Assessment of the Accuracy of Tooth Movement of 3D Printed Versus Thermoformed Aligners in Patients with Lower Anterior Crowding: A Randomized Clinical Trial

A protocol submitted to

Faculty of Dentistry, Cairo University.

In partial fulfillment of the requirements for

The Master's degree in Orthodontics.

By:

Code: ORTH 3-3-9

Supervisors' signature Head of department's signature

30/12/2025

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1.		
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Research plan committee

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I. Administrative information:

1. Title:
Evaluation of Accuracy of 3D Printed Aligners in comparison to Thermoformed Aligners in orthodontic patients: A Randomized Clinical Trial

2. Protocol registration:
The Protocol is not registered yet, but it will be registered on www.clinicaltrials.gov

3. Protocol version:
2025. Version 1

4. Funding:
Self-funding

5. Roles and responsibilities
Dr. Sahar Taher Abdel-Aziz, BDS, MSC, PhD (main supervisor), helped with developing the idea of the research, will help in the diagnosis of the samples, interpretation of the results, and drawing conclusions

Dr. Ahmed Fouda (Co-supervisor), BDS, MSC, PhD, Mortho RCSEd, Department of Orthodontics, Faculty of Dentistry, Cairo University, will help formulate the study design, data analysis, assessing research writing, participate in the treatment plan of cases and designing, interpretation of results and drawing conclusions.

Farouk Khaled Mohamed, BDS (Principal Investigator), will be responsible for the practical part of the study, recruitment of samples, taking oral scans, writing the thesis, data management, interpretation of results and drawing conclusions.
All authors contributed to the refinement of the study protocol.

II. Introduction:

6. Background and rationale:

Research question:
Are 3D printed aligners as accurate as thermoformed aligners for the treatment of crowding cases?

Statement of the problem:
Clear aligner therapy, introduced in the late 1990s, has become a significant part of orthodontics due to its comfort and minimal aesthetic impact. However, the concept dates back to 1945 when Kesling developed a rubber-based tooth positioner capable of facilitating orthodontic tooth movement over time [1]

Santa Clara in 1998 introduced a new align technology called Invisalign, a revolutionary orthodontic system featuring a series of removable polyurethane aligners. These aligners serve as an aesthetic alternative to traditional fixed labial braces. The Invisalign system utilizes advanced Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) stereolithographic technology to predict treatment outcomes and fabricate multiple custom-made aligners from a single scan[2] .
At present, a variety of thermoplastic materials are utilized in the production of clear aligners. These include polyethylene terephthalate glycol (PETG), polypropylene, polycarbonate, thermoplastic polyurethanes (TPU), and polyester. [3] Additionally, multi-hybrid materials have been developed to address the limitations of single materials by enhancing their physical properties, particularly their maximum tensile load-bearing capacity [4].

Despite all this progression in material, clear aligners continue to be produced using the traditional method of vacuum thermoforming machines. This manufacturing process is complex, demanding significant time and effort. Additionally, geometric inaccuracies can occur during the thermoforming process[5].

The geometric inaccuracies introduced by the thermoforming process complicate clinicians' ability to predict the performance and treatment outcomes of clear aligners. Different predictions are made based on the type of tooth movement, but these are often ineffective for extrusion, rotation, and tipping movements, resulting in a low predictability rate of approximately 30%[6].

Recently, a new resin for 3D direct printed aligners (DPA) has been introduced. This resin, characterized by its viscoelastic properties, allows for precise control over material dimensions, structure, and properties. This enables the aligners to exert constant and gradual forces within the physiological limits of tooth movements[7].

Tera Harz Tc-58, a new direct-printed resin material introduced by Graphy Company, exhibits a significant shape memory effect. Approximately 90% of the deformation is recovered within 10 minutes, while 96% recovered after 60 minutes, whereas PETG maintains its deformed shape and shows no shape recovery.[8]

DPA shows a significant enhancement in treating different moderate malocclusion cases by reducing the peer assessment rating (PAR) score by 86% and also reducing the need for attachment which simplifies treatment. [9]

This study aims to determine the accuracy of DPA in facilitating tooth movement and to identify which types of tooth movements are more accurately achieved with DPA compared to conventional aligners.

Rationale for conducting the research:

Tera Harz is a new material demonstrating good stability at high temperatures and excellent shape memory recovery. This technology helps reduce the amount of resin used to print dental models. If DPA shows greater accuracy in tooth movement compared to conventional aligners, it would be a significant breakthrough.

Review of literature

Hertan et al (2022); Rapid Prototyping (RP) technologies, particularly 3D printing, have revolutionized the manufacturing of dental models, offered superior accuracy, and reduced the limitations associated with conventional plaster models. Studies have demonstrated that DPA exhibits superior geometric accuracy and mechanical strength compared to traditional thermoformed aligners. This suggests that DPA could provide a more effective and time-efficient solution for orthodontic treatments. [7]

Islam Atta et al (2024) have demonstrated that Tera Harz exhibits excellent properties, including shape memory recovery under typical oral conditions and a favorable glass transition temperature of approximately 42 degrees Celsius, which facilitates shape memory activation. Additionally, Tera Harz shows higher flexibility and lower flexural force compared to thermoformed materials, as well as structural stability that can withstand elevated temperatures and sterilization chemicals.[10]

Miglioratia et al (2024); DPA production is effective in office management. It shows promising results in treating mildly misalignment cases with accuracy reaching 67%, considering cytocompatibility within 14 days of wearing, resin found to be non-cytotoxic. [11]

Jindal et al (2019); DPA exhibits maximum resistance load and minimal deformation, capable of withstanding masticatory forces of approximately 500N. In contrast, thermoformed aligners demonstrate deformation beyond 10 to 15% strain, resulting in permanent deformation of 1.5-2.5mm under a load of 200N, with no recovery. Conversely, DPA shows reversible deformation.[5]

Explanation for choice of comparators:

Thermoformed aligners are best as the comparator as they have many studies on them and have been used in clinics for many years, they show effective results in non-extraction cases with less chair time and treatment duration.[12]

7. Objectives:

The study aims to compare the accuracy of DPA vs conventional thermoformed aligners.

Hypothesis:

The null hypothesis of this study is that DPA is as accurate in tooth movement as thermoformed aligners.

8. Trial design:

Randomized clinical trial parallel group, two arms, with a 1:1 allocation ratio.

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

The study will take place at the outpatient clinic of the orthodontic department in the faculty of dentistry, at Cairo University.

10. Eligibility criteria:

Inclusion criteria

1. Age ranges from 12- 25 years old
2. Non extraction treatment
3. Lower anterior crowding <5mm
4. Dental rotation <30 degree
5. Relapse cases < 5mm

Exclusion criteria

1. Systematic disease
2. Active or past periodontal disease
3. Temporomandibular joint disorder
4. Missing teeth

11. Interventions

Included participants will undergo extraoral and intraoral photography, as well as digital intraoral scans . The patients will be randomly divided into two groups.

Group1

1. The obtained STL files will be imported into Dentone software (Diorco Co., Korea) for virtual treatment planning. The planning will adhere to functional and esthetic principles, ensuring optimal outcomes
2. The treatment will begin with leveling and alignment of the dental arch, following aligner biomechanics principles. Each aligner will be designed to achieve:
    - 0.4 mm linear movement per aligner
    - 3-degree long-axis rotation per aligner
    - 2.5-degree labio-lingual inclination per aligner
3. The designed STL files will be exported and sent to a certified dental laboratory for aligner fabrication.

4. The aligners will be printed using the Graphy system (Graphy Co., Korea) with Tera Harz TC-85DAC resin, ensuring high precision and durability
5. Participants will be instructed to wear their aligners for 22 hours per day, removing them only for eating and oral hygiene.
6. Aligners will be replaced every 14 days as per the treatment plan.
7. At the end of the treatment, participants will undergo a final intraoral scan to assess the outcomes and compare them with the initial scans

GROUP 2

1. The obtained STL files will be imported into Dentone software (Diorco Co., Korea) for virtual treatment planning. The planning will adhere to functional and esthetic principles, ensuring optimal outcomes
2. The treatment will begin with leveling and alignment of the dental arch, following aligner biomechanics principles. Each aligner will be designed to achieve:
    - 0.2 mm linear movement per aligner,
    - 2-degree long-axis rotation per aligner
    - 2.5-degree labio-lingual inclination per aligner
3. The designed STL files will be exported and sent to a certified dental laboratory for aligner fabrication.
4. Digital dental cast models will be printed using a 3d printer (Anycubic photon mono M5s pro), using Duran sheets following the manufacturer's instructions during the thermoforming process in a vacuum thermoformed machine, aligners will be trimmed 2 mm above the gingival margin
5. Participants will be instructed to wear their aligners for 22 hours per day, removing them only for eating and oral hygiene.
6. Aligners will be replaced every 14 days as per the treatment plan.
7. At the end of the treatment, participants will undergo a final intraoral scan to assess the outcomes and compare them with the initial scans

Dental measurement, by using Medit link software (Medit Co, Seoul, South Korea) for superimposition to conclude the accuracy of tooth movement we will superimpose the planned treatment model (TP) with post-treatment scan(T1) and pre-treatment scan (T0), The superimposition will be on the medial part of the third rugae area as it provides more accurate, reproducible, and precise results. [13]

According to Santos et al [14] . six measurement points will be placed on each tooth including

• Distal point of the occlusal surface (DO)
• Mesial point of the occlusal surface (MO)
• Occlusal limit of the FACCs buccal axis (OL)
• Gingival limit of the FACCs buccal axis (GL)

• Gingival limit of the lingual FACCs (continuation of the buccal FACC axis on the lingual face) (GLL)
• Centroid of teeth (CT): The midpoint of a line passing from the gingival limit of the FACC buccal axis (GL) to the occlusal limit of the FACC buccal axis (OL)
To improve adherence to treatment patients will be followed up with phone calls and clinic visits every two weeks.

12. Outcomes:

Accuracy of tooth movement is determined by knowing the difference between predicted tooth movement and the actual movement that occurred, it will be measured by using this formula:

$$\frac{position\ T1-Position\ T0}{Position\ TP-Position\ T0} \times 100$$

Where Position (T1) is the actual position after treatment, Position (T0) is the initial position, and Position (TP) is the predicted position

Prioritization of Outcome	**Outcome**	**Method of Measurement**	**Unit of Measurement**
Primary outcome	Accuracy of tooth movement	Linear and angular measurement	Numerical
Secondary outcome	Pain	Questionnaire	Visual analogue scale

13. Participant timeline

1. Screening patients at the Orthodontic department, Faculty of Dentistry, Cairo University and selecting potential participants through careful clinical examination.

2. All recruited patients should fulfill the previously mentioned inclusion and exclusion criteria.

3. Prior to study initiation, participants will be provided with detailed information about the study objectives and procedures, and written informed consent will be obtained.

4. After enrollment, for each participant intraoral and extraoral photos and intraoral scans will be taken. In addition, each patient will be referred for panoramic and lateral cephalometric radiographs.

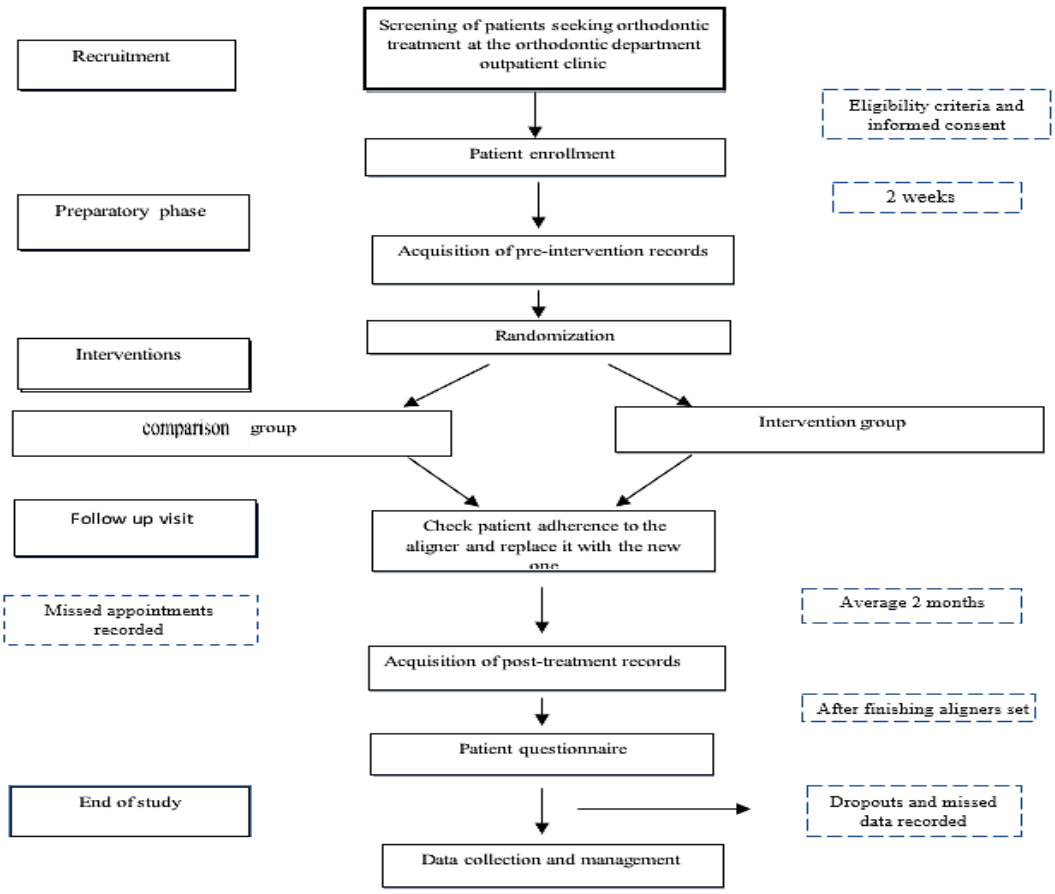
5. Participants will be randomly assigned to either the intervention or control group according to the study's allocation protocol

6. Each participant will be scheduled for follow-up visits at four-week intervals to monitor progress and ensure adherence to the treatment regimen

7. After finishing the aligner set, new records will be taken for each participant.

8. All patients will receive a fixed retainer after the treatment.

8. Each participant will fill up a questionnaire regarding his pain experience with the appliance.



14. Sample size:

According to the results of Sachdev et al. 2021 in which intrusion tooth movement using clear aligners was 0.27±0.21. If the true difference in the experimental and control means is 0.25, we will need to study 12 patients per group to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. Sample size was increased by 15% to compensate for possible dropouts to reach 14 per group. Sample size was calculated using PS Power and Sample for windows version 3.1.6 using independent t test.

15. Recruitment:

Subjects will be selected from the Diagnostic Centre at the Faculty of Dentistry, Cairo University by the principal investigator.

B) Assignment of interventions

16. Allocation:

16a. Randomization:
Randomization will be performed as a 1:1 allocation. The sequence of individuals in the intervention and the comparator group will be done by using computer generated random numbers. This will be done using Microsoft Office Excel version (Redmond, Washington) 15.24 sheet.

16b. Allocation concealment mechanism:
The randomization numbers produced from the sequence generation will be written on opaque papers folded 4 times sealed in opaque envelopes and kept in a sealed box.

16c. Implementation
On the day of starting, each subject will be allowed to choose one of the envelopes to detect his/her number to be able to detect the randomization sequence and detect in which group he/she is. The principal operator will have the code for each patient.

17. Masking/blinding:
Trial participants, outcome assessors, data analysts and statistician will be blinded.

C) Data collection, management, and analysis:

18. Data collection methods
Data will be collected by the principal investigator for the primary and secondary outcomes.

19. Data management:
Data will be entered and organized electronically in Excel sheets and stored on the computer in the orthodontic department.

20. Statistical methods:

Statistical analysis will be performed using Medcalc software, version 22 for windows (MedCalc Software Ltd, Ostend, Belgium). Continuous data will be presented as mean and standard deviation. Comparison between continuous variables will be performed using independent t test. The significance level will be set at $P \leq 0.05$ and all tests will be two tailed.

D) Data monitoring:

21. Monitoring

Monitoring of the study will be strictly done by the supervisors periodically. They will monitor all the steps of the followed protocol and find solutions to all troubles that have occurred during the trial performance.

22. Harms

If any harm occurs to the patient before entry to the study, it will be reported as unrelated. If it happens after, it will be recorded and documented by the primary investigator. The severity of harm and potential causal relationship with intervention will be addressed. If the patient shows any allergic reaction from wearing aligners, the patient will withdraw from the trial.

23. Audit

The trial will be audited by the supervisors in the orthodontic department at Cairo University frequently.

IV. Ethics and dissemination

24. Research ethics approval

This protocol, the template, and the specific informed consent form will be reviewed, approved, and agreed upon by CEBD [Center For Evidence-Based Dentistry CU] Cairo University, Egypt, and approved by the Ethics Committee [Research Ethics Committee Cairo University Faculty of Oral and Dental Medicine]. The research Ethics committee will review the nature of interventions and will have the right to modify the study methods.

25. Protocol amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, intervention procedures will require a formal amendment to the protocol. Such amendment will be agreed upon by the Council of Orthodontics and Dentofacial Orthopedics department.

26. Informed consent

The principal investigator will introduce all the details of the study and the possibility of recruitment will be clearly introduced to the patients.
The researcher will obtain written consent from the patients willing to participate in the study.
The consent form is in Arabic.

27. Confidentiality

All study-related information will be stored securely at the Orthodontic department, at Cairo University. All participant's personal information, family history, social and health status will be stored in locked file cabinets in areas with limited access. Access will be limited to the minimum number of individuals necessary for quality control, audit, and analysis. All records that contain names or other personal identifiers, such as informed consent forms, will be stored separately from study records identified by code number to secure the blinding of assessment.

28. Declaration of interest

There is no conflict of interest between the supervisors and the principal investigator.

Non-financial competing interests: this study is a part of an MSc degree in Orthodontics, Faculty of Dentistry, Cairo University.

No financial conflicts of interest are to be declared. The study is self-funded by the principal investigator.

29. Access to data

The Principal Investigator and the study supervisors will be given access to the final data sets. All data sets will be password protected. The randomization sheet will be accessed only by the supervisor. The data analysts will be blinded from any personal identifier during data analysis. All the data have to be of no access to other parties until the study is terminated.

30. post-trial care

Complications that may accompany the intervention, will be managed by senior staff members in specialized centers and will be sponsored by Cairo University.

31. Dissemination policy

Besides reporting as a MSc thesis, study results will be available to the participants, health care professionals and the public by publication of the study. A copy of the thesis will be available at the faculty library and additional copies will be distributed among the main universities in Egypt. The results of the trial are planned for publication in high quality journals and presentations at national and international conferences. There will be no publication restrictions, regardless of the magnitude of effectiveness of the intervention that is indicated from the data analysis.

V. Appendices

32. Informed consent

Patient's full knowledge of the research steps: Reading [ ] Oral explanation [ ] Other [ ]*

1. **I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.**
2. **The researcher has informed me of the possible therapeutic alternatives for this research.**
3. **The researcher has informed me of all the possible risks of this research and how to deal with it.**
4. **I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.**
5. **I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines,**

food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions for my health.

6. **I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher if I enter any other research throughout the period of this research.**
7. **I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.**

After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons anytime.

The researcher in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as replacing names with code numbers or hiding facial features when photographing (etc.).

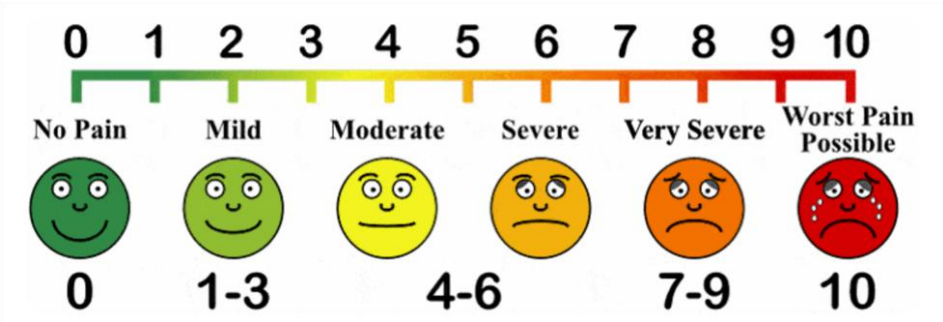
Signature:
Date:

32. visual analogue scale

Visual Analogue Scale

Name: Date:

Place a mark on the line below to indicate your current level of pain



Additional notes

34. Biological specimens

No biological specimen in this study

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