

The Use of Clear Aligners with Movement Enhancement Techniques

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Study Summary

Title	The Use of Clear Aligners with Movement Enhancement Techniques
Objectives	Evaluated whether movement enhancement techniques increased the rate and length of tooth movement, and length of total treatment time.
Purpose	The purpose of this study was to use clear aligners to measure tooth movement and length of treatment.
Relevant Scientific Background	<p>Orthodontic tooth movement is the result of forces applied to the crown of a tooth and the biological remodeling of the soft and hard tissues.</p> <p>The Invisalign® System (Align Technology, San Jose, California, USA) accurately fabricates removable clear aligners to move teeth with relative precision to provide comprehensive orthodontic treatment. Some practitioners advise patients to change aligners at 1-2 week wear time intervals in order to reduce treatment time or for other orthodontic or dental reasons. Animal studies in mice and rats have suggested that low magnitude, high frequency mechanical stimuli increases the healing of bony lesions in non-weight bearing bones, enhances the adaptive remodeling of condylar cartilage as evidenced by the advent of endochondral bone replacing hypertrophic cartilage, and enhances the effect of mechanical and magnetic forces on tooth movement.</p>
Design	This was a non-significant risk, multicenter, randomized prospective study conducted at three sites in North America. A total of 90 adult patients who were eligible for Invisalign® Full treatment per the standard Invisalign® Instructions for Use were recruited for the study. Subjects were randomly placed into either a 7 day or 14 day aligner wear schedule.
Primary Outcome	<p>Tooth movement change was calculated.</p> <ul style="list-style-type: none"> • Participants were followed for the duration of orthodontic treatment, an average of 78 weeks.
Secondary Outcome	<p>Length of treatment change was calculated as number of clear aligners used.</p> <ul style="list-style-type: none"> • Participants were followed for the duration of orthodontic treatment, an average of 78 weeks.
Treatment	Clear aligners with movement enhancement techniques.

<p>Eligibility Criteria</p>	<p><u>Inclusion Criteria:</u></p> <p>A subject were considered eligible if <u>all</u> of following inclusion criteria were fulfilled:</p> <ul style="list-style-type: none"> • Males or females between the ages of 16-46 inclusive • Required orthodontic treatment • Had permanent dentition • No craniofacial anomaly present • No past and present signs and symptoms of periodontal disease • No significant medical history or medication that would adversely affect the development or structure of the teeth and jaws and any subsequent tooth movement • No previous orthodontic or orthopaedic relapse • No history of trauma, bruxism or parafunction • No skeletal jaw discrepancy • Angle Class I or Class II molar and canine relationship • Crowding of at least 4mm per arch • No osteoporosis drugs <p><u>Exclusion Criteria:</u></p> <p>A subject was considered ineligible if <u>any</u> one of the following exclusion criteria were fulfilled:</p> <ul style="list-style-type: none"> • Subjects who did not fulfill all inclusion criteria requirements
<p>Sites</p>	<p>3 participating doctors in the North America.</p>
<p>Sample Size</p>	<p>90 subjects.</p>
<p>Length of Study</p>	<p>Approximately 4 years.</p>
<p>Statistical Analysis Plan</p>	<p>Pretreatment records were analyzed to measure the exact amount of crowding. A discriminate analysis was used to ensure that there was no significant difference between study groups in any parameters (crowding, overjet, overbite, crossbite, gender, age, race,) that may have impacted the analysis of the efficacy of the aligners and the aligners with movement enhancement techniques.</p> <p>A multivariate analysis was conducted to determine if time or treatment modality showed an effect.</p>

	<p>Rate of tooth movement, length of treatment, and length of total treatment time were analyzed between all study groups.</p> <p>A sample size of 90 was selected to determine if future studies should be conducted based on the outcome of this study.</p>
Results	<p>Subject Enrollment</p> <ul style="list-style-type: none">• Started: 90<ul style="list-style-type: none">○ 70 female○ 20 male• Completed: 73• Not completed: 17 <p>All 73 completed subjects were included in the data analysis which was conducted by Align’s own statisticians. Tooth movement change was measured as a millimeters of change per aligner. Length of treatment change was measured as the number of weeks. No Adverse Events were reported.</p>