UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

VINICIUS AUGUSTUS MERINO DA SILVA

Clear Aligners versus 2x4 mechanics comparison in the mixed dentition: a randomized clinical trial

Alinhadores estéticos versus mecânica 4x2, uma comparação na dentadura mista: Estudo Clínico Randomizado

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Orientadora: Profa. Dra. Daniela Garib.

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ERRATA

FOLHA DE APROVAÇÃO

DEDICATÓRIA

Dedico essa dissertação para todos que, de certa forma, estão sempre ao meu lado, me ajudando a realizar meus sonhos. À minha família, que sempre está ao meu lado, meus amigos, que estão sempre presentes e toda a equipe que participou direta ou indiretamente desse trabalho.

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À CAPES e a FAPESP, número do processo 88887.356781/2019-00 e processo 2017/24115-2, respectivamente, pelo apoio financeiro e incentivo ao desenvolvimento da Ciência.

"O ofício da Ortodontia existe desde que se descobriu que a posição dos dentes pode ser manipulada.

Um feito heroico perdido no tempo.

Reconhecida como especialidade, a Ortodontia existe há mais de um século.

Um marco triunfal e científico cravado no tempo.

Há mais de um século, uma infinidade de homens tem se obrigado a esse exercício, descortinando o universo biológico ao redor do dente, jogando luz sobre a biologia molecular e aumentando a destreza na movimentação dentária induzida...

Afinal, outro feito relevante: a **movimentação dentária induzida tornou-se previsível**.

A **ortodontia contemporânea**, com **tecnologia magnífica**, é marcada pela sutileza na **busca de uma utopia idealizada**: a **mecânica que esculpe o belo não transgrede a biologia**.

Esta escalada científica e tecnológica que produziu tanto aparelhos quanto filosofias também ampliou e consolidou a definição conceitual da Ortodontia como a especialidade odontológica com o mister de prevenir, interceptar e corrigir a má oclusão.

Conceito que se revela em toda plenitude neste início de século...

Prevenir, interceptar, corrigir.

Em torno deste conceito, a contemporaneidade abraçou a causa de pensar e aplicar a Ortodontia nas dentaduras decídua, mista e permanente.

A grande responsabilidade: esculpir in vivo a oclusão infante, imatura, ainda inacabada, e, também, a oclusão adulta, retocada pelo tempo.

Nessa trajetória infindável, muitos homens doaram o tempo de uma vida inteira com bravura de animal, com afeto, tolerância e ética de sapiens.

Esta dissertação está dedicada aos animais sapiens que lapidaram e continuam lapidando a ciência ortodôntica.*"*

Omar Gabriel da Silva Filho, 2005.

ABSTRACT

Clear Aligners versus 2x4 mechanics comparison in the mixed dentition: a randomized clinical trial

Introduction: The aim of this study was to compare the efficacy and efficiency of clear aligners and 2x4 fixed appliances for solving maxillary incisor position irregularities in the mixed dentition. **Methods:** The sample was composed by 27 patients from 7 to 11 years of age that were randomly allocated into two treatment groups: Group CA – 14 patients treated with invisible aligners; and Group FA – 13 patients treated partial fixed appliances in a 2x4 mechanics. Digital models were acquired before treatment (T1) and after the appliance removal (T2). Primary outcomes were: Little irregularity index and treatment time. Secondary outcomes were arch width, perimeter and length, arch size and shape, incisors levelling, plaque and ICDAS index. Intergroup comparisons were evaluated using Student t-test and Wilcoxon test with Holm-Bonferroni correction ($p < 0.05$). **Results:** The final sample comprised 14 patients (6 female, 8 male) with a mean age of 9.3 years (SD=1.0) in Group CA and 13 patients (9 female, 4 male) with a mean age of 9.6 years (SD=0.8) in Group FA. No intergroup differences were observed for changes in the incisor irregularity index. Treatment time was similar in both groups. Arch width, length, size and shape changes presented similar changes during treatment. Plaque and ICDAS index showed no differences between groups. **Conclusion:** Clear aligners and 2x4 mechanics presented similar efficacy and efficiency for maxillary incisor positional corrections in the mixed dentition.

Keywords: Interceptive Orthodontics; Orthodontic Appliances; 3-D Image.

RESUMO

Alinhadores estéticos versus mecânica 4x2, uma comparação na dentadura mista: Estudo Clínico Randomizado

Introdução: O objetivo deste estudo foi comparar a eficácia e a eficiência de alinhadores estéticos e aparelhos fixos 4x2 para corrigir irregularidades de posição do incisivo superiores na dentadura mista. **Métodos:** A amostra foi composta por 27 pacientes de 7 a 11 anos de idade que foram alocados aleatoriamente em dois grupos de tratamento: Grupo CA – 14 pacientes tratados com alinhadores estéticos; e Grupo FA – 13 pacientes trataram aparelhos fixos parciais em uma mecânica 4x2. Modelos digitais foram adquiridos antes do tratamento (T1) e após a remoção do aparelho (T2). Os desfechos primários foram: índice de irregularidade de Little e tempo de tratamento. Os desfechos secundários foram largura, perímetro, comprimento, tamanho e forma do arco, nivelamento de incisivos, índice de placa e ICDAS. As comparações intergrupos foram avaliadas utilizando-se o teste T de Student e o teste de Wilcoxon com correção de Holm-Bonferroni ($p < 0,05$). **Resultados:** A amostra final foi composta por 14 pacientes (6 do sexo feminino, 8 do sexo masculino) com idade média de 9,3 anos (DP=1,0) no Grupo CA e 13 pacientes (9 do sexo feminino, 4 do sexo masculino) com idade média de 9,6 anos (DP=0,8) no Grupo FA. Não foram observadas diferenças intergrupos para alterações no índice de irregularidade incisivo. O tempo de tratamento foi semelhante em ambos os grupos. Largura, comprimento, tamanho e forma do arco apresentaram alterações semelhantes durante o tratamento. Os índices de placa e ICDAS não apresentaram diferenças entre os grupos. **Conclusão:** Alinhadores estéticos e mecânica 4x2 apresentaram eficácia e eficiência semelhantes para correções posicionais de incisivo maxilar na dentição mista.

Palavras-chave: Ortodontia Interceptiva; Aparelhos Ortodônticos; Imagem 3D.

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LIST OF ABREVIATIONS AND ACRONYMS

2x4	“Two by four” – Orthodontic term for a fixed appliance mechanic
ICDAS	International Caries Detection Assessment System
SD	Standard Deviation
3-D	Three-dimensional
OHRQoL	Oral Health-related Quality of Life
CONSORT	Consolidated Standards of Reporting Trials
ReBEC	Clinical Trials Registry
LII	Little’s Irregularity Index
ICC	Intraclass correlation coefficients

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1 INTRUDUCTION

1 INTRUDUCTION

There are over 2,62 billion active users on Social Networking Sites (SNSs). (EMARKETED, 2018) Around 83% of the adolescents have a smartphone and 99% spend at least 21 hours-per-week online. (ANDERSON; JIANG, 2018; LIVINGSTONE; HADDON; VINCENT; MASCHERONI *et al.*, 2014; O'REILLY, 2020) For the new generation, SNS is almost ubiquitous, and its use has highlighted their image of aligned, bright and aesthetic smile. (BOURSIER; MANNA, 2018; GIOIA; CINGOLANI, 2019; VALENTINE, 2015; WILLEMS; CARELS, 2000) Previous clinical trial along with other studies has shown that the exposure to "ideal" faces and smiles have a direct effect on man and woman self-dissatisfaction and a higher impact in patients with a greater aesthetical discrepancy. (FARDOULY; DIEDRICHS; VARTANIAN; HALLIWELL, 2015; FARDOULY; VARTANIAN, 2015; SAMPSON; JEREMIAH; ANDIAPPAN; NEWTON, 2020) This is the new scenario for orthodontic practice, aesthetical treatments and with a high expectancy of "ideal" results.

The mixed dentition shows a high prevalence of malocclusion. (VAN DER LINDEN, 1974) The prevalence of malocclusion in this phase can range from 39% to 93%, depending on sex, ethnic group, age and type of malocclusion. (DIMBERG; LENNARTSSON; ARNRUP; BONDEMARK, 2015; TSCHILL; BACON; SONKO, 1997) An increased overjet, dental crowding and spacing are discrepancies normally associated with appearance dissatisfaction and negatively affected children's oral health-related quality of life (OHRQoL). (BANU; ȘERBAN; PRICOP; URECHESCU *et al.*, 2018; DIMBERG; ARNRUP; BONDEMARK, 2015; DIMBERG; LENNARTSSON; ARNRUP; BONDEMARK, 2015; GÓIS; VALE; PAIVA; ABREU *et al.*, 2012; KRAGT; DHAMO; WOLVIUS; ONGKOSUWITO, 2016; TAUSCHE; LUCK; HARZER, 2004) The orthodontic alignment and levelling of permanent incisor crowding can be anticipated to the mixed dentition when a psychosocial problem related to smile aesthetics is observed. (DOWSING; SANDLER, 2004; LOLI, 2017) Additionally, patients and families should demonstrate a willing to receive early correction in a family/patient-centred orthodontics. (ALBINO; CUNAT; FOX; LEWIS *et al.*, 1981; RICHTER; NANDA; SINHA; SMITH, 1998)

The simplified “two by four” (2x4) mechanics orthodontic brackets placed at the four permanent incisors and two tubes bonded in the first permanent molars. (ISAACSON; LINDAUER; RUBENSTEIN, 1993; QUINZI; FERRO; RIZZO; MARRANZINI *et al.*, 2018; SINGHAL; NAMDEV; JINDAL; BODH *et al.*, 2015) The 2x4 mechanics is specially indicated to solving maxillary and mandibular incisor crowding in the mixed dentition. (DOWSING; SANDLER, 2004; ISAACSON; LINDAUER; RUBENSTEIN, 1993; LOLI, 2017; QUINZI; FERRO; RIZZO; MARRANZINI *et al.*, 2018; SOCKALINGAM; ZAKARIA; KHAN; AZMI *et al.*, 2020) During treatment, the maxillary permanent canines have a close relation to the apical third of the lateral incisors that should be maintained in a distal angulation position. (ERICSON; KUROL, 1987; ERICSON; KUROL; EPIDEMIOLOGY, 1986) A previous study showed that 93.9% of the orthodontists used this mechanics in their practice. (QUINZI; FERRO; RIZZO; MARRANZINI *et al.*, 2018)

Clear Aligners are removable orthodontic appliances designed with a software able to generate serial dental changes in digital dental models. (TUNCAY, 2006) Clear aligners had an initial proposal of comfort, adequate hygiene, predictability and better aesthetics compared to conventional fixed appliances. (TUNCAY, 2006) Previous studies have shown that aligners are not able to reach 100% of the setup prediction with movements capability varying from 28% in a mesial rotation of the mandibular first molar to 96,7% in lower premolars mesiodistal tip. (HAOUILI; KRAVITZ; VAID; FERGUSON *et al.*, 2020; LOMBARDO; ARREGHINI; RAMINA; GHISLANZONI *et al.*, 2017) Even though limited, previous studies showed an adequate anterior crowding correction with clear aligners with a 48.7 to 61.1% of predictability of incisor rotation. (HAOUILI; KRAVITZ; VAID; FERGUSON *et al.*, 2020; KRIEGER; SEIFERTH; MARINELLO; JUNG *et al.*, 2012) Achievement of partial dental movements are strong indicators of the requirement for adequate attachments and an overcorrection planning. Efficacy, efficiency, stability, comfort and oral hygiene were evaluated in previous meta-analyses and systematic reviews. (GALAN-LOPEZ; BARCIA-GONZALEZ; PLASENCIA, 2019; PAPADIMITRIOU; MOUSOULEA; GKANTIDIS; KLOUKOS, 2018; ROBERTSON; KAUR; FAGUNDES; ROMANYK *et al.*, 2020) Aligners are efficient in simple orthodontic mechanics with mild to moderate malocclusions. (GALAN-LOPEZ; BARCIA-GONZALEZ; PLASENCIA, 2019; PAPADIMITRIOU; MOUSOULEA; GKANTIDIS; KLOUKOS, 2018; ROBERTSON;

KAUR; FAGUNDES; ROMANYK *et al.*, 2020) An agreement among recent studies is that this appliance still needs more accurate clinical trials.

The applicability of clear aligners for treating the incisor crowding during the mixed dentition is still an incognita due to the high dependence of patient collaboration. No previous study has compared the treatment outcomes and treatment length between clear aligners and 2x4 mechanics in the mixed dentition.

2 ARTICLE

2 ARTICLE

The article presented in this Dissertation was formatted according to the American Journal of Orthodontics and Dentofacial Orthopaedics instructions and guidelines for article submission.

Clear Aligners versus 2x4 mechanics comparison in the mixed dentition: a randomized clinical trial

Abstract:

Introduction: The aim of this study was to compare the efficacy and efficiency of clear aligners and 2x4 fixed appliances for solving maxillary incisor position irregularities in the mixed dentition. **Methods:** The sample was composed by 27 patients from 7 to 11 years of age that were randomly allocated into two treatment groups: Group CA – 14 patients treated with invisible aligners; and Group FA – 13 patients treated partial fixed appliances in a 2x4 mechanics. Digital models were acquired before treatment (T1) and after the appliance removal (T2). Primary outcomes were: Little irregularity index and treatment time. Secondary outcomes were arch width, perimeter and length, arch size and shape, incisors levelling, plaque and ICDAS index. Intergroup comparisons were evaluated using Student t-test and Wilcoxon test with Holm-Bonferroni correction ($p < 0.05$). **Results:** The final sample comprised 14 patients (6 female, 8 male) with a mean age of 9.3 years (SD=1.0) in Group CA and 13 patients (9 female, 4 male) with a mean age of 9.6 years (SD=0.8) in Group FA. No intergroup differences were observed for changes in the incisor irregularity index. Treatment time was similar in both groups. Arch width and length changed similarly in both groups. No significant arch size and changes were observed in both groups. Plaque and ICDAS index showed no differences between groups. **Conclusion:** Clear aligners and 2x4 mechanics presented similar efficacy and efficiency for maxillary incisor positional corrections in the mixed dentition. The appliance choice should be guided by the clinician and family preference.

Keyword: Interceptive Orthodontics; Orthodontic Appliances; 3-D Image; 3-D Printing.

INTRODUCTION:

The mixed dentition shows a high prevalence of malocclusion.[1] The prevalence of malocclusion in this phase can range from 39% to 93%, depending on sex, ethnic group, age and type of maloclusion.[2,3] An increased overjet, dental crowding and spacing are discrepancies normally associated with appearance dissatisfaction and negatively affected children's oral health-related quality of life (OHRQoL).[2,4-8] The orthodontic alignment and levelling of permanent incisor crowding can be anticipated to the mixed dentition when a psychosocial problem related to smile aesthetics is observed.[9,10] Additionally, patients and families should demonstrate a willing to receive early correction in a family/patient-centred orthodontics.[11,12]

In 1933, Joseph E. Johnson first described the Twin Wire Alignment presenting a mechanical option that included only permanent molars and incisors for the mixed dentition.[13] Even though the evolution in orthodontic appliances and techniques occurred since then, the mechanics behind this technique is still the same. The simplified "two by four" (2x4) mechanics orthodontic brackets placed at the four permanent incisors and two tubes bonded in the first permanent molars.[14-16] The 2x4 mechanics is specially indicated to solving maxillary and mandibular incisor crowding in the mixed dentition.[9,10,14,15,17] During treatment, the maxillary permanent canines have a close relation to the apical third of the lateral incisors that should be maintained in a distal angulation position.[18,19] A previous study showed that 93.9% of the orthodontists used this mechanics in their practice.[15]

Currently, clear aligners are an option for solving the incisor crowding during the mixed dentition. Clear Aligners are removable orthodontic appliances designed with a software able to generate serial dental changes in digital dental models.[20] Clear aligners had an initial proposal of comfort, adequate hygiene, predictability and better aesthetics compared to conventional fixed appliances.[20] Previous studies have shown that aligners are not able to reach 100% of the setup prediction with movements capability varying from 28% in a mesial rotation of the mandibular first molar to 96,7% in lower premolars mesiodistal tip.[21,22] Even though limited, previous studies showed an adequate anterior crowding correction with clear aligners with a 48.7 to 61.1% of predictability of incisor rotation.[22,23] Achievement of partial dental movements are strong indicators of the requirement for adequate attachments and an overcorrection planning. Efficacy, efficiency, stability, comfort and oral hygiene were evaluated in

previous meta-analyses and systematic reviews.[24-26] Aligners are efficient in simple orthodontic mechanics with mild to moderate malocclusions.[24-26] An agreement among recent studies is that this appliance still needs more accurate clinical trials.

The applicability of clear aligners for treating the incisor crowding during the mixed dentition is still an incognita due to the high dependence of patient collaboration. No previous study has compared the treatment outcomes and treatment length between clear aligners and 2x4 mechanics in the mixed dentition.

Specific objectives or hypotheses

The objective of this study was evaluating the efficiency and efficacy of clear aligners and 2x4 fixed appliances for solving maxillary incisor position irregularities in the mixed dentition. The null hypothesis was that both orthodontic appliances have similar outcomes.

MATERIAL AND METHODS:

Trial design and any changes after trial commencement

The present study was a single-centre randomized clinical trial (RCT) with two parallel arms in a 1:1 allocation ratio. The protocol of this study followed the Consolidated Standards of Reporting Trials (CONSORT)[27] and was registered in the Clinical Trials Registry (ReBEC) under the identification RBR-9kvw9t.

Ethical considerations

Ethical approval was obtained from the Research Institutional Board of Bauru Dental School – University of São Paulo, Brazil (Process number: 14962119.2.0000.5417; decision number: 3.518.689) before the trial commencement. Participants who met the eligibility criteria were invited to participate and an informed consent was obtained from all volunteers/legal guardians.

Participants, eligibility criteria, and settings

This study was conducted from 2019 to 2020 and the recruitment occurred at the Orthodontics Clinic of Bauru Dental School, University of São Paulo, Brazil. The eligibility criteria included patients of both sexes, from 7 to 11 years of age in the mixed dentition with a Little's Irregularity Index (LII) in the maxillary arch of at least 3mm. Patients with incisors agenesis, non-cavitated caries lesions, cleft lip and palate and syndromes were excluded.

Interventions

The subjects allocated in the Group CA were treated with Clear Aligners (Fig 1). Pre-treatment maxillary dental models were scanned using a 3Shape Scanner (3Shape A/S, Copenhagen, Denmark) and prepared for a digital setup. The treatment digital setup was performed using Maestro3D (AGE Solutions, Pisa, Italy) by the first author (VS). All digital setups were made taking in consideration the laterals distal tip that could not be altered and an overcorrection planning of 20% for each movement. The software automatically generated the necessary number of aligners to reach the final predictive model. Attachments were planned for all movements except for buccal compensation. The attachments architecture was standardized with a 0.8mm depth through the software MAESTRO3D, with a triangular format, positioning the ramp to guide the movements. The digital models generated by the software were printed using Moonray S100 3D printer (Sprintray, Los Angeles, USA). Clear aligners were performed using a 0.75mm biocompatible thermoplastic transparent sheet composed by PET-G (Bio-art, São Carlos, Brazil) using a vacuum forming machine (Bio-art, São Carlos, Brazil). The aligners were replaced every 15 days. The orthodontic appointments were performed monthly. A second phase, named refinement was needed in 14 from 16 patients.

The subjects assigned to group FA were treated with fixed appliance using a "Two by Four" (2x4) mechanics in the maxillary arch (Fig 2). Pre-adjusted metal brackets (Morelli, São Paulo, Brazil) were bonded in all permanent incisors and orthodontic buccal tubes were bonded in the maxillary permanent first molars. In the maxillary lateral incisors, the brackets were bonded changing the right and left side to maintain the natural distal angulation observed in the mixed dentition phase. The arch wire sequence was nickel-titanium .014", nickel-titanium 0.016", stainless steel .016", .018" and .020".

Patients from both groups received rapid maxillary expansion before T1 due to the presence of unilateral/bilateral posterior crossbites. T1 dental models were taken 6 months after maxillary expansion when the expander was removed. Clear aligners/2x4 mechanics started immediately after T1. Oral hygiene and diet orientation was provided for both groups.

Digital dental models were obtained before treatment (T1) and after the appliance removal (T2). All digital dental models were saved in .stl file format.

Outcomes (primary and secondary) and changes after trial commencement

The primary outcomes were the maxillary incisor irregularity index (Fig 3) and the treatment length. Secondary outcomes included intermolar width, arch perimeter and length, arch size and shape, incisors levelling, incisor mesiodistal angulation, plaque and International Caries Detection and Assessment System (ICDAS) index.

The irregularity index, arch width, perimeter and length were measured both in T1 and T2 dental models using the software OrthoAnalyzer (3Shape A/S, Copenhagen, Denmark) (Fig 4). Maxillary incisor levelling and angulation was assessed using the software 3DSlicer Software (www.slicer.org) (Fig 5).

Maxillary dental arch size and shape were assessed using the software Stratovan Checkpoint (Stratovan Corporation, Davis, California, USA). Fourteen landmarks were placed on the occlusal surface of maxillary teeth in T1 and T2 digital dental models (Fig 4D).[28,29] At the MorphoJ software (Klingenberg Lab, Manchester, UK) all the x and z coordinates for each landmark were extracted and imported. The software MorphoJ automatically calculated the dental arch size considering the square root of the distance between the centroid point to all 14 landmarks.[28-31] A Generalized Procrustes Analysis [28,29,32] was performed in the MorphoJ using the same coordinates in order to assess the maxillary and mandibular arch shapes. A mean shape of the dental arch was obtained for each group for both treatment timepoints.

The labial surfaces of the maxillary incisors were assessed for initial non-cavitated caries lesion using the ICDAS. Plaque index was assessed using colour-based plaque staining.

Sample size calculation

Maxillary incisor irregularity index was selected for the sample size calculation. Considering a statistical power of 80%, an alpha of 5%, a standard deviation of

2.23mm[33] and a minimum difference to be detected of 2.5mm. A minimum of 14 patients in each group was required. Considering the dropouts, 32 patients were randomized.

Randomization

A stratified randomization in blocks[34] was performed considering the ascending order of maxillary incisor irregularity index at T1. In pairs with a 1:1 proportion, a coin tossing method randomly assigned the patients to the different sample groups.

Blinding

The study blindness was not possible since the operator and patients were aware of the type of appliance used in each case. The outcome assessment was blinded.

Statistical analyses

All measurements were performed by the same observer. Fifty per cent of the sample was evaluated twice after a minimum 15-days interval. The intra-examiner error was assessed using intraclass correlation coefficients (ICC).[35] The reproducibility of ICDAS score was evaluated using Kappa index.

Intergroup initial age and sex ratio at baseline were analysed using t-tests and chi-square tests, respectively. Normal distribution was assessed using Shapiro Wilk test. Intergroup differences at the baseline were compared using T-tests and Mann-Whitney test. Intergroup comparisons for treatment changes were evaluated with t tests or Wilcoxon test with Holm-Bonferroni correction. Intergroup comparison for arch size was assessed with the analysis of variance (ANOVA). The significance level regarded was 5%. All statistical analyses were performed using SigmaPlot for Windows version 12.0 (Systat Software Inc., Chicago, USA).

RESULTS

Participant flow

A total of 48 volunteers were analysed, 16 did not meet the inclusion criteria and two declined to participate (Fig 6). A total of 32 patients were enrolled in the study commencement. During the follow-up, 2 patients from Clear Aligner group and 3 from

fixed appliance group quit treatment due the coronavirus pandemic. At the end, a total of 27 patients completed treatment and were included in the analyses (Fig 6).

Baseline data

Baseline characteristics were similar in both groups (Table I). All variables showed normal distribution, except the arch width and incisor levelling variable.

Number analysed for each outcome, estimation and precision

The Clear Aligners group (CA) comprised 14 patients (6 female, 8 male) with a mean age of 9.33 years (SD = 1.0). The fixed appliance group (FA) comprised 13 patients (9 female, 4 male) with a mean initial age of 9.65 years (SD = 0.8).

The error study showed an excellent intraexaminer reproducibility for all variables, with ICC varying from 0.756 to 0.993.[36] The Kappa index for the ICDAS score was strong (≥ 0.9).

All variables showed normal distribution except the incisor levelling and lateral incisor angulation.

Maxillary incisor irregularity index decreased similarly in both groups (Table II). Treatment time was approximately 8 months for both CA and FA groups.

Arch width and length changed similarly in both groups (Table II). The maxillary lateral incisors tipped mesially in group CA and distally in group FA without statistical differences. The step between the central and lateral incisors decreased similarly in both groups (Table II). No significant difference between groups was found for arch size and shape changes (Table II and Figure 7).

No difference was found between groups for interphase changes in plaque index. Non-cavitated caries lesions increased similarly in both groups (Table II).

Harms

No important harm was caused to patients during this study. Most patients reported a slight pain in the first days after appliance installation. Ten out of 13 subjects from the group FA reported a slight discomfort due to brackets and arch wires.

DISCUSSION

Main findings in the context of the existing evidence, interpretation

This study was the first randomized clinical trial comparing clear aligners with a partial fixed 2x4 mechanics for solving dental crowding in the mixed dentition. Previous studies have compared fixed orthodontic appliances with clear aligners in the permanent dentition with controversies results regarding effectiveness, movements predictability and treatment time.[37-40] A modified Little's irregularity index for the maxilla was used as a primary outcome. The irregularity index was also used to perform a stratified randomization in order to allow adequate intergroup comparison. The baseline comparisons confirm the homogeneity of the sample (Table 1), reducing the risk of bias in the intergroup comparisons.[41]

Most variables were assessed through three-dimensional (3D) digital dental models. Previous studies demonstrated an adequate accuracy and reproducibility for measurements on digital dental models. [42-44] The results of the present study are in accordance with previous studies, showing an adequate intraexaminer reproducibility. In order to provide a visual representation for the dental arch size and shape treatment changes, an evaluation based on the centroid size and location was performed.[28,30,31] The centroid method was used in many previous studies.[28-31]

The initial irregularity index of maxillary anterior teeth of both groups was moderate to severe. A previous study considered an irregularity index greater than 5 as a severe incisor dealignments.[45,46] Both clear aligners and 2x4 mechanics produced a decrease of 5mm in the maxillary irregularity index. In other words, the efficacy of both appliances was similar. Approximately 3mm of irregularity index was still maintained after treatment as a result of a slight dealignment between the distal aspect of lateral incisors and the mesial aspects of deciduous canines. In the partial fixes 2x4 appliances, deciduous canines were not bonded. In Clear Aligners, the degree of corrections was partially accomplished in this region. A previous study comparing clear aligners and comprehensive fixed appliances in the permanent dentitions also reported that both appliances were adequate to correct slight to moderate crowding.[23]

Treatment time for solving the maxillary incisor crowding was similar with both appliances. The 2x4 fixed appliance used 5 different arch wires with monthly changes. However, the .014" and .016" Nickel-Titanium arch wires were maintained more than one month in some patients with severe incisor rotations. In addition, bracket

debonding was recorded in all of the 14 patients what might have an influence in treatment time of 8 months. A previous study reported a treatment time for partial fixed 2x4 appliances of 5 to 13 months.[16,17,47] In the clear aligner planning, a mean of 10 aligners (range 6 to 14) in the treatment phase and 6 aligners in the refinement (range 3 to 8) were planned for Group CA. Considering the aligners were replaced every 15 days, a mean time of 8 months was expected. Treatment time was 8.29 months. The movement more commonly needed during refinement was rotation. Previous studies corroborate the similarity in treatment length between clear aligners and comprehensive fixed appliance in the permanent dentition.[37,40] Conversely, other studies demonstrated a short treatment time for clear aligners[38] and for fixed appliances[39].

Slight changes were noticed for the secondary outcomes in both groups without intergroup differences (Table II). These results suggest that both appliances have a similar influence on dental arch changes. Arch perimeter decrease in both groups might be related to natural changes of the late mixed dentition as the mesial movement of maxillary molars to the Leeway space.[48] Previous studies in adults showed that clear aligners can increase arch width in cases with mild or severe crowding when planned,[49-51] and also is capable to maintain arch dimensions when necessary.[52]

Considering the close position of maxillary canine germs to lateral incisor roots during the mixed dentition, the lateral incisor distal tip must be preserved during incisor crowding correction.[18,19] Although the results showed no intergroup differences for changes in the lateral incisor angulation (Table II), opposite movements were observed in both groups. The distal angulation of maxillary lateral incisors was maintained in the FA group while a slight mesial tip was observed in CA group. A better control of lateral incisor angulation with fixed 2x4 mechanics is probably due to the passive bonding of lateral incisor brackets. On the other hand, clear aligners could not resist to the mesial angulation of lateral incisor during treatment. Previous studies demonstrated that aligners are not able to control undesired dental inclination throughout the treatment, showing that fixed appliances are better indicated for root control.[50,53]

The relationship between maxillary incisor edges is imperative for an adequate smile esthetics.[54] Both groups had a mean step of 0.78mm between central and lateral incisors in accordance with previous studies.[54] Extrusion and intrusion are both difficult movements to be achieved with clear aligners. Previous studies reported a true extrusion/intrusion effect ranging from 0.72mm to 1.5mm with aligners what should

have been enough in the mixed dentition for an adequate levelling of the maxillary incisiors.[23,55,56]

All patients and parents received oral hygiene orientation, toothbrushes and toothpastes in the first appointment and during treatment. Mean plaque index were similar between fixed and removable appliances before and after treatment. Differently from our results, previous studies showed that adolescents presented a higher compliance with oral hygiene when treated with clear aligners.[57] Speculations that aligners tended to be less plaque accumulative[58] was not confirmed in this study. Even with removable appliances, oral hygiene was not adequate, and a possible explanation is the sample age including subjects younger than adolescents and adults.

Despite of hygiene guidance and adequate follow-up, non-cavitated caries lesions were observed in both groups after treatment. The ICDAS index showed non-cavitated caries lesions from 0 (sound surface) to 3 (microcavity in dry enamel, without visible dentin) in both groups. Group FA presented non-cavitated caries lesion in 26% of the analysed surfaces while the group CA showed 17%. Previous studies have shown a smaller incidence of non-cavitated lesions in patients treated with clear aligners with significant difference from fixed appliances patients.[59,60] In the present study no difference was found between both groups probably because the short treatment time compared to comprehensive treatments. The increase of non-cavitated lesions in both groups corroborate a previous study in adult patients showing that both fixed and removable appliances are capable of causing caries lesions.[61]

Considering the similarities in the primary and secondary outcomes in this study, the appliance choice should be guided by the clinician and family preference.

Limitations

This study was a single-centre study and conducted by one operator. The blindness of the study was not possible because of the appliance's designs. On the other hand, all data was de-identified before analysis. An important limitation of this study was the lack of information on the influence of compliance on the treatment outcome once compliance was not measured especially in the clear aligner group. Additionally, the research went through the quarantine period and 9 out of 13 patients from the fixed appliance group had appliance damage as bracket debonding. Future studies should compare family/patient self-report, pain and satisfaction with the outcomes.

Generalizability

The results of the present study may be generalized for patients in the mixed dentition with maxillary incisor crowding. The movements accomplished in this study included tooth rotation, space closure, labial/lingual movements and minor extrusion/intrusion movements.

CONCLUSIONS

- Clear aligners and fixed partial 2x4 mechanics presented similar efficacy and efficiency for corrections of maxillary incisor crowding in the mixed dentition;
- Both appliances showed a similar dental plaque index and non-cavitated caries lesions incidence during treatment.

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FIGURES LEGENDS:

Fig 1. Maxillary treatment with In-office Clear aligner.

Fig 2. Maxillary treatment with fixed orthodontic appliance 2x4 mechanics.

Fig 3. Maxillary Little irregularity index was assessed by the sum of all five contact point distances starting on the mesial surface of the right deciduous canine and finishing at the mesial surface of the contralateral tooth.

Fig 4. Maxillary arch dimensions assessment: (A) arch width was measured at the level of the cusp tips of the first permanent molars; (B) arch perimeter was the sum of the four segments from mesial aspect of the right first permanent molar to the mesial aspect of the contralateral tooth; (C) arch length was measured on the horizontal plane from the mesial aspect of the first permanent molars to the mesial edge of the right permanent incisor; (D) In the cusp tips and incisal edges of the maxillary teeth 14 landmarks were selected to provide raw coordinates representing dental arch shape and size. The dental arch size was automatically calculated using the centroid size method in the MorphoJ software. It is considered the square root of the sum of the squared distances between the arch centroid to all landmarks.

Fig 5. Analyses using vertical plane (occlusal plane) as reference: (A) Incisors step was measured by the distance between the median point of the lateral incisal to the same point in the central incisal of both sides; (B) Incisors angulation was calculated using a frontal image of each patient's digital casts in a position parallel to the occlusal plane, the angle was measured using the centre of clinical crown point on central and lateral incisors.

Fig 6. Participants flow chat.

Fig 7. Superimpositions of maxillary dental arch shape. (A) Pre-treatment maxillary dental arch in the CA group (red line) and in the FA group (blue line). (B) Post-treatment maxillary dental arch in the CA group (red line) and in the FA group (blue line).

Fig 1.

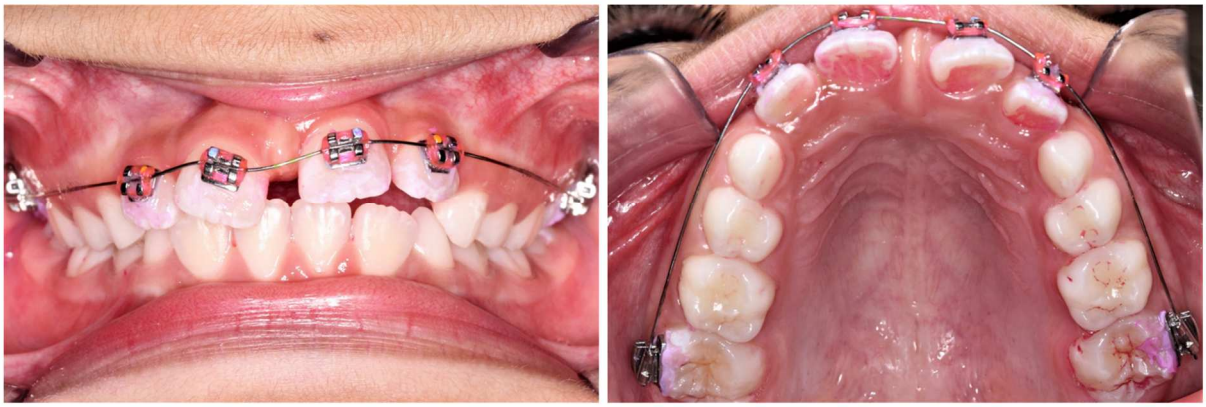

Fig 2.

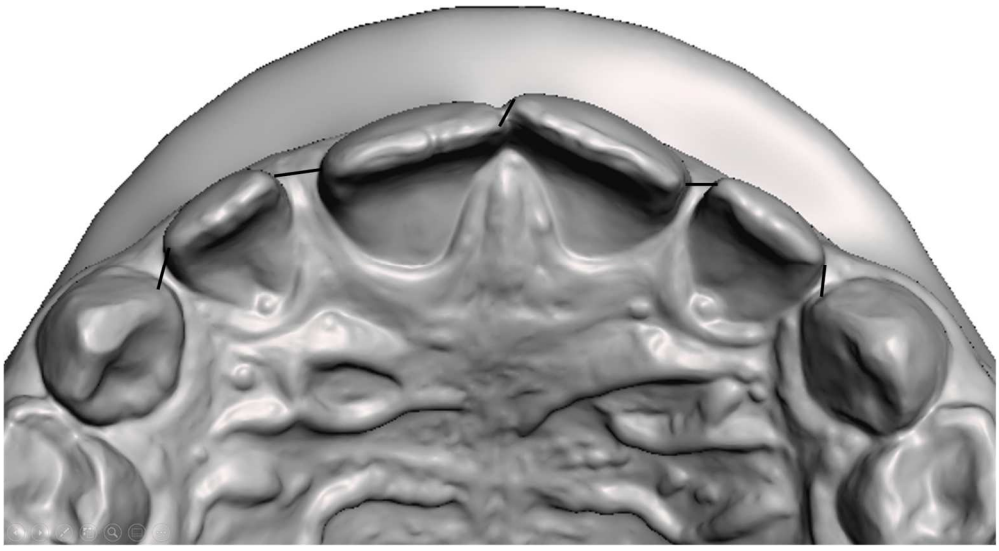

Fig 3.

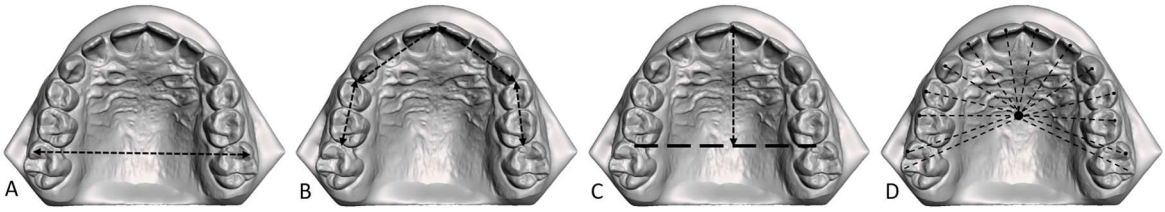

Fig 4A, B, C and D.

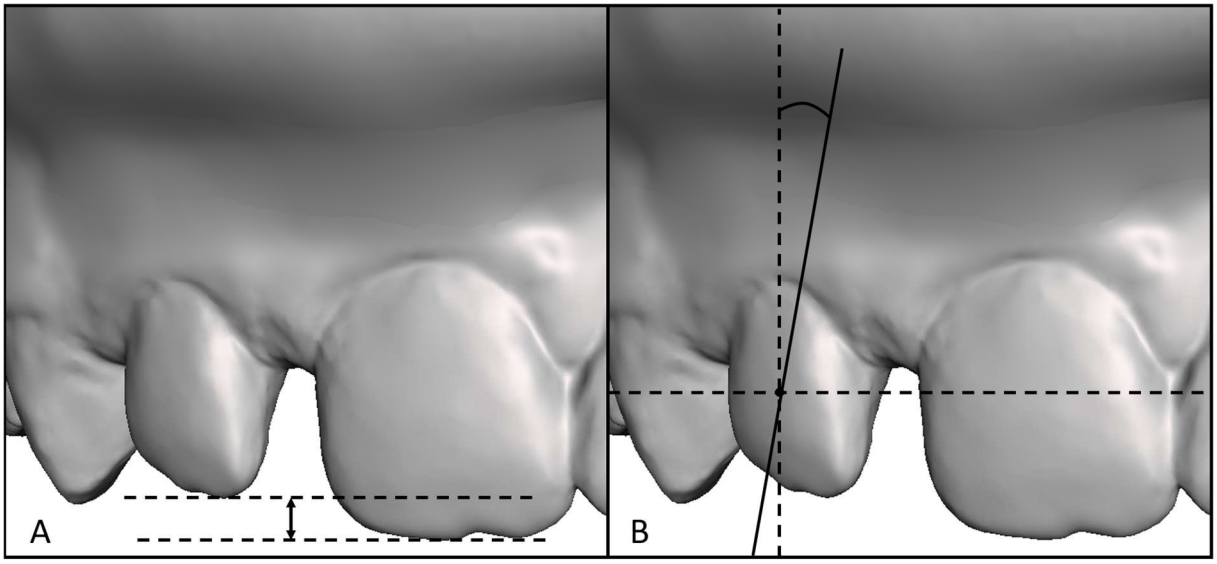

Fig 5A and B.

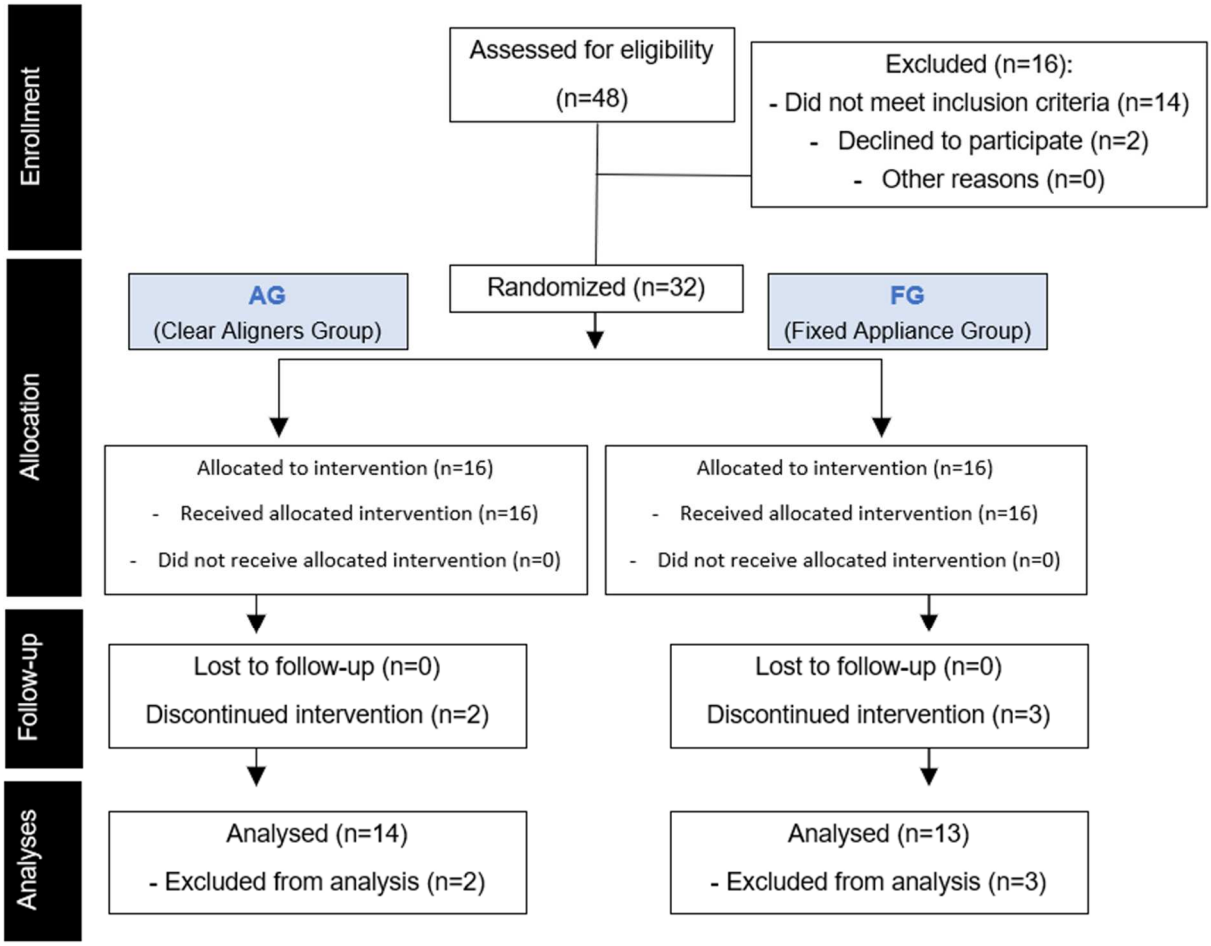
Enrollment
Assessed for eligibility
(n=48)
Excluded (n=16):
- Did not meet inclusion criteria (n=14)
- Declined to participate (n=2)
- Other reasons (n=0)
Allocation
AG
(Clear Aligners Group)
Randomized (n=32)
FG
(Fixed Appliance Group)
Allocated to intervention (n=16)
- Received allocated intervention (n=16)
- Did not receive allocated intervention (n=0)
Allocated to intervention (n=16)
- Received allocated intervention (n=16)
- Did not receive allocated intervention (n=0)
Follow-up
Lost to follow-up (n=0)
Discontinued intervention (n=2)
Lost to follow-up (n=0)
Discontinued intervention (n=3)
Analyses
Analysed (n=14)
- Excluded from analysis (n=2)
Analysed (n=13)
- Excluded from analysis (n=3)

Fig 6.

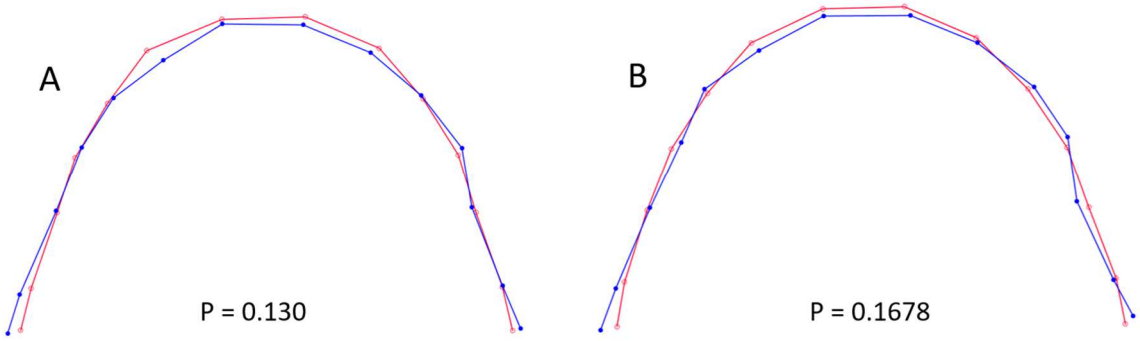

Fig 7.

Table I –Intergroup comparisons at baseline.

Variables	CA (n = 14)	FA (n=13)	p
	Mean (SD)	Mean (SD)	
Initial Age (y) §	9.33 (1.01)	9.65 (0.80)	0.322
Male □	06 (42.8%)	09 (69.2%)	0.981
Female □	08 (57.1%)	04 (30.7%)	
Little irregularity index§	8.29 (2.73)	8.52 (2.73)	0.830
Arch width¥	51.86 (3.10)	51.89 (1.55)	1.000
Arch perimeter§	78.38 (4.03)	77.55 (3.46)	0.569
Arch length§	29.84 (2.64)	29.15 (1.35)	0.408
Arch size§	87.10 (3.82)	87.60 (4.30)	0.782
Central incisor Angulation§	0.20 (3.64)	0.32 (3.16)	0.926
Lateral incisor Angulation§	-7.22 (5.11)	-8.32 (6.66)	0.637
Right incisors step§	1.55 (0.98)	1.07 (0.7)	0.154
Left incisors step¥	1.43 (0.86)	1.20 (1.37)	0.216
Plaque Index (%)¥	28.57 (33.76)	58.33 (42.95)	0.057
ICDAS¥	0.00 (0.00)	0.00 (0.00)	1.000

CA – Clear Aligners Group; FA – Fixed Appliances Group.

Q1, first quartile; Q3, third quartile; SD, standard deviation.

§ T-test, ¥Mann-Whitney, □ Chi-Square

* Statistically significant at $P<0.05$

Table II – Intergroup comparison for treatment change (T-test and Mann-Whitney with Holm-Bonferroni correction).

Variables	Group CA (n = 14)	Group FA (n=13)	p
	Mean (SD)	Mean (SD)	
Treatment time (months) §	8.00 (2.9)	8.69 (2.65)	0.525
Little irregularity index (mm)§	-5.84 (2.92)	-5.15 (2.75)	0.536
Arch width (mm)§	0.204 (0.7)	0.98 (1.19)	0.048
Arch perimeter (mm)§	-1.44 (1.35)	-2.21 (1.65)	0.196
Arch length (mm)§	0.03 (0.93)	-1.18 (1.16)	0.006
Arch size (mm)§	0.01 (1.74)	0.12 (1.28)	0.865
Central incisor Angulation (º)§	0.26 (3.45)	0.04 (3.62)	0.873
Lateral incisor Angulation (º)¥	3.19 (6.33)	0.21 (6.15)	0.027
Right incisors step (mm)¥	-0.72 (0.70)	-0.26 (0.77)	0.157
Left incisors step (mm)¥	-0.59 (0.85)	-0.53 (1.25)	0.297
Plaque Index (%)§	17.85 (31.66)	-10.00 (44.11)	0.063
ICDAS¥	0.25 (0.45)	0.26 (0.38)	0.531

P<0.05; Holm-Bonferroni method was applied.

* Statistically significant

§ T-test, ¥Mann-Whitney

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3 DISCUSSION

3 DISCUSSION

This study was the first randomized clinical trial comparing clear aligners with a partial fixed 2x4 mechanics for solving dental crowding in the mixed dentition. Previous studies have compared fixed orthodontic appliances with clear aligners in the permanent dentition with controversies results regarding effectiveness, movements predictability and treatment time. (DJEU; SHELTON; MAGANZINI, 2005; KUNCIO; MAGANZINI; SHELTON; FREEMAN, 2007; LI; WANG; ZHANG, 2015; PAVONI; LIONE; LAGANÀ; COZZA, 2011) A modified Little's irregularity index for the maxilla was used as a primary outcome. The irregularity index was also used to perform a stratified randomization in order to allow adequate intergroup comparison. The baseline comparisons confirm the homogeneity of the sample (Table 1), reducing the risk of bias in the intergroup comparisons. (BERGER; EXNER, 1999)

Most variables were assessed through three-dimensional (3D) digital dental models. Previous studies demonstrated an adequate accuracy and reproducibility for measurements on digital dental models. (ARAGÓN; PONTES; BICHARA; FLORES-MIR *et al.*, 2016; CAMARDELLA; BREUNING; DE VASCONCELLOS VILELLA, 2017; HACK; PATZELT, 2015) The results of the present study are in accordance with previous studies, showing an adequate intraexaminer reproducibility. In order to provide a visual representation for the dental arch size and shape treatment changes, an evaluation based on the centroid size and location was performed. (KLINGENBERG, 2016; PUGLIESE; PALOMO; CALIL; DE MEDEIROS ALVES *et al.*, 2020; WEBSTER; SHEETS, 2010) The centroid method was used in many previous studies. (KLINGENBERG, 2016; MASSARO; JANSON; MIRANDA; CASTILLO *et al.*, 2020; PUGLIESE; PALOMO; CALIL; DE MEDEIROS ALVES *et al.*, 2020; WEBSTER; SHEETS, 2010)

The initial irregularity index of maxillary anterior teeth of both groups was moderate to severe. A previous study considered an irregularity index greater than 5 as a severe incisor dealignments. (KAU; DURNING; RICHMOND; MIOTTI *et al.*, 2004; LITTLE, 1975) Both clear aligners and 2x4 mechanics produced a decrease of 5mm in the maxillary irregularity index. In other words, the efficacy of both appliances was

similar. Approximately 3mm of irregularity index was still maintained after treatment as a result of a slight dealignment between the distal aspect of lateral incisors and the mesial aspects of deciduous canines. In the partial fixes 2x4 appliances, deciduous canines were not bonded. In Clear Aligners, the degree of corrections was partially accomplished in this region. A previous study comparing clear aligners and comprehensive fixed appliances in the permanent dentitions also reported that both appliances were adequate to correct slight to moderate crowding. (KRIEGER; SEIFERTH; MARINELLO; JUNG *et al.*, 2012)

Treatment time for solving the maxillary incisor crowding was similar with both appliances. The 2x4 fixed appliance used 5 different arch wires with monthly changes. However, the .014”and .016” Nickel-Titanium arch wires were maintained more than one month in some patients with severe incisor rotations. In addition, bracket debonding was recorded in all of the 14 patients what might have an influence in treatment time of 8 months. A previous study reported a treatment time for partial fixed 2x4 appliances of 5 to 13 months. (GU; RABIE; HÄGG; ORTHOPEDICS, 2000; SINGHAL; NAMDEV; JINDAL; BODH *et al.*, 2015; SOCKALINGAM; ZAKARIA; KHAN; AZMI *et al.*, 2020) In the clear aligner planning, a mean of 10 aligners (range 6 to 14) in the treatment phase and 6 aligners in the refinement (range 3 to 8) were planned for Group CA. Considering the aligners were replaced every 15 days, a mean time of 8 months was expected. Treatment time was 8.29 months. The movement more commonly needed during refinement was rotation. Previous studies corroborate the similarity in treatment length between clear aligners and comprehensive fixed appliance in the permanent dentition. (DJEU; SHELTON; MAGANZINI, 2005; PAVONI; LIONE; LAGANÀ; COZZA, 2011) Conversely, other studies demonstrated a short treatment time for clear aligners (KUNCIO; MAGANZINI; SHELTON; FREEMAN, 2007) and for fixed appliances (LI; WANG; ZHANG, 2015).

Slight changes were noticed for the secondary outcomes in both groups without intergroup differences (Table II). These results suggest that both appliances have a similar influence on dental arch changes. Arch perimeter decrease in both groups might be related to natural changes of the late mixed dentition as the mesial movement of maxillary molars to the Leeway space. (MOORREES, 1959) Previous studies in adults showed that clear aligners can increase arch width in cases with mild or severe crowding when planned, (DUNCAN; PIEDADE; LEKIC; CUNHA *et al.*, 2016;

GRÜNHEID; GAALAAS; HAMDAN; LARSON, 2016; KRAVITZ; KUSNOTO; AGRAN; VIANA, 2008) and also is capable to maintain arch dimensions when necessary. (AKYALCIN; MISNER; ENGLISH; ALEXANDER *et al.*, 2017)

Considering the close position of maxillary canine germs to lateral incisor roots during the mixed dentition, the lateral incisor distal tip must be preserved during incisor crowding correction. (ERICSON; KUROL, 1987; ERICSON; KUROL; EPIDEMIOLOGY, 1986) Although the results showed no intergroup differences for changes in the lateral incisor angulation (Table II), opposite movements were observed in both groups. The distal angulation of maxillary lateral incisors was maintained in the FA group while a slight mesial tip was observed in CA group. A better control of lateral incisor angulation with fixed 2x4 mechanics is probably due to the passive bonding of lateral incisor brackets. On the other hand, clear aligners could not resist to the mesial angulation of lateral incisor during treatment. Previous studies demonstrated that aligners are not able to control undesired dental inclination throughout the treatment, showing that fixed appliances are better indicated for root control. (DRAKE; MCGORRAY; DOLCE; NAIR *et al.*, 2012; GRÜNHEID; GAALAAS; HAMDAN; LARSON, 2016)

The relationship between maxillary incisor edges is imperative for an adequate smile aesthetics. (MACHADO, 2014) Both groups had a mean step of 0.78mm between central and lateral incisors in accordance with previous studies. (MACHADO, 2014) Extrusion and intrusion are both difficult movements to be achieved with clear aligners. Previous studies reported a true extrusion/intrusion effect ranging from 0.72mm to 1.5mm with aligners what should have been enough in the mixed dentition for an adequate levelling of the maxillary incisors. (GU; TANG; SKULSKI; FIELDS JR *et al.*, 2017; KHOSRAVI; COHANIM; HUJOEL; DAHER *et al.*, 2017; KRIEGER; SEIFERTH; MARINELLO; JUNG *et al.*, 2012)

All patients and parents received oral hygiene orientation, toothbrushes and toothpastes in the first appointment and during treatment. Mean plaque index were similar between fixed and removable appliances before and after treatment. Differently from our results, previous studies showed that adolescents presented a higher compliance with oral hygiene when treated with clear aligners. (ABBATE; CARIA; MONTANARI; MANNU *et al.*, 2015) Speculations that aligners tended to be less

plaque accumulative (MOSHIRI; ECKHART; MCSHANE; GERMAN, 2013) was not confirmed in this study. Even with removable appliances, oral hygiene was not adequate, and a possible explanation is the sample age including subjects younger than adolescents and adults.

Despite of hygiene guidance and adequate follow-up, non-cavitated caries lesions were observed in both groups after treatment. The ICDAS index showed non-cavitated caries lesions from 0 (sound surface) to 3 (microcavity in dry enamel, without visible dentin) in both groups. Group FA presented non-cavitated caries lesion in 26% of the analysed surfaces while the group CA showed 17%. Previous studies have shown a smaller incidence of non-cavitated lesions in patients treated with clear aligners with significant difference from fixed appliances patients. (AZEEM; HAMID, 2017; BUSCHANG; CHASTAIN; KEYLOR; CROSBY *et al.*, 2019) In the present study no difference was found between both groups probably because the short treatment time compared to comprehensive treatments. The increase of non-cavitated lesions in both groups corroborate a previous study in adult patients showing that both fixed and removable appliances are capable of causing caries lesions. (ALBHAISI; AL-KHATEEB; ALHAIJA; ORTHOPEDICS, 2020)

This study was a single-centre study and conducted by one operator. The blindness of the study was not possible because of the appliance's designs. On the other hand, all data was de-identified before analysis. An important limitation of this study was the lack of information on the influence of compliance on the treatment outcome once compliance was not measured especially in the clear aligner group. Additionally, the research went through the quarantine period and 9 out of 13 patients from the fixed appliance group had appliance damage as bracket debonding. Future studies should compare family/patient self-report, pain and satisfaction with the outcomes.

Considering the similarities in the primary and secondary outcomes in this study, the appliance choice should be guided by the clinician and family preference.

4 CONCLUSIONS

4 CONCLUSIONS

The presented results of this study indicate the following conclusions:

- maxillary incisor crowding in the mixed dentition can be corrected with clear aligners and fixed partial 2x4 mechanics with similar efficacy and efficiency;
- Dental plaque and non-cavitated caries lesions index had equal incidence for both groups during treatment.

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APPENDIX

APPENDIX A – DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS

We hereby declare that we are aware of the article “” will be included in Dissertation of the student Vinicius Augustus Merino da Silva and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, January 26th, 2021.

_Vinicius Augustus Merino da Silva__ _____

Author **Signature**

_Daniela Garib_____ _____

Author **Signature**

ANNEXES

ANNEXES

ANNEX A. Ethics Committee Approval, protocol number 14962119.2.0000.5417 (front).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Comparação da eficácia e eficiência de alinhadores invisíveis na correção de apinhamento anterior na dentadura mista: um estudo clínico randomizado

Pesquisador: DANIELA GAMBA GARIB CARREIRA

Área Temática:

Versão: 2

CAAE: 14962119.2.0000.5417

Instituição Proponente: Universidade de Sao Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.518.689

Apresentação do Projeto:

O objetivo do projeto acima intitulado será comparar o conforto, higiene, eficácia e eficiência do alinhamento e nivelamento dos incisivos superiores permanentes, na fase da dentadura mista, comparando-se a mecânica convencional 4x2 e os alinhadores transparentes. Material e métodos: Uma amostra de 40 participantes de 7 e 11 anos com apinhamento primário anterior serão alocados de forma randomizada em dois grupos experimentais: grupo A - 20 participantes tratados com alinhadores invisíveis; e grupo B - 20 participantes tratados aparelho fixo parcial na mecânica 4x2. Modelos dentários digitais serão obtidos em T1 (antes do tratamento) e T2 (após a remoção dos aparelhos) e o tempo de tratamento serão contabilizados para cada grupo de estudo. Nos modelos digitais, serão mensuradas as variáveis largura, perímetro, comprimento e forma do arco dentário superior e índice de irregularidade de Little, assim como as angulações mesiodistais dos incisivos, o degrau vertical entre o 11/12 e entre o 21/22. Serão usados os índices de placa, sangramento, ICDAS e a análise quantitativa de fluorescência do esmalte serão analisados nos incisivos superiores. Um questionário com escala visual analógica será aplicado às crianças e aos responsáveis, 15 dias após a instalação e no final do tratamento para avaliar a dor, desconforto, aparência estética e facilidade de higienização. Análise dos resultados: Em análises quantitativas será usado teste de Kolmogorov-Smirnov, na comparação das alterações interfases e intergrupos, será usado respectivamente, no caso de distribuição normal, teste t pareado e t de Student, e para

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ANNEX A. Ethics Committee Approval, protocol number 14962119.2.0000.5417 (front).

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Continuação do Parecer: 3.518.689

distribuição anormal Wilcoxon e Mann-Whitney. Para variáveis qualitativas será usado teste de McNemar para variáveis interfases e teste do qui-quadrado ou teste exato de Fisher para análises intergrupos.

Objetivo da Pesquisa:
Objetivo Primário:
O objetivo deste estudo será comparar a eficácia e eficiência do alinhamento e nivelamento dos incisivos superiores permanentes, na fase da dentadura mista, comparando a mecânica convencional 4x2 e com os alinhadores invisíveis.
Objetivo Secundário:
Serão comparados conforto, higiene, aparência e tempo de tratamento no uso dos dois diferentes aparatos.

Avaliação dos Riscos e Benefícios:
Os riscos são mínimos, envolvem desconforto com o uso dos aparatos de metal do aparelho, causando, algumas vezes um desconforto no tecido mole circundante, por isso o participante será devidamente orientado, junto ao responsável, quanto ao uso de uma cera, que será oferecida ao mesmo, para coloca-la no local que está causando desconforto. Além disso, os participantes podem vivenciar uma situação de desconforto com o movimento ortodôntico, que acrescenta certa "força" nos dentes para movimentá-los, os responsáveis serão orientados que esse desconforto é apenas nos 2 primeiros dias e que o participante pode tomar qualquer analgésico que esteja acostumado. E, por último, os participantes têm uma chance de se cansarem com o tempo de atendimento, com a colagem ou adaptação das placas, por tanto, o pesquisador será responsável por fazer um atendimento rápido, de forma agradável e eficaz.

Comentários e Considerações sobre a Pesquisa:
Não há.

Considerações sobre os Termos de apresentação obrigatória:
Todos os documentos foram devidamente retificados e anexados.

Recomendações:
Não há.

Conclusões ou Pendências e Lista de Inadequações:
Referido projeto já analisado anteriormente fora considerado Pendente para que a pesquisadora adequado os riscos da pesquisa e retificasse o Termo de Assentimento.
Foram retificados os documentos de forma correta, desta forma, sou de parecer favorável a

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ANNEX A. Ethics Committee Approval, protocol number 14962119.2.0000.5417 (verse).

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Continuação do Parecer: 3.518.689

Necessita Apreciação da CONEP:
Não

BAURU, 20 de Agosto de 2019

Assinado por:
Ana Lúcia Pompéia Fraga de Almeida
(Coordenador(a))

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ANNEX B. Patient's guardian informed consent. (front)

Universidade de São Paulo
Faculdade de Odontologia de Bauru
Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

Termo de Consentimento Livre e Esclarecido (Ao responsável do menor)

O menor sob sua responsabilidade está sendo convidado a participar como voluntário da pesquisa intitulada **"Comparação da eficácia e eficiência de alinhadores invisíveis na correção de apinhamento anterior na dentadura mista: um estudo clínico randomizado"**. Essa pesquisa científica será realizada pelo dentista Vinicius Augustus Merino da Silva, Mestrando em Ortodontia na Faculdade de Odontologia de Bauru da Universidade de São Paulo, sob orientação da Profª. Drª. Daniela Gamba Garib Carreira e terá como objetivo avaliar, por meio de modelos dentários e exames intraorais, os efeitos de dois tipos de aparelhos, o nivelamento 4x2, composto por peças quadradas prateadas (braquetes) e fios ortodônticos que são colocados (fixados) nos dentes, OU os alinhadores invisíveis, que são placas de acetato (material parecido com o plástico) removíveis. Serão empregadas em participantes de 7 aos 11 anos de idade. O aparelho terá a função de corrigir (nivelar e alinhar) os dentes do arco superior (de cima), que se encontram em desarmonia. A finalidade deste aparelho será proporcionar um bom relacionamento entre os arcos dentários e a adequada posição dos dentes no sorriso. Correta higiene bucal e cuidados com alimentos duros serão importantes para a manutenção da saúde bucal e do aparelho em boas condições. Você e o menor, sob sua responsabilidade, serão orientados durante todo o tratamento sobre os cuidados necessários e sobre eventuais questionamentos.

Serão realizados no (na) participante duas moldagens das arcadas dentárias superior: uma antes e outra no final do tratamento. Serão realizados também uma série de exames intraorais: índice de placa (observar quantas regiões dos dentes estão sujas), índice de sangramento (observar se a gengiva está inflamada, sintoma de má higienização), índice ICDAS (método visual de encontrar cárie nos primeiros estágios) e o QLF, computador que irá tirar uma foto dos dentes e será possível analisar de o esmalte do dente possui ou não ação de cárie no local. Todos os testes serão realizados antes e ao final do tratamento. Por fim, durante todo o acompanhamento da terapia serão realizadas também algumas fotografias intrabucais (frontal, lateral do sorriso e oclusal) e extrabucais (frente e lateral da face), para complementar a avaliação acima descrita e aplicação de questionários. Os procedimentos citados geram um desconforto, devido ao uso do aparelho fixo ou das placas removíveis e o longo tempo de atendimento, e apresentam risco mínimo ao participante, que envolve possíveis machucados causados pelos acessórios de metal e leves e passageiros momentos de sensibilidade por conta da movimentação dentária. Para evitar o desconforto, o paciente será atendido em um ambiente agradável, com técnica de moldagem, exames rápidos e simples e uso de protetores e cera de proteção para evitar que o aparelho fixo machuque a boca, os responsáveis serão orientados quanto ao uso de analgésicos, caso seja necessário. Os procedimentos não envolvem radiação ionizante. Se acontecer algum tipo de desconforto durante qualquer um dos procedimentos, o profissional saberá como alivia-o imediatamente.

O tempo do tratamento será em torno de 6 meses a 1 ano. Todos os procedimentos clínicos serão realizados pelo próprio pesquisador responsável, na clínica de Ortodontia da Faculdade de Odontologia de Bauru, Universidade de São Paulo, com supervisão da orientadora. Ao participar desta pesquisa, o menor sob sua responsabilidade receberá como benefícios a gratuidade do planejamento ortodôntico, do tratamento das suas más oclusões (posicionamento incorreto dos dentes), do acompanhamento clínico, e, caso apresentem a necessidade de algum outro tratamento bucal, serão encaminhados para o sistema de Triagem da Faculdade de Odontologia de Bauru para serem posteriormente encaminhados a outros Departamentos. Se houver suspeita de qualquer alteração médica ou psicológica, os responsáveis serão orientados a buscar tratamento e acompanhamento adequado para o menor. Ao final do estudo, os participantes terão garantido o acompanhamento e/ou tratamento ortodôntico complementar (se necessário). Não será oferecida remuneração, auxílio para alimentação ou transporte até o local nos dias de atendimento. É garantida a indenização em casos de danos que ocorram decorrentes dos procedimentos empregados nesta pesquisa.

Após a instalação do aparelho, o participante pode sentir algum tipo de desconforto para mastigas alimentos, porém suportável, na região dos lábios e bochecha, assim como leve pressão nos dentes que serão movimentados. Os desconfortos que o (a) seu (sua) filho (a) pode sentir consistem em sensações de pressão variadas, porém suportáveis na região entre os incisivos centrais superiores (os dentes de cima e da frente). O nivelamento dos dentes é bem documentado na literatura e os riscos existentes com a realização do procedimento estudado são mínimos e limitam-se a possíveis quebras das peças metálicas e os alinhadores invisíveis removíveis são placas que exercerão uma força no dente e com o único risco de perdê-las durante o tratamento, neste caso, o pesquisador deve ser imediatamente avisado e nova placa será confeccionada sem custos para o (a) senhor (a) ou seu (sua) filho (a).

Rubrica do Participante da Pesquisa

Rubrica do Pesquisador Responsável:

Al. Dr. Octávio Pinheiro Brisolla, 9-75 – Bauru-SP – CEP 17012-901 – C.P. 73
e-mail: veragato@fob.usp.br – Fone/FAX (0xx14) 3235-8217
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ANNEX B. Patient's guardian informed consent. (verse)

Universidade de São Paulo
Faculdade de Odontologia de Bauru

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Esse tratamento requisitará muita colaboração do (a) seu (sua) filho (a) e da família, pois o sucesso da terapia somente será possível com o devido retorno para as consultas, correta utilização dos aparelhos e adequada higiene oral, conforme será orientado a vocês durante todo o tratamento.

É importante que você saiba que sua privacidade será respeitada, ou seja, o nome do seu filho (a) ou qualquer outro dado que possa, de qualquer forma, identificá-lo, será mantido em sigilo. Além disso, o menor receberá um termo como este o convidando a participar desta pesquisa e que, caso ele recuse o convite, a vontade dele será prevalecida, mesmo que o Sr(a) (pais/responsável legal) permita sua participação. O menor poderá deixar de participar da pesquisa a qualquer momento sem sofrer prejuízos, retirando, então, seu consentimento, sem precisar justificar.

O **pesquisador** envolvido com a referida pesquisa é **Vinicius Augustus Merino da Silva** e com ele você poderá manter contato via **e-mail** (vinisilva@usp.br) ou **telefone** (14) 98808-9805.

É assegurado o esclarecimento de dúvidas durante toda pesquisa, bem como será garantido o livre acesso a todas as informações e esclarecimentos adicionais sobre o estudo.

Pelo presente instrumento que atende às exigências legais, o(a) Sr.(a) _____, responsável pelo menor _____, portador da cédula de identidade _____, após leitura minuciosa das informações constantes neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus mínimos detalhes, ciente dos serviços e procedimentos aos quais será submetido, não restando quaisquer dúvidas a respeito do lido e explicado, DECLARA e FIRMA seu CONSENTIMENTO LIVRE E ESCLARECIDO concordando em participar da pesquisa proposta. Fica claro que o participante da pesquisa, pode a qualquer momento retirar seu CONSENTIMENTO LIVRE E ESCLARECIDO e deixar de participar desta pesquisa e ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas por força de sigilo profissional (Art. 9° do Código de Ética Odontológica).

Por fim, como pesquisador responsável pela pesquisa, DECLARO o cumprimento do disposto na Resolução CNS nº 466 de 2012, contidos nos itens IV.3 e IV.5.a e, na íntegra com a resolução CNS nº 466 de dezembro de 2012.

Por estarmos de acordo com o presente termo o firmamos em duas vias igualmente válidas (uma via para o participante da pesquisa e outra para o pesquisador) que serão rubricadas em todas as suas páginas e assinadas ao seu término, conforme o disposto pela Resolução CNS nº 466 de 2012, itens IV.3.f e IV.5.d.

Bauru, ____ de _____ de _____.

Vinicius Augustus Merino da Silva
Pesquisador responsável

Assinatura do responsável pelo menor

O **Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0688/FOB**), previsto no item VII da Resolução nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

Horário e local de funcionamento:
Comitê de Ética em Pesquisa
Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das **13h30 às 17 horas**, em dias úteis.
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Vila Universitária – Bauru – SP – CEP 17012-901
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ANNEX C. Patient's guardian informed consent.

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

Termo de Assentimento

Você está sendo convidado (a) a participar da pesquisa **"Comparação da eficácia e eficiência de alinhadores invisíveis na correção de apinhamento anterior na dentadura mista: um estudo clínico randomizado".**

Seu dentista será o Dr. Vinicius Augustus Merino da Silva, aqui na Faculdade de Odontologia de Bauru da Universidade de São Paulo. Se você concordar em participar, é importante que você saiba que os atendimentos serão aqui na clínica de Ortodontia (mesmo lugar onde você está sendo atendida agora) e o seu responsável (pai, mãe, vô, tio...) também será informado sobre a sua participação neste estudo.

Você vai usar aparelho nos dentinhos da frente. O aparelho vai corrigir os dentes que estão tortos e/ou fechar os espaços entres os dentes.

Durantes as consultas, vamos tirar algumas fotos dos dentes e do seu rosto. Para fazer o seu aparelho, vamos fazer uma cópia dos seus dentes de cima com uma massinha. Você vai usar UM desses dois aparelhos: ou uma plaquinha ou 4 quadradinhos cinzas, um em cada um dos 4 dentinhos da frente.

É muito importante você escovar e limpar muito bem os seus dentes e o seu aparelho. Você ficará de aparelho por mais ou menos 10 meses. Se você sentir qualquer incômodo ou desconforto (dor, vergonha, medo...), você pode me falar. Ninguém saberá que você está participando da pesquisa.

Se você tiver alguma dúvida, pode me perguntar a qualquer momento. Se você não quiser, não precisa participar da pesquisa. Não terá nenhum problema e você receberá atendimento da mesma forma. Se você não tiver o desejo de participar, pode pintar a carinha triste.

Sendo assim, após me explicarem ou ter lido e entendido todas as informações deste texto, eu, _____ aceito participar da pesquisa **"Comparação da eficácia e eficiência de alinhadores invisíveis na correção de apinhamento anterior na dentadura mista: estudo clínico randomizado"**, pintando a carinha feliz.

Entendi as coisas ruins e as coisas boas que podem acontecer.

Entendi que posso dizer "sim" e participar, mas que, a qualquer momento, posso dizer "não" e desistir. Ninguém vai ficar bravo.

Bauru, ____ de _____ de_____.

_____
Vinicius Augustus Merino da Silva
Pesquisador responsável

_____
Assinatura do menor

SIM, EU CONCORDO!

NÃO, EU NÃO CONCORDO!

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