Primer Aligner Study

NCT02550938

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Study Summary

Title	Primary Aligner Study
Objectives	The primary objective was to determine the impact of primer aligners in both the 7 aligner set Invisalign treatment and the 12 aligner set Invisalign treatment. Results were measured by total treatment time (in days), and refinement rate per cohort.
Purpose	The purpose of this study was to demonstrate that allowing time for the biological response of the periodontal ligament (PDL) resulted in successful achievement of clinical outcomes and subject/doctor satisfaction.
Relevant Scientific Background	Align offers treatment options to treat minor tooth movements. These products consist of a limited number of aligners in a treatment. One of the clinical barriers to adoption for treatments requiring a pre-set low number of aligners can be the lack of clinical outcomes and predictability in the set number of aligner sets. A potential explanation for this hypothesis is that a biological delay, or "lag", in tooth movement occurs at the beginning of treatment. This lag is usually quantifiable and takes up to 3 aligner sets for the biological response to begin. This biological delay may particularly impact low number aligner treatments.
Design	This was a non-significant risk, multicenter, randomized prospective study. A total of twenty-one (21) doctors participated in this study, 13 in the U.S. and eight (8) in the U.K. There were 253 subjects enrolled into the study, 198 from the U.S. and 55 from the U.K. All subjects received Invisalign® Full treatment per the standard Invisalign® Instructions for Use. Subjects were randomly placed into one of four different cohorts: • Cohort 1: 7 aligner Cohort wear time 1 • Cohort 2: 7 aligner cohort wear time 2 • Cohort 3: 12 aligner cohort wear time 1 • Cohort 4: 12 aligner cohort wear time 2
Primary Outcomes	Total treatment time (in days) and refinement rate (%) was compared between the 7 aligner and 12 aligner cohorts. • Subjects were followed for the duration of orthodontic treatment, an average of 37 weeks/262 days.
Treatment	The Invisalign® System.

Eligibility Criteria	Inclusion Criteria: A subject were considered eligible if all of following inclusion criteria were fulfilled: • Subject must have fully erupted dentition • Age range ≥18 years old (Adult subject) • Subjects who are indicated for either: 5, 7, 10, or 12 aligner sets Exclusion Criteria: A subject was considered ineligible if any one of the following exclusion criteria were fulfilled: • Subject who has unerupted, erupting, partially erupted dentition (except for 2nd and 3rd molars) • Subject who has mixed dentition • Subject with periodontal disease • Subject with active caries • Subject with TMD symptoms • Subject has undergone pre-treatment with any orthodontic appliance 3 months prior to the start of treatment • Subject has undergone any accelerated orthodontic treatment prior to or during treatment as part of this study • Subject has known allergy to latex or plastic • Subjects who are pregnant or will become pregnant during treatment
Sites	21 participating doctors in the US and UK.
Sample Size	215 subjects.
Length of Study	Approximately 4 years.

Results	Subject Enrollment
	
	• Started: 253
	  ○ 178 female
	  ○ 75 male
	• Completed: 215
	• Not completed: 38
	
	215 completed subjects were included in the data analysis which was conducted by Align's own statisticians. These 215 subjects all had initial and final data points for analysis. Total treatment time was measured in days and

	refinement rate was measured as a percentage per cohort. No Adverse Events were reported.