



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

EDUARDO TERUMI BLATT OHIRA

**COMPARAÇÃO DO GRAU DE PERCEPÇÃO DOS PACIENTES
COM USO DE ALINHADORES IN-OFFICE RECORTADOS EM
DUAS ALTURAS DIFERENTES DE MARGEM GENGIVAL**

**COMPARISON OF PATIENT ADAPTION WITH IN-OFFICE
ALIGNERS WITH TWO DIFFERENT LEVELS OF THE GINGIVAL
MARGIN**

MARINGÁ

2023



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Dissertação formato artigo apresentada ao Programa de Mestrado Profissional em Odontologia, do Centro Universitário Ingá UNINGÁ, como parte dos requisitos a obtenção do título de Mestre em Odontologia, área de concentração Ortodontia.

Orientadora: Prof.^a Dr.^a Paula Cotrin

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Maringá, ____ de _____ de 2023.

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DEDICATÓRIA

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RESUMO

RESUMO

Objetivo: O objetivo deste estudo clínico prospectivo foi comparar a adaptação geral do paciente, a percepção e a saúde periodontal entre o uso de alinhadores *in-office* com duas alturas de margem gengival diferentes (0 e 1 mm). **Material e métodos:** A amostra foi composta por 23 pacientes que receberam tratamento ortodôntico com alinhadores *in-office*. A ordem de uso de cada par de alinhadores foi alocada aleatoriamente, com 12 pacientes iniciando com 2 pares de alinhadores com corte reto na margem gengival – 0mm e 11 pacientes iniciando com 2 pares de alinhadores com corte reto 1mm acima da margem gengival. Em seguida, o uso dos próximos 2 pares de alinhadores foi invertido. O Índice de Sangramento Gengival (ISG) foi avaliado ao final do uso de cada tipo de alinhador. Em um formulário do Google, os pacientes responderam a um questionário de nove itens sobre sua percepção em relação ao conforto, adaptação, fala e deglutição durante o uso dos 2 tipos de recorte dos alinhadores. A normalidade da amostra foi avaliada através do teste de Shapiro-Wil. Para avaliar a comparação entre os itens do questionário foi utilizado o teste de Wilcoxon. Em relação ao ISG foi utilizado o teste t dependente. Estatística descritiva foi utilizada para avaliar as razões que levaram a preferência entre os alinhadores. **Resultados:** Não houve diferença estatisticamente significativa entre os alinhadores com 0mm e 1mm de margem gengival nos nove itens avaliados. A maioria (69,57%) dos pacientes preferiram o alinhador de 0mm, sendo o conforto e a adaptação apontados como o principal motivo da escolha. Os que optaram pelo alinhador com 1mm citaram o bom ajuste, adaptação e retenção como principais motivos. Não houve diferença significativa no ISG entre as duas alturas de recorte dos alinhadores. **Conclusão:** O recorte ao nível gengival (0 mm) foi escolhido pela maioria dos pacientes, porém não houve diferença entre os itens avaliados no questionário.

Palavras-chave: Ortodontia. Má oclusão. Aparelhos Ortodônticos Removíveis.

ABSTRACT

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Objective: This prospective clinical study aimed to compare the overall patient adaptation, perception, and periodontal health using in-office clear aligners with two gingival margin level heights (0 and 1mm). **Material and Methods:** The sample comprised 23 patients who received orthodontic treatment with in-office aligners. The order of use of each pair of aligners was randomly allocated. Twelve patients started using 2 pairs of aligners with a straight cut at the gingival margin level (0mm), and 11 patients began using 2 pairs of aligners with a straight cut 1mm above the gingival margin level. After that, the following 2 sets of aligners were inverted. The Gingival Index (G.I.) was performed at the end of the use of each type of aligner. On Google Forms, patients answered a 9-item questionnaire about their perception of comfort, adaptation, speech, and swallowing while using the 2 aligners. The normality of the data was evaluated using the Shapiro-Wilk test. The comparison between the grades received for each item from the questionnaire was performed using the Wilcoxon test. The difference between the G.I. for each gingival margin was performed using a dependent t-test. Descriptive statistics were used to determine the preference between aligners. **Results:** There was no statistically significant difference between the 0mm and 1mm gingival margin in the nine evaluated items. Most patients (69.57%) preferred the 0mm, with comfort and adaptation identified as the main reason for the choice. Those who opted for the 1mm mentioned good fit, adaptation, and retention as the main reasons. There was no significant difference in G.I. between the 2 heights of the aligner's marginal level. **Conclusion:** Patients had the same perception when speaking and cleaning their aligners, and the esthetics, fit, and retention with the 2 evaluated level heights. The majority of the patients preferred the 0mm gingival margin level. The gingival health was similar for both 0 and 1 mm aligners.

Keywords: Orthodontics. Malocclusion. Orthodontic Appliances, Removable.

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LISTA DE ABREVIATURA E SIGLAS

PET-G	Polietileno Tereftalato Glicol Modificado / Polyethylene Terephthalate Glycol
PU	Poliuretano / Polyurethane
ISG / GI	Índice de Sangramento Gengival / Gingival Index

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1 INTRODUÇÃO

1 INTRODUÇÃO

A ortodontia é a especialidade da odontologia que busca corrigir as más oclusões e deformidades faciais. A prevalência de má oclusão varia conforme diferentes populações. Em um estudo comparando o tipo de má oclusão presente nas regiões sul, sudeste e nordeste do Brasil, foi possível observar que cerca de 70% da população estudada apresentava apinhamento (ALMEIDA *et al.*, 2020). A literatura tem demonstrado que as más oclusões podem impactar negativamente na qualidade de vida dos indivíduos (CHEN *et al.*, 2015; CHOI *et al.*, 2015). Em um estudo conduzido por Phiton *et al.* (PITHON *et al.*, 2014), pessoas com um sorriso considerado ideal, apresentaram mais chances de serem contratadas do que pessoas com um sorriso não ideal. Nesse contexto, o tratamento ortodôntico bem-sucedido pode ser essencial (CHEN *et al.*, 2015).

Apesar de bastante utilizado, o tratamento ortodôntico com bráquetes metálicos apresenta uma baixa aceitação pelos pacientes adultos ao ser comparado com opções mais confortáveis e com melhor estética como é o caso dos alinhadores ortodônticos (ALANSARI *et al.*, 2019). Os motivos que levam a recusa do tratamento com bráquetes metálicos incluem a estética, dificuldade na alimentação, dor e desconforto (MARANON-VASQUEZ *et al.*, 2021). Portanto, os alinhadores se apresentam como mais uma alternativa ao tratamento ortodôntico, uma vez que entre as possibilidades que existem hoje no mercado, apresenta alto índice de aceitação pelos pacientes (ALANSARI *et al.*, 2019).

A primeira apresentação de um protótipo de alinhador descrita na literatura foi realizada por Kesling (KESLING, 1945) em 1945. O autor apresentou um modelo de placa removível confeccionada sobre um modelo de gesso com os dentes recortados e reposicionados, que buscava pequenas correções de posicionamento dentário. Com o passar do tempo, outros autores começaram a desenvolver placas alinhadoras trabalhando com diferentes formas de confecções e materiais (PONITZ, 1971) (MODLIN, 1974; SHERIDAN; LEDOUX; MCMINN, 1993). No entanto, a produção em série desses sistemas era limitada, já que era necessário a confecção de modelos, segmentação e reposicionamento dos dentes em cada etapa do tratamento (BICHU *et al.*, 2023). Em 1998 a *Align Company* introduziu no mercado os alinhadores

produzidos através do processamento digital, o que possibilitou confeccionar uma série de *subsetups* (modelos) a partir da divisão do *setup* inicial (WONG, 2002).

Em 2000, Boyd *et al.* (BOYD *et al.*, 2002) publicaram pela primeira vez uma série de casos tratados com sucesso com a primeira geração de alinhadores *Invisalign*®. A amostra era composta por casos com má oclusão de classe I, pequenos apinhamentos e diastemas. Entretanto, em uma revisão sistemática publicada em 2005 (LAGRAVERE; FLORES-MIR, 2005), foram citados alguns relatos que evidenciavam uma baixa resposta ao tratamento em relação a movimentação planejada no *software*, apontando a necessidade de se conduzir mais estudos para avaliar a resposta da movimentação com alinhadores ortodônticos.

Desde a primeira pesquisa que avaliou a previsibilidade do tratamento com alinhadores *Invisalign*® (KRAVITZ *et al.*, 2009), vários estudos sobre previsibilidade de movimentação com alinhadores continuaram sendo conduzidos (ROSSINI *et al.*, 2015; CHARALAMPAKIS *et al.*, 2018; JIANG *et al.*, 2021; MOTA JUNIOR *et al.*, 2021). Atualmente existe um consenso de que a previsibilidade do movimento com alinhadores *Invisalign*® é na faixa de 50%, variando conforme o tipo de movimento a ser realizado, necessitando de refinamentos ou mecânicas acessórias para atingir a quantidade de movimentos planejados (UPADHYAY; ARQUB, 2022).

Além da *Align Company*, várias empresas iniciaram a produção dos seus alinhadores com diferentes tipos de materiais de placa, espessura, formato de *attachments* e altura de recorte de margem gengival (BICHU *et al.*, 2023). Dessa maneira, atualmente não existe um padrão para a confecção dos alinhadores, uma vez que cada empresa conduz a produção conforme suas especificações e desenvolvimentos internos. É necessário produzir-se evidências para que protocolos sejam criados e assim utilizados por ortodontistas e empresas (KHOSRAVI; GIDARAKOU; SALAZAR, 2022; THAKKAR *et al.*, 2023).

Nos últimos anos, com o avanço da tecnologia e o acesso cada vez maior ao escaneamento intraoral, softwares de planejamento e impressoras 3D, o ortodontista tem como possibilidade de tratamento a confecção de alinhadores em seus próprios consultórios. Esta modalidade de alinhadores é conhecida como alinhadores *in-office*. As vantagens desses alinhadores *in-office* incluem uma maior individualização do

tratamento, sem a necessidade de se comunicar com empresas de alinhadores ortodônticos (JABER; HAJEER; BURHAN, 2022).

Em um ensaio clínico randomizado, Jaber *et al.* (JABER; HAJEER; BURHAN, 2022) concluíram que o tratamento com alinhadores *in-office* é tão efetivo quanto aqueles com ortodontia fixa convencional, atingindo uma boa oclusão final. Além disso, Sachdev *et al.* (SACHDEV; TANTIDHNAZET; SAENGFAL, 2021) evidenciaram que a previsibilidade média dos com alinhadores *in-office* é de 56,18%, semelhante àquela observada na literatura com alinhadores *Invisalign*®.

A marca comercial de alinhadores mais utilizada atualmente, tanto comercialmente como em estudos é a *Invisalign*® (KRAVITZ *et al.*, 2009; WEIR, 2017; HAOUILI *et al.*, 2020; PUTRINO; BARBATO; GALLUCCIO, 2021; UPADHYAY; ARQUB, 2022; BICHU *et al.*, 2023). Os alinhadores da marca *Invisalign*® são confeccionados com um recorte de altura contornando a margem gengival dos dentes. Algumas empresas seguem esse mesmo padrão, porém, Cowley *et al.* (COWLEY; MAH; O'TOOLE, 2012) mostraram que alinhadores com esse recorte ao nível gengival possuem menos retenção do que aqueles com recorte de 2 mm acima do nível gengival.

Apesar dos alinhadores *in-office* já serem uma realidade em alguns consultórios odontológicos e de muitas pesquisas estarem sendo realizadas para avaliar as características dos materiais ou efetividades do tratamento, ainda existem dúvidas acerca da padronização de sua confecção, principalmente sobre a altura ideal de recorte dos alinhadores em relação ao conforto e a retenção. Recortes ao nível gengival, contornando a gengiva ou com alturas de 1 a 2mm são adotados por diferentes empresas de alinhadores seguindo protocolo próprio de cada uma delas. Portanto, avaliar o conforto, percepção de retenção e saúde gengival são importantes para a decisão do ortodontista com relação à altura com que deve recortar o seu alinhador.

Nesse contexto, o objetivo do presente trabalho é avaliar a diferença na percepção de conforto e de retenção do paciente utilizando alinhadores produzido *in-office* com duas alturas diferentes de recorte gengival: 0 e 1mm.

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 patient adaption with in-office aligners with two different levels of the gingival margin

ABSTRACT

Objective: This prospective clinical study aimed to compare the overall patient adaptation, perception, and periodontal health using in-office clear aligners with two gingival margin level heights (0 and 1mm). **Material and Methods:** The sample comprised 23 patients who received orthodontic treatment with in-office aligners. The order of use of each pair of aligners was randomly allocated. Twelve patients started using 2 pairs of aligners with a straight cut at the gingival margin level (0mm), and 11 patients began using 2 pairs of aligners with a straight cut 1mm above the gingival margin level. After that, the following 2 sets of aligners were inverted. The Gingival Index (G.I.) was performed at the end of the use of each type of aligner. On Google Forms, patients answered a 9-item questionnaire about their perception of comfort, adaptation, speech, and swallowing while using the 2 aligners. The normality of the data was evaluated using the Shapiro-Wilk test. The comparison between the grades received for each item from the questionnaire was performed using the Wilcoxon test. The difference between the G.I. for each gingival margin was performed using a dependent t-test. Descriptive statistics were used to determine the preference between aligners. **Results:** There was no statistically significant difference between the 0mm and 1mm gingival margin in the nine evaluated items. Most patients (69.57%) preferred the 0mm, with comfort and adaptation identified as the main reason for the choice. Those who opted for the 1mm mentioned good fit, adaptation, and retention as the main reasons. There was no significant difference in G.I. between the 2 heights of the aligner's marginal level. **Conclusion:** Patients had the same perception when speaking and cleaning their aligners, and the esthetics, fit, and retention with the 2 evaluated level heights. The majority of the patients preferred the 0mm gingival margin level. The gingival health was similar for both 0 and 1 mm aligners.

Keywords: Orthodontics. Malocclusion. Orthodontic Appliances, Removable.

INTRODUCTION

In the last decades, the treatment with clear aligners has become a popular alternative for orthodontic treatments and currently is the most accepted option by adult patients.¹ With the increasing popularity of the digital workflow, the possibility of producing aligners in their private dental offices is a reality for many orthodontists.² Since the clear aligners introduced by Invisalign, there has been an increase in companies offering the same service to the orthodontist. However, this service has a higher cost and dependence on the company, which may result in extra fees and delays in the delivery of the aligners.³ With the evolution and access to the necessary technologies, in-office aligners have become a faster option for production, with a lower cost, and allow customization by the orthodontist at all stages.⁴

Currently, there is no standard for manufacturing clear aligners, as each company follows its recommendation regarding the material, thickness, and gingival margin of the aligners – colocar as 2 refs da seminars.. Among the types of thermoplastic material used are modified polyethylene terephthalate glycol (PET-G) and polyurethane.⁵ The thickness can vary from 0.5mm to 0.8mm. The height and design of the gingival margin level cut also differ significantly.⁶ The clear aligners can have a scalloped margin or a straight cut at the gingival margin varying from 0 to 2mm above the gingival margin.⁷

The Invisalign system has reached the mark of 14 million cases⁸ and is considered the most used commercial clear aligner system worldwide.⁶ Also, more than 90% of research is carried out with Invisalign.⁵ Currently, the company cut their aligners with a scalloped gingival margin.^{6,8} There is no consensus regarding the ideal height and design of the gingival margin level in in-office aligners. *In vitro* studies show that aligners with straight gingival margins greater than 2mm present better retention than those trimmed at the gingival margin.^{9,10} Despite the studies that evaluated materials, the accuracy, and the previsibility of clear aligner therapy,¹¹⁻¹⁵ almost none specify the height of the marginal level at which this aligner was manufactured.¹⁶⁻¹⁸ There are still doubts regarding the ideal gingival margin height and design for strimming the aligners. Studies on the size and design of the gingival margin of the aligners are primarily *in vitro*,^{9,10} not allowing their results to be extrapolated to the clinical routine. That is, the patient's perception is underestimated. Therefore, evaluating the sensation of comfort, retention, and gingival health becomes essential

for the orthodontist to decide how to trim the in-office aligner. In this context, the objective of the present study is to compare the overall patient adaptation and periodontal health between the use of in-office clear aligners with two different gingival margin level heights (0 and 1mm).

MATERIAL AND METHODS

This prospective study was submitted and approved by the ethics Research Committee of Uningá University Center (51507321.9.0000.5220; Annex II). All patients signed informed consent for participation.

The sample size calculation was based on an alpha significance level of 5% (0.05) and a beta of 20% (0.20) to reach a test power of 80% and detect a minimum difference of 2 points with a standard deviation average of 2.19 for a numerical scale indicating comfort, in a previous article.¹⁹ Therefore, the minimum sample required was 20 patients.

Participants, eligibility criteria, and settings

This prospective study was conducted from 2021 to 2022, and the sample selection was carried out in a private clinic in Pomerode, SC, Brazil. Inclusion criteria for sample selection were patients of both sexes aged 18 to 45 years, the presence of all erupted permanent teeth up to first molars, and malocclusion that could be treated with in-office aligners. Patients who fit the inclusion criteria were invited to participate, and all patients filled out an informed consent form.

All patients in the sample were treated with in-office clear aligners produced in partnership with Contrast Radiology (Contraste, Blumenau, SC, Brazil). Before treatment, all orthodontic digital planning with the OrthoAnalyzer software (3Shape) was performed by the same experienced professional (ETBO). Each case received its prescription for attachments and interproximal reduction as indicated. No treatment accessory mechanics (elastic, buttons, or other accessories) were used.

The final sample comprised 23 patients (17 women and 6 men) with a mean age of 28.74 ± 6.8 . The mean initial maxillary and mandibular irregularity indexes were 3.95 (1.5) and 3.66 (2.16), respectively. The mean number of initial attachments was 1.91 (3.38). All patients used the 2 pairs of aligners with a straight cut at the gingival

level - 0mm (Figure 1) and 2 pairs of aligners with a straight cut 1mm above the gingival level (Figure 2). The order of use of each pair of aligners was randomized with a simple randomization method using a coin toss by the operator (ETBO).²⁰ On the first patient allocated, the operator determined that the text side of the coin indicated that the first aligner would be 0mm and the head side 1mm. The coin toss indicated that the first patient would use the 1mm alignment. From the next patient to further, the order of use was alternated.

Half of the sample started using the 0mm aligners, and the other half used the 1mm. Patients were asked to wear their aligners 20 hours a day and instructed to change each set of aligners every 15 days. The total treatment time for each sequence of aligners was 1 month. At the end of 1 month, the patients received their subsequent aligner with a different marginal cut. In addition, they were also advised to remove the aligners on the lingual surface of the upper molars and the buccal surface of the lower molars.

All aligners were made with 0.6mm PET-G (Forestadent Track-A, Germany), using a pressure thermoforming (Drufosmart D3200, Drevem, Germany), and the cutting and polish were performed manually with disks and cutters (DhPro, Kit Paschetto & Ohira, Brazil) by the same professional (ETBO).

Questionnaire

Immediately after using each pair of aligners, the patients answered in Google forms a closed questionnaire to assess their perception regarding using the 2 types of aligners (Figure 3).

In the questionnaire, based on a previous study that evaluated comfort,¹⁹ nine items were evaluated (adaptability, speech, swallowing, soft tissue comfort, overall satisfaction, cleaning, aesthetics, durability, fitting, and retention). The patient scored 0-10, with 0 being poor and 10 excellent. The questions were as follows:

1. How well were you able to adapt to this aligner?
2. How easy was it to talk with this aligner?
3. How easy was it to swallow fluid and saliva with this aligner?
4. How was your comfort when using this aligner, especially related to soft tissues such as the gingiva, cheek, and tongue?

5. How easy was it to clean this aligner?
6. What do you think about the aesthetics of this aligner?
7. What do you think about the durability of this aligner?
8. How was the fit of this aligner?
9. How was the retention of this aligner?

After completing the two research phases, the patients answered a final comparative questionnaire. In this questionnaire, the patient had to choose the two aligners with their preferred gingival margin edges. For the last open question, they explained the reasons (adaptation, speech, swallowing, comfort, hygiene, esthetics, satisfaction, durability, fitting, and retention) that led to this choice (Figure 4). Once the questionnaires were answered, the data were uploaded to Excel (Microsoft Office 365).

The Gingival Index (G.I.) was evaluated at pretreatment and at the end of each aligner sequence by the same operator (ETBO) to assess periodontal health. The G.I. was evaluated according to Loe's methodology.²¹

Statistical analysis

The normality of the data was evaluated using the Shapiro-Wilk test. The comparison between the grades received for each item from the questionnaire was performed using the Wilcoxon test.

The difference between the G.I. for each gingival margin was performed using a dependent t-test.

Descriptive statistics were used to determine the preference between aligners, and descriptive statistics and percentage comparison were used to assess the reasons that led patients to choose the gingival margin.

All statistical analyses were performed using the Statistica software for Windows (Version 10.0; StatSoft, Tulsa, Okla) and were considered significant when $p < 0.05$.

RESULTS

During recruitment, 32 patients were assessed for eligibility. However, 6 were excluded for not meeting the inclusion criteria. Twenty-six patients participated in the

research and were randomized to determine the order of use of the aligners. Three patients dropped out of treatment during follow-up and were removed from the study (Figure 5).

There was no statistically significant difference in the answers to the questions regarding the nine evaluated items between the 0mm and 1mm aligners (Table I). The 0mm gingival margin was chosen for 69.57% of the patients (Table II). When questioned about the reasons for preference, comfort, adaptation, and aesthetics were the most mentioned (Figure 6). Those who opted for the 1mm aligner said good fit, adaptation, and retention as the main reasons (Figure 7).

There was no significant difference in G.I. after using the 0mm or 1mm aligners (Table III).

Harms

No significant harm was observed in the patients of this study, such as aligner fractures and soft tissue injuries. All aligners were discarded after treatment.

DISCUSSION

In the present study, 0.6mm PET-G aligners were used, with material and thickness similar to that used by Takara *et al.*,⁹ who also evaluated in the laboratory the retention of aligners with 3 different gingival margin designs: in the middle of the clinical crown, on the gingival margin and 2 mm above the gingival margin. As the level in the center of the clinical crown is not used clinically, the great relevance was the comparison between the clear aligner at the gingival margin and 2mm above. Takara *et al.*⁹ showed no significant difference between the two designs of gingival margin when the aligner was removed in the posterior region, which is similar to the present study's findings since all patients were instructed to remove the maxillary aligners in the lingual of the molars. As most of the laboratory studies occur with vertical removal of the aligner by the occlusal surface,^{10,22,23} the study conducted by Takara is more similar to clinical reality, where the patient is instructed to remove their aligners by applying force to one point and then gradually lift and remove them.

All patients wore each type of aligner for one month. The progressive replacement regimen was recommended to be carried out every 15 days and is in accordance with the current orthodontic literature.^{17,24,25} According to Chagas *et al.*¹⁹ a period of 1 month of use is sufficient for the patient to evaluate their adaptation and satisfaction with the device. Furthermore, to avoid bias, we randomized the order of sample use, and all patients used both types of aligners. In addition, little's irregularity index at the beginning of treatment was small. Therefore the degree of crowding, associated with a low rate of movement per aligner, may not have interfered with the comparison, which brought more reliable results. It is essential to highlight that the objective of our study was not to evaluate the correction of the malocclusion but only the patient's perception during the use of the aligners.

To assess the patient's perception of the characteristics of each type of aligner, we used a questionnaire based on the study of Chagas *et al.*,¹⁹ which evaluated patients' preference between 2 types of removable retainers. One can say that this is not a validated questionnaire. However, the questions used allowed a more accurate assessment of patients concerning specific aspects, such as perception of fit and retention of the aligner. Pogal-Sussman-Gandia *et al.*²⁵ also used a non-validated questionnaire in their study about the effects of clear aligners on speech articulation.

The most used brand of aligners worldwide is Invisalign.^{6,24-31} The height of the Invisalign aligner level is made at the gingival margin.^{5,8} As in-office aligners have increased lately, there is no standard gingival margin level height at which in-office aligners are made.^{32,33} Recently, Thakkar *et al.*,³³ published a workflow where the suggestion would be trimming the aligner 2mm above the gingival margin, in the level of gingival margin or scalloping the gingival margin. Laboratory studies show the greater the edge height of the aligner, the greater retentivity it will have.¹⁰ On the other hand, it is speculated that the greater the height of the aligner level, the more discomfort the patient will feel in the lips and cheeks. Based on these speculations and due to the lack of standards, we clinically evaluated patient satisfaction when using aligners with the edge at the gingival margin level and 1 mm high.

There was no difference in the responses to the questionnaire regarding the nine evaluated items when using the 2 types of in-office clear aligners (Table I). Patients had the same perception when speaking and cleaning their aligners and the esthetics, fit, and retention with the 2 evaluated level heights. The first evaluated item was the adaptation to the aligners with 0 and 1mm heights, and all the patients reported

an easy adaptation to both. Studies show that treatment with clear aligners has a high acceptance, and there is a faster adaptation to them.^{30,31} Overall, these results corroborate studies that show that treatments with clear aligners improve the Oral Health-Related Quality of Life (OHRQoL),^{34,35} mainly when compared to other orthodontic treatment modalities.^{27,36-38} In addition, according to Gao *et al.*,³⁸ patients treated with clear aligners experience lower pain levels and less anxiety.

Interestingly, patients gave high scores for all evaluated items to aligners with 0 and 1 mm marginal levels. It can be presumed that patients had a good adaptation, and the acceptance was similar for both gingival margin level heights. According to Pacheco-Pereira *et al.*,³⁴ the negative experiences with clear aligners are not strong enough to reduce patients' positive experiences while using clear aligners. Also, patients reported no difficulties speaking with both aligners (Table I). Our results are different from most found in the literature. Recent studies showed that speech difficulties appear high with clear aligners.^{39,40} Pogal-Sussman-Gandia *et al.*²⁵ stated that these difficulties occur mainly in articulating some consonants. Perhaps this difference was because we did not assess specific words to quantify difficulty in pronouncing them while wearing the aligners. However, patients adapt quickly, and speech returns to normal within a few months.^{39,40}

Patients found it easy to swallow fluids and saliva with both aligners (Table I). This was expected since swallowing is the item that presents the best results for quality of life when comparing orthodontic treatment with aligners and fixed appliances.²⁸

The 0mm gingival margin level was chosen for 69.57% of the patients (Table II). The reasons for that were mainly comfort, adaptation, and aesthetics. (Figure 6) Those who opted for the 1mm aligner mentioned good fit, adaptation, and retention as the main reasons (Figure 7). Despite this, among the patients who chose the 1mm aligner, retention was mentioned by 43% of them as one of the factors for choosing it. This data corroborates with an in vitro study conducted by Cowley *et al.*,¹⁰ which showed that aligners with a 2mm gingival margin have greater retention than those trim at the gingival level. In addition, the author concludes that 2mm gingival margin aligners, even without attachments, have better retention than the scalloped design with attachments. However, these data must be interpreted with caution since the study has limitations since the material with which the aligners were made (polypropylene and copolyester) and the thickness of the aligner (1mm) is not used, according to two systematic reviews.^{6,5} Additionally, depending on the material of the aligner (PET-G,

PU, or multilayer) there may be interference in the clinical performance of the aligners.⁴¹

Among patients who opted for the edge at the gingival level, comfort was the most mentioned reason (69%), followed by good adaptation (56%) (Figure 6). As discussed, data from the literature indicate that the comfort of the aligners provides a better quality of life for patients than treatment with fixed appliances.⁴²

The present study did not show a significant difference in the Gingival Index (G.I.) between the aligners with 0mm and 1mm gingival levels (Table III). This result indicates that the 2 heights of the gingival margin levels of the aligners are compatible with maintaining good periodontal health. It is essential to point out that most of the studies that evaluate the status of periodontal health during the use of aligners compare it with conventional fixed orthodontic appliances, and patients undergoing orthodontic treatment with clear aligners show superior periodontal health.^{24,29,43-45} Besides, the patients improved this index during treatment (Table III). This result is in agreement with some authors.^{24,45,46} It can be speculated that this improvement in the G.I. is due to the constant motivation for oral hygiene that the patient received during treatment. In addition, studies show that patients increase beneficial oral hygiene habits and awareness during the first months of clear aligner therapy.^{46,47} Therefore, it is well known that orthodontic therapy with clear aligners is better for periodontal health than fixed appliances. It might be recommended for patients at high risk of developing gingivitis.^{24,48}

Our study has some limitations. Among the subjects enrolled in this study, most of them were female, which may affect the results of our study. Another limitation was the lack of long-term observation. Therefore, research with a larger sample and extended observation period might be interesting.

Clinical implications

The results of this study show that although most patients chose the aligner at the gingival margin as the best option, there was no significant difference between the two designs for all the evaluated indicators. Therefore, it is possible to individualize the design of the aligners according to the anatomical characteristics of each patient, as well as to evaluate, according to the need, the inclusion of a greater or smaller gingival

margin according to the planned movement for each tooth and in each stage of the treatment.

CONCLUSION

- There was no difference in the adaptation, comfort, and retention between the aligners with 0 and 1mm gingival marginal levels
- Aligners with 0mm marginal level were chosen by 69.57% of patients, who mentioned that comfort and good fit were the main reasons for choosing them.
- Aligners with 1mm marginal level were chosen by 30.43% of patients, who mentioned good fit, good adaptation, and retention as the main reasons for choosing them.
- There was no difference in G.I. between the 0mm and 1mm gingival marginal levels.

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Figure 1 – Clear aligner cut at the gingival margin – 0mm

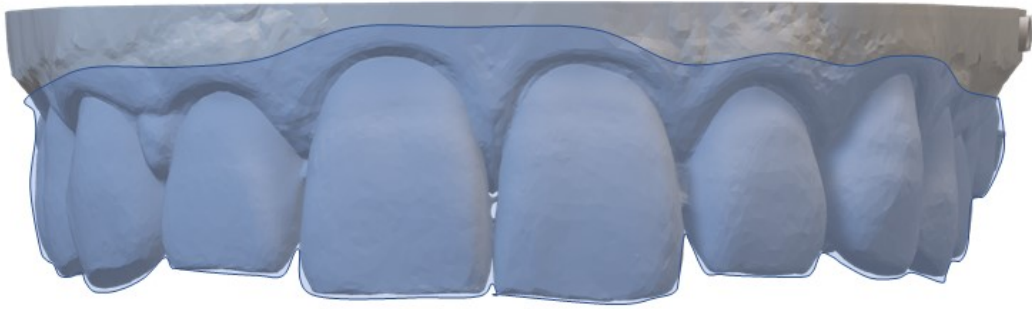


Figure 2 – Clear aligner cut 1mm above gingival marginal – 1mm

Comparison of the patient satisfaction with the use of in-office aligners with two different gingival margin design.

My name is Eduardo Ohira and I am student at Uningá - PR. I am developing a survey to assess the level of satisfaction with the use of orthodontic clear aligners. The objective of this research is to verify the comfort with two different gingival margin design, therefore I request your participation by answering the questionnaire below.

How do you rate your adaptation to this aligner?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

How do you rate your ease of speaking while using this aligner?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

How do you rate the ease of swallowing liquids and saliva while using this aligner?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

How do you rate your comfort while using this aligner, especially related to soft tissues such as gums and tongue?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

How do you rate the ease of cleaning this aligner?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

What did you think about the durability of this aligner?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

What did you think of the aesthetics of this aligner?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

What do you think of the fit of this aligner to your teeth?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

How do you rate the retention of this aligner to your teeth?

1 2 3 4 5 6 7 8 9 10

Poor Excellent

Enviar
Limpar formulário

Figure 3 – Questionnaire 1 of clear aligner use satisfaction.

Comparison between the two gingival margin design of clear aligners

Which of the two aligners did you prefer?

Clear aligner 1

Clear aligner 2

What was the main reason you chose this aligner?

Good adaptation

Ease of speech

Ease of swallowing

Comfort

Ease of cleaning

Aesthetics

Satisfaction with use

Durability

Good fitting

Better retention

[Enviar](#) [Limpar formulário](#)

Figure 4 – Questionnaire 2 comparing the two designs of gingival margin.

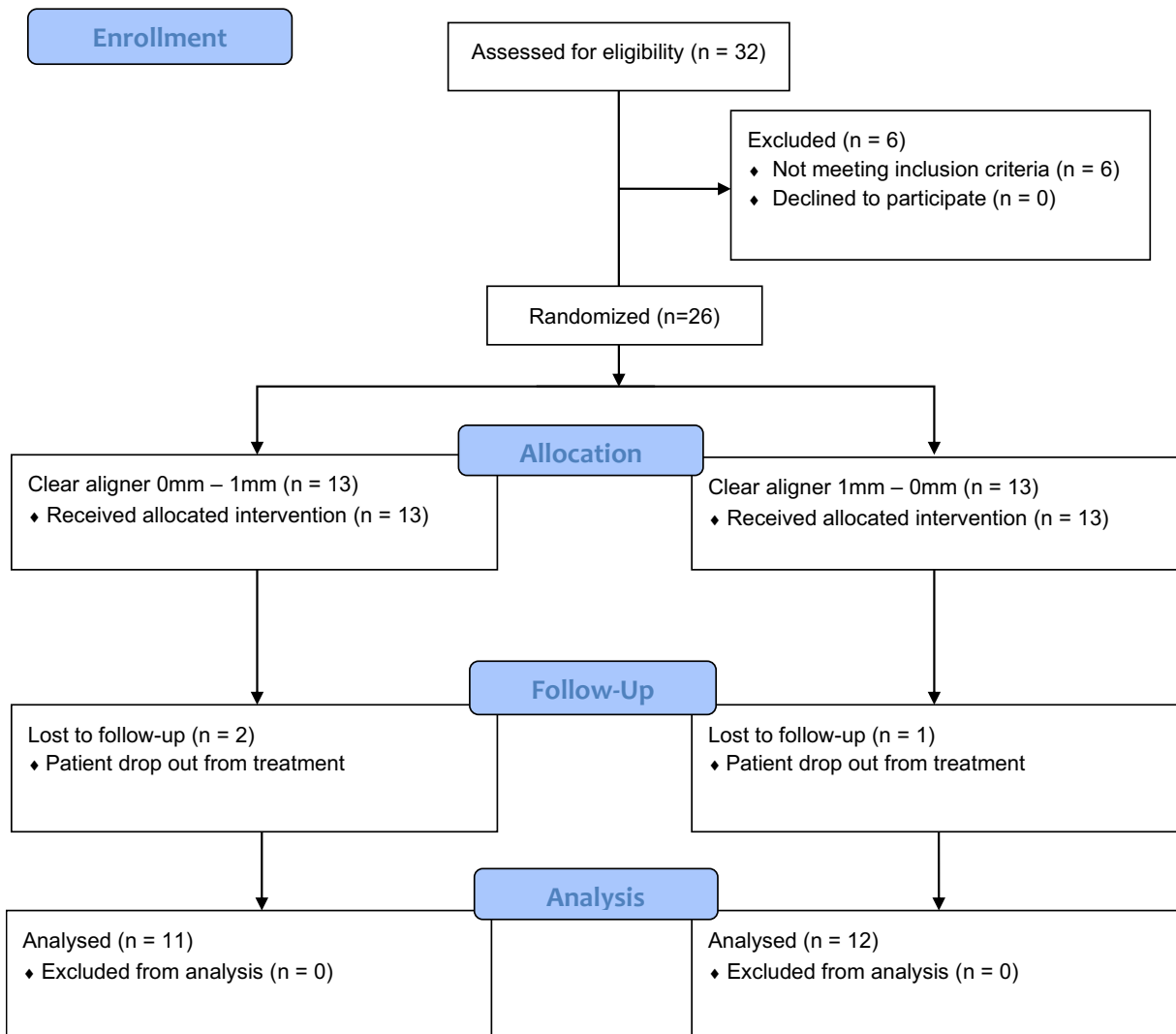


Figure 5 – CONSORT diagram showing patient flow.

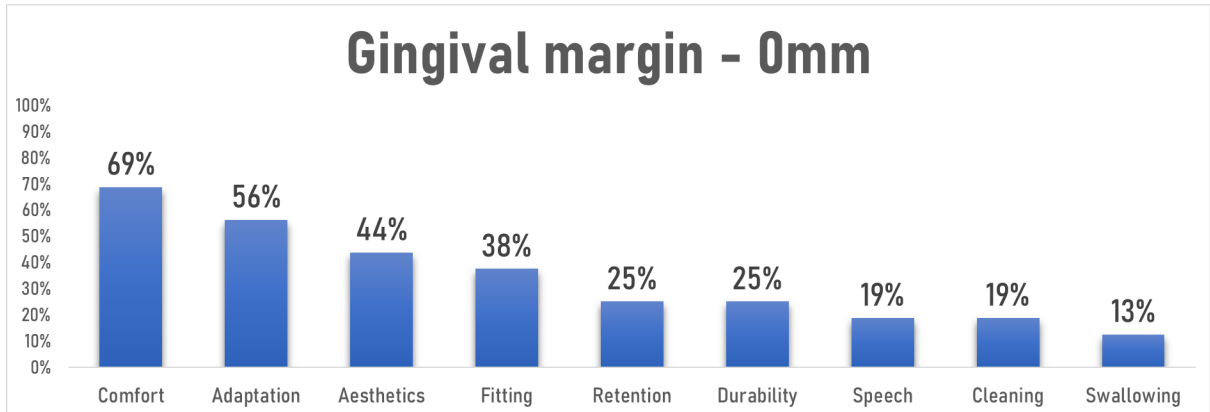


Figure 6 – Reasons for choosing the aligner with 0mm gingival margin level.

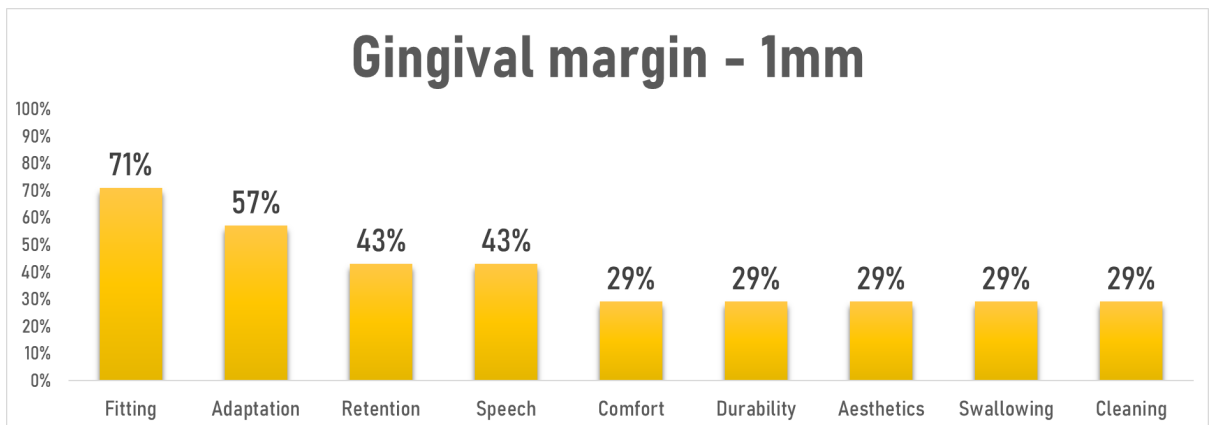


Figure 7 – Reasons for choosing the aligner with 1mm gingival margin level.

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Table I – Comparison of responses to the questionnaire evaluating the items for satisfaction use of clear aligners (Wilcoxon Test).

Question	0mm		1mm		P
	Median (Mean)	d.i. (s.d.)	Median (Mean)	d.i. (s.d.)	
1 – Adaptation	10.00 (9.35)	1.00 (0.88)	10.00 (9.09)	2.00 (1.41)	0.374
2 – Speech	10.00 (9.22)	1.00 (1.04)	9.00 (9.22)	1.00 (0.95)	1.000
3 – Swallowing	10.00 (9.22)	1.00 (0.99)	10.00 (9.26)	2.00 (1.01)	0.906
4 – Comfort	10.00 (9.17)	2.00 (1.11)	9.00 (9.00)	2.00 (1.17)	0.456
5 – Cleaning	10.00 (9.22)	2.00 (1.24)	10.00 (9.26)	1.00 (1.14)	0.779
6 – Aesthetics	10.00 (9.56)	1.00 (0.84)	10.00 (9.48)	1.00 (1.08)	0.584
7 – Durability	10.00 (9.17)	1.00 (1.33)	10.00 (9.30)	2.00 (1.06)	0.554
8 – Fitting	10.00 (9.43)	1.00 (0.79)	10.00 (9.48)	1.00 (1.08)	0.745
9 – Retention	10.00 (9.22)	1.00 (0.99)	10.00 (9.52)	1.00 (0.79)	0.529

Table II – Patients preference between the two different gingival margin levels.

	0 mm	1mm	p
Patients preference (%)	69.57%	30.43%	0.008

Table III – Comparison in the gingival index (G.I.) with two different gingival margins of clear aligners - 0mm and 1mm (dependent t test).

	0 mm		1mm		p
	Mean	s.d.	Mean	s.d.	
GI	-0.42	1.84	-0.10	1.43	0.549

3 CONSIDERAÇÕES FINAIS

3 CONSIDERAÇÕES FINAIS

Com este estudo foi possível observar que não houve diferença na sensação de conforto e na percepção dos pacientes com os diferentes recortes de altura de margem gengival dos alinhadores *in-office*. Além disso também não possível observar diferença na saúde gengival.

No entanto, os alinhadores recortados na margem gengival foram preferidos por cerca de 2/3 da amostra, sendo o conforto o motivo principal apontado para escolha. Além disso os pacientes que escolheram o alinhador de 1mm apontaram o bom encaixe como o principal motivo de escolha.

Acredita-se ser interessante o desenvolvimento de mais pesquisas semelhantes, avaliando além do conforto e retenção, mas também a influência da altura do recorte na resposta da movimentação ortodôntica.

4 RELEVÂNCIA E IMPACTO DO TRABALHO PARA A SOCIEDADE

4 RELEVÂNCIA E IMPACTO DO TRABALHO PARA A SOCIEDADE

Este trabalho acrescenta à literatura científica um estudo clínico importante relacionado ao grau de satisfação com o uso dos alinhadores *in-office* com diferentes alturas de recorte da margem gengival. O que pode trazer uma melhor padronização de recorte dos alinhadores *in-office*, de maneira a proporcionar um maior conforto no uso pelos pacientes.

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ANEXOS

ANEXO 1



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Pesquisador: Eduardo Terumi Blatt Ohira

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Os critérios de inclusão do presente estudo são: pacientes com idade entre 18 e 45 anos; presença de todos os dentes permanentes irrompidos até primeiros molares; má-oclusão que possibilite tratamento ortodôntico com uso de alinhadores in-office.

Todos os pacientes da amostra serão tratados com alinhadores ortodônticos in-office da Contraste Radiologia (Contraste, Blumenau, SC, Brasil) e utilizarão os alinhadores in-office como método único da correção do tratamento, realizando a troca dos alinhadores na sequência prevista no planejamento, a cada 15 dias. Os pacientes serão submetidos a um exame clínico onde será avaliado o Índice de sangramento gengival (ISG) de acordo com a metodologia de Loe (LOE, 1967), antes do uso dos alinhadores e após a sequência dos quatro alinhadores. Para determinar esse índice será realizada sondagem periodontal em três pontos na vestibular e na palatina (mesial, central e distal) de todos os dentes. Dessa maneira será possível verificar o índice de

sangramento gengival de cada paciente. Após a utilização dos dois alinhadores iniciais o paciente será orientado a responder um questionário construído no Google forms com questões referentes à percepção em relação a conforto, fala, deglutição e retenção dos alinhadores. O mesmo questionário será aplicado ao final do uso dos

dois alinhadores subsequentes. Concluída a utilização dos 4 alinhadores o paciente será orientado a preencher um questionário comparativo entre as duas alturas de recorte. Após obtenção dos dados, será realizada análise estatística. A comparação entre os tipos de alinhadores será realizada pelo teste t independente. A análise estatística será realizada com o programa Statistica for Windows 12.0, sendo considerados estatisticamente significantes os resultados com valor de $p < 0,05$.

Objetivo da Pesquisa:

De acordo com as informações apresentadas na PB, informações básicas do projeto apresentado pelo pesquisador Eduardo Terumi Blatt Ohira, no projeto intitulado: Comparação do nível de satisfação dos pacientes com uso de alinhadores in-office recortados em duas alturas diferentes de margem gengival, versão 1, submetido dia 25/08/2021, CAAE: 51507321.9.0000.5220: Objetivo Primário: O objetivo do presente trabalho é comparar o conforto do paciente e a percepção de retenção do alinhador com duas alturas diferentes de recorte dos alinhadores in-office.

Objetivo Secundário: - Avaliar o nível de conforto do paciente durante o uso dos alinhadores com recorte de 1mm de altura através de questionário específico.- Avaliar o nível de conforto do paciente durante o uso dos alinhadores com recorte na cervical através de questionário específico.- Avaliar e comparar a saúde periodontal com as duas alturas de recorte dos alinhadores.

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Avaliação dos Riscos e Benefícios:

De acordo com as informações apresentadas na PB, informações básicas do projeto apresentado pelo pesquisador Eduardo Terumi Blatt Ohira, no projeto intitulado: Comparação do nível de satisfação dos pacientes com uso de alinhadores in-office recortados em duas alturas diferentes de margem gengival, versão 1, submetido dia 25/08/2021, CAAE: 51507321.9.0000.5220: Riscos: Conforme a resolução 466/2012, toda pesquisa com seres humanos envolve riscos em tipo e graduações. 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. Todos os cuidados serão tomados pelos pesquisadores para minimizar os riscos mencionados, e também evitando a identificação do participante da pesquisa. Os riscos envolvidos não são inaceitáveis de acordo com a resolução 466/2012. Benefícios: A partir dos resultados deste trabalho, poderemos detectar qual altura de recorte dos alinhadores é mais confortável e que mantém melhor a saúde periodontal.

Comentários e Considerações sobre a Pesquisa:

De acordo com as informações apresentadas na PB, informações básicas do projeto apresentado pelo pesquisador Eduardo Terumi Blatt Ohira, no projeto intitulado: Comparação do nível de satisfação dos pacientes com uso de alinhadores in-office recortados em duas alturas diferentes de margem gengival, versão 1, submetido dia 25/08/2021, CAAE: 51507321.9.0000.5220: Trata-se de estudo nacional, financiamento próprio (9.600,00 reais), 30 participantes. Início previsto para 01/11/2021 e término para 31/12/2021.

Considerações sobre os Termos de apresentação obrigatória:

De acordo com as informações apresentadas na PB, informações básicas do projeto apresentado pelo pesquisador Eduardo Terumi Blatt Ohira, no projeto intitulado: Comparação do nível de satisfação dos pacientes com uso de alinhadores in-office recortados em duas alturas diferentes de margem gengival, versão 1, submetido dia 25/08/2021, CAAE: 51507321.9.0000.5220: Todos os termos de apresentação obrigatória foram contemplados.

Recomendações:

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Conclusões ou Pendências e Lista de Inadequações:

De acordo com as informações apresentadas na PB, informações básicas do projeto apresentado pelo pesquisador Eduardo Terumi Blatt Ohira, no projeto intitulado: Comparação do nível de satisfação dos pacientes com uso de alinhadores in-office recortados em duas alturas diferentes de margem gengival, versão 1, submetido dia 25/08/2021, CAAE: 51507321.9.0000.5220: Aprovado

Considerações Finais a critério do CEP:

"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_BASICAS_DO_PROJETO_1815342.pdf	25/08/2021 18:02:39		Aceito
Declaração de Instituição e Infraestrutura	autorizacao_ohira.pdf	25/08/2021 18:01:23	Eduardo Terumi Blatt Ohira	Aceito
Outros	Questionario2.pdf	25/08/2021 17:59:01	Eduardo Terumi Blatt Ohira	Aceito
Outros	Questionario1.pdf	25/08/2021 17:58:49	Eduardo Terumi Blatt Ohira	Aceito
Projeto Detalhado / Brochura Investigador	projeto_Eduardo.docx	25/08/2021 17:49:45	Eduardo Terumi Blatt Ohira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_EduardoOhira.doc	25/08/2021 17:48:52	Eduardo Terumi Blatt Ohira	Aceito
Folha de Rosto	folhaDeRostoEdu.pdf	25/08/2021 17:26:11	Karina Maria Salvatore de Freitas	Aceito

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Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

MARINGÁ, 25 de Setembro de 2021

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

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