STUDY PROPOSAL

Evaluating the effectiveness of 3D directly printed shape memory aligners in the management of anterior open bite in adult patients.

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Abstract

Conventional clear aligners (CA) have emerged as a popular alternative due to their advantages over fixed appliances in the treatment of anterior dental open bite. Open bite cases require controlled vertical movements, which are difficult to manage with traditional aligners. The 3D-direct printing has advantages over conventional aligners (continuous force, high-precision fit, and high vertical control). Graphy, a South Korean company, offers the world's first direct 3D-printed clear aligner made from shape memory photopolymer. This study will investigate the efficiency of 3D-printed shape memory clear aligners in treating anterior dental open bite (AOB) in adult patients. The finite element analysis will proceed before the clinical trial and standardisation to establish common procedures for model creation. Three models will be designed as follows: Model 1: no composite attachment with 3D direct-printed shape memory aligner. Model 2: attachment with 3D direct-printed shape memory aligner. Model 3: attachment with conventional clear aligner. The clinical trial will be a multicentre randomised clinical trial with three parallel arms for Iraqi adult patients with anterior dental open bite (18-35 y.) according to the study criteria. Three groups of participants will be tested: Group I (conventional aligner with attachment), Group II (3D shape memory aligner without attachment), and Group III (3D shape memory with attachment). All patients will receive the same treatment and sign informed consent to participate. Outcome measurement will be recorded before the treatment (T0) and reported after the first series of aligners (15-20 aligners) (T1). Cephalometric analysis (from the CBCT DICOM file) will be performed using Dolphin Imaging™ software, which will be used to identify and approximate landmarks in the spatial space. The study will also include measurements of dental and skeletal leaners and angular changes. SPSS Statistics (Shapiro-Wilk and Kolmogorov-Smirnov tests, ANOVA, a paired T-test and Tukey's Honestly) will be used to gather numerical and inferential data from finite element analysis tests and clinical trials and will compare patient-reported outcome measures. The expected general outcome will provide a satisfactory outcome of 3D shape memory aligner in the treatment of anterior open bite without the need for attachment in a highly comfortable way for the patients.

1.0 Introduction

1.1 Background of the study:

Anterior open bite (AOB) is a malocclusion of the maxillary and mandibular incisors when they do not overlap vertically, with varying degrees of severity. This malocclusion adversely affects an individual’s quality of life by hindering and impairing essential oral functions (1). The aetiology of an AOB is multifactorial in nature. Unfavourable growth patterns, oral habits, respiratory factors, and neuromuscular imbalances have been suggested to play a role. AOB results in significant aesthetic and functional concerns often (2). Managing AOB poses challenges in diagnosis and treatment planning due to its multifactorial aetiology and high propensity to relapse, as vertical growth is the last to cease (3). Open bites are classified as mild (2 mm), moderate (3-4 mm) and severe (higher than 4 mm) (4). Traditionally, fixed appliances have been the mainstay of treatment for such malocclusions, often requiring the use of auxiliaries such as mini-screws and occlusal bite blocks to achieve desired outcomes (5). In recent years, conventional clear aligners (CA) have emerged as a popular alternative to traditional fixed appliances due to many advantages (e.g., posterior intrusion and the "bite block" effect, aesthetics and discretion, improved oral hygiene and patient comfort). Clear aligners are used to treat a variety of orthodontic conditions,

especially those considered mild to moderate (e.g., correction of crowding and spacing, overbites, and crossbites) (6). Clear aligners are fabricated from a variety of thermoplastic polymeric materials. These materials are heated and then vacuum- or pressure-formed over a 3D-printed model of the patient's teeth (e.g., Polyethylene Terephthalate Glycol (PETG), Thermoplastic Polyurethanes (TPU)). Early clear aligners were limited because they were less effective at achieving complex movements, especially those that involve extruding (pulling out) anterior teeth or intruding (pushing in) posterior teeth—both of which are key for correcting an AOB. This was primarily due to the simple plastic material and a lack of additional features to control force application (7). With recent advances in clear aligner therapy, improved materials, attachment techniques and digital treatment planning, the potential for non-invasive treatment has increased. The orthodontic treatment of anterior open bite aims to guide the extrusion of the upper and lower incisors and the molar intrusion to achieve a positive overbite. Also, the lower molar intrusion leads to anticlockwise mandibular rotation (8). The decision for posterior intrusion or upper incisor extrusion is made following a smile analysis and the evaluation of the facial lower-third type. Attachments are required for the anterior extrusion (9).

3D-direct printing has advantages when compared to conventional clear thermoformed techniques, including (a) manufacturing speed, (b) improved patient fit, and (c) less invasive modelling techniques (10). Graphy, a South Korean company, offers the world's first direct 3D-printed clear aligner made from shape memory photopolymer Tera Harz (TC-85) (11). This resin enables aligners to hold a programmed shape and recover if deformed and provides a transformative upgrade over traditional aligners by combining the following advantages: (i) continuous force, (ii) high-precision fit (figure 1.1), (iii) lower stage count, (iv) improved comfort, and (v) aesthetic clarity (12). These advantages are especially meaningful for open bite treatment, where vertical control and predictable biomechanics matter most. However, their design and the primary mechanisms of action for clear aligners involve incisor extrusion and tipping (13). Therefore, this study aimed to evaluate the efficacy of 3D direct-printed shape memory aligners for treating AOB.

1.1.1 Problem statement

AOB correction requires controlled vertical movements (extrusion of anterior teeth and intrusion of posterior ones), while the most popular conventional clear aligners struggle to achieve these movements reliably due to unpredictable force decay and limited control of vertical biomechanics. Yet, results show variability in the underlying mechanisms, with the exact method of correction remaining debatable. Moreover, the conventional clear aligner has low adaptability in comparison with the 3D direct-printed aligner. Figure(1.1).

In this study, we have conducted an electronic search in many engines, such as Google Scholar, Semantic Scholar, Scopus, ResearchGate, PubMed Medline, ScienceDirect, NCBI, PubMed Central, PubMed Search and Cochrane Library. There wasn't any conducted research using 3D direct-printed shape memory clear aligners in the treatment of open bite cases in adult patients, and even evidence for conventional aligners in open bite management is limited, especially in high-quality trials.

1.1.2 Research gap:

Despite recent advances in clear aligner therapy, there is limited high-quality evidence on their effectiveness in managing anterior open bite (AOB) in adults. Moreover, no studies have evaluated the clinical or biomechanical performance of 3D direct-printed shape memory aligners for AOB correction, highlighting a critical need for comparative research to establish the 3D printed shape memory aligners potential advantages over conventional thermoformed aligners.

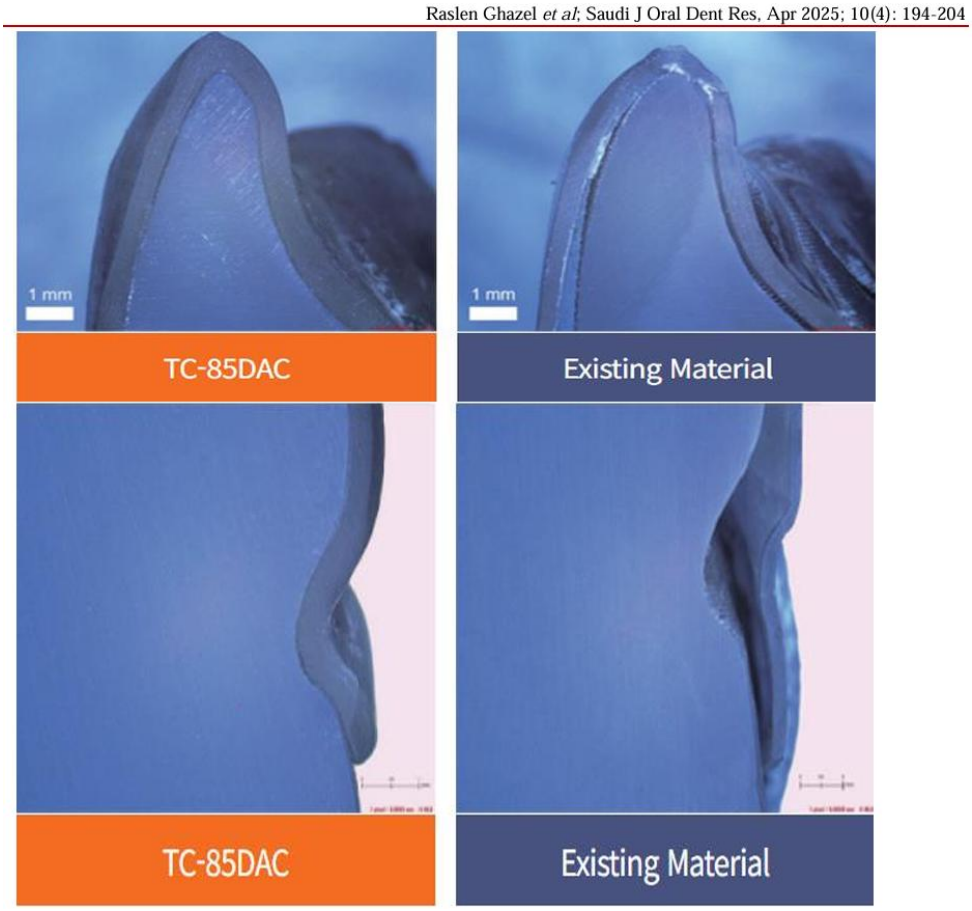

Figure 1.1: Adaptation of a 3D direct-printed memory shape aligner to that of conventional aligners.

1.2 Study objectives:

1.2.1 General objective:

The general objective of this study to investigate of 3D-printed shape memory aligners in the treatment of anterior dental open bite adult patients.

1.2.2 Specific objective:

1. Investigate 3D direct-printed shape memory aligners for potential AOB correction with and without extrusion attachments.

2. Investigate and compare the amount of stress distribution and initial teeth displacement applied by conventional clear aligners and 3D direct-printed shape memory aligners during treatment.

3. Investigate and compare the effect of the 3D-printed shape memory aligner (with or without extrusion attachment) and the conventional clear aligner on dental (molar intrusion and incisor extrusion and angulation) changes and patients' satisfactory outcomes.

1.3 Research questions:

1. Do 3D-direct-printed shape memory aligners demonstrate potentiality in the management of AOB?
2. What is the effect of 3D-direct printed shape memory aligners on molar intrusion?
3. Can the 3D-direct printed shape memory aligners extrude anterior teeth without the use of attachments?
4. Do 3D-direct printed shape memory aligners generate greater/higher stress distribution and initial teeth displacement compared to conventional clear aligners?

1.4 Research hypothesis:

1. 3D direct-printed shape memory aligners provide a clinically significant improvement in the correction of anterior open bite (AOB) compared to conventional clear aligners.

2. The 3D-direct printed shape memory aligner has better stress distribution and initial teeth displacement than conventional clear aligners in the treatment of anterior dental open bite cases.

3. 3D direct-printed shape memory aligners can produce effective anterior tooth extrusion without the incorporation of attachments.

4. The 3D-direct printed memory shape aligner can intrude the posterior upper and lower molars.

1.5 Clinical significance of study:

1. Using a 3D direct-printed shape memory clear aligner (Graphy TC-85) has a clinical significance:

a. Easier to use and faster chairside production (14).

b. Lower cost (15).

c. Less force (16).

d. No attachments (more comfort and aesthetics) (17).

e. Eliminates the need for models' storage (18).

2. Well understanding and discovering the strong and weak points in the biomechanical effects of both conventional and 3D-printed shape memory aligners in the treatment of anterior dental open bite cases.

3. Understanding the stress distribution and initial displacement during teeth movement when using conventional and 3D-direct printed memory shape aligners.

2.0 Literature review

2.1 Anterior dental open bite:

Anterior open bites (AOBs), characterised by the absence of contact between the anterior teeth, represent a complex treatment challenge. Consequently, a precise diagnosis is imperative for formulating a treatment plan. Correa et al. (19) reported a global prevalence of 4.83% for anterior open bites in individuals with permanent dentition. The aetiology of an AOB can be classified as hereditary or non-hereditary. In hereditary cases, it may be purely inherited from one of the parents. Non-hereditary causes encompass non-nutritive sucking (such as finger or pacifier habits), abnormal tongue function, neurological disorders, mandibular condyle pathology, and iatrogenic factors (20). Dental AOB is characterised by a normal craniofacial pattern with proclined and under-erupted anterior teeth. Skeletal AOB is marked by specific anatomical characteristics, including an overlarge mandibular plane angle, gonial angle, anterior facial height, and total facial height, as well as an anteriorly upward-tilting palatal plane and a retrognathic mandible. Functional AOB is closely associated with the behaviour of the head and neck muscles during speaking, breathing, chewing, and swallowing. The equilibrium of the dentition can be affected by imbalances in the orofacial muscular system, particularly by abnormalities in the tongue, lips, and cheeks (21). Treatment options for correcting anterior open bites in permanent dentition include conventional fixed appliances or orthodontic surgical orthognathic treatment. With technological advancements, an alternative therapeutic option emerged in the 1990s: invisible aligners (22). These aligners are designed using computer technology to correct dental positions and have gained popularity among adult patients due to their aesthetics and comfort. Studies suggest potential molar intrusion attributed to the coverage provided by the aligner material, which can enhance control over the vertical dimension, making it a viable option for anterior open bite treatment (23). Aligners are composed of a plastic material, potentially consisting of polyethylene terephthalate glycol, polyvinyl chloride, or polyethylene terephthalate, among other materials. Orthodontic materials are subject to continual evolution, thereby enhancing mechanical properties and consequently impacting treatment outcomes. This treatment promotes three-dimensional force distribution across the entire contact surface (24). Dental movement is realised by a disparity between the device and the geometric configuration of the teeth, as predetermined in the treatment plan. Presently, aligner treatment is executed utilising software that simulates tooth movement and fabricates the devices via CAD-CAM (computer-aided design-computer-aided manufacturing) technology (25). This system integrates interactive planning using 3D computational technology, 3D movement within CAD-CAM, and the digital design/manufacturing of the device. Additionally, it defines the positioning of attachments, affixed with composite resin, tailored for

intricate tasks across all spatial planes. With such precision, it becomes feasible to delineate a treatment plan aimed at correcting complex issues like an anterior dental open bite (26).

2.2 Clinical Implications in Open Bite Cases:

Open bite correction often relies on (27):

- **Posterior intrusion** (to allow anterior closure).
- **Anterior extrusion** (to reduce the open bite).
- **Vertical control**, which is difficult with CCAs (conventional clear aligners) due to less effective vertical forces.

2.3 Conventional clear aligner (made from thermoformed plastics (e.g., PETG, polyurethane)**):**

Open bite correction with clear aligners provides adult patients with a quicker and more aesthetic treatment alternative (28). Literature has reported that open bite correction via clear aligners facilitates a better mechanical advantage due to additional occlusal coverage. This provides better vertical dimension control when compared with traditional braces, a removable clear aligner system as an alternative to fixed orthodontic treatment (29). Clinicians have reported that aligners help deepen the dental overbite during orthodontic tooth movement. Therefore, aligners can possibly be used as an effective modality to treat patients with anterior open bite (30).

Harris et al. (31) found that most anterior open bite correction during clear aligner treatment occurred due to anterior tooth extrusion rather than posterior intrusion. However, a 2009 study by Kravitz et al. found that extrusion is the least accurate type of tooth movement during clear aligner treatment, with only 29.6% accuracy (32). Rossini et al. also reported extrusion as being a difficult movement with clear aligners with a 30% accuracy (33). Another recent systematic review found that one of the limitations of clear aligner treatment is effective and predictable extrusion of maxillary incisors (34).

One solution to increase the effectiveness of difficult tooth movements, such as incisor extrusion, is to incorporate attachments or composite projections on certain tooth surfaces (35). A study by Karras et al. (36) found that adding attachments on certain teeth increased the accuracy of achieved-to-predicted movements. When it comes to attachments. Conventional attachments are standardised in shape and size and can be selected from a wide attachment library.

2.4 3D direct printed memory shape aligner (Graphy **–** typically made from advanced materials like TC-85 shape memory polymers (SMPs)**):**

With extensive digital technological advancements, 3D printers have evolved in parallel, allowing the printing of various resin materials. With 3D printers becoming more advanced, cheaper, and more compact, the concept of in-office aligner production gained popularity. The ability to print aligners directly without the need for a dental model printing step could be the next big step in the aligner treatment revolution (37). This major achievement was made by Graphy (Seoul, Korea), a Korean-based company that introduced in 2019 a resin material called TC-85 DAC as the first aligner resin for direct aligner printing, followed by the new resin material TA-25 for aligner printing (38). The era of printed aligners has just begun in the orthodontic field, so

evidence-based studies are limited. Studies on material mechanical properties, surface roughness, cytotoxicity, estrogenicity, leaching, and fitting accuracy are required. Furthermore, comparison of printed aligners with thermoformed ones must be studied extensively (39). 3D-printed aligners could be the next paradigm shift in orthodontic treatment. 3D printing via photopolymerisation from clear resins seems to be a promising option, as the specific characteristics and requirements of the material properties are more appropriate (40). Although diverse materials are present in the market, not one 3D printable material currently available commercially meets the standards of biocompatibility, translucency, and appropriate mechanical properties. The only exception is Tera Harz TC-85 (Graphy, Seoul, South Korea), which, according to the company website, has been approved by multiple international agencies, including the Korea Food and Drug Administration, European Commission, and U.S. Food and Drug Administration (41).

2.5 Properties of 3D-direct printed shape memory aligners over conventional aligners:

a. True Shape Memory Mechanics:

- The aligner can be briefly softened in warm/hot water (up to ~100°C for 1–2 minutes), then regain its original printed shape, restoring its corrective force and fit (42).
- This reduces force decay and deformation, allowing one aligner stage to replace two to three traditional ones (42).

b. Continuous, Gentle Force

- At body temperature (~30–40°C), the aligner gradually returns to its programmed form, applying light but persistent force, ideal for vertical movements like anterior intrusion or posterior extrusion in open bite treatment (43).

c. Direct 3D Printing for Precision

- The aligner is printed directly from the patient's digital scan—with no thermoformed models—resulting in a near-perfect fit, accurate engagement of undercuts, and precise force application (44).
- Flexible thickness zones can be incorporated to fine-tune biomechanics per case (44).

d. No Attachments Needed

- Graphy's aligners often avoid bonded attachments altogether, even in complex movements like rotations or extraction cases, thanks to shape memory action and integrated design features (bite blocks, pressure spots, etc.). (45).

e. Improved Comfort & Hygiene

- Softened in warm water before insertion, the aligner is easier to seat—even in crowded or tight cases—minimising insertion/removal discomfort (46).

- Being scratch-resistant and heat-tolerant, the material can be brushed and disinfected reliably, maintaining transparency and hygiene (46).

f. 3D printing enables precise, patient-specific designs, **which is critical in open bite treatment:**

- **Variable thickness control**: 3D printing allows the aligner to have areas of different stiffness or flexibility to target specific teeth more effectively (47).
- **Embedded force programming**: SMPs can be pre-stressed during printing to deliver specific forces once in the mouth (47).
- **Improved fit and engagement**: More accurate printing can create better tooth contact and retention, which is crucial in vertical corrections (48).

2.6 CBCT and 3D intraoral scanner:

CBCT (Cone Beam Computed Tomography), is a type of X-ray imaging that produces high-resolution, three-dimensional images of teeth, jaws, and other hard tissues in the head and neck. Unlike traditional X-rays, CBCT uses a cone-shaped X-ray beam to capture a full 360-degree rotation around the patient, which is then processed by a computer to create a 3D model. This advanced imaging technique offers detailed anatomical views with lower radiation exposure compared to traditional CT scans, making it invaluable in fields like dental surgery and orthodontics (47). 3D dental scanners create highly accurate digital replicas of a patient's mouth, teeth, and gums, eliminating the need for traditional, messy physical impressions. The technology significantly improves speed, accuracy, and patient comfort across various dental procedures. There are two primary types of scanners: intraoral scanners used directly in the mouth and laboratory scanners for models and impressions (48).

2.7 Finite element analysis:

Finite element analysis (FEA) was initially introduced by Turner et al. (49) in 1956. The FEA is a computer-based numerical method used to simulate complex geometrical objects and their physical properties. The FEA is a non-invasive and accurate method that provides useful data for an orthodontist to understand the biomechanical and physiological responses that occur in tissues such as the periodontal ligament and the alveolar bone (50). Previous FEA studies on clear aligners found that composite attachments played an important role in precise tooth movement with a clear aligner (49).

Usage in clear aligner studies:

- Simulates how aligners exert forces on teeth (especially anterior extrusion) (50). Figure (2.1)
- Evaluates stress distribution in periodontal ligament (PDL), bone, and aligner (50). Figure (2.2).

- **Advantages:**
  - Non-invasive and allows detailed 3D analysis (51).

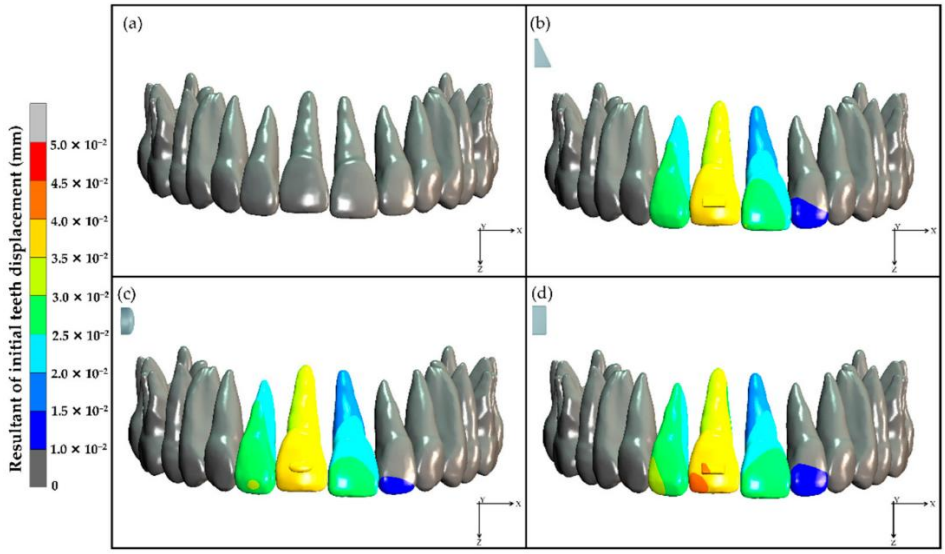

Figure 2-1: Resultant values of initial teeth displacement: (**a**) no composite attachment, (**b**) rectangular beveled attachment.

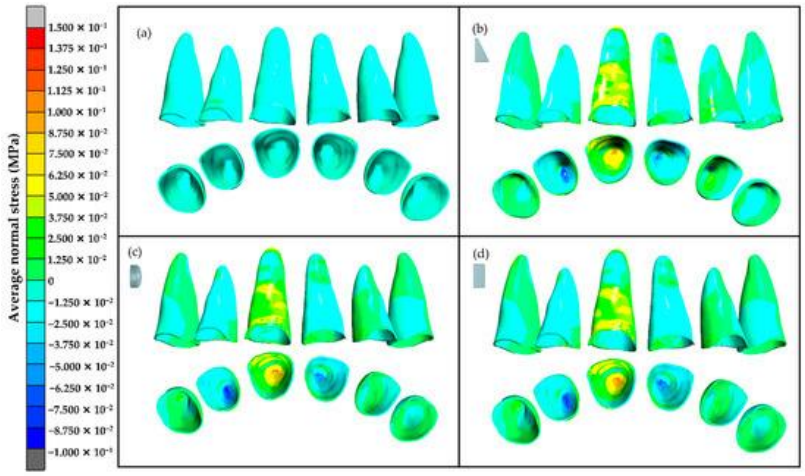

Figure 2-2: Distribution of the average normal stress at the upper anterior teeth PDL: (**a**) no composite attachment, (**b**) rectangular beveled attachment.

3.0 Material and methods

3.1 Ethical approval

Ethical clearance will be obtained from the Medical Ethics Committee, Faculty of Medicine, University of Kufa, Iraq (MEC-163). This randomised clinical trial will be registered and reported at clinicaltrials.gov, among Class I molars and skeletal relationships with anterior dental open bite Iraqi patients.

3.2 Sample size calculation:

Sample size calculations were performed. In each group, a sample size will be calculated by G-power (version 3.1), at a power of 80% and a 0.05 level of significance, which enabled the detection of significance between the three treatment groups in overbite changes of 1.5 mm with a standard deviation of 1.5. The final anterior open bite sample consisted of 15 patients for each group. To account for a potential 10% dropout rate, two individuals will be added to each group, resulting in a final sample size of 51 individuals—17 per group, according to a previous study done by Serdar et al. (52).

3.3 Participants, eligibility criteria, and settings:

Patients will be recruited from the Department of P.O.P., University of Kufa, Azadi Dental Centre, and a private dental clinic located in Iraq. The treatment will be done by a specialist orthodontist. Patients will be recruited at the time of their consultation if they meet the study criteria: Table (3.1).

Table 3.1: Study criteria.

The inclusion criteria:	**The exclusion criteria:**
(1) Adult patients, age 18–35 years, all teeth present and fully erupted (excluding third molars) Adults have completed craniofacial growth, which makes orthodontic movements more predictable and stable; Adults are typically more motivated and compliant with the 20–22 hours/day wear time, essential for treatment success (not forgetting to wear them, reducing effectiveness). Moreover, in mixed dentition there will be teeth eruption and exfoliation that could be effect on the aligner fitting and accuracy] (53,54). (2) Mild-moderate dental anterior open bite (-1 to 3 mm vertical gap between the incisal edge of upper and lower incisors). (3) Angle Class I molar relationship. (4) Skeletal Class I (ANB 3±2°). (5) Average (normodivergent) vertical dimension (MMPA 27±5°). (6) Healthy periodontal status.	(1) Moderate to severe crowding. (2) Loss of posterior teeth. (3) History of trauma to the molars or incisors. (4) History of endodontic treatment to the maxillary first molar or incisors. (5) Systemic disease related to bone metabolism. (6) Taking immunosuppressive drugs or drugs inhibiting or accelerating tooth movement; and (7) Neuromuscular deficiencies. (8) Skeletal open bite. (9) Short upper lip. (10) Average or increased incisors show. (11) treatment plan requiring surgery or extraction of any maxillary teeth.

(7) Well-aligned or mildly crowded dentition. (8) Patients should be treated with incisor extrusion (upper only or both).	(12) severely rotated or heavily restored (direct or indirect restoration) maxillary anterior teeth

3.3.1 Interventions:

All patients will be received the same treatment and will be a signed informed consent to participate in the study. The patient intervention will be summarized as following timeline flow chart: (Figure 3.1).

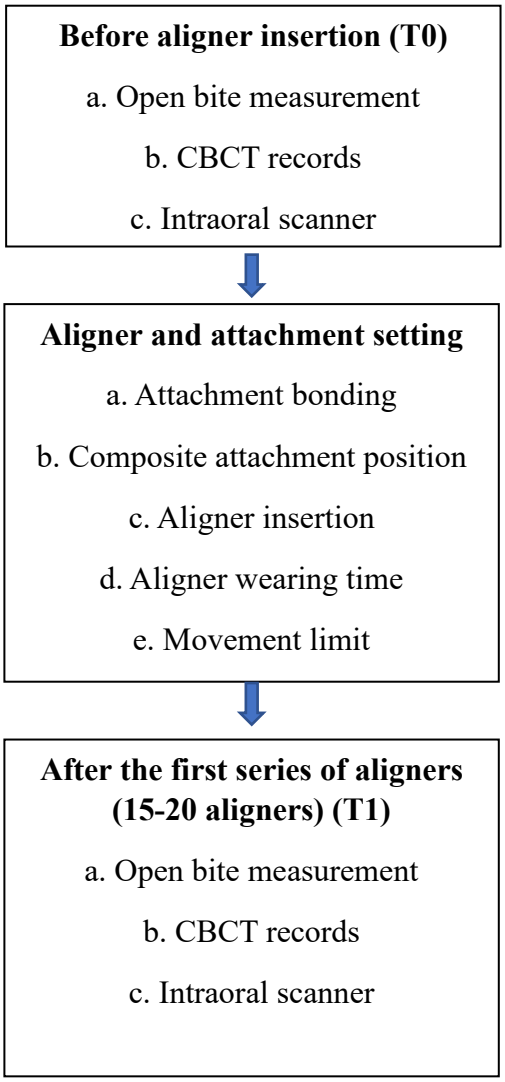

Figure 3.1: Patient intervention timeline flow chart.

1. Before aligner insertion (T0):

a. Open bite measurement: Will use digital software (3Shape OrthoAnalyzer) from the incisor's edges of upper and lower central incisors, also; clinically using digital clipper (Kroeplin Caliper, Germany) (54).

b. CBCT records: CBCT radiography will be done for each patient after signing the informed consent. All the patients will take a CBCT (T0) (80 kV, 5 mA, 9.2 s exposure time, 0.125 mm voxel resolution, 80 x 80 mm field of view; Veraviewepocs J Morita MPG, Fushimi, Kyoto, Japan). CBCT images will be reconstructed every 0.125 mm. One Volume Viewer Software (Version 11.0, J Morita, Chatsworth, CA, USA) will be taken before treatment (T0) and after the first series of aligners (15-20 aligners) (T1).

c. Intraoral scanner: An intraoral scanner (TRIOS, 3Shape, Copenhagen, Denmark) will be used to scan the upper and lower jaws with occlusion, also to render an STL file, which will be imported to the 3Shape OrthoAnalyzer (USA), that will be used to design each patient's treatment sequence and will be taken before (T0) treatment.

2. Aligner and attachment setting:

a. Attachment bonding: The protocol for attachment bonding was standardised using the commonly accepted bonding procedures. Attachments and IPR were tailored to each patient's needs, based on each of the three practitioners' clinical experience. Therefore, attachment location and IPR on teeth cannot be reported systematically.

b. Composite attachment position: The incisal margin of the composite attachments will be placed 3.5 mm gingivally to the incisal edge. Both mesial and distal margins of the composite attachments were 2.5 mm away from the mesial and distal surfaces of the tooth and will be designed to be 4 mm wide mesiodistally; the incisogingival dimension and the angulation were unaltered (55).

c. Aligner insertion: Proper demonstration of aligner insertion as instructed will be observed. Participants will verbally confirm compliance at each appointment, and compliance will be self-recorded by participants in hours per day.

d. Aligner wearing time: Patients will be instructed to wear each aligner for a minimum of 22 h/d, 7 d/wk each, before moving to the next aligner, the standard aligner protocol used by the participating providers (55).

e. Movement limit: The movement (extrusion) limit will be set to 0.25 mm maximum per aligner (55).

3. After the first series of aligners (15-20 aligners) (T1):

All the records that have been taken before treatment (open bite measurement, CBCT (T1), intraoral scanner) will be taken after the first series of aligners (15-20 aligners by the same criteria as before treatment.

3.3.2 Interim analysis and stopping guidelines:

Participants will be informed that they could discontinue participation at any time and that it would not affect their remaining treatment. Patients with poor tracking requiring midcourse intervention or failure to complete the aligners prescribed will be noted for reporting purposes but not included in the final analysis.

3.4 Study design and grouping:

The study design will be a multicentre randomised clinical trial with three parallel arms.

Three groups of participants with different treatments will be tested in the present study as follows:

Group I: Patients treated with conventional clear aligners with attachments [rectangular-shaped attachments with bevelled edges toward the gingiva on anterior upper and lower teeth (53)].

Group II: Patients treated with 3D direct-printed shape-memory aligner without attachment, and

Group III: Patients treated with 3D direct-printed shape memory clear aligners with attachments [rectangular-shaped attachments with bevelled edges toward the gingiva on anterior upper and lower teeth (53)].

3.5 Treatment duration:

The treatment duration for each patient will be about 8-14 months, and the general study time will take about 3 years to complete.

3.6 Digital impression-taking technique and appliance fabrication:

3.6.1 Thermoforming on the 3D-printed models:

The conventional thermoforming technique is indirect in nature. After treatment planning, sequential dental models representing the patient's treatment progress will be printed after digital impression scanning of the upper and lower jaws and taking occlusion using an intraoral digital scanner (Trios, 3Shape, Copenhagen, Denmark); the thermally manipulated transparent plastic sheets (Tristar, 0.75 mm thickness, Australia) will be moulded against each dental model (3shape orthoanalyser, 1.9 software, Denmark-LINIZ printer, Seoul, Korea) by a pressure- or vacuum-forming machine (BioStar, Germany) for aligner production. The retrieved aligners will be trimmed and finished for patient delivery and insertion (Figure 3.2).

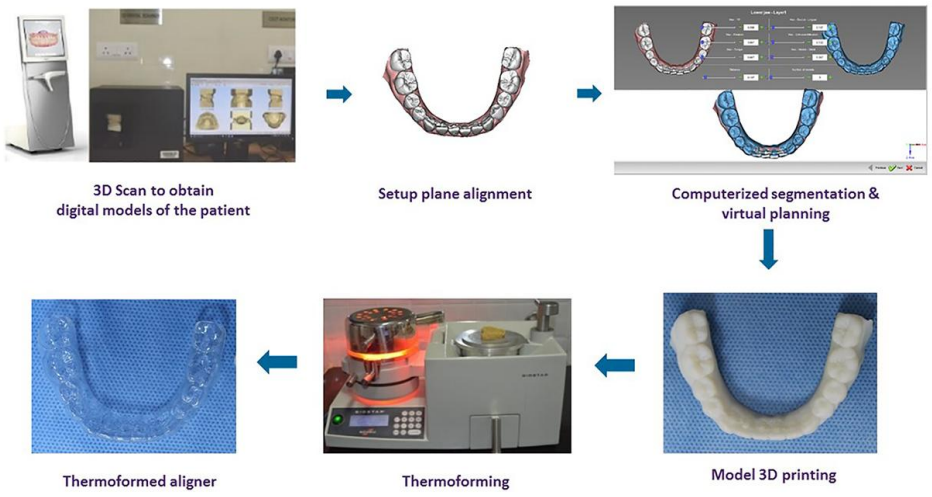

Figure 3.2 : schematic diagram of the laboratory technique to fabricate the conventional thermoformed clear aligner.

3.6.2 Direct 3D printing shape memory aligners:

The direct 3D printing technique designs and fabricates the aligner directly using biocompatible clear resins (Tera Harz TC-85 (Graphy, Seoul, South Korea)) without requiring a dental model. The digital orthodontic workflow of 3D-printed aligners The sequential steps encompassing the process of direct 3D-printed clear aligner manufacturing are: (i) data acquisition using intraoral digital scanning (Trios, 3Shape, Copenhagen, Denmark), (ii) virtual planning (3D models) and computer-aided designing of clear aligners (3shape orthoanalyser, 1.9 software, Denmark), (iii) 3D printing (LINIZ, developed by Graphy 0.75 mm thickness, Inc., Seoul, Korea), and (iv) post-processing (cleaning the uncured residual resin, support removal, and post-production curing; for the Tera Harz TC-85 aligners, recommendations mention the process of cleaning by centrifugation (Tera Harz Spinner developed by Graphy, Inc., Seoul, Korea) for around 3–4 min or removal with a soft scraper). This will be followed by support removal and post-production curing with Cure M (Graphy, Seoul, Korea). The nitrogen generation curing unit (Tera Harz cure developed by Graphy, Inc., Seoul, Korea) will be utilised and recommended to enhance the physical properties of the resin material by providing an inert environment, thereby preventing the formation of an oxygen inhibition layer. The THC 2 UV Curing system (Graphy Inc., Seoul, Korea) is a known representation of this category. For the Dental LT-clear resin aligners, washing by ultrasonication with isopropyl alcohol (96/99%) and postproduction curing with the Form Cure unit (Formlabs, Somerville, Mass., USA) (24, 34, 38) are undertaken (Figure 3.3).

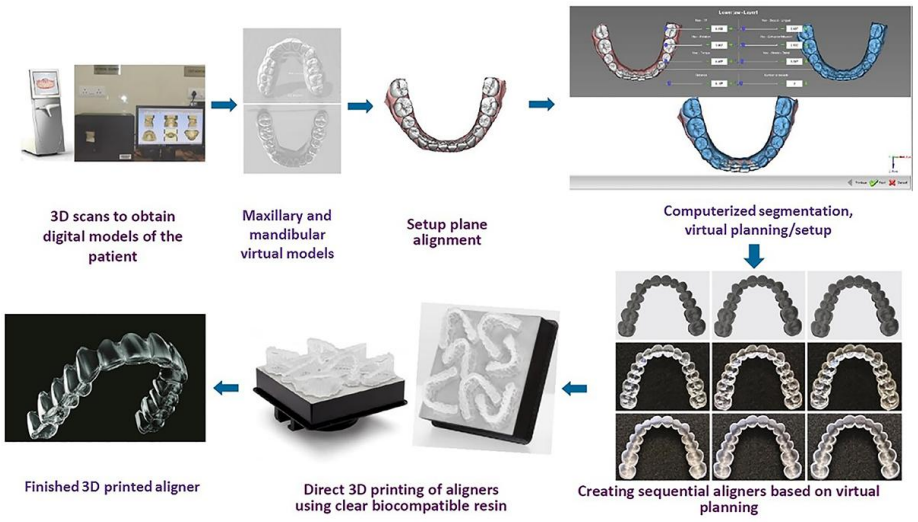

Figure 3.3: schematic diagram of the laboratory technique to fabricate the 3D-direct printed memory shape aligner

3.7 Finite Element Analysis (FEA):

The workflow chart to obtain results of finite element analysis (Figure 3.4):

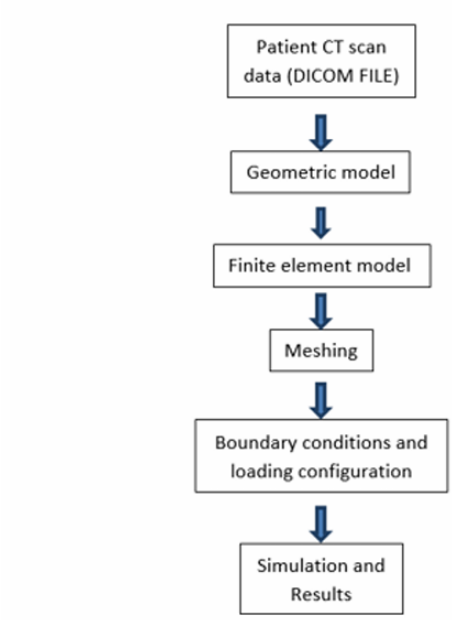

Figure (3.4): schematic diagram of the workflow chart to obtain results of finite element analysis.

This study will be approved by the Medical Ethics Committee, Faculty of Medicine, University of Kufa, Iraq (MEC-163). A 3D geometric model will be prepared of a maxilla arch that includes the maxilla, periodontal ligament (PDL), upper teeth with the upper right central incisor intruded, clear

aligners, and composite attachments (Figure 3.5a). The maxilla and upper teeth will be constructed from cone-beam computed tomography (CBCT) data of a patient who had an Angle Class I skeletal relationship with well-aligned teeth and normal tooth shape. The CBCT image will be taken with a 3D Accuitomo 170 (J. Morita Mfg. Corp., Kyoto, Japan) using an FOV of 170 mm × 120 mm and a voxel size of 0.25 mm. The image will be imported into ITK-SNAP software (51) to generate the 3D geometric model with a high-resolution FE model for simulations. The PDL will be modelled on the root shape with a thickness of 0.25 mm (52). A rectangular bevelled shape of composite attachments (Figure 3.6) will be constructed on the upper right central incisor with the shape derived from the Invisalign® system (53). Specifically, the incisal margin of the composite attachments will be placed 3.5 mm gingivally to the incisal edge (54). Both mesial and distal margins of the composite attachments were 2.5 mm away from the mesial and distal surfaces of the tooth, respectively. The clear aligners (conventional and 3D direct-printed clear aligners) will be made based on the target dentition to perform upper central incisor extrusion. Target dentition will be developed by extrusion of the upper right central incisor and composite attachment with a 0.15 mm displacement along the tooth axis (55). After that, the clear aligners will develop from an external offset of all teeth crowns and attachments at the target dentition. Clear aligner thickness was set at 0.75 mm with a scalloped trimline margin, precisely following the gingival contour of the teeth (56). To minimise the effect of upper incisor angulation on experimental outcomes, maxillary central incisors were adjusted to a 90° orientation during reconstruction.

Finally, three models will be designed as follows:

Model 1: no composite attachment with 3D direct-printed shape memory clear aligner.

Model 2: rectangular bevelled attachment with 3D direct-printed shape memory clear aligner.

Model 3: rectangular bevelled attachment with conventional clear aligner.

The meshing process will produce a total of 1,467,263 nodes and 5,338,190 elements in a model without a composite attachment and 1,472,483 nodes and 5,355,482 elements in a model with a rectangular bevelled attachment (Figure 3.5b). Bonded contacts will be set at the interfaces between the bone and PDL, PDL and teeth, and teeth and composite attachment. Surface-to-surface contact will be used between the clear aligner and teeth as well as the clear aligner and the composite attachment. Fixed supports were applied on the upper part of the maxilla. A friction coefficient of $\mu = 0.2$ was used between the aligner and teeth as well as the aligner and the composite attachment. Table (3.2) shows the material properties and mesh size that will be used in this study (Jedliński et al. (53)). The finite element analysis will proceed before the clinical trial according to the selection criteria and standardisation to establish common procedures for model creation, data exchange, and validation to ensure model quality, reliability, and consistency across different software and users.

Table 3.2: Material properties and mesh size.

Components	Young's Modulus (MPa)	Poisson's Ratio	Mesh Size (mm)
Maxilla	1.37×10^3	0.30	0.2–0.5
PDL	6.67×10^{-1}	0.45	0.1
Teeth	1.96×10^4	0.30	0.2
Composite attachment	1.25×10^4	0.36	0.2
Clear aligner	528	0.36	0.2

Figure 3.5: Maxilla model with PDL, upper teeth, clear aligner, and composite attachment: (a) 3D model and (b) finite element meshing models.

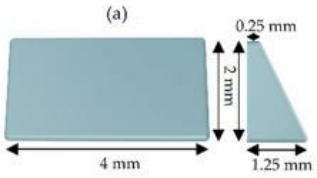

Figure 3.6: Dimensions of the rectangular beveled attachment.

An anatomical coordinate system will be established by defining the occlusal plane using reference points at the incisal edges of central incisors and the mesiobuccal cusp tips of first molars. The X-axis (coronal plane) will be orientated positively toward the mesial aspect, the Y-axis (sagittal plane) positively toward the lingual aspect, and the Z-axis (vertical plane) positively toward the gingival direction. Sequential and simultaneous extrusion movements of maxillary central incisor teeth will be simulated. Clear aligners will be applied with an extrusive force corresponding to a displacement of 0.15 mm along the long axis of the teeth. Reaction forces resulting from each extrusive method will be calculated using ITK-SNAP software after applying the preset displacement of 0.15 mm to the aligners (56). Forces equal in magnitude to these reaction forces will then be applied to the corresponding teeth to evaluate initial displacement and PDL stress distribution.

Therefore, this study will aim to evaluate the initial tooth displacement and stress distribution generated during central incisor extrusion with conventional clear aligners (with attachments) and 3D direct printed shape memory aligners (with and without attachments).

3.8 Clinical trial

3.8.1 Randomisation and Blinding:

The randomisation sequence will be generated using randomisation software (sealed envelope) with a 1:1:1 allocation ratio using block randomisation. The allocation sequence will be concealed from the investigator with sequentially numbered, opaque, and sealed envelopes. Operator and subject blinding will not be possible due to the nature of the intervention. The data will be coded and presented to the blinded evaluator. All subjects will be randomised into conventional and 3D direct-printed shape memory aligner groups (with or without attachment). All data will be collected at two time points: pretreatment (T0) and after the treatment (the first series of aligners (15-20 aligners) (T1)). The dental and skeletal changes were recorded by lateral cephalograms (Dolphin software, USA). Maxillary first molar intrusion will be recorded by cone-beam computed tomography (CBCT), and force distribution and initial tooth displacement will be recorded by a finite element analysis program.

3.8.2 Outcome measurement:

Outcomes and any changes after trial commencement, midcourse interventions to improve tracking, such as rescanning or introducing auxiliary appliances, will be recorded and reported, but the teeth involved will not be analysed as part of the corresponding group. Maxillary and/or mandibular incisors not tracking, noted by a minimum of 1 mm of aligner material incisally when the aligner was fully seated, will be recorded and reported but not analysed within the group assigned (56). Patients will be evaluated only after the first series of aligners (15-20 aligners (T1)). After that, treatment proceeded as necessary, determined by patients and individual practitioners, and was not recorded (57). Maxillary and mandibular arches will be evaluated in this study.

3.8.2.1 Processing and data collection (cephalometric tracing):

DICOM (Digital Imaging and Communications in Medicine) files will be reoriented to standardise head position and converted into Nearly Raw Raster Data (NRRD) format using ITK-SNAP software, version 3.8.0 (University of Pennsylvania, https://www.itksnap.org). The converted files will be uploaded to 3D Slicer software, version 5.2.2 (https://www.slicer.org/), an open-source 3D medical image viewing software. 3D models of the scans will be rendered using the “Segment editor” module, and the view layout will be set to “four-up” mode to simultaneously display the 3D rendering along with the three orthogonal views (sagittal, coronal, and axial). The 3D view facilitated confirmation of landmarks' positions in the spatial space (58). Cephalometric analysis pre-treatment (T0) and post-treatment (T1) (after the first series of aligners (15-20 aligners)) lateral cephalograms will be imported into Dolphin Imaging™ software. Cephalometric landmark location measurements (linear and angular) Landmark points will be initially identified and approximated in the sagittal view by scrolling through the slices, then will be refined in the coronal and axial views. Final positional confirmation will be done on the 3D model when visualisation of the landmark is possible (59). This standardised viewing sequence will be implemented to enhance consistency across the cases, and superimpositions will be independently performed using Dolphin Imaging™ by two orthodontic faculty members. Following anterior cranial base, maxillary, and mandibular structural superimpositions, three reference planes (S-N, ANS-PNS, and Go-Me) were transferred from the T0 tracing to the T1 tracing. Eight cephalometric

measurements were generated by the computer operations in Dolphin Imaging™ (Figure 3.6). The average values of estimates derived by the two orthodontists were used.

3.8.2.2 Measurement variable outcomes will be as follows:

1. Dental and skeletal leaners and angular changes (Figure 3.7):

The cephalometric analysis will include the following:(1) Overbite (the overlap of the anterior teeth in the vertical dimension); (2) U1 to palatal plane angle (the inclination of the maxillary central incisor relative to the palatal plane); (3) L1 to mandibular plane angle (IMPA) (the angle formed by the long axis of the lower incisor (L1) and the mandibular plane); (4) Interincisal angle. (The relative spatial position along the long axis of the most prominent (anteriorly positioned) maxillary and mandibular central incisors); (5) U6 to palatal plane distance (Represents the perpendicular distance from the mesiobuccally cusp of the maxillary first molar (U6) to the palatal plane (PP)); (6) U1 to palatal plane distance (the perpendicular distance from the tip of the maxillary central incisor (U1) to the palatal plane (PP)); (7) L6 to mandibular plane distance (the perpendicular distance from the mesial cusp tip of the lower first molar (L6) to the mandibular plane (MP), also known as the mandibular plane); (8) L1 to mandibular plane distance (a linear cephalometric measurement in orthodontics that quantifies the distance from the incisal edge of the mandibular central incisor (L1) to the mandibular plane).

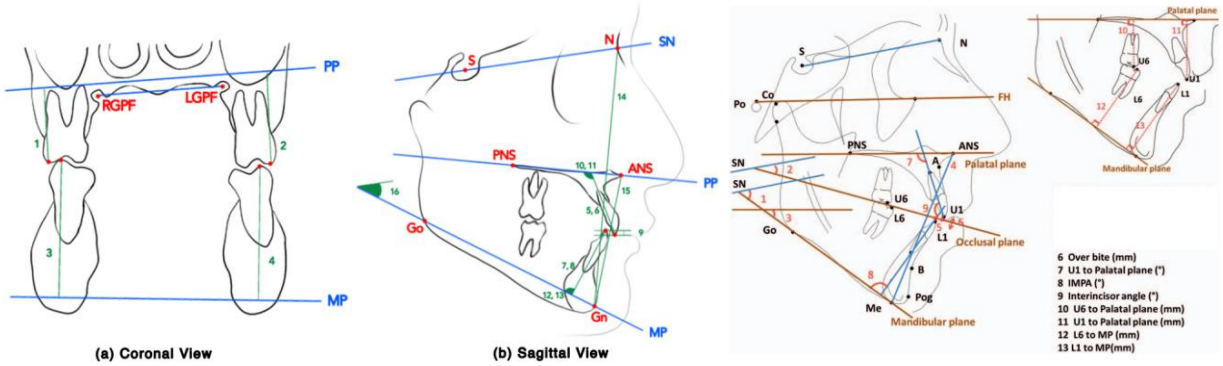

Figure 3.7: Cephalometric analysis: i. Overbite; mm; ii. U6 (Upper 1st molar) to palatal plane distance, mm; iii. U1 (Upper central incisor) to palatal plane distance, mm; iv. L6 (Lower 1st molar) to mandibular plane distance, mm; v. L1 (Lower central incisor) to mandibular plane distance, mm; vi. L1 (Lower central incisor) to mandibular plane angle (IMPA); vii. U1 (Upper central incisor) to palatal plane angle; viii. Interincisal angle.

The amount of molar intrusion will be measured following these steps (Figure 3.8) Withayanukonkij et al. (60):

(1) Palatal plane (PP) will set,

(2) The deepest point of the central pit (C-pit) will be in the coronal and sagittal view, and

(3) The vertical distance from C-pit to PP (U6-PP) will be measured.

The difference between T0 and T1 will be the intrusion amount, and the right and left sides will be averaged.

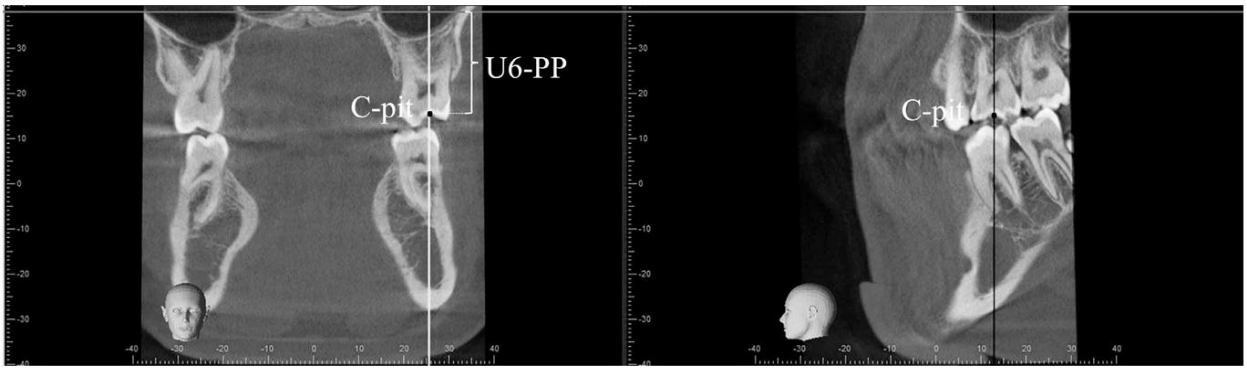

Figure 3.8: Show maxillary molar measurement. C-pit indicates central pit of maxillary molar; PP. palatal plane; U6-PP, vertical distance from C-pit to PP.

2. Patient-reported outcomes measures (PROMs) (appendix 1)

Participants will complete a set of Patient-Reported Outcome Measures (PROMs). Initially, participants will be required to provide several pieces of information, including name, date of birth, gender, residential address, phone number, email address, and date of consultation. Subsequently, participants from all three study groups will respond to ten PROM items assessing various aspects of outcome measures: “I feel pain”, “I can move more easily”, “I feel strong”, “I feel coordinated”, “I feel tired”, “I can sleep”, “I can do activities of daily living”, “I can return to work and sports”, “I am satisfied with my care”, and “I would recommend physical therapy to others”. Each item will be rated using a 5-point Likert scale, with response options ranging from 1 (strongly disagree) to 5 (strongly agree) (Figure 8). All personal and response data will be treated with strict confidentiality. This interview questioner will take before and after the treatment.

4.0 Statistical analysis

Numerical data obtained from finite element analysis tests and clinical trials will be gathered using Microsoft Excel and subsequently analysed using SPSS Statistics for Windows version 26.0 (IBM Corp., Armonk, NY, USA). Prior to inferential analyses, the distribution of the data will be assessed for normality using the Shapiro-Wilk and Kolmogorov-Smirnov tests. A one-way analysis of variance (ANOVA) will be employed to evaluate statistically significant differences among the three groups—conventional clear aligners with attachments, 3D direct printed shape-memory aligners with attachments and 3D direct printed shape-memory aligners without attachments—across a range of dependent variables, including: (i). Overbite (mm); (ii). U6 (upper 1st molar) to palatal plane distance (mm); (iii). U1 (upper central incisor) to palatal plane distance (mm); (iv). L6 (lower 1st molar) to mandibular plane distance (mm); (v). L1 (lower central incisor) to mandibular plane distance (mm); (vi). L1 (lower central incisor) to mandibular plane angle (IMPA); (vii). U1 (upper central incisor) to palatal plane angle; (viii). Interincisal angle. A paired T-test will be conducted to compare the results of the patient-reported outcome

measures (PROMs), and where significant group effects are identified, post hoc comparisons using Tukey's Honestly Significant Difference (HSD), or Bonferroni correction will be conducted to determine specific intergroup differences. The significance level was set at $p < 0.05$.

4.1 Intra-examiner and inter-examiner reliability:

One researcher performed all the measurements at the start. Two weeks later, the same and another calibrated independent examiner repeated the whole measurements on 10 randomly selected measurements for analysis of intra- and inter-examiner reliability using the Intraclass Correlation Coefficient (ICC). The calculated ICC ranged from 0.82 to 0.96, indicating good to excellent agreement between examiners and across time.

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6.0 Appendices

Appendix 1: Patient-reported outcomes measures (PROMs).

Outcome Measures

Client Information

Name:

Date of Birth:

Gender:

Address:

Phone Number:

Email Address:

Date of Consultation:

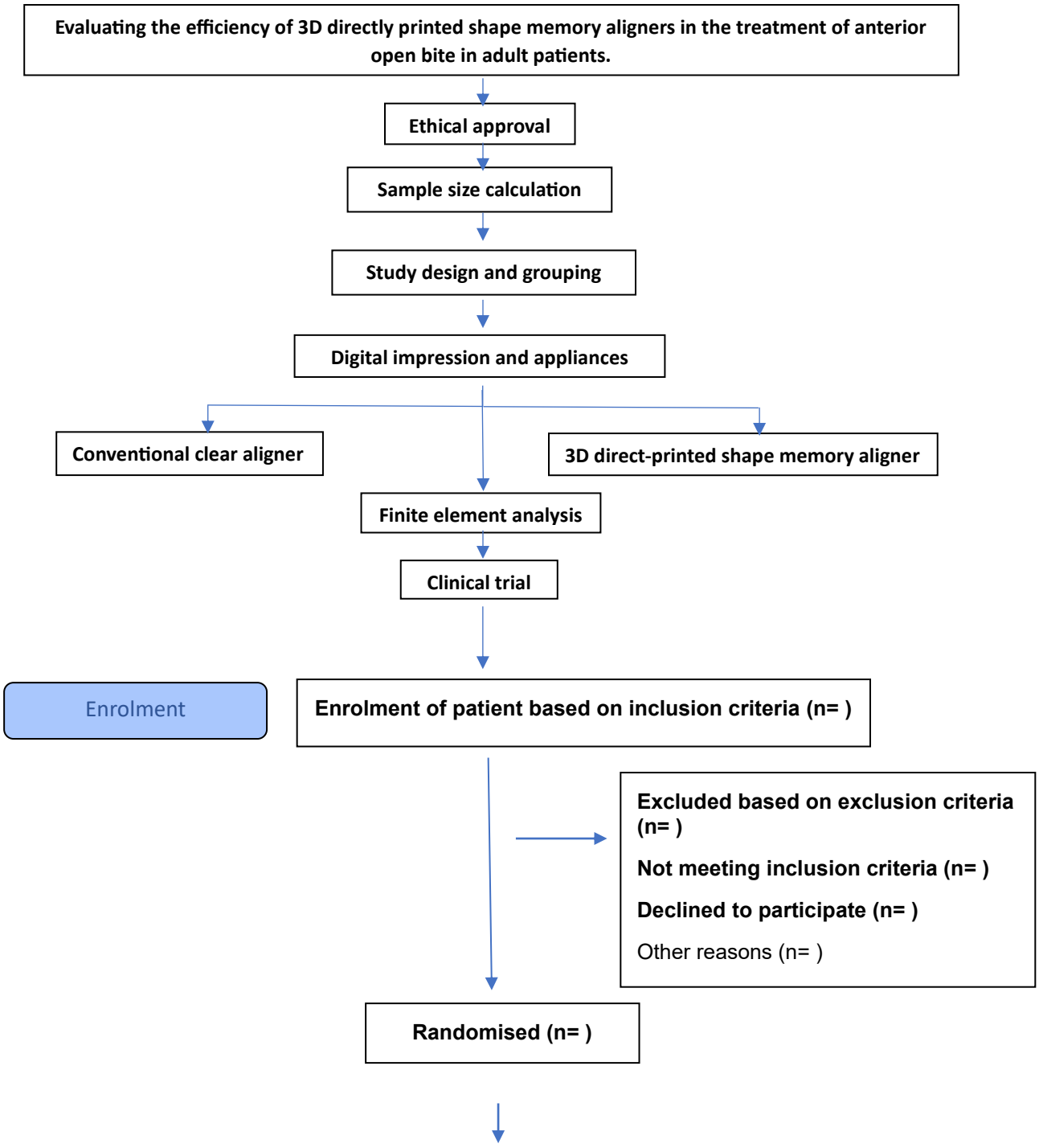
	(1) - Strongly Disagree	(2) - Disagree	(3) - Neutral	(4) - Agree	(5) - Strongly Agree
1. I feel pain.	☐	☐	☐	☐	☐
2. I can move more easily.	☐	☐	☐	☐	☐
3. I feel strong.	☐	☐	☐	☐	☐
4. I feel coordinated.	☐	☐	☐	☐	☐
5. I feel tired.	☐	☐	☐	☐	☐
6. I can sleep.	☐	☐	☐	☐	☐
7. I can do activities of daily living.	☐	☐	☐	☐	☐
8. I can return to work or sports.	☐	☐	☐	☐	☐
9. I am satisfied with my care.	☐	☐	☐	☐	☐
10. I would recommend physical therapy to others.	☐	☐	☐	☐	☐

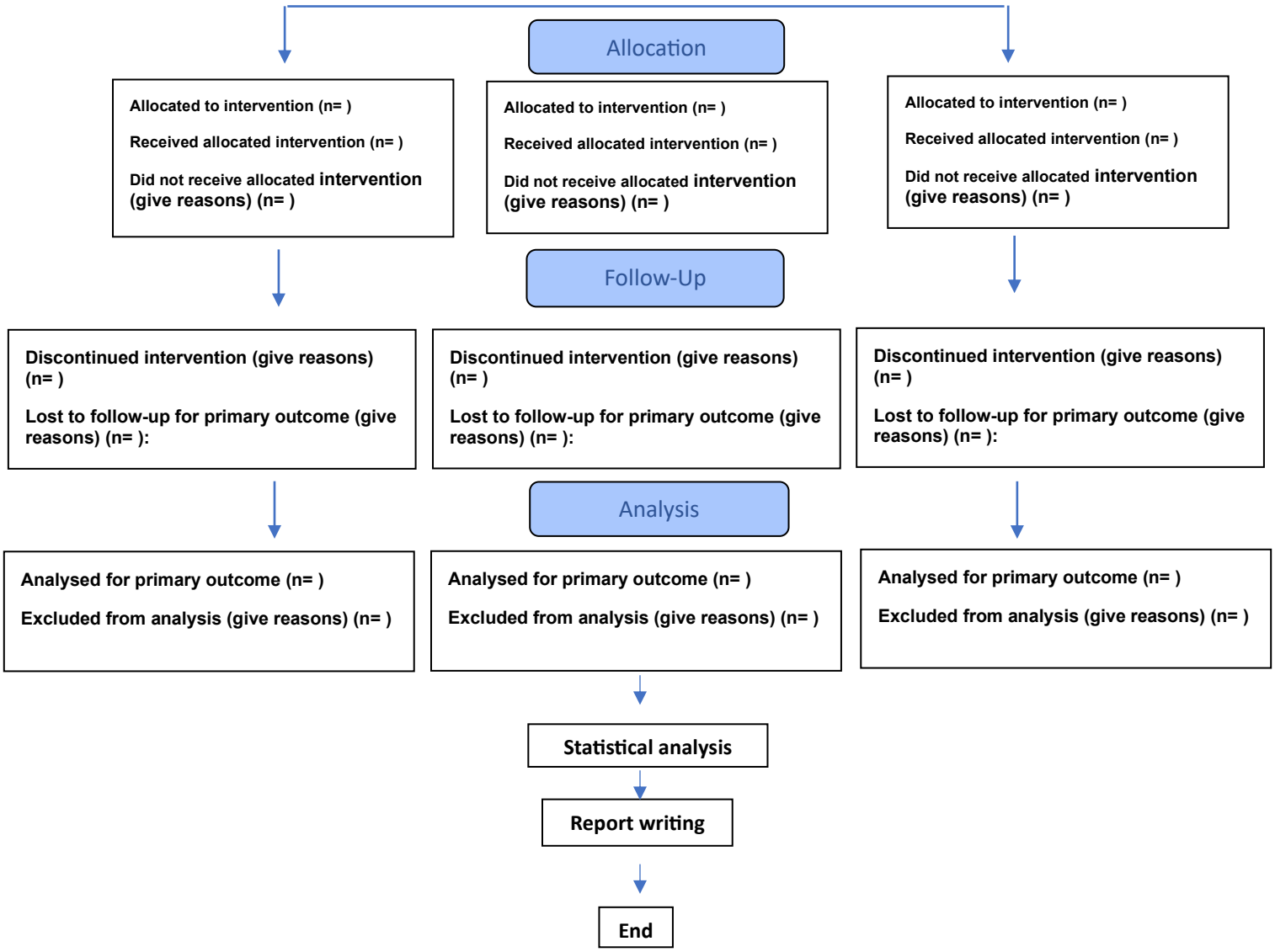
STUDY WORKFLOW

Evaluating the effectiveness of 3D directly printed shape memory aligners in the management of anterior open bite in adult patients.

Date: 28/Jan/2026

Study flowchart:




Allocation
Allocated to intervention (n=)
Received allocated intervention (n=)
Did not receive allocated intervention (give reasons) (n=)
Allocated to intervention (n=)
Received allocated intervention (n=)
Did not receive allocated intervention (give reasons) (n=)
Allocated to intervention (n=)
Received allocated intervention (n=)
Did not receive allocated intervention (give reasons) (n=)
Follow-Up
Discontinued intervention (give reasons) (n=)
Lost to follow-up for primary outcome (give reasons) (n=):
Discontinued intervention (give reasons) (n=)
Lost to follow-up for primary outcome (give reasons) (n=):
Discontinued intervention (give reasons) (n=)
Lost to follow-up for primary outcome (give reasons) (n=):
Analysis
Analysed for primary outcome (n=)
Excluded from analysis (give reasons) (n=)
Analysed for primary outcome (n=)
Excluded from analysis (give reasons) (n=)
Analysed for primary outcome (n=)
Excluded from analysis (give reasons) (n=)
Statistical analysis
Report writing
End

سجل المناقشة والموافقة المستنيرة
لأشعة التصوير المقطعي المحوسب باستخدام شعاع المخروط (CBCT)

Evaluating the effectiveness of 3D directly printed shape memory aligners in the management of anterior open bite in adult patients.

INFORMED CONSENT/ Date: 28/Jan/2026

اسم المريض:

تاريخ الميلاد/ / :

الإجراء: تصوير مقطعي محوسب باستخدام شعاع مخروطي(CBCT) ، والذي يُسمى أحيانًا بالأشعة السينية ثلاثية الأبعاد، هو تقنية أشعة سينية تشبه التصوير المقطعي المحوسب الطبي. تنتج فحوصات التصوير المقطعي المخروطي (CBCT) صورًا لجسمك تُظهر الهياكل الداخلية في مقطع عرضي بدلاً من الصور المتداخلة التي تنتج عادةً عن الأشعة السينية السنية التقليدية. يتطلب التشخيص وتخطيط العلاج فهمًا أكثر اكتمالًا لتشريح وجهك، بما في ذلك على سبيل المثال لا الحصر: الأسنان، الفك، والهياكل/العظام الوجهية. تعد أشعة CBCT مفيدة بشكل خاص لتشخيص المرضى الذين لديهم أسنان مدمرة، أو زراعة أسنان، أو خضعوا لعلاجات جراحية و/أو قد يعانون من مشاكل في مجرى الهواء. باختصار، قد تكون أشعة CBCT مفيدة في تقييم وتشخيص الحالات التي لا يمكن رؤيتها بشكل صحيح باستخدام الأشعة السينية التقليدية للأسنان.

النساء: لا يُوصى بإجراء فحوصات CBCT للنساء الحوامل بسبب الخطر المحتمل على الجنين. (التوقيع أدناه حسب الاقتضاء.)
لست حاملاً أنا حامل لست متأكدة مما إذا كنت حاملاً.

المخاطر: تعرضك أشعةCBCT ، مثل الأشعة السينية التقليدية، للإشعاع. هناك بعض المخاطر الكامنة والمحتملة من الأشعة السينية. الجرعة تقريبًا هي نفسها ما يلي من مكافئات جرعة الإشعاع الخلفية في الولايات المتحدة: يوم واحد للأسنان العلوية، 3 أيام للأسنان الأمامية السفلية و5 أيام للأسنان الخلفية السفلية. بديل لفحص CBCT هو الأشعة السينية التقليدية للأسنان، ومع ذلك، فإن لها القيود التي تم الإشارة إليها سابقًا.

بينما قد تُرى أجزاء من تشريحك خارج فمك وفكك في الفحص، فإن تدريب الدكتور فوربس ورخصته في طب الأسنان لا تسمح له بالتقييم والتشخيص خارج تخصصه في تقويم الأسنان. مسح CBCT الذي تم اليوم، / / ، يهدف فقط إلى تسهيل تشخيص حالتك السنية والمساعدة في إكمال خطة علاجك السني.

الإقرار/الموافقة: أقر بأن البديل لفحوصات CBCT هو الأشعة السينية التقليدية للأسنان، ومع ذلك، فإن لها قيودًا تم الإشارة إليها سابقًا. أقر أيضًا بأن طبيب التقويم غير مسؤول عن قراءة أو تفسير أو إجراء تشخيص بناءً على مسح CBCT يتجاوز نطاق خبرته/مجال رعايته التقويمية.

أنا، ، البالغ من العمر 18 عامًا أو أكثر، أقر بأنني قرأت نموذج الموافقة هذا وأنني أفهم الإجراء الذي سيتم تنفيذه، وفوائده ومخاطره والبدائل المتاحة. أقر بأنني قد أتيحت لي الفرصة الكاملة لمناقشة هذا الإجراء مع طبيب تقويم الأسنان، أو من ينوب عنه، وأن جميع أسئلتي قد تم الإجابة عليها بما يرضيني قبل توقيع هذا النموذج. وبالتالي، أقدم موافقتي المستنيرة لأخصائي تقويم الأسنان وموظفيه المعينين لإجراء فحص.CBCT

بالإضافة إلى ذلك، أسمح لأخصائي تقويم الأسنان وموظفيه المعينين بمشاركة الصور السريرية المأخوذة من مسح CBCT اليوم مع أشخاص آخرين بغرض الحصول على رؤى إضافية حول حالتي السريرية، ولأغراض تعليمية و/أو لتطوير المجال الطبي/الأسنان.

توقيع المريض/الوصي/ / / :

سجل المناقشة والموافقة المستنيرة
لأشعة التصوير المقطعي المحوسب باستخدام شعاع المخروط (CBCT)

Evaluating the effectiveness of 3D directly printed shape memory aligners in the management of anterior open bite in adult patients.

INFORMED CONSENT/ Date: 28/Jan/2026

RECORD OF DISCUSSION & INFORMED CONSENT
FOR CONE BEAM COMPUTERIZED TOMOGRAPHY (CBCT) SCAN

PATIENT'S NAME: _____
Last First
DATE OF BIRTH: _____ /_____ /_____

PROCEDURE: A Cone Beam Computer Tomography (CBCT) scan, sometimes called a 3-D radiograph or x-ray, is an x-ray technique that is similar to medical CT scans. CBCT scans produce images of your body that depict internal structures in cross-section rather than the overlapping images typically produced by conventional dental x-rays.

Diagnosis and treatment planning requires a more complete understanding of your facial anatomy, including but not limited to: teeth, jaw, and facial structures/bones. CBCT scans are especially beneficial to the diagnoses of patients who have impacted teeth, dental implants, had surgical treatments and/or may suffer from airway issues. In short, CBCT scans may be useful in evaluating and potentially diagnosing conditions which cannot be properly seen with conventional dental x-rays.

WOMEN: CBCT scans are NOT recommended for pregnant women because of possible danger to the fetus. (Initial below as appropriate.)
___ I am not pregnant ___ I am pregnant ___ I am unsure whether I am pregnant

RISKS: CBCT scans, like conventional x-rays, expose you to radiation. There are certain inherent and potential risks from x-rays. The dose is approximately the same as the following U.S. background radiation dose equivalents: 1 day for upper teeth, 3 days for lower front teeth and 5 days for lower back teeth. An alternative to a CBCT scan are conventional dental x-rays, however, they have the limitations previously noted.

While parts of your anatomy beyond your mouth and jaw may be seen on the scan, Dr. Forbes' training and dental license does not provide for evaluating and diagnosing outside of his specialization of orthodontia. The CBCT scan taken today, ___ / / _____, is intended solely to facilitate diagnosis of your dental condition and aid in completion of your dental treatment plan.

ACKNOWLEDGE/CONSENT: I acknowledge that an alternative to CBCT scans are conventional dental x-rays, however, they have limitations previously noted. I also acknowledge that Orthodontist is not liable for reading, interpreting and/or making a diagnosis based upon the CBCT scan beyond the orthodontic expertise/scope of care.

I, _____, being 18 years or older, certify that I have read this consent form and that I understand the procedure to be performed, and its benefits, risks and alternatives. I acknowledge that I have had a full opportunity to discuss this procedure with the orthodontist, or his designee, and have had any/all questions answered to my satisfaction prior to signing this form. Thus, I give my informed consent to the orthodontist and his designated staff to perform the CBCT scan.

In addition, I give permission to the orthodontist and his designated staff to share clinical images taken from today's CBCT scan with other persons for the purpose of gaining additional insight on my clinical condition, for educational purposes and/or the development of the medical/dental field.

PATIENT/GUARDIAN SIGNATURE: _____/____ /____ /_____