Research Proposal
Clear Aligners: Treating Bimaxillary Protrusion and Crowding with the First Premolar Extraction

Assoc. Prof. Nita Viwattanatipa, Mahidol University

Introduction

Definition

Clear aligners are removable orthodontic devices that are fabricated from transparent plastic. It applies pressure to the malaligned teeth to move them into the aligner's position. The introduction of clear aligners and removable originated from the Invisalign aligners by Align Technology, Inc. The system has provided clinicians with an alternative modality of orthodontic treatment.(1) Nowadays, besides the Invisalign aligners, there are numerous brands of clear aligner such as Orthoclear, ClearCorrect, CA Clear Aligner.

Clear aligners system starts with taking dental impressions or intraoral scan in order to create a digital 3D of upper and lower dental arches. A computer graphic representation of the projected teeth movements is created in the software program. The virtual teeth model was madeusing CAD-CAM (computer-aided-design and computer-aided-manufacturing) software and manufactured using a rapid prototyping technique called stereolithography. The molds of the virtual teeth model for the aligners are built in layers using a photo-sensitive liquid resin that cures into a hard plastic when exposed to a laser. After that the aligners are made using elastic thermoplastic material. (1) Composite attachments (Tetric Ceram composite) may be used to facilitate movement by changing the shape of the tooth.(2)

Fig 1. Clear aligners orthodontic devices
(from: https://www.bwcdentalclinic.com/th/dentalservices/invisalign/invisalign)

Indications

At the beginning of the Invisalign® system, it was indicated for the treatment of mild orthodontic conditions of the front teeth.(3) It was considered less effective than conventional braces for several aspects. Mainly, it was recommended for non extraction cases and was not recommended for children.(4) In particular, they are indicated for "mild to moderate crowding (1–6 mm) and mild to moderate spacing (1–6 mm)", in cases where there are no skeletal discrepancies. They are also indicated for patients who have experienced a relapse after fixed orthodontic treatment.(2)

Limitations

Since the introduction of Invisalign treatment,controversy has existed over whether moderate to difficult orthodontic treatment can be routinely accomplished with the Invisalign system. Many limitations were encountered during orthodontic treatment with clear aligners such as posterior openbite or inadequate incisor torque. Treatment outcome studies have highlighted Invisalign's weaknesses compared to conventional braces in arch expansion, treating anterior-posterior discrepancies, large rotation (premolars and canines) and the extrusion/ intrusion of teeth, bodily movement, torquing of roots. (4, 5). Similarly, Papadimitriou et al.(6) conducted the clinical effectiveness of Invisalign® orthodontic treatment which included 3 RCTs, 8 prospective, and 11 retrospective studies. They reported that there was substantial consistency among studies showing that Invisalign® aligners can predictably level, tip, and derotate teeth (except for cuspids and premolars). It seemed that initially, the Invisalign® system was an alternative to conventional orthodontic therapy in the correction of mild to moderate malocclusions in non-growing patients that do not require extraction. (6)

Bimaxillary protrusion

Unfortnately, bimaxillary protrusion and dental crowding are orthodontic problems commonly observed among Asian populations.(7) Lips protrusion and facial esthetics is a common concern for majority of patients. (7) Treatment of these complex issues often involves extraction of the four first premolars to relieve crowding, and subsequent retraction of the maxillary and mandibular anterior teeth to close the extraction spaces. (7-9) Some clinicians have attempted to use the Invisalign® system in extraction cases.(10-12) Nevertheless, mixed outcomes have been reported with the Invisalign System in cases requiring extraction of the first premolars with the need for further treatment with a fixed appliance to correct tipping of the teeth adjacent to extraction sites being highlighted. Treatment with aligners resulted in significant tipping of the teeth adjacent to premolar extraction sites. (12, 13) In terms of treatment outcome of extraction case, an RCT study from China reported that both Invisalign and fixed appliances were successful in treating Class I adult extraction cases.(14)

Extraction Principle/ Invisalign G6

Opportunely, the Invisalign System (Align Technology. Inc., San Jose, CA, USA) developed refinement and specialization which has allowed successful treatment of more complex orthodontic cases with Invisalign aligners.(4) (9) To improve the clinical outcomes of patients requiring extraction of their four first premolars, Align Technology, Inc., has introduced the Invisalign G6 first premolar extraction solution. Features of the system have been developed to provide maximum posterior anchorage while preventing unfavorable tipping of the canines during space closure. This

ensures that the roots of the teeth adjacent to extraction sites remain parallel. (9)

Rationale

Several treatment difficulties and techniques are yet needed to be resolved and studied**.** However, papers published related clear aligner treatment in extraction cases are mostly case reports. Treatment technique for extraction cases has been continually progressing. However, the evidence is not solid and published research for extraction treatment is still lacking. .

Clinicians still have much to learn regarding the biomechanics and efficacy of the clear aligner system. A better understanding of clear aligner ability to move teeth might help the clinician select suitable patients for treatment, guide the proper sequencing of movement, and reduce the need for case refinement.

Research question

How is the efficacy and accuracy of clear aligners in premolar extraction case?.

Objectives

The aim of this study is to find out the accuracy of tooth movement: (Comparison of actual vs.virtual tooth movement) of clear aligner in first premolar extraction cases. Outcome will be measured in the following stages.

1. Canine / Incisor Retraction
2. Completion of orthodontic treatment

Material and methods

Ethical Approval: Proposal will be submitted to the IRB of the Faculty of Dentistry, Mahidol University.

Sample size calculation

Since there has been no research done on canine tooth movement measurements in extraction case using clear aligner appliance, we have to infer from mean and SD reported by Kravitz et al.(5) Although our design is randomization/ split-mouth technique, we also need to compare the computerized virtual set up group and the actual tooth movement group. Therefore sample size calculation for independent group is used rather than same subjects (paired) category.

Web site for sample size calculation is https://www.ai-therapy.com/psychology-statistics/sample-size-calculator)

Note: Kravitz et al.(5) reported the mean of the followings.
Canine Accuracy mean = 34.7% (SD 33.5%)
Total Accuracy mean = 40.5 % (SD 35.5%)
The value were arbitrarily devided by 10 to make it most relevant to actual situation: amount of canine movement distance).

Effect size calculation:

$SD_{pooled} = \sqrt{(3.35^2 + 3.55^2\ /2}\ = 3.4$

Cohen's d = $\frac{40.5 - 34.7}{3.4} = 1.7$

Cohen's d is 1.68, which is considered to be a relatively large effect size.
Sample size calculation for t-test

$$n = \frac{(t_{n-1,\alpha/2} + t_{n-1,\beta})^2}{d^2}$$

t-test / independent groups/ 2 tails/ effect size = 1.7/
Significance level (α) = 0.01/ Power = 0.8
The total number of subjects required: 20 (10 in each group)

We will recruit subjects of 25 to err on the safe side that there could be drop-out samples during treatment.

Inclusion and exclusion criteria

Inclusion and exclusion criteria are reported in Table 1.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Adult subjects >18 years • Complete permanent dentition dentition • Class I or Class II div1 • Treatments requiring extraction space closure in upper arch (upper premolar) with the treatment objectives were to: (1) reduce the patient's anterior protrusion to improve lip profile, (2) alleviate the anterior crowding, and 3) achieve a Class I canine relationship. • No tooth/ root anomalies • No dental rotation >35° • Moderate to severe crowding in upper arch	• Systemic pathologies • Ongoing pharmacological treatment able to affect bone metabolism or influence orthodontic movement (e.g. thyroid medication, prostaglandin inhibitors, biphosphonates) • Active periodontal disease

General records taking protocol

Protocol of record taking in this study is shown in table 2.

Table 2 Protocol of record taking and treatment.

Stage	
Patient screening	
Patient Consent	
Pretreatment	
Routine Records taking	Photos IO/EO Examination form Periapical U/L anterior teeth Impression (silicone)/ bite registration
Intraoral scan	
3D CBCT Skull	
Case Analysis	
Treatment plan discussion	
Computerized clear aligner fabrication	
Composite attachment CA. Delivery	
Premolars extraction	
Data Collection/ Evaluation of results **Canine retraction at 6^{th} /12^{th} set of clear Aligner**	
During treatment	
Records taking	Photos IO/EO Intraoral scan Dental Impression
Post treatment	
Records taking	Photos IO/EO Periapical U/L anterior teeth Dental Impression
Intraoral scan	
3D CBCT	
Intraoral scan, 3D CBCT skull are routine procedure in orthodontic clinic.	

Randomization of canine distalization technique

Randomization table will be used for split mouth design. Patients will be allocated to the following 2 canine distalization technique.

1. Experimental: Canine distalization supplemented with power arm on one side. It is hypothesized that the distalization force will move the canine more bodily as the line of force will pass nearer to the center of resistance

2. Control: Canine distalization without power arm on the other side

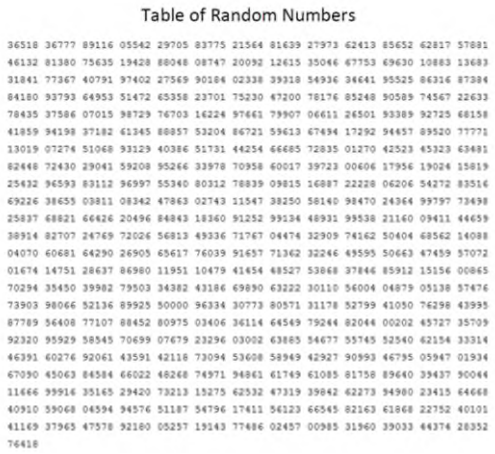

Table of Random Numbers

36518	36777	89116	05542	29705	83775	21564	81639	27973	62413	85652	62817	57881		
46132	81380	75635	19428	88048	08747	20092	12615	35046	67753	69630	10883	13683		
31841	77367	40791	97402	27569	90184	02338	39318	54936	34641	95525	86316	87384		
84180	93793	64953	51472	65358	23701	75230	47200	78176	85248	90589	74567	22633		
78435	37586	07015	98729	76703	16224	97661	79907	06611	26501	93389	92725	68158		
41859	94198	37182	61345	68857	53204	86721	59613	67494	17292	94457	89520	77771		
13019	07274	51068	93129	40386	51731	44254	66685	72835	01270	42523	45323	63481		
82448	72430	29041	59208	95266	33978	70958	60017	39723	00606	17956	19024	15819		
25432	96593	83112	96997	55340	80312	78839	09815	16887	22228	06206	54272	83516		
69226	38655	03811	08342	47863	02743	11547	38250	58140	98470	24364	99797	73498		
25837	68821	66426	20496	84843	18360	91252	99134	48931	99538	21160	09411	44659		
38914	82707	24769	72026	56813	49336	71767	04474	32909	74162	50404	68562	14088		
04070	60681	64290	26905	65617	76039	91657	71362	32246	49595	50663	47459	57072		
01674	14751	28637	86980	11951	10479	41454	48527	53868	37846	85912	15156	00865		
70294	35450	39982	79503	34382	43186	69890	63222	30110	56004	04879	05138	57476		
73903	98066	52136	89925	50000	96334	30773	80571	31178	52799	41050	76298	43995		
87789	56408	77107	88452	80975	03406	36114	64549	79244	82044	00202	45727	35709		
92320	95929	58545	70699	07679	23296	03002	63885	54677	55745	52540	62154	33314		
46391	60276	92061	43591	42118	73094	53608	58949	42927	90993	46795	05947	01934		
67090	45063	84584	66022	48268	74971	94861	61749	61085	81758	89640	39437	90044		
11666	99916	35165	29420	73213	15275	62532	47319	39842	62273	94980	23415	64668		
40910	59068	04594	94576	51187	54796	17411	56123	66545	82163	61868	22752	40101		
41169	37965	47578	92180	05257	19143	77486	02457	00985	31960	39033	44374	28352		
76418														

Fig 2. Randomization table

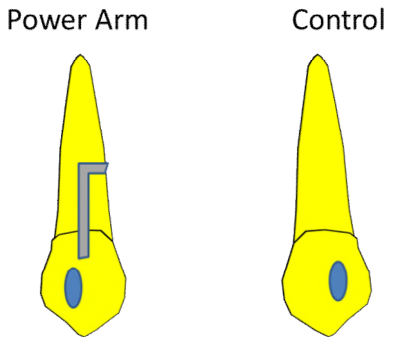

Fig 3. Canine distalization supplemented with power hook (lingual) side (left) VS. Control (right)

Intraoral scanner (15)

Pre-treatment, post canine retraction and post-treatment dentition were acquired using intraoral scanner (3Shape, Copenhagen, Denmark) by researcher.

Digital model preparation

Pre-treatment, post canine retraction, post-treatment plaster models of 1st clear aligner and each refinement models were scanned in centric occlusion using a 3D desktop

scanner (3Shape R700, 3Shape A/S, Copenhagen, Denmark) and saved as standard triangle language (STL) files. (16)
STL files were imported into the 3D software.

Digital tooth movement
Virtual Model set up will be prepared using 3 Shape's Ortho Analyzer^{TM} software (3Shape, Copenhagen, Denmark).
Extraction situation will be simulated then virtual tooth movement will be carried out to close extraction space.

Attachments Design

Attachments Design is modified from SmartForce features recommended in Invisalign G6 which was designed to deliver force systems necessary to achieve predictable tooth movement for premolar extraction case.(17) The modified attachments are consisted of the following components. (17)

1. Canine distalization attachment
This attachment is for effective bodily movement of canine retraction, with or without elastics / power arm

2. Posterior anchorage preparation attachments
The attachments on premolar and molars serve to maximize posterior anchorage

3. Incisor palatal root torque
The attachments on incisors serve to maximize palatal root torque of incisor
In general clear aligner attachments and tooth movement direction must be engineered to eliminate both unwanted tipping and anterior extrusion during retraction.

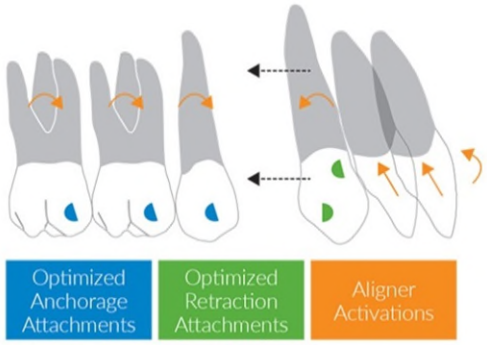

Fig 4. Attachments Design for premolar extraction case (17)

Clear aligner staging protocol

According to Lombardo et al. (18), the maximum movement planned for each aligner, had been 2° rotation, 2.5° vestibulolingual and mesiodistal tip, and 0.2-mm linear displacement. No auxiliaries of any kind had been used (intermaxillary elastics, buttons, chains) (18). Our protocol will be modified slightly with the aim to enhance the amount of tooth movement while still having good control. Auxiliaries will be used as needed.

Patients were instructed to wear their aligners for 24 h per day, excepting mealtimes and tooth brushing procedures. Aligners change will be every 1-2 week/ set.

Table 3. Comparison of clear aligner treatment staging protocol for virtual tooth set up

Lombardo et al. (18)	**Our study**
0.2 mm linear movement A-P / Vertical/ Transverse	0.5 mm linear movement A-P / Vertical/ Transverse
2.5° vestibulolingual and mesiodistal tip	2-5° vestibulolingual and mesiodistal tip
2° rotation	2-5° rotation
	1 set of Clear aligner 0.5 mm 0.75 mm
No auxiliaries	-Auxiliaries as needed -Power arm at canine and molar -Buttons -Intra and intermaxillary elastics -miniscrew -Powerchains / spring -Bite stick
Aligners change were every 14 days/ set	Aligners change were every 1-2 week / set

Table 4. Digital models acquired for evaluation of teeth movement change

	Pre-treatment	Virtual set up (V)	Actual post-treatment (A)
T1:Canine retraction	To	T1V	T1A
T2:Anterior space closure		T2V	T2A
T3: Post-treatment		T3V	T3A
T4: Refinement		T4V	T4V

Experimental: Canine distalization supplemented with power arm on one side.
A light NiTi closed coil spring will be used to retract canine on experimental side posteriorly to give an initial force of 200 g. The spring will be engaged via power arm which will be bonded palatally between the upper canine and the first molar. The force will be reactivated averagely once every 2 months to reactivate the spring tension to 200 g set with a tension gauge.

After 12^{th} pieces /24 pieces/ Final space closure and completion of 1^{st} set of clear aligner treatment, results will be evaluated. Treatment will be pursued with clear aligner until completion of treatment.

Data Collection

Reference Planes Construction for Measurement (The coordinate system)
In order to prepare for outcome measurements from digital models, 3 dimensional planes must be set up as follows.
1. Horizontal plane
2. Midsagittal plane
3. Coronal plane

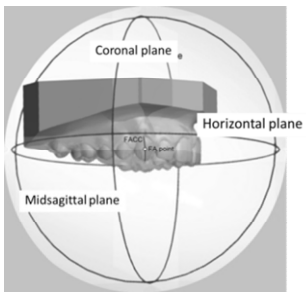

Fig 6. Reference Planes Construction (Castro, Frazão Gribel et al. 2018)

Once the reference points had been marked, their three-dimensional coordinates were extrapolated. Differences of the landmarks (linear measurements) or axis (tip and rotation) are then measures and documented onto a spreadsheet.

Superimposition of digital model

Superimposition of digital models pertaining to each patient were analysed in STL format by a single operator using accuracy measurement software (eg Orthoanalyzer software (3Shape, Copenhagen, Denmark).

Palatal best fit reference of model superimposition have been reported in many publications. (19, 20). In addition, 3 point surface technique or best fit geometric technique will be used to superimpose the models (anatomical reference points of palatal rugae).

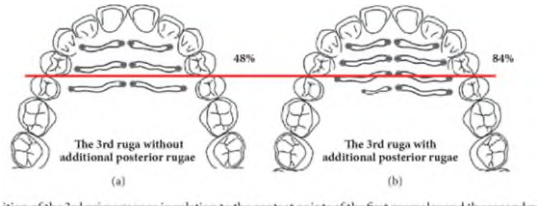

Fig 5. Palatal best fit and anatomical reference points using palatal rugae will be used for model superimposition (19)

Measurements

Measurement of digital models at various treatment stage (Table 4) will be made for all teeth in the following parts.

The Measurement are classified into

1. Linear measurements
2. Angular measurements

Linear measurements

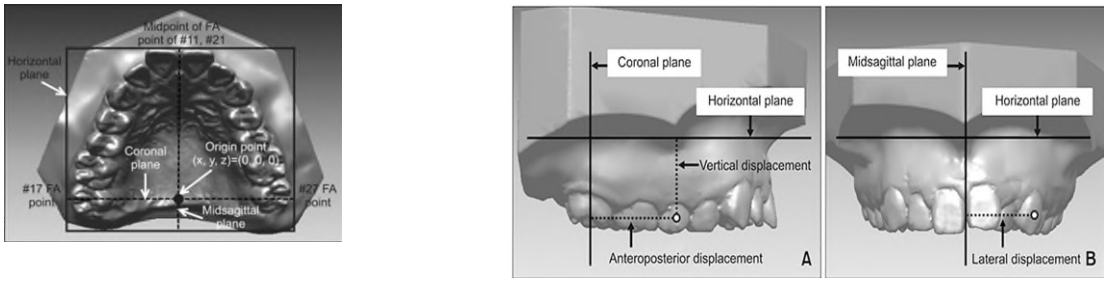

Fig. 7. Linear measurements (mm). (21)

A, Anteroposterior displacement:
Anterior teeth: is the distance from the incisal edge to horizontal plane
Posterior teeth: is the distance from the the buccal cusp to the midsagittal plane
+positive means posterior movement / - negative means anterior movement.
B. Vertical displacement
Anterior teeth: is the distance from the Incisal edge to coronal plane
Posterior teeth: is the distance from the buccal cusp to the midsagittal plane
+ positive means intrusion / - negative means extrusion;
C. Transverse displacement
Anterior teeth: is the distance from the Incisal edge to horizontal plane
Posterior teeth: is the distance from the the buccal cusp to horizontal plane
+ positive means medial movement and / - negative means lateral movement.

Crown angulation measurements

The lines will be traced along the facial axis of the clinical crown (FACC) to determine crown angulation difference between the superimposed teeth of computerized virtual set up group vs. the actual canine tooth movement.

1. **Horizontal (mm)**

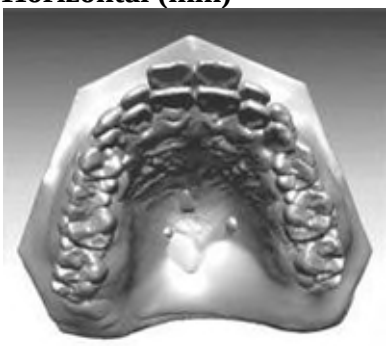

Fig 8. Superimposition three-dimensional virtual maxillary models of pre- and post-orthodontic treatment. (Park, Kim et al. 2012)

2. **Vertical mm**

Fig 9. Superposition of pre-treatment (in yellow) and post-treatment (in gray) models: A) occlusal view, B) front view. (22)

3. **Transverse (mm)**

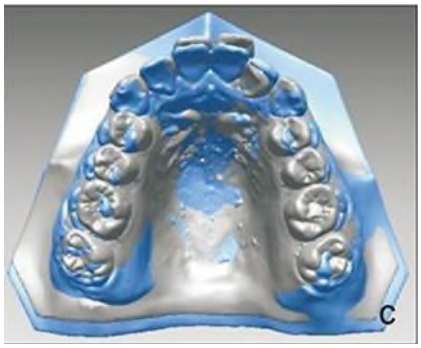

Fig 10. Transverse change measurement of posterior teeth (21)

4. Mesio-distal tipping / Palatal root torque/ Rotation (Degree)

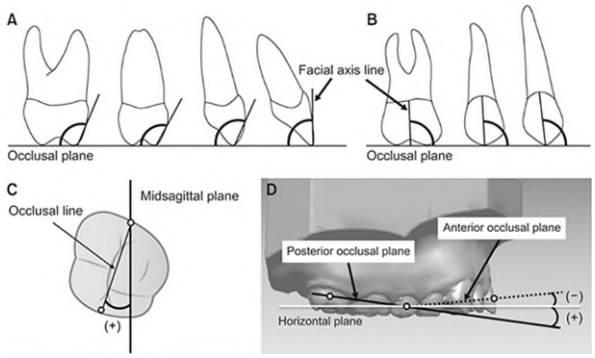

Fig 11. Angular measurements (°). **A**, Inclination. For the difference between pre- and post-treatment (T0–T1), positive means labioversion or buccoversion and negative means palatoversion; **B**, Angulation. For T0–T1, positive means distal crown tipping and negative means mesial crown tipping; **C**, Rotation. When the occlusal line was inclined inward and backward to the midsagittal plane, the angle of rotation was taken to be negative. For T0–T1, positive means distal-in rotation and negative means mesial-in rotation; (21)

Outcome measurements from model superimposition

Virtual and imprecision values of each upper teeth were recorded and grouped into 6 types of movement (Table 5).

1. A-P change (mm)
2. Vertical change (mm)
3. Transverse change (mm)
4. Mesiodistal tip change (degree)
5. Bucco-lingual tip change/Root Torque (degree)
6. Rotation change (degree)

The different types of tooth (incisors, canines, premolars and molars) were analysed separately because of the different anatomy of the crown and the root (both in shape and length), which inevitably results in a different response to the application of orthodontic forces, in particular, in the treatment with clear aligners.

Table 5. Summary of outcome measurements from model superimposition

Stage	**Tooth**	**A-P change (mm)**			**Vertical change (mm)**	**Transverse change (mm)**	**Mesiodistal tip change (degree)**	**Bucco-lingual tip change /Root Torque (degree)**	**Rotation change (degree)**
		A	B	%					
To	**11 21 12 22 13 23 15 25 16 26 17 27**								
T1	**11 21 12 22 13 23 15 25 16 26 17 27**								
A= Change between Virtual-Actual post Tx ; B = Change between Pre Tx- Virtual									

Analysis of Primary outcome: Analysis of movement accuracy percentage:
The following formula was used to quantify the accuracy percentage of each movement for each tooth type with respect to the the virtual change.

- **The imprecision (A)**: the difference between virtual set up and actual post-treatment measurements.
  The imprecision (A) = Virtual set up - actual post-treatment
- **The virtual change (B)**: is the difference between post-treatment virtual set up and pre-treatment measurements.
  Virtual change (B), = Virtual set up –Pretreatment
- **The imprecision percentage**; is the percentage
  The imprecision percentage = A/B x 100
- **The accuracy percentage** = 100% - The imprecision percentage

Thus, an index of the accuracy of each movement was obtained: the closer the value to 1, the more precise the dental movement achieved by the aligner series (100% of the prescription).

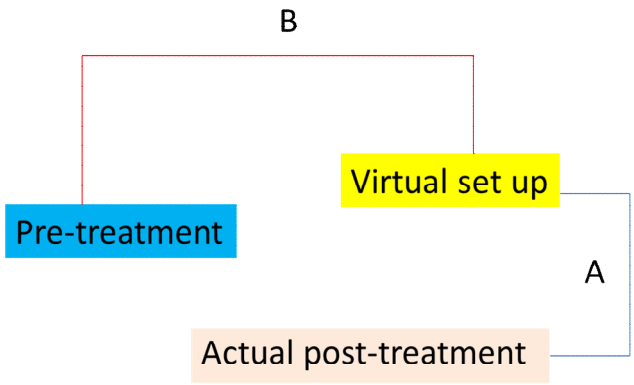

Fig 12. Measurement of the imprecision (A) and the virtual change (B)

Analysis Secondary outcome:
Information will be gathered from each case.
Treatment time
Any side effect such as pain / root resorption

Statistic test
Normal distribution
The Kolmogorov-Smirnov statistical test was used to determine normal distribution. In case of the non-normal distribution of the mean imprecision, median as a measure of central tendency and the interquartile interval will be used as an expression of its distribution.

Descriptive Statistics
The mean accuracy index, standard deviation and mean standard error were calculated for each type of movement in each tooth category.

Comparative Statistics

Right/ Left Canine distalization

- Paired T-test/ or Wilcoxon signed-rank test for single samples ($p < 0.05$) will be applied to contrast upper canine tooth movement between experimental and control group (Gr. 1 Canine distalization supplemented with power arm on one side and Gr. 2 Canine distalization without power arm)
- T- test or Mann-Whitney U test for single samples ($p < 0.05$) will be applied to contrast differences of virtual vs. actual amount of tooth movement for each tooth and 6 tooth movement types.

Error Measurement with ICC or Dahlburg formula

One month the analysis was repeated on 10 randomly selected digital models. Dahlberg's D will be calculated in order to quantify the measurement error.

12. Timeline:

July 2020- April 2024 (study begin after permitted from ethics committee and research funding approval)

(2020 – 2022: Covid 19 standstill period)

<table>
<tr><td>Review literature</td><td rowspan="3">Feb – June. 2020</td><td></td><td></td><td></td></tr>
<tr><td>Research Protocol</td><td></td><td></td><td></td></tr>
<tr><td>Ethic Approval</td><td></td><td></td><td></td></tr>
<tr><td>Subject Recruitment</td><td></td><td rowspan="2">July 2020 – July 2023</td><td></td><td></td></tr>
<tr><td>Clinical trial</td><td></td><td></td><td></td></tr>
<tr><td>Data collection</td><td></td><td></td><td>Oct 2022 – Dec 2023</td><td></td></tr>
<tr><td>Statistic evaluation</td><td></td><td></td><td>Jan 2024</td><td></td></tr>
<tr><td>Research Manuscript presentation</td><td></td><td></td><td></td><td>April 2024</td></tr>
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