

Evaluation of Treatment Outcome of Lower Incisors Crowding Using Clear Aligners with Laser Acceleration (Randomized Clinical Study)

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Aim: The current study intended to determine the effect of Low-Level Laser Therapy (LLLT) on the overall leveling and alignment outcomes of mandibular anterior crowding.

Materials and Methods: The current study included 22 orthodontic patients (females) aged 16 to 23 years who had mild to moderate anterior lower crowding. The patients were randomly split into two groups. Group I: Eleven patients were treated with a removable clear aligner. Group II: Eleven patients treated with removable clear aligners with application of low-level laser sessions weekly for 7 weeks .

Results: The results show no significant difference in the Little Irregularity Index.

Conclusion: The Low Level Laser treatment aimed to accelerate the leveling and alignment of lower incisors with crowding, but the results showed no statistically significant difference compared to the non-laser group.

Keywords: Low-Level Laser; Acceleration; Crowding; Clear Aligners.

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Introduction

Malocclusion, defined as a deviation from ideal occlusion or societal norms, It's widely recognized as multifactorial as it is affected by hereditary variables, behaviors, food choices, oral or tongue position, and swallowing features.¹⁻³

Dental crowding, or swarming, is characterized by a discrepancy between tooth size and arch dimensions ,This condition is prevalent among children and adolescents worldwide, impacting not only oral health but also psychological, social, and functional well-being.⁴⁻⁶

As a result, modern orthodontic treatments prioritize patient comfort and satisfaction, focusing on patient-centered outcomes. The rise in adult orthodontic patients has heightened demand for aesthetic alternatives like clear aligners, which benefit from ongoing technological advancements in materials and manufacturing.⁷

Originally intended for mild crowding, clear aligners now accommodate moderate to severe malocclusions, including both extraction and non-extraction cases, due to advancements in material development and computer-aided tooth movement design.⁸⁻¹⁰

Orthodontic treatment typically lasts between 24 and 36 months. In general, patients reject this treatment modality due to the lengthy treatment period. In prolonged treatment procedures, root resorption, cavities, and poor patient compliance are more prevalent..^{11,12}

As a result, In order to prevent those negative effects and to motivate patients to finish their orthodontic treatment, an acceleration of tooth movement is recommended. Reduced leveling and alignment times have been achieved with the effective use of orthodontic tooth movement (OTM) acceleration through a variety of surgical and non-surgical techniques.^{11,13,14}

Orthodontic treatment is driven by bone remodeling through applied forces on the

periodontal ligament, involving intricate cellular interactions and inflammation phases crucial for tooth movement. Numerous investigations look into procedures including corticotomy, electric stimulation, medication injections, pulsed electromagnetic fields, and mechanical approaches. to enhance the efficiency of this process.¹⁵⁻¹⁷

Low-Level Laser Therapy is one of these interventions (LLLT). LLLT is a simple, localized, nonsurgical, noninvasive method with no side effects that is gaining popularity among OTM researchers.¹⁸⁻²⁰ LLLT has been demonstrated in several studies to enhance vascularization, collagen fiber organization, and osteoblastic activity therefore accelerates tooth movement.^{21,22}

So the purpose of this study was to assess how low-level laser treatment (LLLT) affected the orthodontic tooth movement rate. through the correction of lower incisors crowding using clear aligners .

Materials and methods

Study design

With an equal allocation ratio of 1:1, the current investigation used a two-arm parallel randomized clinical trial design. The CONSORT's reporting guidelines (Figure 1) statement were adhered to.

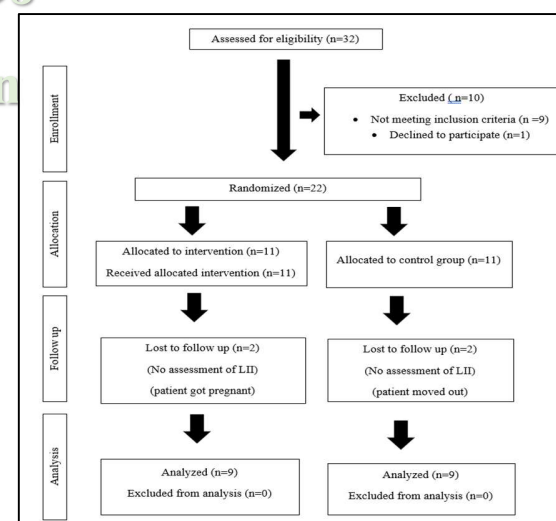


Figure 1: CONSORT flow chart

Ethical consideration

The Faculty of Dental Medicine for Girls at Al-Azhar University in Cairo, Egypt's Research Ethical Committee gave its ethical permission (protocol number: ORTHO-109-2-F /REC-OR-24-02). Additionally, the trial was listed in Egypt's Clinical Trials Registry (NCT06526871).

Before starting orthodontic treatment, the parents or legal guardians of the participants gave their written informed permission after being educated about the study's goals.

Patient selection

The study was first carried out on 22 orthodontic patients who were recruited from the outpatient clinic at the Orthodontic Department, Faculty of Dental Medicine, females, Al-Azhar University, Cairo, Egypt. The study was authorized by the department council and the orthodontic scientific committee.

Sample size calculation and statistical power :

This power analysis used leveling and alignment improving % as the primary outcome. Based upon the results of . AlSayed-Hassan et al ; the mean (Standard deviation) values were 89.42 (7.16) and 71.7 (16.18) %, respectively. The effect size (d) was 1.416. Using alpha (α) level of (5%), β level of 0.8 (Power = 80%); the minimum estimated sample size was 9 subjects per group. Sample size was increased to 11 subjects per group to compensate for a dropout rate of 20% after 6 months. Sample size calculation was performed using G*Power version 3.1.9.2.

Inclusion criteria:

1. All patients aged 16 to 23 years.
2. mild to moderate anterior lower crowding.¹
3. Full set of teeth, excluding wisdom teeth.
4. Class I Angle malocclusion.

5. well-behaved, compliant, and motivated candidates.

Exclusion criteria

1. Missing anterior teeth.
2. Class II or III malocclusion (either dental or skeletal).
3. Systemic diseases that may impact the treatment plan.
4. Periodontal issues, particularly affecting the lower anterior teeth.

These conditions pose challenges to achieving desired alignment and may require alternative or additional interventions.

Preoperative procedures

Each patient underwent a comprehensive diagnostic assessment, which included a detailed case history, thorough extraoral and intraoral examinations, and a comprehensive medical history review to rule out systemic conditions that could affect orthodontic or medical operations. Patients were assessed to ensure they met the predefined inclusion criteria. Additionally, standard orthodontic records were obtained, comprising four extraoral and five intraoral photographs , orthodontic study plaster and 3D models, a standardized lateral cephalometric radiograph, and a panoramic radiograph.

Research related records

In order to achieve the goals of the present investigation, For each patient, three 3D digital scans . (upper and lower) pretreatment (T1) was taken , then one more right away after finishing of first set of aligners (T2), and last one after completion of treatment (T3) .

The 3D scans were acquired using Medit i500 scanner (Medit i500 scanner (Medit, Korea))

Randomization

Randomization was conducted using a computer-generated sequence created with Microsoft Excel software (Redmond, Washington, USA). Participants were randomized to the intervention group based on the first eleven random numbers, with the remaining numbers going to the control group.

Participant Flow

A total of thirty-two female patients (mean age: 16–23 years) had their eligibility evaluated. Nine of these patients failed to fulfill the inclusion requirements, thus 22 patients were randomly assigned 1:1 to the laser or control groups. The remaining 18 patients successfully finished the trial, despite the fact that four patients were lost to follow-up because they relocated, missed their appointments for laser application, or did not get LII evaluations. (Figure :1).

Operative procedures

Digital scanning for 3D model acquisition

The digital scanning process for 3D model acquisition involved several key steps. First, the intraoral scanner Medit i500⁽¹⁾ (Medit i500 scanner (Medit, Korea)) , was prepared and calibrated according to manufacturer specifications. The scanner tip was positioned intraorally, typically starting from the posterior region. Sequential images were captured systematically along the dental arch to ensure comprehensive coverage of all surfaces. Proper moisture control was maintained using air drying and absorbent materials to optimize scan quality. The scanning process was repeated for the same arch if necessary. The accuracy and completeness of the scanned images were verified in real-time on the scanner's screen, and any areas requiring rescanning or refinement were identified and addressed. Finally, the scanned data was saved in the desired format like stereolithography (STL) and sent to the lab for treatment planning design.

Treatment plan design

The evaluation process began with a thorough examination of the patient's dental records to assess existing dental conditions. Digital scans were imported into U-Lab (U-Lab systems, USA) treatment planning to produce a digital three-dimensional model of the patient's teeth. This particular model was analyzed to identify areas needing correction. A customized treatment plan was developed, considering desired tooth movements and alignment goals.

The need for attachments was determined, and they were strategically placed on the virtual model to facilitate tooth movement. The timing and amount of interproximal reduction (IPR) were planned to create adequate space for alignment. Biological and occlusal considerations were incorporated to ensure safe, effective tooth movement and proper bite alignment.

The treatment plan underwent thorough review and adjustments for optimization. It was then presented to the patient, with explanations of the proposed approach, expected outcomes, and associated considerations. Based on patient feedback, the plan was finalized.

A sequence of aligners was meticulously designed to incrementally shift tooth positions according to the treatment plan. The number of aligners and predicted treatment duration were estimated. All treatment details were documented for future reference.

Clear Aligner fabrication

The process of fabricating clear aligners involved several systematic steps: CAD software was used to refine the digital model for accuracy and compatibility with 3D printing. Slicing software divided the model into layers prior to 3D printing on the Anycubic Photon mono X printer (Anycubic, china)

Post-printing, support removal and model preparation were performed, followed

by curing using the Anycubic Photon mono x 6k wash & cure (Anycubic, china) station. Thermoforming was conducted using the Manual STAVAC BIOART (Plast Press, Brazil) where a Zendura FLX (Zendura, USA) sheet was heated and vacuumed to conform tightly to the dental model's contours.

After cooling and hardening, the thermoformed aligner was carefully extracted, and finishing procedures were executed with a dental micromotor and handpiece to ensure a precise fit and smooth edges.

Clear aligner delivery

Prior to initiating clear aligner therapy, thorough preparation was undertaken, including the arrangement of aligners, materials essential for interproximal reduction (IPR), and attachment bonding.

A comprehensive oral examination ensured the absence of debris or obstructions in the oral cavity. The initial set of aligners was then carefully inserted.

Attachment bonding followed, involving meticulous preparation of tooth surfaces to ensure cleanliness and debris removal using high-volume suction. Etching with Charmetch-37HV etchant (Dentkist Korea, Korea) was performed for 20-30 seconds as per manufacturer's guidelines, followed by rinsing with water spray and gentle air-drying to maintain a dry surface. Thin application of Bondfix (VOCO, GmbH) bonding agent to the etched enamel surface was followed by light curing for 20 seconds per tooth.

Next, Tetric N-flow (IVOCLAR-USA) flowable composite was applied inside the template tray and placed intraorally, with attachments being light cured for 20-40 seconds per attachment to ensure complete polymerization.

Interproximal reduction (IPR) was conducted based on the treatment plan's requirements and assessment of tooth size

and spacing. This process involved measurement to determine the necessary amount of enamel reduction. Isolation was achieved by inserting a wire sleeve interdentally to protect the interdental papilla.

Fine-grit abrasive strips were used to gradually reduce interproximal enamel between marked teeth, with periodic checks using an IPR Gauge to monitor progress and ensure desired space creation.

Documentation of the performed IPR included details of specific teeth involved and the amount of enamel reduction for future reference. Fluoride application followed to promote remineralization and protect against potential sensitivity or demineralization post-IPR.

Additionally, a printed care guide and detailed instructions on aligner care and maintenance were provided to the patient. A final check ensured proper aligner fit, secure attachment bonding, and patient comprehension of care instructions. Dental floss was used to verify proper tooth contact, preventing interference with tooth movement. (figure 2)

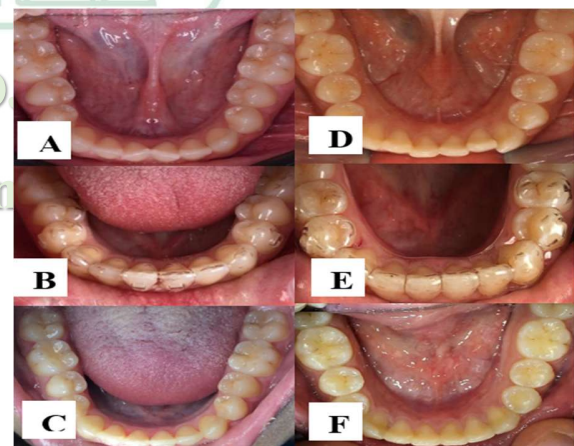


Figure 2 : Photos showing : A : case from group 1 pretreatment , B : Case from group 1 midtreatment , C :Case from group 1 post treatment , D : case from group 2 pretreatment, E : Case from group 2 midtreatment , F :Case from group 2 posttreatment

Low Level Laser therapy protocol

The low-level laser therapy (LLLT) protocol, tailored for the laser therapy group, ensured precise treatment application and patient safety. Patients were prepared with protective eyewear and positioned comfortably. The Biolase Epic X (Biolase, USA) device was set as follows: a wavelength of $940 \text{ nm} \pm 10$, a power output of 0.2 W , and an energy density of 4 J/cm^2 . A dose of 0.16 J was delivered per point across 9 points, totaling 1.44 J per tooth. Each point was treated for 0.8 seconds using a fiber optic tip with a $400 \mu\text{m}$ diameter. These settings were meticulously selected to ensure precise and effective laser application. The laser was applied to first experimental laser group weekly for 7 weeks. Treatment sessions included application at five buccal points (cervical mesial, cervical distal, middle root, apical mesial, and apical distal) and four lingual points (cervical mesial, cervical distal, middle root, and middle apical). (figure 3)

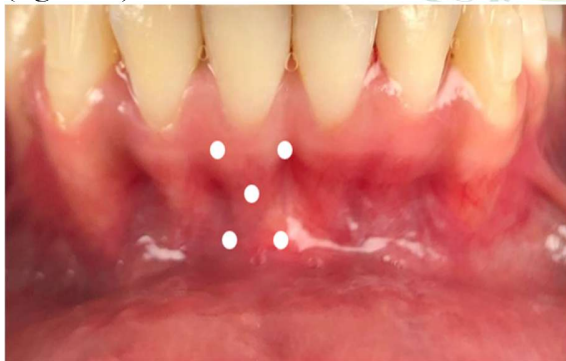


Figure 3 Photo shows five buccal points of application (cervical mesial, cervical distal, middle root, apical mesial, and apical distal)

Little Irregularity Index measurement

In the present study, initial scans (T1) were used in order to estimate the Little Irregularity Index. (figure 4) using 3Shape 3D Viewer software (3shape, USA), a metric assessing tooth alignment. Final scan (T3), subsequent measurements of the index were taken to evaluate the effectiveness of the orthodontic intervention in both the laser and

non-laser treatment groups. This index provides quantitative data on the degree of irregularity in tooth alignment before and after treatment, allowing for a precise comparison between the groups in

Finishing and retention.

achieving optimal tooth positioning and alignment outcomes.(Figure :4)

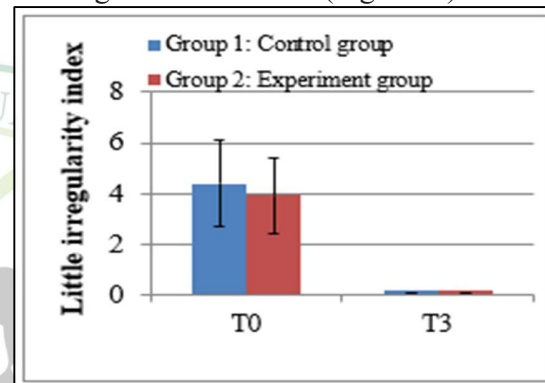


Figure 4 Comparison between group 1 control group and group2 experiment group according to little irregularity index.

After completing leveling and alignment, subsequent steps typically involve further detailing and refinement of occlusion, and assessing bite relationships took place.

Statistical analysis

The statistical software for social sciences, version 26.0 (SPSS Inc., Chicago, Illinois, USA), was used to evaluate the recorded data. When the distribution of the quantitative data was parametric (normal), it was shown as mean \pm standard deviation and ranges; for non-parametric (non-normally distributed) variables, it was shown as median with inter-quartile range (IQR). Quantitative variables were also shown as percentages and numbers. Using the Shapiro-Wilk and Kolmogorov-Smirnov tests, data were examined for normality.

Table(1): Comparison between group 1: control group and group 2: experiment group according to little irregularity index.

Little irregularity index	Group 1: Control group	Group 2: Experiment group	Test value	p-value
T1				
Mean±SD	4.40±1.69	3.93±1.48	0.423	0.687
Range	2.1-5.9	2.3-5.5		
T3				
Mean±SD	0.00±0.00	0.00±0.00	0.000	1.000
Range	0-0	0-0		

Using: t-Independent Sample t-test for Mean±SD; p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant

Baseline characteristics and outcomes

Regarding Little Irregularity There is no statistically significant variation in the outcomes of the index between group 1: control group and group 2: experiment group according to little irregularity index, with p-value ($p > 0.05$). (Table:1)(Figure ; 5).

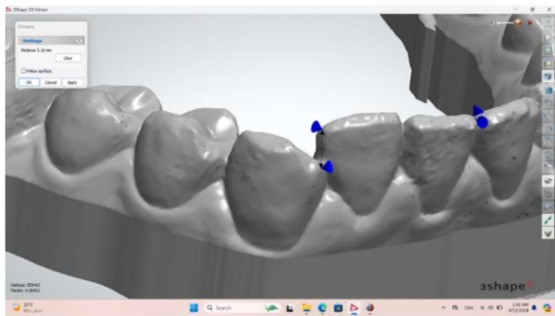


Figure 5: photo shows Little's Irregularity Index measured on digital models using 3Shape 3D Viwer software

Discussion

Recent advancements in orthodontic technology, such as laser-assisted treatment, have been proposed to enhance pain management and potentially accelerate tooth movement. However, the clinical efficacy of these methods remains a topic of ongoing research and debate.^{2,9}

In the present study, aligners were introduced with a one-week wearing protocol. This approach was based on findings by Wei et al., who said that the results of therapy do not significantly differ between a one-week and a two-week wearing protocol. This protocol aims to optimize patient compliance and streamline the treatment process without compromising effectiveness.²³

Based on the study by Illescas-Montes et al., the laser gadget employed in this investigation was a Biolase Diode Laser, operating in continuous mode. The parameters were set as follows: a Wavelength of $940 \text{ nm} \pm 10$, a power output of 0.2 W, and an energy density of 4 J/cm^2 . The dose was 0.16 J per point at 9 points, totaling 1.44 J per tooth. Each surface was treated for 4 seconds, utilizing a fiber optic tip with a diameter of $400 \mu\text{m}$. These settings were carefully chosen to ensure precise and effective laser application.²¹

Regarding leveling and alignment outcomes assessed using the Little Irregularity Index, the findings show that Group 2 (the experiment group) and Group 1 (the control group) do not differ significantly in terms of tooth movement. This result is in line with previous studies by Sonesson et al.⁴ Fini et al.,⁶ El-shehawy et al.,²² and Dalaie et al.¹³, which also found no noticeable variations in tooth movement results across comparable experimental and control settings.^{4,6,13,22}

Conversely, Reports have indicated that low-level laser treatment (LLLT) positively influence leveling and alignment outcomes, which contrasts with the findings of the current study. This discrepancy may be attributed to the greater dosage of 12 J per tooth and a higher energy density of 25.7 J/cm^2 used in the studies by Abdel-Ghaffar et al.¹¹ Additionally, Abdel-Ghaffar et al. implemented laser sessions during the early stages of orthodontic treatment. Specifically,

their study scheduled laser applications on days 3, 7, and 14, then at 1 month, and subsequently every 2 weeks until leveling and alignment were achieved. In contrast, the current study administered laser sessions on a weekly basis.¹¹

However, AL-Sayed Hasan et al. utilized an 830-nm wavelength and an energy density of 2 J/cm² per point. Despite differing parameters from those used by Abdel-Ghaffar et al.,¹¹ their study also observed significant improvements in leveling and alignment outcomes following low-level laser therapy (LLLT).

This difference may be attributed to the fact that the referenced study assessed outcomes at short intervals, specifically after 1 month and then 2 months, which highlighted differences in the early stages. In contrast, the current study measured outcomes either upon completion of treatment or after a period of six months, whichever came first. Considering that the cases in the present study involved mild to moderate crowding, complete alignment was achieved before the six-month mark.²

Conclusion

The Low Level Laser treatment aimed to accelerate the leveling and alignment of lower incisors with crowding, but the results showed no statistically significant difference compared to the non-laser group.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declarations:

Ethics Approval and Consent to Participate: The research protocol was approved by the Ethical Committee of the Faculty of Dental Medicine, Girls, Al-Azhar University (REC-OR-24-02). The study objectives were thoroughly communicated to the patients,

and written informed consent was obtained from all participants prior to the commencement of orthodontic treatment.

Competing interests:

The authors declare that they have no competing interests.

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