14, $P = 0.39$; Day 25, $P = 0.65$). Age was also not significantly correlated with tooth movement, overall, nor within material groups.

Compliance

There was no significant difference in self-reported aligner wear compliance at day 14 and day 25, as shown in Table 5. However, overall, significant correlation was found between compliance and tooth movement. Considering compliance and tooth movement at day 25, the Pearson correlation coefficient estimate was 0.49 ($P = 0.0075$). Correlation was higher in the SmartTrack material group, $r = 0.58$ ($P = 0.0240$), compared with $r = 0.39$ ($P = 0.17$) in the EX30 group.

Discussion

When aligners were first introduced to the market, the prescribed wear schedule for each aligner was 20 to 22 h per day for 1 to 2 weeks[7]. Previous studies have shown that the majority of tooth movement occurred during the first week of wear[5]; however, most clinicians prescribed 2-week wear until October, 2016, when Align Technology released a recommendation that 1-week wear would be sufficient for most cases treated with Invisalign. In addition, various clinicians advocate many different wear schedules that vary from several days per aligner to only night time wear.

Orthodontic wires impact tooth movement dependent on composition and size[8]. Performance of aligner material influences tooth movement. Studies have shown that a hard vs soft aligner material had no statistically significant difference in the outcome of extraction space closure[9-11], but it has been shown that a combination of a hard aligner material and a 2-week interval allows for optimal tooth movement[9]. Working range and initial insertion force are two of the important properties in the performance of the aligner material. Initial insertion force is defined as the force influencing the movement of the teeth according to the prescription expressed in the aligner upon initial insertion. Patients tend to feel more elevated levels of discomfort within the initial days after insertion of the appliance[12]. The working range of an appliance is the difference between the full amount of force imparted by the appliance at initial activation until deactivation. Larger working ranges are favourable due to the decreased discomfort perceived by patients and the force influencing tooth movement is able to work over a larger range of distance.

Table 5 Mean self-reported aligner wear compliance (h) at day 14 and day 25 for each material. SmartTrack material (ST), EX30 material (EX)

	Day	Mean	SD	Min	Max	*P*-Value
Material ST	14	21.30	1.73	15.89	22.81	14 $P = 0.65$ (NS)
	25	21.44	1.36	17.69	22.84	
Material EX	14	21.17	0.87	19.39	22.42	25 $P = 0.61$ (NS)
	25	21.21	0.99	18.74	22.63	

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SmartTrack was developed for Invisalign® treatment and is made from a multilayer aromatic thermoplastic polyurethane[3]. This material has been reported to maintain a more constant force over time, much like a nitinol wire, which then could express more tooth movement[3]. Our study confirmed that in a human tooth movement model, the SmartTrack material produces significantly more tooth movement than the previous Invisalign plastic, EX30. This illustrates the point that not all plastics are equal and need to be considered when used to treat patients efficiently.

We have previously shown that tooth movement with clear aligners over a 14-day period elicits less than 100% of that attempted[4-6]. The results of this study confirmed this finding, however the SmartTrack material did elicit a greater percentage of the tooth movement attempted. Our study also shows that the majority of the tooth movement is expressed by day 3, another 5% is expressed between day 3 and day 7. It should be remembered that this is for a tipping tooth movement of a central incisor and might be very different for rotational movement or other teeth. However, the clinician can use this information as a guide to determining how often a patient should change aligners.

Conclusion

The following conclusions can be deduced from the results of this study:

- The SmartTrack material produces a greater amount of tooth movement over time compared with the EX30 Invisalign material
- No statistical difference was noted between tooth movement and gender or age.

Acknowledgements

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