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COMPARAÇÃO DO ALINHAMENTO DENTÁRIO INICIAL EM ADULTOS MADUROS COM ALINHADORES *INVISALIGN*® TROCADOS A CADA 7 OU 14 DIAS: ENSAIO CLÍNICO RANDOMIZADO

COMPARISON OF INITIAL DENTAL ALIGNMENT WITH *INVISALIGN*® ALIGNERS CHANGED EVERY 7 OR 14 DAYS IN MATURE ADULTS: RANDOMIZED CLINICAL TRIAL

MARINGÁ

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PRÓ-REITORIA ACADÊMICA
DIRETORIA DE PESQUISA, EXTENSÃO E PÓS-GRADUAÇÃO
PROGRAMA DE MESTRADO PROFISSIONAL EM ODONTOLOGIA

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Orientadora: Prof.ª Dr.ª Paula Cotrin

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FOLHA DE APROVAÇÃO

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Maringá, ___ de _____ de 2023.

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DEDICATÓRIA

*Agradeço a **Deus**, por tudo e por tanto sempre. Por Ele ser quem é, apesar eu ser quem sou. Não há amor maior. E meu amor por Ti é incondicional.*

*Aos meus pais, **Jorge** e **Rita Fialho**, por tudo e por tanto sempre. Pelo apoio e incentivo. Pela preocupação e pelo cuidado. Pelo amor que sempre será recíproco. Vocês são tudo para mim.*

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RESUMO

RESUMO

Objetivo: O objetivo deste estudo foi comparar a correção do apinhamento anterior após o uso sequencial dos 5 primeiros alinhadores entre dois protocolos de troca de alinhadores (7 e 14 dias) em pacientes adultos maduros. **Material e Métodos:** trinta e seis pacientes com idade superior a 35 anos que receberam tratamento ortodôntico com *Invisalign*® foram alocados aleatoriamente em dois protocolos de sequência de troca de alinhadores diferentes: Grupo 1: troca a cada 7 dias (n=18); e Grupo 2: troca a cada 14 dias (n=18). Todos os pacientes foram escaneados intraoralmente com *iTero Element 5D*® (*Align Technologies*, San José, CA, EUA) em dois períodos: no início do tratamento (T1) e após o uso dos 5 primeiros alinhadores (T2). O Índice de Irregularidade de Little e as larguras dos arcos foram avaliados com o software *OrthoCAD*. As comparações intra e intergrupos foram realizadas aplicando-se respectivamente os testes t dependente e independente. Os resultados foram considerados significativos para p<0,05. **Resultados:** Trinta e cinco pacientes completaram o tratamento no período avaliado. O índice de irregularidade superior e inferior apresentaram-se significativamente menores em T2 em ambos os grupos. O G2 (14 dias) demonstrou uma maior diminuição no índice de irregularidade inferior quando comparado ao G1 (7 dias). **Conclusão:** Ambos os protocolos de troca (7 e 14 dias) foram eficazes para a correção do apinhamento anterior na fase inicial do tratamento ortodôntico com alinhadores em pacientes adultos maduros. No entanto, o protocolo de troca a cada 14 dias proporcionou uma maior correção no apinhamento anteroinferior no período avaliado do que o protocolo de troca a cada 7 dias.

Palavras-chave: Má oclusão. Aparelhos Ortodônticos Removíveis. Técnicas de Movimentação Dentária.

ABSTRACT

ABSTRACT

Comparison of initial dental alignment with *Invisalign*® aligners changed every 7 or 14 days in mature adults: Randomized Clínical Trial

Objective: To compare the anterior crowding correction after sequential use of the first 5 aligners between two aligner exchange protocols (7 and 14 days) in mature adult patients.

Material and Methods: Thirty-six patients over 35 years who received orthodontic treatment with Invisalign® were randomly allocated to two different aligner replacement sequence protocols: Group 1: exchange every 7 days (n=18); and Group 2: exchange every 14 days (n=18). All patients were scanned with iTero Element 5D® (Align Technologies, San José, CA, USA) in two treatment times: at pretreatment (T1) and after using the first 5 aligners (T2). Little's Irregularity Index and arch widths were evaluated with OrthoCAD software. Intra and intergroup comparisons were performed with the dependent and independent t-tests respectively. The results were considered significant for $p<0.05$.

Results: Thirty-five patients completed the study. The maxillary and mandibular irregularity index were significantly lower at T2 in both groups. There was no significant difference in intercanine, interpremolar, and intermolar distances. G2 (14 days) presented a greater decrease in mandibular irregularity than G1 (7 days).

Conclusion: Both exchange protocols (7 and 14 days) effectively correct anterior crowding in the initial phase of orthodontic treatment with aligners in mature adult patients. However, the 14 days exchange protocol provided a greater correction in mandibular anterior crowding in the evaluated period than the 7 days exchange protocol.

Keywords: Malocclusion. Orthodontic Appliances, Removable. Tooth Movement Techniques.

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CAT   Clear Aligner Therapy

IPR   Interproximal Reduction

SUMÁRIO

1 INTRODUÇÃO

1 INTRODUÇÃO

Nos últimos anos, a demanda por tratamentos ortodônticos em adultos tem crescido exponencialmente.(CEDRO; MOLES; HODGES, 2010; PABARI; MOLES; CUNNINGHAM, 2011; MCMORROW; MILLETT, 2017; LEE *et al.*, 2018) De acordo com Keim *et al.*(KEIM *et al.*) o número de pacientes ortodônticos adultos nos Estados Unidos aumentou de 15,4% para 23% entre 1981 e 2013. Em países asiáticos, a taxa de pacientes adultos também dobrou entre 2008 e 2012.(PIAO *et al.*, 2016) Não há dados semelhantes para o Brasil, mas é provável que este número seja semelhante ou até maior em nosso país, visto que temos um número maior de ortodontistas e um acesso mais facilitado a tratamentos ortodônticos do que em grande parte do mundo.

A melhora da estética do sorriso e dentes mais alinhados são dois dos principais motivos que levam pacientes adultos a procurarem por tratamentos ortodônticos.(LEE *et al.*, 2018; CHOW *et al.*, 2020) Além disso, os pacientes adultos também têm preferência por tratamentos que sejam mais estéticos e confortáveis. Neste sentido, alinhadores ortodônticos não apenas preenchem esses fatores como também são mais práticos na higienização e alimentação.(ADOBES-MARTIN *et al.*, 2021; MARAÑÓN-VÁSQUEZ *et al.*, 2021)

Os alinhadores ortodônticos invisíveis estão a cada dia tornando-se uma realidade tanto para os ortodontistas quanto para os pacientes. O nível de exigência destes tem aumentado, especialmente quando sabem que existe uma opção mais estética, discreta e prática no dia a dia.(ALAJMI; SHABAN; AL-AZEMI, 2020) O conceito dos alinhadores ortodônticos surgiu em 1945 criado por Kesling, denominado *Tooth Positioning Appliance*®.(KESLING, 1945) Em seu artigo, Kesling relatou a utilização do primeiro conceito de alinhadores, onde recortava nos modelos de gesso os dentes individualmente e os reposicionava na posição considerada ideal. A partir desse reposicionamento, confeccionava uma placa com uma borracha flexível que envolvesse tanto dentes superiores quanto inferiores, e seu uso constante pelo paciente resultava no reposicionamento dos dentes no arco.(KESLING, 1945) Em 1946 este mesmo autor publicou outro artigo detalhando

como preparar os modelos de gesso para a confecção de seu aparelho.(KESLING, 1946)

Vários autores nos anos seguintes publicaram estudos avaliando o aparelho desenvolvido por Kesling, demonstrando suas indicações, vantagens e desvantagens.(ELSASSER, 1950; VORHIES, 1960; BUNCH, 1961; WELLS, 1970) Anos depois, em 1998 a *Align Technology* desenvolveu o primeiro modelo de alinhadores comerciais baseados nos princípios de Kesling: *o Invisalign®*.(WONG, 2002; NEDWED; MIETHKE, 2005; HAOUILI *et al.*, 2020) Este modelo de alinhador foi desenvolvido como um sistema que utiliza do método CAD/CAM para o planejamento e confecção de uma sequência de alinhadores termoplásticos que realizam a movimentação dentária. Inicialmente ele foi preconizado para adultos que necessitavam de correções no alinhamento dentário.(HAOUILI *et al.*, 2020) Com o passar dos anos, essa tecnologia foi sendo aprimorada, aumentando progressivamente a capacidade de tratamento para mecânicas mais complexas, e também abrangendo pacientes com dentadura mista, o que ampliou as possibilidades de uso desses alinhadores.(HAOUILI *et al.*, 2020)

Alguns movimentos dentários apresentam bons resultados com esses dispositivos. Inclinações anteroposteriores (vestibular e palatina ou lingual), expansões dentárias de maxila, fechamentos de diastemas e melhoras dos contatos dentários interproximais são movimentos com boa previsibilidade.(HAOUILI *et al.*, 2020; MORALES-BURRUEZO *et al.*, 2020; PATTERSON *et al.*, 2021) Contudo, movimentos como rotação dentária, intrusão e extrusão de incisivos são tidos como movimentos difíceis de serem obtidos apenas com alinhadores, gerando grandes desafios para os ortodontistas.(HAOUILI *et al.*, 2020; KASSAM; STOOPS, 2020)

O protocolo atual de uso dos alinhadores *Invisalign*® é de 20 a 22 horas por dia, trocados a cada 7 dias.(AL-NADAWI *et al.*, 2021) No entanto, a recomendação inicial era de troca a cada 14 dias, e ainda hoje há muitos ortodontistas que seguem essa prescrição inicial da empresa.(AL-NADAWI *et al.*, 2021) Essa alteração de protocolo aconteceu devido à mudança no plástico usado para a confecção dos alinhadores, substituindo o Essix 30® pelo atual *SmarTrack*®, e esse novo material emprega uma tecnologia mais avançada que o anterior.(BRÄSCHER *et al.*, 2016) Devido a esses diferentes protocolos usados para alinhadores, não existe ainda um

consenso quanto ao tempo de uso de cada alinhador por parte do paciente para a obtenção dos resultados pretendidos no planejamento. Recentemente, Al-Nadawi *et al.* (AL-NADAWI *et al.*, 2021) compararam a eficácia da movimentação ortodôntica com 3 protocolos de troca de alinhadores: a cada 7, 10 e 14 dias. Os autores concluíram que as alterações clínicas conseguidas foram semelhantes para os protocolos de 7 e 14 dias, sugerindo que a troca a cada 7 dias pode ser aceitável, embora os mesmos também afirmem que para movimentos mais complexos de dentes posteriores a troca a cada 14 dias também seja recomendada.

É interessante notar que, apesar da tendência de pacientes mais velhos procurarem por atendimento, há uma lacuna de estudos conduzidos especificamente nesta faixa etária. Geralmente, os estudos em adultos apresentam amostras com idade média que varia de 25-40 anos, sendo difícil identificar estudos com médias de idades mais elevadas.(LEE *et al.*, 2018; CHOW *et al.*, 2020; AL-NADAWI *et al.*, 2021) Sabendo que a melhor taxa de movimentação ocorre na primeira semana de uso do alinhador, e que a segunda semana de uso apresenta baixa movimentação devido à fadiga do material, é necessário conhecer se isso também se aplica a pacientes mais velhos. (BOLLEN *et al.*, 2003; AL-NADAWI *et al.*, 2021) Baseado nessas informações, há uma lacuna na literatura sobre qual seria o tempo mínimo ideal de uso dos alinhadores para que estes consigam chegar ao planejamento programado. Dada a presença cada vez maior de pacientes adultos que procuram por tratamentos ortodônticos estéticos, também é necessário avaliar como os alinhadores ortodônticos atuam em pacientes mais velhos.

Ambos os protocolos (7 e 14 dias) são efetivos para o tratamento ortodôntico, mas não há literatura nenhum trabalho avaliando qual seria mais efetivo para a correção do apinhamento anterior em pacientes adultos maduros. Baseado nessas informações, o objetivo deste trabalho é testar a hipótese nula de que não existe diferença na correção do apinhamento anterior em pacientes adultos maduros durante o uso dos 5 primeiros alinhadores ortodônticos.

2 ARTIGO

2 ARTIGO

O artigo apresentado foi escrito de acordo com as normas do periódico American Journal of Orthodontics and Dentofacial Orthopedics (Anexo 1).

Comparison of initial dental alignment with Invisalign® aligners changed every 7 or 14 days in mature adults: Randomized Clinical Trial

ABSTRACT

Objective: To compare the anterior crowding correction after sequential use of the first 5 aligners between two aligner exchange protocols (7 and 14 days) in mature adult patients.

Material and Methods: Thirty-six patients over 35 years who received orthodontic treatment with Invisalign® were randomly allocated to two different aligner replacement sequence protocols: Group 1: exchange every 7 days (n=18); and Group 2: exchange every 14 days (n=18). All patients were scanned with iTero Element 5D® (Align Technologies, San José, CA, USA) in two treatment times: at pretreatment (T1) and after using the first 5 aligners (T2). Little's Irregularity Index and arch widths were evaluated with OrthoCAD software. Intra and intergroup comparisons were performed with the dependent and independent t-tests respectively. The results were considered significant for p<0.05.

Results: Thirty-five patients completed the study. The maxillary and mandibular irregularity index were significantly lower at T2 in both groups. There was no significant difference in intercanine, interpremolar, and intermolar distances. G2 (14 days) presented a greater decrease in mandibular irregularity than G1 (7 days).

Conclusion: Both exchange protocols (7 and 14 days) effectively correct anterior crowding in the initial phase of orthodontic treatment with aligners in mature adult patients. However, the 14 days exchange protocol provided a greater correction in mandibular anterior crowding in the evaluated period than the 7 days exchange protocol.

Trial Registration: The trial was registered at ensaiosclinicos.gov.br, REBEC (number: RBR-6y2wtnd). **Protocol:** The protocol was not published before trial commencement. **Funding:** There are no fundings to declare.

Keywords: Malocclusion. Orthodontic Appliances, Removable. Tooth Movement Techniques.

INTRODUCTION

Clear aligner therapy (CAT) is a reality in the routine of orthodontists today. Especially adult patients have sought this system not only for comfort and esthetics but also because the patient perceives it as a faster treatment compared to fixed appliances.[1] However, it is known that the supposedly faster treatment with aligners is not related to the quality of treatment.[2,3]

One point that has been under-evaluated is the effectiveness of aligners according to the sequential aligner replacement timing protocol. The oldest protocol, recommended by the manufacturer of Invisalign® aligners (Align Technologies, San Jose, CA, USA) when it was commercially launched in 1998, was to use each aligner for 20-22 hours a day and change the sequential aligners every 14 days.[3,4]

In 2013, Align Technology® launched a new material for its aligners, called SmartTrack®, which replaced the material used until Exceed 30®.[5-7] According to the manufacturer, this new material presented greater translucency, flexibility, better adaptation to the dental arch, and greater consistency in the applied forces. The company began to indicate the change of aligners in a new time protocol every 7 days, which would make the treatment faster.[6] This is because most orthodontic movement occurs within the first week of wearing the aligner; therefore, the use for 2 weeks would be unnecessary.[8]

The demand for orthodontic treatment has significantly increased in recent decades, rising from 15.4% to 23% between 1981 and 2013 in the United States.[9] In Asian countries, the rate of older adult patients (over 40 years) also doubled between 2008 and 2012.[10] Mature adult patients have different treatment characteristics than younger patients, such as bone loss or periodontitis. These factors may require a different approach to the use and replacement of aligners.[11] Recently, a more esthetic orthodontic treatment has been the primary pursuit of adult patients.

Orthodontic aligners fulfill this factor and are more practical in cleaning and feeding.[1] Studies have sought to assess the efficiency alignment correction in different protocols for changing aligners, but all have analyzed patients with a mean age between 30 and 35 years.[4,12] To the best of our knowledge, no studies evaluated different aligner exchange protocols in mature adult patients..

The question of which protocol is most efficient remains unclear. New studies have been published comparing these periods. Still, most of them evaluate specific movements, such as intrusion, extrusion, and rotation, or the adaptation of attachments to aligners in these time protocols, or even young adult patients, with an average age of up to 35 years.[3,4,13] Based on this, the objective of the present study is to test the null hypothesis that there is no difference in the anterior alignment correction in mature adult patients with a 7-days and 14-days aligner changes protocol in the initial phase of orthodontic treatment with CAT.

MATERIAL AND METHODS

Trial design and any changes after trial commencement

This study is a single-center randomized clinical trial with 2 parallel arms and a 1:1 allocation ratio. The Research Ethics Committee approved this prospective study of the Centro Universitário Ingá – Uningá (CAAE: 51030921.3.0000.5220), Protocol number 4.945.082. This study was also submitted to the Brazilian Registry of Clinical Trials (REBEC), approved with the identifier UTN U1111-1281-8045.

Sample size calculation

The sample size calculation was based on an alpha significance level of 5% (0.05) and a beta of 20% (0.2), to detect a minimum difference of 1.25 mm with a deviation standard of 0.98 for the Little's Irregularity Index.[14] Sample size calculation indicated a minimum need for 11 individuals in each group.

Participants, eligibility criteria, and settings

This study was conducted from 2021 to 2022, and recruitment occurred at a Private Practice in Gramado, RS. The eligibility criteria included patients of both sexes aged 35 years or older, with complete permanent dentition, good periodontal health, and mild to moderate Little's irregularity index. Patients with previous orthodontic treatment, incisor agenesis, teeth loss (except third molars), or indication of premolar extraction for orthodontic purposes were excluded. Patients who met the inclusion criteria were invited to participate, and informed consent was obtained from all patients.

All patients in the sample were treated with Invisalign® orthodontic aligners with SmartTrack material. The Clincheck were all made by the same professional (TF). Both groups used no intermaxillary elastic or dental ramps during the first five aligners. In addition, no interproximal reduction (IPR) was made and attachments were placed when required. Also, all aligners had the Compliance Indicator, so it was possible to confirm if the patient used it properly. Each patient had their ClinCheck modified by the primary researcher to achieve the best possible clinical results[15] and was randomly divided into a 1:1 allocation into 2 groups:

Group 1 (G1 – 7 days) comprised 18 (5 men, 13 women) patients who changed the first five prescribed aligners every 7 days. The mean initial age was 50.80 (12.03) years. The mean initial maxillary and mandibular Irregularity index were 6.04 (1.71) and 5.28 (2.10), respectively. The mean maxillary intercanine, inter second premolar, and inter-first molar distances were 34.0 (1.92), 42.21 (2.30), and 50.20 (2.70) mm respectively. The mean mandibular intercanine, second inter premolar, and first intermolar distances were 25.88 (1.32), 35.60 (2.87), and 45.64 (4.28) mm, respectively.

Group 2 (G2 – 14 days) comprised 18 (8 men, 10 women) patients who changed the first five prescribed aligners every 14 days. The mean initial age was 55.68 (7.83) years. The mean initial maxillary and mandibular Irregularity index were 6.41 (1.54) and 6.06 (2.28), respectively. The mean maxillary intercanine, second inter premolar, and first intermolar distances were 34.0 (1.94), 43.38 (3.33), and 52.47 (4.08) mm respectively. The mean mandibular intercanine, second inter premolar, and first intermolar distances were 27.35 (1.50), 36.71 (3.24), and 46.43 (3.00) m,m respectively.

As part of the treatment planning for the preparation and the monitoring of treatment changes, the patients underwent digital intraoral scanning. The intraoral

scanning was performed in 2 treatment times: at pretreatment (T1) and after using the first five aligners (T2). The Intraoral Scanner was the iTero Element 5D® (Align Technologies, San Jose, CA, USA). The images obtained from the scans were stored in a digital database available to the leading researcher.

Blinding was not possible because the operator and patients knew the days the aligners were changed, but blinding was performed at the time of measurements. The primary outcome was maxillary and mandibular irregularity index, and secondary outcomes included arch widths.

After performing the second scanning, all files were uploaded into the OrthoCAD® software (Align Technologies, San Jose, CA, USA). The following measurements were obtained from maxillary and mandibular arches:

- Little irregularity index (Figure 1): The linear displacement of the five anatomical contact points of the anterior teeth in the horizontal occlusal plane[16,17]
- Intercanine distance (Figure 2 – blue lines): the linear distance between the cusp tip of the right canine to the contralateral one[16]
- Inter premolar distance (Figure 2 – green lines): the linear distance between the buccal cusp tip of the right second premolar to the contralateral one[16]
- Inter molar distance (Figure 2 – magenta lines): the linear distance between the mesiobuccal cusp tip of the first molar to the contralateral one[16]

Error study

The method error was calculated by remeasuring 30% of digital files, regardless of whether they were initial or final, with a time interval of 30 days. Random error was determined using Dahlberg's formula. To calculate the systematic error, the paired t test was used with a significance level of 5% ($P<0.05$).

Statistical analyses

The normality of the data was checked with the Shapiro-Wilk test.

The intergroup comparability of sex distribution was performed with the chi-square test.

Independent t-tests performed the intergroup comparability of the ages at T1.

Dependent t-tests performed the intragroup comparison of the Little Irregularity index and the arch widths

The intergroup comparisons of all variables studied at the 2 stages evaluated (T1 and T2) were performed with independent *t-tests*.

All statistical analyses were performed using the Statistica for Windows software (version 10.0; StatSoft, Tulsa, Okla) at P <0.05.

RESULTS

Participants flow

During recruitment, 72 patients were assessed for eligibility; 36 were excluded for not meeting the inclusion criteria. Thirty-six patients were randomized in a 1:1 ratio and 35 received the interventions according to the group allocation (Figure 3). One patient moved to another city after allocation and did not undergone the orthodontic treatment.

Baseline data

Baseline characteristics were similar regarding age and sex distribution (Table I).

Numbers analyzed for each outcome, estimation, and precision, subgroup analyses

The random errors varied from 0.09 (maxillary and mandibular Little irregularity index) to 0.32 (maxillary intercanine width). There were no significant systematic errors.

The groups were comparable at T1 regarding age, gender, maxillary and mandibular Little irregularity index, and maxillary and mandibular intercanine, inter premolar, and intermolar widths (Table I).

There was no statistically significant difference between the groups in Little's Irregularity Index and the interdental on T2 (Table II)

The maxillary and mandibular Little irregularity index were significantly corrected with treatment at T2 in both groups (Table III).

The mandibular Little irregularity index showed a statistically greater correction in the 14 days group (Table IV).

Harms

No significant harm was observed in the patients of this study, such as debonded attachments. Some patients reported slight discomfort in the cheeks and lips while using the first aligners. However, nothing would affect their use. All aligners were discarded after the patient's usage.

DISCUSSION

It is impossible to state that orthodontic appliances produce a 100% expression of prescribed movements.[15-17] Studies on crowding solving show that the correction of moderate mandibular anterior crowding takes an average 90 days, while the correction of severe crowding takes an average of 117 days.[18-20] Due to this relatively short time needed for correction, and to the good periodontal health condition of the patients, we decided to evaluate the changes that occurred with the first 5 aligners, which would already give us an idea of   the efficacy of the chosen exchange regimens. Moreover, due to the short time evaluated, the initial malocclusion type was not considered. The objective of this study was to compare the correction of anterior crowding in 2 aligner exchange protocols during the first 5 aligners and not to evaluate the total correction of malocclusion from pre to posttreatment..

All patients had their Clincheck planned by the same orthodontist (TF). For the first five aligners only alignment and expansion were planned, and the movement was limited to 0.25 mm per aligner.[21]

In this study, we call a mature adult a patient over 35 years, and this term is used in other orthodontics studies.[22,23] This population has its characteristics, such as

a higher incidence of periodontal problems and bone loss, which require greater attention from the orthodontist and knowledge of these particularities.[24,25] Specific periodontal characteristics of adults favor the formation of hyaline zones, leading to slower initial movements in this age group between 8 to 10 days, while it takes only 2 to 3 days in young people. However, after 4 weeks, the adult periodontal tissue reaches the optimal stage of proliferation, so the second phase of movement equals speed.[26] This leads to the understanding that orthodontic movement will happen the same way in older patients, but its onset will be slower.

An essential factor to consider is the amount of crowding being treated. Severe crowding above 6 mm will undoubtedly need different mechanics from the simple use of aligners for its correction, not being the objective of this study.[27] In addition, solving of crowding is a treatment process in which both initial and final stages can be easily determined with the irregularity index, and measurements can be made regardless of tooth inclination or rotations.[19] Commonly, the irregularity index is measured with a digital caliper.[28,29]. Recently, with the advent of digital models, these measurements can also be made using software such as the Orthoanalyzer.[30,31] In the present study, the irregularity index and the arch widths were assessed with the *OrthoCad* software. Kau *et al*.[32] also evaluated the irregularity index with the *OrthoCad* and concluded that this software is accurate.

The groups were comparable at pretreatment regarding age, sex, Irregularity index, and arch widths, validating the random assignment of patients to each group. The null hypothesis was partially accepted in the present study. The results of this study suggest that, overall, both aligner exchange regimens (7 or 14 days) correct anterior crowding with the first 5 prescribed aligners (Tables I and II). However, the 14-days use regimen provided a greater correction of mandibular anterior crowding than the 7-days group (Table III). These results are consistent with some studies, which demonstrate no statistically significant difference when comparing aligner change periods.[3,4] When the alignment and the crowding correction were evaluated, it was shown that most of the movement performed by the aligners happens in the first week of use, which would make use for 2 weeks, in most cases, unnecessary.[8] This information could not be corroborated in this study. However, another study evaluated which protocol for wearing the aligners (3, 7, 10 or 15 days) would be the most suitable for them to have an effective adjustment with the attachments, leading to the complete movement proposed in the planning.[3] The result showed that only

the protocol of 14 days of use of the aligners could faithfully adjust the aligners with the attachments, concluding that this protocol would be ideal, at least for more complex cases that require greater tooth movement. Moreover, the analysis by Al-Nadawi, M *et al.* [4] demonstrates that the 7-days protocol is efficient in orthodontic treatment but that the 14-days protocol presented better results for complex orthodontic movements and movements of posterior teeth.

The 14-days use regimen provided a greater correction of mandibular anterior crowding than the 7-days group (Table III). This shows a greater decrease in the irregularity index in the mandibular arch when using the 14-days protocol for changing the aligners. This greater crowding correction in the 14-days group in mandibular teeth is in agreement with the study by Giannopoulou *et al.*[33], which demonstrates that orthodontic movements in the mandibular arch tend to occur more slowly than in the upper arch. Based on this, it can be inferred that when the patient has a greater amount of lower crowding, the 14-days protocol for changing the aligners would be more indicated, as this will allow the slower movement of the mandible to be monitored, leading to better results. One also can say that this 14-days protocol also leads to a better fit of the aligner to the attachments, which consequently improves the quality of the desired alignment.[3]

There was no statistically significant difference in the intercanine, inter second premolar, and first intermolar distances in all stages evaluated (Tables II, III, and IV). This probably occurred due to the short treatment time evaluated. The treatment time evaluated may not have been sufficient to produce significant changes in these variables. Studies with longer treatment times show changes in the transverse measurements of arches with aligners, regardless of the exchange regime used.[34-36]

Limitations and generalizability:

The generalizability of these results is limited because this is a single-center study, making it difficult to generalize to a more heterogeneous population. Future studies should verify, in a more diverse population, the alignment correction in mature adults using aligners.

Clinical implications:

The results of the present study indicate that both protocols (7 and 14 days) are efficient for correcting crowding in mature adult patients. However, the 14-days protocol proved more efficient for mandibular alignment correction. This is important for orthodontists because they can prescribe the exchange regimen of the CAT according to the initial severity of the crowding, always aiming to provide the most efficient orthodontic treatment possible for mature adult patients. Further studies are needed in similar groups to assess other orthodontic movements.

CONCLUSION

- The 7-days and 14-days protocols were effective in correcting anterior crowding in mature adults in the initial stage of orthodontic treatment with clear aligner therapy
- The 14-days protocol provided a greater correction in the mandibular anterior crowding in the initial stage of orthodontic treatment with clear align therapy

Acknowledgements

We would like to thank all patients for participating and making this study possible.

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Conflict of interest

None to declare.

Data availability

The data underlying this article will be shared on a reasonable request to the corresponding author

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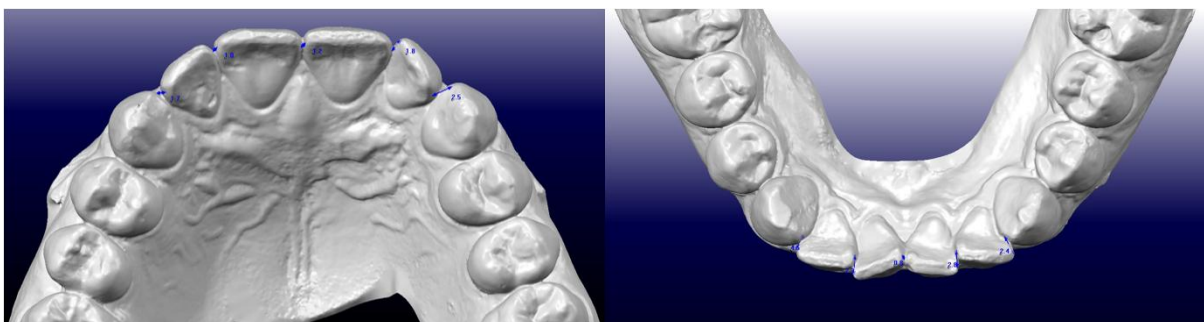
LISTA DE FIGURAS

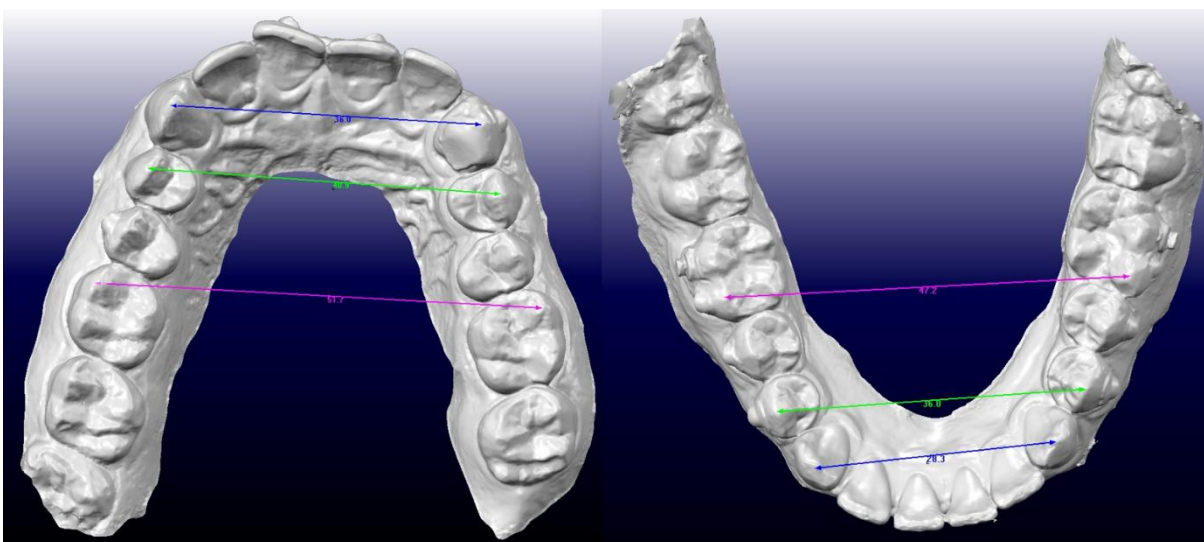**Figure 1** – Little irregularity index

Figure 2 – Intercanine distance (blue lines), Inter premolar distance (green lines) and Inter molar distance (magenta)
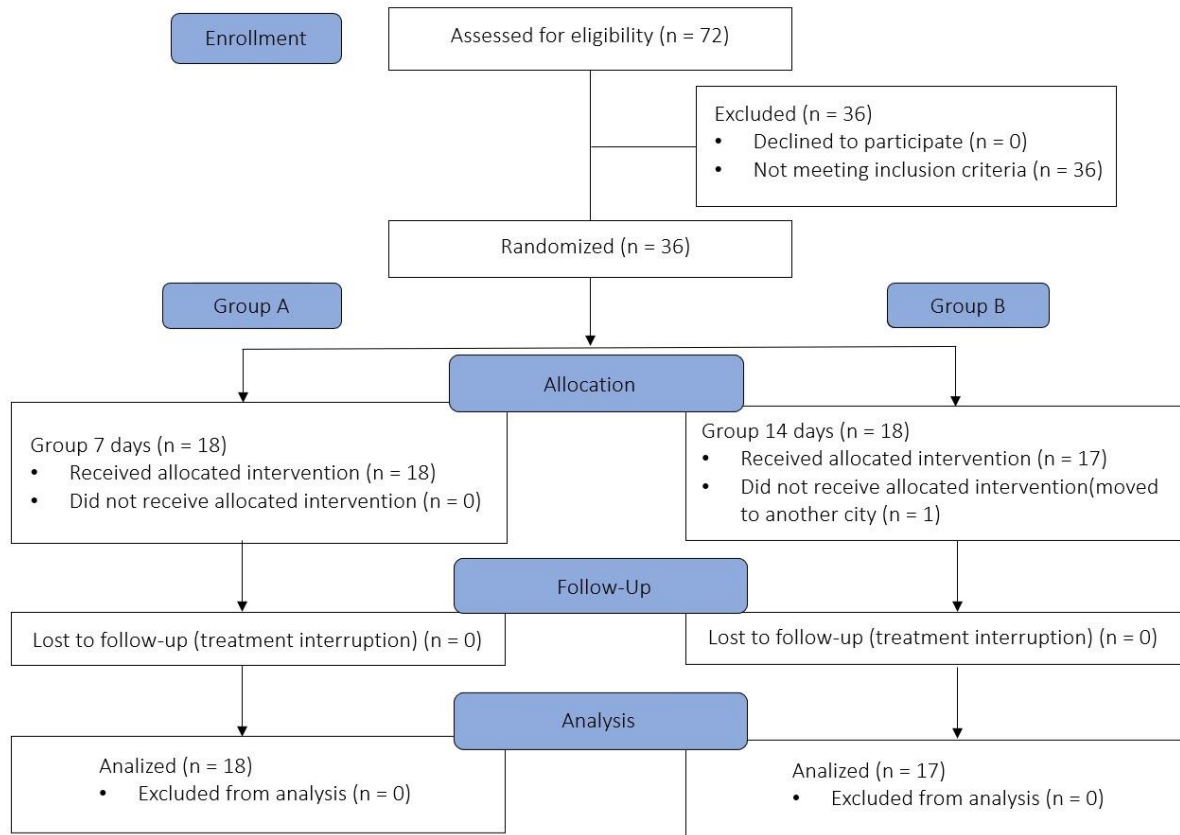
Figure 3 – CONSORT diagram showing patient flow

LIST OF TABLES

Table I. Intergroup comparison of the initial phase

Variables	7-days (n = 18) Mean (SD)	14-days (n = 17) Mean (SD)	p
Initial age (years)	50.80 (12.03)	55.68 (7.83)	0.167 [T]
Gender			$X^2=1,39$
Male	5	8	DF=1
Female	13	9	p=0.238 [α]
Mx Little (mm)	6.04 (1.71)	6.41 (1.54)	0.783 [T]
Mx 3-3 width (mm)	34.00 (1.92)	35.00 (1.94)	0.765 [T]
Mx 5-5 width (mm)	42.21 (2.30)	43.38 (3.33)	0.439 [T]
Mx 6-6 width (mm)	50.20 (2.70)	52.47 (4.08)	0.325 [T]
Md Little (mm)	5.28 (2.10)	6.06 (2.28)	0.391 [T]
Md 3-3 width (mm)	25.88 (1.32)	27.35 (1.50)	0.250 [T]
Md 5-5 width (mm)	35.60 (2.87)	36.71 (3.24)	0.778 [T]
Md 6-6 width (mm)	45.64 (4.28)	46.53 (3.00)	0.747 [T]

[T] independent t-test; [α] chi-square test

Table II. Intergroup comparison of T2 phase (independent t-test).

Variables (mm)	7-days (n=18)		14-days (n=17)		p
	Mean	SD	Mean	SD	
Mx Little	4.28	0.80	4.94	1.34	0.085
Mx 3-3 width	34.02	1.81	34.65	1.93	0.700
Mx 5-5 width	42.33	2.37	43.35	2.55	0.790
Mx 6-6 width	51.26	4.05	51.24	4.25	0.636
Md Little	3.91	2.11	3.82	1.29	0.696
Md 3-3 width	26.11	1.48	27.53	1.28	0.613
Md 5-5 width	35.44	2.59	36.47	2.09	0.563
Md 6-6 width	45.02	4.49	46.76	3.58	0.438

[T] independent t-test

Table III. Intragroup comparison between T1 and T2 phases (dependent t-test).

Variables (mm)	T1		T2		p
	Mean	SD	Mean	SD	
7 DAYS					
Mx Little	6.04	1.71	4.28	0.80	**0.000***
Mx 3-3 width	34.00	1.92	34.02	1.81	0.929
Mx 5-5 width	42.21	2.30	42.33	2.37	0.567
Mx 6-6 width	50.20	2.70	51.26	4.05	0.422
Md Little	5.28	2.10	3.91	2.11	**0.000***
Md 3-3 width	25.88	1.32	26.11	1.48	0.235
Md 5-5 width	35.60	2.87	35.44	2.59	0.640
Md 6-6 width	45.64	4.28	45.02	4.49	0.200
14 DAYS					
Mx Little	6.41	1.54	4.94	1.34	**0.000***
Mx 3-3 width	35.00	1.94	34.65	1.93	0.195
Mx 5-5 width	43.88	3.33	43.35	2.55	0.175
Mx 6-6 width	52.47	4.08	51.24	4.25	0.420
Md Little	6.06	2.28	3.82	1.29	**0.000***
Md 3-3 width	27.35	1.50	27.53	1.28	0.659
Md 5-5 width	36.71	3.24	36.47	2.09	0.397
Md 6-6 width	46.53	3.00	46.76	3.58	0.915

* Statistically significant for $p < 0.05$

Table IV. Intergroup comparison of changes with treatment (T2-T1) (independent t-test).

Variables (mm)	7 days (n = 18)		14 days (n = 17)		p
	Mean	**SD**	**Mean**	**SD**	
Mx Little	-1.76	1.29	-1.71	1.26	0.957
Mx 3-3 width	0.02	1.04	-0.25	1.05	0.790
Mx 5-5 width	0.12	0.89	-0.39	1.45	0.217
Mx 6-6 width	1.06	5.44	-1.21	5.74	0.373
Md Little	-1.37	0.51	-2.29	1.40	**0.000***
Md 3-3 width	0.23	0.79	0.21	1.38	0.068
Md 5-5 width	-0.16	1.39	-0.29	1.68	0.459
Md 6-6 width	-0.62	1.98	0.53	3.12	0.307

* Statistically significant for p<0.05

3 Considerações Finais

3 CONSIDERAÇÕES FINAIS

Com este estudo pôde-se observar que a correção do apinhamento inicial em pacientes adultos maduros usando alinhadores *Invisalign*® ocorre satisfatoriamente com ambos os protocolos de troca avaliados, de 7 e 14 dias.

No entanto, quanto mais complexo for o apinhamento, em especial no arco inferior, o protocolo de troca a cada 14 dias mostrou-se mais eficiente para o alinhamento, sugerindo que um apinhamento severa demanda mais tempo de uso de cada alinhador para a correta correção proposta.

Acredita-se ser interessante o desenvolvimento de mais pesquisas semelhantes, avaliando outros movimentos ortodônticos em pacientes da mesma faixa etária.

4 RELEVÂNCIA E IMPACTO DO TRABALHO PARA A SOCIEDADE

4 RELEVÂNCIA E IMPACTO DO TRABALHO PARA A SOCIEDADE

Este trabalho acrescenta ao ortodontista o conhecimento de que a troca dos alinhadores a cada 14 dias se mostra mais eficiente para pacientes adultos acima dos 35 anos. Mesmo que o tempo do tratamento se estenda nesse protocolo, o resultado do alinhamento será mais adequado para atingir os objetivos traçados no planejamento, garantindo um bom resultado final e a satisfação do paciente.

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ANEXOS

AN

Guidelines for Randomized Clinical Trials

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EXO 1

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Provide an adequate background so readers can understand the nature of the problem and its significance. State the objectives of the work. Cite literature selectively, avoiding a detailed literature survey or a summary of the results.

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Results

Results should be clear and concise.

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Explain your findings and explore their significance. Compare and contrast your results
Conclusions

Write a short Conclusions section that can stand alone. If possible, refer back to the goals or objectives of the research.

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Abstract

A structured abstract using the headings Introduction, Methods, Results, and Conclusions is required for Original Article, Systematic Review, Randomized Controlled Trial, and Techno Bytes. An unstructured abstract is acceptable for Case Report and Clinician's Corner.

Graphical abstract

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view Example Graphical Abstracts on our information site.

Acknowledgments

Collate acknowledgments in a separate section at the end of the article before the references; do not include them on the title page, as a footnote to the title page, or otherwise. List here those individuals who provided help during the research (eg, providing help with language or writing assistance, or proofreading the article).

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

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

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• Number the illustrations according to their sequence in the text.
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• Size the illustrations close to the desired dimensions of the published version.
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TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings, keep to a minimum of 1000 dpi.
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As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

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3. Mettam GR, Adams LB. How to prepare an electronic version of your article. In: Jones BS, Smith RZ, editors. Introduction to the electronic age. New York: E-Publishing Inc; 2009. p. 281-304.
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ANEXO 2 - Aprovação do comitê de ética em pesquisa.

FACULDADE INGÁ /
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PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: COMPARAÇÃO DA EFICIÊNCIA DO ALINHAMENTO DENTÁRIO COM USO DE ALINHADORES INVISALIGN TROCADOS A CADA 7 OU 14 DIAS
Pesquisador: Karina Maria Salvatore de Freitas
Área Temática:
Versão: 1
CAAE: 51030921.3.0000.5220
Instituição Proponente: Faculdade Ingá / UNINGÁ/PR
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.945.082

Apresentação do Projeto:
De acordo com as informações apresentadas na PB_Informações básicas do projeto apresentada pelo pesquisador, no projeto intitulado COMPARAÇÃO DA EFICIÊNCIA DO ALINHAMENTO DENTÁRIO COM USO DE ALINHADORES INVISALIGN TROCADOS A CADA 7 OU 14 DIAS 20/08/2021, CAAE nº 51030921.3.0000.5220. A amostra será composta por 30 pacientes ortodônticos, divididos em 2 grupos. Grupo 1: Quinze pacientes ortodônticos que deverão trocar seus alinhadores a cada 7 dias. Grupo 2: Quinze pacientes ortodônticos que deverão trocar seus alinhadores a cada 14 dias. Ao final da sequência dos 5 primeiros alinhadores, cada paciente será submetido a um novo escaneamento intraoral, com o scanner digital I-Tero. As imagens obtidas serão armazenadas em um banco de dados digital disponível ao pesquisador principal. Posteriormente, utilizando o software Orthoanalyzer, essas imagens serão sobrepostas às imagens do planejamento para a etapa correspondente, de forma a avaliar as alterações das posições dentárias de acordo com o período de troca de alinhadores indicado para cada grupo. Também será avaliado o Índice de irregularidade de Little. A comparação intragrupos será feita com o teste t -dependente e a comparação intergrupos será feita com o teste t-independente. Após essas avaliações, espera-se conhecer a efetividade do uso de alinhadores Invisalign por cada período de tempo, e dessa maneira indicar o período de troca mais efetivo para o paciente.

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Continuação do Parecer: 4.945.082

Objetivo da Pesquisa:

De acordo com as informações apresentadas na PB_Informações básicas do projeto apresentada pelo pesquisador, no projeto intitulado COMPARAÇÃO DA EFICIÊNCIA DO ALINHAMENTO DENTÁRIO COM USO DE ALINHADORES INVISALIGN TROCADOS A CADA 7 OU 14 DIAS 20/08/2021, CAAE nº 51030921.3.0000.5220. O objetivo do presente trabalho é comparar a eficiência do uso dos alinhadores por 7 ou 14 dias.

Avaliação dos Riscos e Benefícios:

De acordo com as informações apresentadas na PB_Informações básicas do projeto apresentada pelo pesquisador, no projeto intitulado COMPARAÇÃO DA EFICIÊNCIA DO ALINHAMENTO DENTÁRIO COM USO DE ALINHADORES INVISALIGN TROCADOS A CADA 7 OU 14 DIAS 20/08/2021, CAAE nº 51030921.3.0000.5220. Os riscos Pelas características da pesquisa, pode-se afirmar que os riscos não são inaceitáveis. Durante o tratamento ortodôntico com alinhadores, o paciente poderá sentir dores, desconforto, náuseas, mobilidade dentária, apresentar machucados como aftas e ulcerações intrabucais. Na realização do escaneamento, também pode haver

náuseas e desconforto. Os riscos são inerentes ao tratamento ortodôntico com alinhadores. Além disso, os pesquisadores tomarão cuidado para preservar a identidade de cada participante, evitando que seja feita a identificação dos mesmos. Caso os riscos aconteçam, o ortodontista estará à disposição para atender o paciente em caso de urgências, e para medicar o paciente com analgésicos caso necessário. O benefício é detectar qual tempo de troca dos alinhadores é mais efetivo, tornando o tratamento mais

previsível e com melhores resultados finais e em longo prazo.

Comentários e Considerações sobre a Pesquisa:

De acordo com as informações apresentadas na PB_Informações básicas do projeto apresentada pelo pesquisador, no projeto intitulado COMPARAÇÃO DA EFICIÊNCIA DO ALINHAMENTO DENTÁRIO COM USO DE ALINHADORES INVISALIGN TROCADOS A CADA 7 OU 14 DIAS 20/08/2021, CAAE nº 51030921.3.0000.5220. Trata-se de estudo nacional prospectivo, no qual será realizado uma comparação de 2 grupos de 15 participantes cada um, os quais usarão um alinhador invisalign por periodos de tempo diferentes 7 e 14 dias respectivamente. Patrocínio: financiamento próprio. Início previsto para 1/10/2021 e término em 31/0/2022.

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados todos os termos de apresentação obrigatória.

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Continuação do Parecer: 4.945.082

Recomendações:

-

Conclusões ou Pendências e Lista de Inadequações:

O projeto apresenta as condições necessárias para sua execução por esta razão está APROVADO.

Considerações Finais a critério do CEP:

APROVADO: Ressalta-se que cabe ao pesquisador responsável encaminhar os relatórios parciais e final da pesquisa, por meio da Plataforma Brasil, via notificação "relatório" para que sejam devidamente apreciados no CEP, conforme Norma Operacional CNS nº 001/13, item XI, 2.d.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1800697.pdf	20/08/2021 12:02:32		Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Tiago.docx	20/08/2021 12:02:19	Karina Maria Salvatore de Freitas	Aceito
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Declaração de Instituição e Infraestrutura	autoriza_clinica_Tiago.pdf	28/07/2021 21:18:23	Karina Maria Salvatore de Freitas	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

MARINGA, 31 de Agosto de 2021

_____

Assinado por:
Daiane Pereira Camacho
(Coordenador(a))

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