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Effect of aligner material on orthodontic tooth movement

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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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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.

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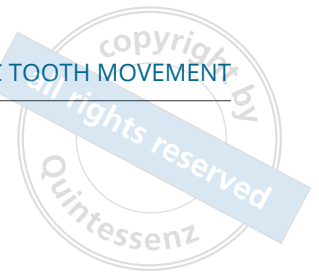
At the end of data collection, study subjects were given the opportunity to be treated for routine orthodontic treatment using the Invisalign appliances.

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.

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.

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
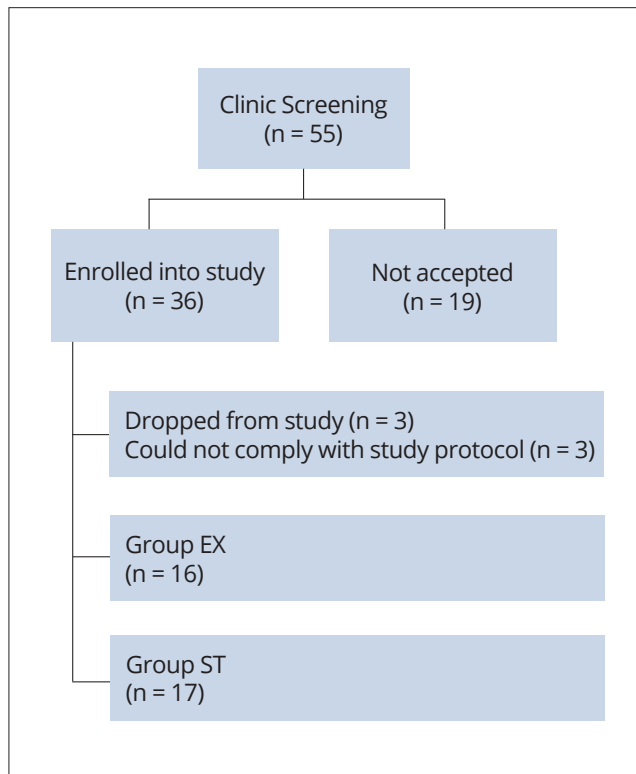
Fig 1 CONSORT flow chart of study sample.

Clinic Screening (n = 55)

Enrolled into study (n = 36)

Not accepted (n = 19)

Dropped from study (n = 3)
Could not comply with study protocol (n = 3)

Group EX (n = 16)

Group ST (n = 17)

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

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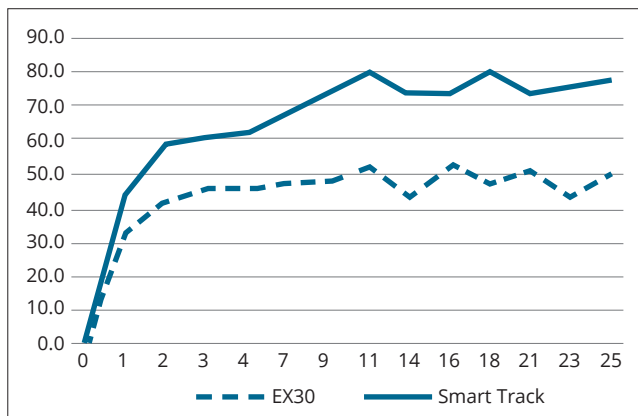
Fig 2 Percentage mean of tooth movement attempted by material over the 25-day study period.

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	
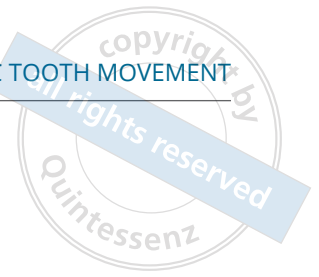
SmartTrack was developed for Invisalign® treatment and is made from a multilayer aromatic thermoplastic polyurethane[3]. This material has been reported to maintain a more constant force over time, much like a nitinol wire, which then could express more tooth movement[3]. Our study confirmed that in 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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