UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

SILVIO AUGUSTO BELLINI PEREIRA

Treatment stability with bonded versus vacuum-formed retainers after 12 months: a systematic review and randomized clinical trial

Estabilidade de tratamento com contenções fixas versus termoplásticas após 12 meses: uma revisão sistemática e ensaio clínico randomizado

BAURU
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Tese constituída por artigo apresentada à Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Doutor em Ciências no Programa de Ciências Odontológicas Aplicadas, na área de concentração Ortodontia.

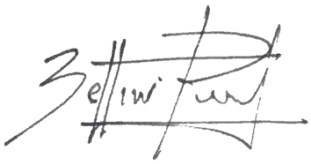
Orientador: Prof. Dr. José Fernando Castanha Henriques

BAURU
2022

Bellini Pereira, Silvio Augusto
Treatment stability with bonded versus vacuum-formed retainers after 12 months: a systematic review and randomized clinical trial / Silvio Augusto Bellini Pereira. -- Bauru, 2022.
106 p. : il. ; 31 cm.

Tese (Doutorado) -- Faculdade de Odontologia de Bauru, Universidade de São Paulo, 2022.

Orientador: Prof. Dr. José Fernando Castanha Henriques



Comitê de Ética da FOB-USP
Protocolo nº: 22092919.7.0000.5417/3.835.225
Data: 12 de fevereiro de 2020

Universidade de São Paulo
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Assistência Técnica Acadêmica
Serviço de Pós-Graduação

ANOS
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FOLHA DE APROVAÇÃO

Tese apresentada e defendida por
SÍLVIO AUGUSTO BELLINI PEREIRA
e aprovada pela Comissão Julgadora
em 24 de março de 2022.

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DEDICATÓRIA

Aos meus pais Inês e Silvio, meus exemplos.

Ao meu irmão Lucas, meu melhor amigo.

Tudo foi graças a vocês.

AGRADECIMENTOS

Agradeço primeiramente a **Deus**. Esta força maior que observa de longe não só a minha, mas todas a vidas desse mundo. O maior presente que nos deu foi o livre arbítrio. Mesmo assim eu acredito que em cada decisão o Senhor está lá nos guiando para que seja a melhor. Agradeço muito e sei que está ao meu lado em todos os momentos.

Agradeço a minha família. A base de tudo.

Meu Pai, **Silvio Antônio dos Santos Pereira**. Cirurgião-Dentista, professor, administrador, economista, mecânico, astrólogo, arqueólogo, atleta e pai. O senhor é a definição do Pai herói. Não sei como é capaz de fazer de tudo e mesmo assim ter tempo de ser pai. Espero um dia ser um Pai herói como o senhor.

Minha mãe, **Inês Horie Bellini Pereira**. O ser mais amável que existe no mundo. A senhora meu deu tudo e fez de tudo por mim. Minha professora de Ortodontia. Está sendo um privilégio melhorar e crescer com a senhora. A senhora é o coração de nossa família, o suporte em todas as horas, o que equilibra todos nós.

Pai e **Mãe**, obrigado por acreditarem em mim. Eu sei que vocês abdicaram de muitas coisas que queriam fazer para que eu chegasse até aqui. Prometo fazer valer o sacrifício de vocês.

Agradeço ao meu irmão **Lucas Bellini Pereira**. Você é a personificação da bondade e perseverança. Eu simplesmente sei que tudo que você quiser alcançar na vida você vai alcançar. Geralmente as famílias dizem que o irmão mais velho deve ser o exemplo para o mais novo. No nosso caso, você é meu exemplo irmão. Continue cuidando da Ste, ela faz muito bem para você e a recíproca também é verdadeira. **Stephani Garbúlio Amaral**, obrigado por já fazer parte da nossa família. Amo vocês.

Aos meus queridos avós. **Alzira**, **Antônio**, **Danilo** e **Lourdes**. Vocês me educaram na ausência dos meus pais e cuidaram de mim como filho. Sentir o amor e o carinho de vocês foi fundamental. Agradeço ao meu tio e padrinho **Danilo** por cada tapa. Me sinto privilegiado por ser seu colega de trabalho e aprender com o senhor dentro e fora da odontologia. Desejo toda a felicidade juntamente a **Kátia** e agradeço o grande presente que foi minha afilhada. Agradeço a minha madrinha **Dulce** por ser minha segunda mãe. Eu sei o quanto a senhora torce por mim. **Mariana**, minha irmã caçula. Cada dia te vejo mais o espelho da Tia Du, uma mulher forte, independente, que ama o que faz, e que muitas vezes coloca os outros na frente até da própria

saúde. Talvez seja uma das características dos bons médicos. Amo vocês duas. Tio **Carlos**, obrigado por estar sempre presente e cuidar de mim. Junto a **Akemi** vocês estão formando uma família maravilhosa. Prometo estar sempre com vocês quando possível e ajudar quando necessário.

Cada um de vocês contribuiu para minha personalidade e eu sou muito agradecido pela sorte de ter essa família maravilhosa.

Em especial, agradeço a minha companheira **Fernanda Sandes de Lucena**. Trilhamos juntos este caminho árduo que foi a pós-graduação. Agradeço por todo amor, compreensão e carinho que temos um pelo outro. Eu aprendo com você todos os dias, e você sabe que eu sou lento no aprendizado, por isso também agradeço a sua paciência comigo. Eu sou uma pessoa melhor ao seu lado Fer. Espero que continuemos a crescer juntos um com o outro e sempre somar! Obrigado pelo privilégio de poder dividir a vida contigo.

Agradeço ao meu orientador Prof. Dr. **José Fernando Castanha Henriques**. Sou muito grato por ter escolhido um jovem imaturo e desconhecido a 5 anos atrás. Foi essa pequena chance que transformou minha vida. Obrigado por estar sempre presente e disponível. O senhor sempre me tratou com respeito, amizade, e abriu muitas portas. É o fim de uma etapa, mas eu sei que não é o fim de nossa parceria e amizade. Obrigado mestre.

Ao meu co-orientador Prof. Dr. **Guilherme Janson**. Obrigado por tanto que fez por nós e pela ortodontia mundial. Queria que estivesse aqui para poder te agradecer uma última vez e dar boas risadas destes 5 anos de cobranças. Espero ter alcançado a expectativa que o senhor sempre colocou em mim. Continue brilhando e rindo aí de cima.

A minha turma de Doutorado: **Cinthya** (Quagli), **Cristina** (Cris), **Gabriela** (Gabas), **Graziane** (Grazi), **José** (Chéo), **Luciana** (Lu), **Marcelo Valério** (Mar), **Marcelo Corrêa** (Marcelão), **Maria Pia** (Pi), **Olga** (Olgs), **Rodrigo** (Shor). Foram 3 anos de convivência, trabalho, reuniões, risadas, e muitos sentimentos que só quem passou pelo que passamos é capaz de reconhecer. Sou extremamente grato de ter participado de tudo isso ao lado de pessoas que tão diferentes se uniram ao propósito comum. Fico feliz em saber que faço parte de uma nova safra de professores incríveis e espero nunca para de ouvir o nome de vocês. Vamos continuar sempre em frente turma! Aos amigos que convivi mais durante esse trajeto, Cris, Gabas, Chéo, Pi, Olgs e Shor. Obrigado por estarem lá nos dias bons, nos dias ruins, e nos dias que

precisávamos sempre uns dos outros. O laço que criei com vocês prometo manter até o fim da vida. Obrigado por serem meus amigos.

Aos meus colegas já formados e doutores: **Aron**, **Camila**, **Carol**, **Deborah**, **Diego**, **Fabíola**, **Felícia**, **Lorena**, **Ludmila**, **Paula**, **Raquel** e **Wilana**. O caminho trilhado foi mais fácil porque nós seguimos os passos de vocês. Em especial, agradeço ao meu amigo e irmão **Aron Aliaga-Del Castillo**. Você é o meu mentor. Sem os seus conselhos estes 5 anos teriam sido completamente diferentes. Sou extremamente grato por acreditar em mim. Me espelho muito em você e lhe admiro muito.

Aos meus colegas e amigos que vão continuar na FOB.

Doutorado: **Cássio**, **Vinícius**, **Gonzalo**, **Henrique**, **Renan**, **Thagid**, **Érika** e **Laura**. Vocês são brilhantes e me surpreendo sempre com a capacidade de todos. Tenho certeza ainda vou encontrá-los e aprender muito com cada um. Futuros professores.

Mestrado: **Alexandre**, **Beatriz**, **Gabriela Alcatraz**, **Gabriela Janson**, **Heloisa**, **Jessica**, **Lorena**, **Pamela**, **Rodrigo**, **Vinicius**, **Gabriel Querobim**, **Gabriel Bravo** e **Ivan**. Durante o pouco tempo que passamos juntos já é notável a união deste grupo e a energia boa que vem de vocês. Mal posso esperar para ver o crescimento de todos. Estou muito ansioso.

Em especial, agradeço aos também orientados do Prof. Fernando. Alexandre, Cássio, Érika, Heloisa, Lorena, Vinicius e Gabriel Querobim. Trabalhamos muito juntos e sei que é só o começo. Ainda temos muito pela frente! Desculpem se um dia cobrei vocês demais. Continuem dando o máximo de vocês que a recompensa sempre vem!

Aos meus queridos orientados de iniciação científica e agora colegas de profissão: **Carolina Anraki**, **Gabriel Querobim** e **Gabriela Utrago**. Vocês fizeram um trabalho excepcional. Nosso trabalho em conjunto foi um aprendizado constante de ambos os lados. Sou grato por vocês me permitirem participar na formação de vocês. Espero ter contribuído como vocês também contribuíram para minha formação. Orgulhoso por ver o que vocês já alcançaram.

Aos professores do departamento de Ortodontia, Prof. Dr. **Arnaldo Pinzan**, Profa. Dra. **Daniela Garib**, Prof. Dr. **Marcos Freitas**, Prof. Dr. **José Fernando Castanha Henriques**; Prof. Dr. **Guilherme Janson**; e Prof. Dr. **Renato Almeida**.

Em especial, a Profa. Dra. **Daniela Garib**. Na minha opinião um exemplo do(a) professor(a) ideal. Uma professora que consegue equilibrar a vida e a docência de

forma excepcional. Consegue ensinar e ao mesmo tempo cobrar os alunos de forma respeitosa e amável. Espero um dia alcançar essa sensibilidade com os alunos e esse equilíbrio constante. Muito feliz e ansioso para ver como a senhora vai conduzir o departamento daqui para frente. Sinto que cada vez mais a ortodontia da FOB vai crescer!

Sou grato a banca examinadora deste trabalho. Por aceitarem o convite e por toda atenção e tempo disponibilizado.

Agradeço aos funcionários do Departamento de Ortodontia da FOB-USP: Cleonice (Cléo), Daniel (Boné), Lourisvalda (Lo/Flor), Sérgio (Sérgião), Vera Lucia (Vevé) e Wagner (Wagnão). **Cléo**, muito obrigado por sempre me ajudar na clínica e confiar em mim. Seus conselhos foram fundamentais. Você sempre estava disposta, mesmo quando o dia estava complicado. Obrigado por toda ajuda, você é uma mãe excepcional. **Boné**, enquanto a Cléo me ajudava lá embaixo, você me ajudava lá em cima. Sempre disposto a me ajudar sem nem pedir nada em troca. Obrigado pela amizade. Um dia marcamos nosso churrasco. **Lo**, parece que não, mas o seu café e escutar você cantando no departamento deixava aquele lugar muito mais familiar. Eu adorava aquela sensação e trabalhava ainda melhor. Muito obrigado! **Sérgião** e **Wagnão**, de vocês tenho muito a agradecer. Vocês me ensinaram a fazer os aparelhos da pesquisa, então sem vocês eu não teria conseguido chegar até aqui. Aprendi muito com vocês, obrigado pela paciência e tempo durante esses 5 anos. **Wagnão**, valeu pela parceria, pelas cervejas e espetinhos. Quando eu voltar para Bauru vamos sair juntos. **Vevé**, não consigo nem contar quantas vezes você já me ajudou. Principalmente me lembrando de datas importantes e trabalhos. Obrigado pela confiança e por me receber até na sua casa. Espero ter te ajudado pelo menos um pouco, porque você sempre me ajudou muito!

A **56ª Turma de Odontologia da FOB-USP**. Muito obrigado pela homenagem inesquecível. É um privilégio ser um dos pós-graduandos homenageados escolhidos por vocês. Vocês estão no meu coração. Isso é uma das coisas que nos dá força para trilhar o caminho na docência.

Agradeço aos meus **pacientes**. Não somente aqueles atendidos durante a realização desta tese, mas de todos os pacientes que confiaram em mim para realização de seus tratamentos. Vocês foram fundamentas para minha formação.

A **Faculdade de Odontologia de Bauru, Universidade de São Paulo**, na pessoa do diretor Prof. Dr. Carlos Ferreira dos Santos; e da vice-diretora Profa. Dra. Marília Afonso Rabelo Buzalaf.

O presente trabalho foi realizado com o apoio da **Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES)** – Código de Financiamento 001.

“Resiliência é a capacidade de se adaptar e conviver com situações difíceis. É saber aprender com elas, superando-as oportunamente. É preciso ter a mente flexível, ser otimista, consciente de que tudo na vida é passageiro. Resiliência é a minha qualidade favorita”.

Roberto José Faria de Gusmão (Modificado)

ABSTRACT

Treatment stability with bonded versus vacuum-formed retainers after 12 months: a systematic review and randomized clinical trial

Introduction: This systematic review (SR) and randomized clinical trial (RCT) aimed to compare the clinical effectiveness of bonded versus vacuum-formed retainers (VFRs) regarding their capacity to maintain treatment stability, periodontal effects, and failure rates. **Methods**: For the SR, ten databases were systematically searched up to August 2021. RCTs comparing both retainers were included. The Risk of Bias (RoB) evaluation was performed with the Cochrane RoB tool 2.0. All steps of the review were performed independently by two reviewers. The GRADE was used to evaluate the certainty of the evidence. For the RCT, patients finishing orthodontic treatment were recruited and randomly allocated into two experimental groups. The bonded retainer (BR) group received upper and lower V-bend BRs bonded in the lingual surfaces of the anterior teeth. The VFR group received upper and lower VFRs right after fixed appliances removal. The patients were evaluated in four time-points: at fixed appliances removal (T0), after 3 months (T1), 6 months (T2), and 12 months (T3). Treatment stability based on occlusal outcomes and retainers' survival rates were the primary and secondary outcomes, respectively. Intergroup comparisons regarding stability outcomes were performed using Mann-Whitney U-tests ($P < 0.05$). The Kaplan-Meier survival plot and the log-rank test were employed to assess the retainers' survival. **Results**: Initial search yielded 923 studies. After full-text assessment, five RCTs remained. On a short-term (3-6 months) and long-term (4 years) basis, BRs were more effective to maintain stability than VFRs in the lower arch. From 12 to 24 months both retainers presented the same efficacy. In the upper arch, the retainers were equally effective. BRs were associated with greater plaque and calculus accumulation than VFRs after 12 months. The retainers' failure rates were similar in the upper arch on the first year of retention. Contrarily, BRs presented greater failure rates in the lower arch than VFRs. In the RCT, both groups included 25 patients. The groups were comparable regarding their baseline characteristics. Up to 6 months both retainers were equally effective; however, after 12 months, BRs were more effective in to maintain the incisors' alignment in the maxilla ($P < 0.001$) and in the mandible ($P < 0.006$) compared to the VFRs. No differences were noticed in the intercanine and

intermolar widths, overjet and overbite. There were also no differences in the retainers' survival rates in the maxillary and mandibular arches. **Conclusion**: The SR concluded that in the lower arch BRs were more effective than VFRs to maintain stability in the initial 6 months of retention and in the long term. In the upper arch, both retention protocols are equally effective. The RCT concluded that BRs were more effective to maintain the incisors alignment in the maxilla and mandible compared to VFRs after 12 months. Moreover, both retainers present the same survival rates in the maxillary and mandibular arches after the same period. **Registration**: This SR was registered in PROSPERO CRD42020199392. This trial was registered at ClinicalTrials.gov (NCT04847323). **Funding**: Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES), Finance Code 001.

Keywords: Orthodontics. Orthodontic Retainers. Systematic Review. Randomized Clinical Trial.

RESUMO

Estabilidade de tratamento com contenções fixas versus removíveis após 12 meses: uma revisão sistemática e ensaio clínico randomizado

Introdução: Esta revisão sistemática (RS) e ensaio clínico randomizado (RCT) teve como objetivo comparar a efetividade clínica de contenções fixas versus termoplásticas (VFR) em relação a sua capacidade de manter a estabilidade do tratamento, efeitos periodontais e taxas de falha. **Métodos**: Para a RS, dez bases de dados foram pesquisadas até agosto de 2021. RCTs comparando ambas contenções foram incluídos. A avaliação do risco de viés (RoB) foi realizada com a ferramenta Cochrane RoB 2.0. Todas as etapas da revisão foram realizadas independentemente por dois revisores. O GRADE foi usado para avaliar a certeza da evidência. Para o RCT, pacientes finalizando o tratamento ortodôntico foram recrutados e alocados em dois grupos experimentais. O grupo contenção fixa (BR) recebeu BRs superiores e inferiores com V-bends na lingual dos dentes anteriores. O grupo VFR recebeu VFRs nos arcos superior e inferior. Os pacientes foram avaliados em quatro momentos: Na remoção do aparelho fixo (T0), após 3 meses (T1), 6 meses (T2) e 12 meses (T3). A estabilidade do tratamento com base em variáveis oclusais e as taxas de sobrevivência das contenções foram os resultados primários e secundários, respectivamente. As comparações intergrupo foram feitas pelo teste U de Mann-Whitney ($P < 0,05$). O gráfico de sobrevivência de Kaplan-Meier e o teste Log-rank foram empregados para avaliar a sobrevivência das contenções. **Resultados**: A busca rendeu 923 estudos. Após a avaliação, 5 RCTs permaneceram. Em curto prazo (3-6 meses) e longo prazo (4 anos), os BRs foram mais efetivos em manter a estabilidade no arco inferior. De 12 a 24 meses ambas as contenções apresentaram a mesma efetividade. Na arcada superior, as contenções foram igualmente efetivas. BRs foram associados ao maior acúmulo de placa e cálculo do que VFRs após 12 meses. As taxas de falha das contenções foram semelhantes na arcada superior. Os BRs apresentaram maiores taxas de falha na arcada inferior. No RCT, ambos os grupos incluíram 25 pacientes. Os grupos foram comparáveis em relação às suas características no baseline. Até 6 meses, ambas as contenções foram igualmente efetivas; no entanto, após 12 meses, os BRs foram mais efetivos em manter o alinhamento dos incisivos na maxila ($P < 0,001$) e na mandíbula ($P < 0,006$) em

comparação as VFRs. Não foram observadas diferenças nas larguras intercaninos e intermolares, sobressalência e sobremordida. Não houve diferenças nas taxas de sobrevivência das contenções nos arcos maxilar e mandibular. **Conclusão**: A RS concluiu que no arco inferior os BRs foram mais efetivos que os VFRs em manter a estabilidade nos 6 meses iniciais de contenção e a longo prazo. Na arcada superior, ambos os protocolos de contenção foram igualmente eficazes. O RCT concluiu que os BRs foram mais efetivos em manter o alinhamento dos incisivos na maxila e mandíbula em comparação aos VFRs após 12 meses. Além disso, ambas as contenções apresentaram as mesmas taxas de sobrevivência. **Registro**: Esta RS foi registrada no PROSPERO CRD42020199392. Este estudo foi registrado em ClinicalTrials.gov (NCT04847323). **Financiamento**: Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES), Código 001.

Palavras-chave: Ortodontia. Contenções Ortodônticas. Revisão Sistemática. Ensaio Clínico Randomizado.

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LIST OF ABBREVIATIONS AND ACRONYMS

AL	Arch length
BR	Bonded retainer
CAPES	Coordination for the Improvement of Higher Education Personnel
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
F	Female
G1	Group 1
G2	Group 1
GRADE	Grade of Recommendations, Assessment, Development and Evaluation
ICC	Intraclass Correlation Coefficient
ICW	Intercanine width
IMW	Intermolar width
LII	Little Irregularity Index
M	Male
mm	Millimeters
n.r.	Not reported
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PROSPERO	International Prospective Register of Systematic Reviews
PICOS	Population, Intervention, Comparator, Outcome, Study Design
RCT	Randomized clinical trial
RoB	Risk of bias
SS	Stainless steel
T0	Fixed appliances removal
T1	3-month follow-up
T2	6-month follow-up
T3	12-month follow-up
VFR	Vacuum-formed retainer

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1 INTRODUCTION

1. INTRODUCTION

Relapse is unpredictable and should be expected in every orthodontic treatment. (LITTLEWOOD; KANDASAMY; HUANG, 2017) Even though the orthodontist made a correct diagnosis and planned the case correctly, there is no guarantee that stability will be obtained. (O'ROURKE; ALBEEDH; SHARMA; JOHAL, 2016) Moreover, orthodontic treatment should only be considered successful if long-term stability was achieved. (O'ROURKE; ALBEEDH; SHARMA; JOHAL, 2016) The best alternative to contain relapse is the retention phase. (LITTLE; RIEDEL; ARTUN, 1988) However, the ideal retention protocol remains uncertain. (FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018; LITTLEWOOD; MILLETT; DOUBLEDAY; BEARN *et al.*, 2016)

Although the subject has been extensively studied, the major causes of relapse are still not comprehended. Some factors such as growth and skeletal development; (NANDA; NANDA, 1992) considerable changes in the arch form; (DE LA CRUZ; SAMPSON; LITTLE; ARTUN *et al.*, 1995) dental factors; (RICHARDSON, 1996) and characteristics of the initial malocclusion (LITTLE; RIEDEL, 1989) have been related to potential causes of relapse. Independently of the cause, the use of retainers seems gold standard. Nonetheless, it is worth mention that the choice of the retainer should consider the initial malocclusion, treatment performed, and more importantly, the patients' willingness to use the retainer. (ANDRIEKUTE; VASILIAUSKAS; SIDLAUSKAS, 2017; PADMOS; FUDALEJ; RENKEMA, 2018) The most commonly used retainers worldwide are Hawley retainers, bonded retainers, and vacuum-formed retainers. (FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018)

One of the most traditional retainers in orthodontics is the bonded retainer (BR). Firstly described in 1973, this retainer consists of bonded wires in the lingual and palatal surfaces of the anterior teeth. (ILIADI; KLOUKOS; GKANTIDIS; KATSAROS *et al.*, 2015; KNIERIM, 1973) Different variations of BRs exist, but they are frequently made of solid or braided stainless steel wires. (MODA; DA SILVA BARROS; FAGUNDES; NORMANDO *et al.*, 2020) Minimum requirement of patient compliance can be considered the main advantage of these bonded wires. Still, these retainers were associated with greater periodontal problems compared to removable retainers, and the placement technique is operator sensitive.(DAHL; ZACHRISSON, 1991; STOREY; FORDE; LITTLEWOOD; SCOTT *et al.*, 2018)

Contrarily to the fixed BRs, vacuum-formed retainers (VFR) are removable retainers made of plastic. The popularity of these retainers is increasing progressively due to their comfort and greater demand of orthodontic aligners. (BONDEMARK; HOLM; HANSEN; AXELSSON *et al.*, 2007) Curiously, these retainers were firstly presented in the same decade as the BRs. (PONITZ, 1971) The effectiveness of the VFRs to maintain treatment stability has been reported in the literature, even when used nights-only. (LITTLEWOOD; MILLETT; DOUBLEDAY; BEARN *et al.*, 2016) Additionally, their minor periodontal complications have been highlighted. (STOREY; FORDE; LITTLEWOOD; SCOTT *et al.*, 2018) Nonetheless, the entire need of patients can be considered the greatest disadvantage of these retainers.

Recently, randomized clinical trials (RCTs) compared BRs and VFRs regarding their retention capacity. (AL-MOGHRABI; JOHAL; O'ROURKE; DONOS *et al.*, 2018; FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018; KRÄMER; SJÖSTRÖM; HALLMAN; FELDMANN, 2020; NARAGHI; GANZER; BONDEMARK; SONESSON, 2021; O'ROURKE; ALBEEDH; SHARMA; JOHAL, 2016) Although, their findings are contradictory. Some of them suggest the greater retention capacity of BRs, (AL-MOGHRABI; JOHAL; O'ROURKE; DONOS *et al.*, 2018; FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018) while other studies claim that the retainers present the same retention capacity. (KRÄMER; SJÖSTRÖM; HALLMAN; FELDMANN, 2020; NARAGHI; GANZER; BONDEMARK; SONESSON, 2021)

Previous systematic reviews were performed with these retainers individually with the attempt to combine the evidence from the RCTs; however, no direct comparison between BRs and VFRs was performed. (BUZATTA; SHIMIZU; SHIMIZU; PACHÊCO-PEREIRA *et al.*, 2017; LITTLEWOOD; MILLETT; DOUBLEDAY; BEARN *et al.*, 2016; MODA; DA SILVA BARROS; FAGUNDES; NORMANDO *et al.*, 2020) In view of this lack of consensus, a systematic review combining the evidence from RCTs would support clinical decision-making for the orthodontic practice. Moreover, the performance of an RCT with strict methodology would increase the robustness of the evidence regarding this topic.

Therefore, the aim of this systematic review was to synthesize the available evidence comparing the effectiveness of BRs and VFRs in maintaining treatment stability, periodontal effects and survival rates. Additionally, perform an RCT comparing both retainers regarding their capacity to maintain treatment stability and

survival rates; to complement the evidence from the systematic review. The null hypothesis tested considered was that there were no differences between retainers.

2 ARTICLES

2 ARTICLES

The first article presented in this thesis was written according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and the European Journal of Orthodontics guidelines for article submission.

Treatment stability with bonded versus vacuum-formed retainers: A systematic review of randomized clinical trials

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2.1 ARTICLE 1

TREATMENT STABILITY WITH BONDED VERSUS VACUUM-FORMED RETAINERS: A SYSTEMATIC REVIEW OF RANDOMIZED CLINICAL TRIALS

SUMMARY

Background: In orthodontics, the retention phase can be considered challenging and unpredictable. Therefore, evidence obtained from different retention protocols is important to facilitate clinical decision-making. **Objectives:** This systematic review aimed to compare the clinical effectiveness of bonded versus vacuum-formed retainers (VFRs) regarding their capacity to maintain treatment stability, periodontal effects, and failure rates. **Search methods and eligibility criteria:** Ten databases comprising published and unpublished literature were systematically searched up to August 2021. Randomized clinical trials (RCTs) comparing both retainers were included. **Data collection and analysis:** The Risk of Bias (RoB) evaluation was performed with the Cochrane Collaboration RoB tool 2.0. All steps of the screening phase and RoB assessment were performed independently by two reviewers. The Grade of Recommendations, Assessment, Development and Evaluation (GRADE) was used to evaluate the certainty of the evidence. **Results:** Initial database search yielded 923 studies. After duplicates removal and full-text assessment, five RCTs remained. Overall, the studies presented Low RoB, except one study judged with “Some concerns”. Based on the included studies, on a short-term (3-6 months) and long-term (4 years) basis, bonded retainers (BR) were more effective to maintain treatment stability than VFRs in the lower arch. However, from 12 to 24 months both retainers presented the same efficacy. In the upper arch, the retainers were equally effective. BRs were associated with greater plaque and calculus accumulation than VFRs after 12 months. The retainers’ failure rates were similar in the upper arch on the first year of retention; however, after 2 years VFRs showed significantly greater failure rates. Contrarily, BRs presented greater failure rates in the lower arch than VFRs.

Conclusions: Most of the evidence generated in this systematic review derived from a moderate level of certainty. In the lower arch, BRs are more effective than VFRs to maintain treatment stability in the initial 6 months of retention and in the long term. In

the upper arch, both retention protocols are equally effective. **Registration:** Registration number: PROSPERO CRD42020199392.

Keywords: Orthodontics; Orthodontic Retainers; Systematic Review.

INTRODUCTION

In orthodontics, the possibility of relapse after treatment should always be taken into account (1). Although an accurate diagnosis and adequate mechanics are performed, the results obtained with orthodontic treatment may not be completely stable over time (2). The unpredictable nature of relapse inspired many researchers to investigate the most clinically effective retention protocol to enhance treatment stability. Nonetheless, the ideal retention protocol remains unclear (3,4).

The retention phase is recognized as the best attempt to maintain teeth in the correct position in the short- and long-terms (5). The most frequently used retention appliances are Hawley retainers, bonded retainers, and vacuum-formed retainers (3). Moreover, the decision-making for each one of them seems to be influenced by a different range of factors such as initial malocclusion, treatment applied, patients' assumptions, and orthodontists' experience (6,7).

Bonded retainers (BRs) were firstly described in 1973 (8). Basically, this type of retainer consists of solid or braided wires bonded to the lingual surface of the anterior teeth to maintain their alignment (9). Some variations of the retainer exist and its effectiveness is well-established in the literature (10,11). The main advantage of the technique is the minimum requirement of patient compliance when compared to the removable retainers (3). Notwithstanding, BRs have been related to greater plaque and calculus accumulation (12).

Regarding removable retainers, vacuum-formed retainers (VFR) are currently gaining popularity among patients and orthodontists owing to their ease of production and comfort (13). Interestingly, these plastic retainers were introduced in the same decade as BRs (14). The effectiveness of this kind of retainer has also been proved and is speculated their minor periodontal complications (12). Logically, the greater disadvantage of VFR resides in the entire need for patient compliance.

Previous systematic reviews evaluated the abovementioned retainers individually (10,11,15). Nonetheless, a direct systematic comparison between them has not yet been carried out. Recent clinical research compared the retention capacity

of both retainers (2,3,16-18). However, their findings were controversial. Some of them suggest that BRs are more effective to maintain treatment stability compared to VFRs (3,16), while others state that no differences between retainers exist (17,18). Inconsistent evidence is also reported regarding the retainers' survival rates and retention wear time (4,9). A synthesis of the available evidence from randomized controlled trials (RCTs) would provide relevant information regarding both retainers and improve the orthodontist's decision-making of which retainer is more suitable for each individualized case.

Therefore, the primary aim of this systematic review was to compare the effectiveness of bonded versus vacuum-formed retainers regarding their capacity to maintain treatment stability. The secondary aim was to compare the retainers regarding their periodontal effects and failure rates.

MATERIAL AND METHODS

Protocol and Registration

The present review was conducted following the Cochrane Handbook for Systematic Reviews of Interventions (19) and was reported according to the PRISMA statement (20). Furthermore, a pre-existing protocol was registered on PROSPERO (CRD42020199392).

Eligibility criteria

The selection criteria were based on the PICOS strategy:

1. Participants: patients of any age and sex who underwent orthodontic treatment and followed a retention protocol.

2. Intervention: VFRs after active orthodontic treatment.

3. Comparator: BRs after active orthodontic treatment.

4. Outcome: treatment stability evaluated in millimeters with different occlusal variables at any available follow-up. Periodontal changes and failure rates were considered secondary outcomes.

5. Study Design: randomized clinical trials.

In summary, RCTs comparing the effectiveness of bonded versus VFRs in maintaining the results obtained with orthodontic treatment were included. Studies were excluded if they not exclusively compared VFRs and BRs; if the patients included

presented an initial malocclusion requiring extensive transverse corrections (rapid maxillary expansion or surgical expansion); tooth anomalies of number/form; and craniofacial syndromes.

Information sources, search strategy and study selection

Seven electronic databases (PubMed, Scopus, Web of Science, The Cochrane Library, Lilacs, Embase, and Livivo) were searched up to August 2021. Grey literature search included Google Scholar, OpenGrey, and ClinicalTrials (www.clinicaltrials.gov). Overall, 10 databases comprising published and unpublished literature were searched without limitations regarding language, publication year, and status. Detailed search strategies of each database are shown in Supplementary Table 1. Additionally, hand-search was performed in Orthodontic journals to identify any potential article loss.

The search was performed in two phases. Initially, two reviewers (S.A.B.P. and A.A.D.C) screened the titles and abstracts of all retrieved studies. Duplicate records were removed with the reference management software Endnote (Clarivate Analytics, Philadelphia, USA). The remaining studies were transferred for the second phase, where both reviewers assessed the full report of publications and applied the eligibility criteria. Both screening phases were performed independently and any disagreement was resolved by discussion or consulting with a third reviewer (C.C.O.S.). Finally, the reference lists of the included studies were searched for additional studies.

Data items and collection

The following qualitative and quantitative data were extracted from the included studies in a piloted electronic spreadsheet (Excel, Microsoft Corporation 2019): Authors; publication year; sample characteristics (sample size, patients' sex, age, type of retainer); stability assessment and outcomes; follow-ups; retention protocol; failure rates and main findings). During the process, if unreported relevant data was noticed, the trial investigators were contacted by e-mail for clarification.

Risk of bias in individual studies

The risk of bias (RoB) of the selected RCTs was assessed with the Cochrane Collaboration RoB Tool 2.0 (21). The tool considers five domains and results in an overall RoB judgment of "Low RoB" (low risk for all domains), "Some concerns" (some

concerns in at least one domain, but no high risk for any domain), and “High RoB” (high risk for at least one domain, or some concerns in multiple domains).

Equally to the screening phase (study selection and data extraction), the RoB assessment was performed independently by both reviewers, and the third reviewer acted as a judge to resolve disagreements, if necessary.

Summary measures and approach to synthesis

A qualitative summary of the findings focusing on treatment stability was decided a priori. Moreover, due to the anticipated continuous nature of the outcomes, mean differences and 95% confidence intervals were planned for quantitative synthesis, if possible. Meta-analysis was planned if the included studies presented acceptable homogeneity and reported similar outcomes with appropriate statistical forms. In such case, a random-effects meta-analysis was deemed more suitable considering the possible differences among patients and implementation of interventions (22).

Risk of bias across studies and additional analysis

If feasible, publication bias would be evaluated through the inspection of the contour-enhanced funnel plots (23). The certainty of the evidence was judged with the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) approach (24) for each outcome and time-point evaluated.

RESULTS

Study selection and characteristics

The database search identified 923 studies. After duplicates removal, 511 studies remained. Grey literature search did not identify any potential study following the eligibility criteria. Moreover, the titles and abstracts were screened and 500 studies were discarded. During the first phase, disagreements were rare between reviewers. Of the 511 titles and abstracts reviewed only 8 presented different judgments and were discussed with the third reviewer. The second phase included 11 studies for full-text evaluation. Of these, 6 were excluded with reasons (Supplementary Table 2). Finally, 5 studies were included in the qualitative synthesis. Second phase screening was performed with no disagreements between reviewers. The process of identification,

screening, and exclusion of studies is described in the PRISMA flow diagram (20) (Figure 1).

The 5 included studies involved 348 patients (60% female / 40% male). They presented a two-arm (2,3,16,17) or three-arm (18) RCT design comparing bonded versus VFRs. The mean average age of the patients ranged between 13.8 ± 1.5 and 21.5 ± 3.0 years. Overall, the studies evaluated treatment stability with the following variables: Little Irregularity Index (LII), intercanine and intermolar width, and arch length. Additionally, extraction site opening was assessed in two studies (2,16), overbite and overjet were evaluated in the other three studies (3,17,18). These variables were assessed in digitized (3,17,18) or plaster models (2,16). Only two studies evaluated the upper arch (3,18).

The outcomes were assessed at debonding and at different follow-ups, which varied among studies. The maximum follow-ups evaluated were 12 (3), 18 (2,17), 24 (18), and 48 (16) months. In three studies it was possible to extract data at debonding and the longest follow-up (3,16,17), while in two studies only the treatment changes between periods were provided (2,18).

The retention protocol with VFRs differed among studies. Some authors suggested full-time use for 1 week (17), 4 weeks (18), or 6 months (2,16), followed by nights-only use for 1 year. Then, intermittent use after this period. Other authors instructed patients to wear the retainers only at night since debonding (3).

The overall retainer failure rates ranged from 5.8% to 50% for both retainers but differed in the upper and lower arches. A detailed description of the study's characteristics can be observed in Table 1.

Risk of bias within studies

In general, all the included studies in this systematic review were well-designed and followed the CONSORT guidelines (25). Thus, 4 included studies (2,3,17,18) presented Low RoB and only one study (16) was judged with “Some concerns” (Figure 2). The randomization process involving random sequence generation, allocation concealment, and implementation was adequate. Likewise, no signs of deviations from intended interventions were noticed in all studies.

One study (2) presented a great number of drop-outs; therefore, possible bias due to missing outcome data was speculated. Even though the drop-outs were clearly reported and explained, it was decided to judge the study with “Some concerns” for

this domain. The authors reported a considerable drop-out rate of 36% and 48% in the bonded and vacuum-formed groups respectively.

Two studies (17,18) presented the trial protocol registration and permitted a direct evaluation of bias in the selection of the reported result. In the remaining studies, the authors were contacted for clarifications and no evidence or suggestion of selection bias were noticed leading to a Low RoB judgment. The risk of bias assessment occasionally resulted in disagreements between reviewers in two studies (2,16). However, an agreement was obtained after discussion and contacting the study's authors.

Results of individual studies, meta-analysis, and additional analysis

Initially, the performance of meta-analysis was expected; however, due to the substantial clinical and methodological heterogeneity between studies quantitative analysis was not feasible. Then, for descriptive reasons, findings will be presented regarding treatment stability at 3 to 6, 12 to 24, and 48 months to ease understanding. These were the follow-up times during retention provided in the included studies.

3 to 6 months follow-up: On a short-term basis, two studies (2,3) stated that BRs were more effective to maintain treatment stability in the lower arch compared to VFRs. Contrarily, one study (17) showed that the retention capacity of both retainers was similar during this period. Concerning the upper arch, no differences were found between retainers in the study of Forde et al. (3).

12 to 24 months follow-up: After 1-year, two studies (2,17) observed the same retention capacity between retainers; however, one study (3) suggested that BRs were more effective in the lower arch. Again, no differences were exhibited in the upper arch (3,18).

48 months follow-up: On a long-term basis BRs were more effective in maintaining treatment stability in the lower arch when compared to VFRs, although some relapse was observed in both groups (16). None of the included studies presented long-term data regarding the upper arch.

Two studies assessed the patient's periodontal health. The first study described that after one year BRs were associated with greater plaque and calculus accumulation and gingival inflammation than VFRs (3). Moreover, after 4 years both retainers were associated with plaque accumulation and gingival inflammation without significant differences (16).

Concerning the retainers' failure rates, in the upper arch, both retainers presented similar rates after 1-year in one study (3); however, another study (18) showed significantly greater failure rates with VFRs (50%) compared to BRs (23%) after 2 years (Table 1). In the lower arch, two studies reported significantly greater failure rates with BRs compared to VFRs (2,3). The study from Kramer et al. (17) did not find significant differences between the retainers' failure rates.

The certainty of evidence evaluated through the GRADE approach is described in Table 2. The overall certainty of evidence ranged from low to moderate for the outcomes assessed. In case of low certainty, the confidence in the effect estimated is limited and may be substantially different. Moreover, a moderate judgment suggests that the estimated effect is likely to be close to the true effect. This was the case for the great majority of outcomes. Publication bias was not evaluated because meta-analysis was not undertaken.

DISCUSSION

Summary of evidence

The present systematic review included 5 RCTs exclusively comparing BRs and VFRs. A broader Cochrane review (4) performed this comparison indirectly, and previous reviews were performed with different retainers (26,27). However, this is the first systematic review to directly compare these types of retainers.

The study from Al-Moghrabi et al. (16) was the long-term (4-year) evaluation of the RCT from O'Rourke et al. (2). Nonetheless, they were considered independent studies in this systematic review because different research teams performed the outcomes evaluation, and both short- and long-term data would provide clinically relevant findings for the present review.

Overall, during the first 6 months of retention evidence of moderate certainty suggests that BRs are more effective in maintaining treatment stability than VFRs in the lower arch. It could be speculated that the worse performance of VFRs on a short-term basis compared to BRs might be related to the non-compliance of patients regarding the retention regimen rather than a proper failure of the retainer (2). In accordance, the RCT that found no differences between retainers reported minimum failure rates and great patient adherence with the VFR (17). Curiously, in this study, the VFRs were made up to the first premolars. Again, it seems that the possible short-

term failure of VFRs in maintaining lower incisors alignment might be more related to the patients' non-compliance than the retainer itself. If the patient is unwilling or unable to wear the retainer as prescribed, some degree of relapse should be expected (1).

Orthodontic studies comparing fixed versus removable appliances are susceptible to this kind of shortcoming because researchers do not know the true amount of time the appliance was wear during the observational period. In this regard, short-term retention remains a controversial topic. Nonetheless, the evidence generated in this review reiterates the greater effectiveness of BRs compared to VFRs in the short term.

The retention capacity of both retainers in the lower arch was similar after 1 and 2 years in most of the included studies (2,17). This was an interesting finding and may be explained by different aspects of retention. Firstly, the literature describes that relapse mainly occurs in the first 6 to 12 months of retention; therefore, after this period it should be less expected (17,28). Additionally, the failure rates of the retainers are also greater in the short-term corroborating with a greater chance of relapse (2,3,17). In this regard, the first 12 months of retention are critical. It could be speculated that after this period the chance of relapse might be reduced enhancing the retainers' effectiveness.

The longest follow-up assessed was 4 years. Evidence suggested that BRs were more effective than VFRs to maintain treatment stability in the lower arch in the long term. Nonetheless, these findings are supported by only one study (16), and therefore, represent a low level of certainty. In this study, the authors were contacted for clarifications and confirmed that approximately 70% of the patients in the VFR group stopped wearing the retainers at the 4-year follow-up, probably explaining the greater effectiveness of BRs. Once more, the greater disadvantage of VFRs compared to BRs is the entire need for patient compliance. Although it could be suggested that both retainers present the same retention capacity in the lower arch in the long term, it seems that the patients' responsibility decreases progressively over time, which may lead to relapse. Retention clinical studies are difficult to undertake from a practical and financial perspective, but further long-term studies should be performed for more robust information regarding this subject.

It was possible to gather evidence from two studies regarding the effect of the retainers in the upper arch. In this case, both RCTs indicated that the retainers present the same retention capacity after 1 and 2 years (3,18). The literature shows

considerably smaller relapse in the upper arch when compared to the lower arch in both short- and long-terms (29). These findings are in accordance with previous retrospective studies that showed minimum relapse in the upper arch after 5 and 7 years (29,30). That reduced tendency of relapse in the upper arch might explain the effectiveness of different maxillary retention protocols (3,18,29). Overall, there is a lack of sufficient evidence to affirm that one retainer is better than the other on a long-term basis.

The periodontal effects and failure rates of the retainers were secondary outcomes of this systematic review. In this regard, there seems to be a consensus that BRs present greater plaque and calculus accumulation, and consequently cause greater gingival inflammation than VFRs in the short term (3). Logically, these effects are restricted to the canine-to-canine area. Moreover, on a long-term basis, both retainers were related to plaque accumulation and negative periodontal effects. Nonetheless, these effects were not strong enough to be clinically significant (12). It is reasonable to state that orthodontists must follow their patients and control their periodontal health in the long term as part of overall orthodontic treatment.

The survivability of the retainers might be influenced by a different range of factors. Especially when different studies and populations are considered. Likewise, a previous systematic review showed that the failure rate of BRs could range from 11% to 71% (9). Similarly, VFRs can reach important failure rates of 50% to 70% (16,18). It seems clear that both retainers are susceptible to failure and require great care from the patient and orthodontist. Based on the RCTs included in this review, it could be considered that after 18 months of retention VFRs present greater failure rates in the upper arch compared to BRs. Contrarily, BRs showed greater failures rates in the lower arch after this period (Table 1). It should be emphasized that these findings are based on a moderate level of certainty, and further studies are required to confirm them.

To date, there is no standardized retention protocol for VFRs. However, high-quality evidence included in this systematic review indicates that VFRs part-time wear is equally effective compared to full-time wear (3,4,17). Thus, it is reasonable to affirm that these retainers could be prescribed for night-only use. The part-time wear of the VFR might also be related to the increased longevity of the material. On the contrary, full-time wear could be associated with greater failure rates (31).

From a clinical perspective, the decision-making regarding BRs and VFRs might consider other variables, such as cost-benefit, the differences between upper and

lower arches, orthodontist's preferences, quality of life, but more importantly the level of patient compliance/motivation (9). Post-orthodontic appointments for treatment stability assessments are also part of orthodontic treatment. The patient should be followed up regularly after fixed appliances removal independently of the retainer of choice.

Limitations

The results of this review should be interpreted with caution. Even though the studies included were well conducted in a methodological perspective, it should be highlighted that their findings may be influenced by different initial malocclusions included, amounts of tooth movement, the patients' age, the true amount of VFRs wear time, the different materials of BRs, among other factors that are related to the unpredictability of relapse (4). However, these factors are beyond the objectives of this review.

CONCLUSIONS

According to the existing evidence found in this systematic review, the following can be concluded based on Low to Moderate level of certainty:

- In the lower arch, BRs are more effective to maintain treatment stability during the initial 6 months of retention compared to VFRs. After 12 months there is a tendency for both retention protocols to be equally effective. Nonetheless, in the long term, BRs seem to prevail over the VFRs regarding their retention capacity.
- In the upper arch, both retainers are an effective retention protocol to maintain the results obtained with orthodontic treatment.
- Bonded retainers are related to greater plaque and calculus accumulation than VFRs in the short term. In the long-term, both retainers are associated with negative periodontal effects highlighting the importance of post-orthodontic periodontal control.
- Both retainers present similar failure rates in the upper arch during the first year of retention; however, after this period VFRs present greater failure rates in the upper arch than BRs. In contrast, BRs present greater failure rates in the lower arch when compared to VFRs.

Acknowledgments

We thank the authors' Ama Johal (Queen Mary University of London, London, UK), Dalya Al-Moghrabi (Queen Mary University of London, London, UK), Padhraig Fleming (Queen Mary University of London, London, UK), Simon Littlewood (St Luke's Hospital, Bradford, UK) for providing clarifications and/or additional data for this systematic review.

Funding

This work was supported by the Coordination for the Improvement of Higher Educational Personnel (CAPES, Process code – 001).

Conflict of interest statement

None to declare.

Data availability statement

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

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FIGURE LEGENDS

Figure 1. Modified PRISMA flow diagram.

Figure 2. Cochrane Risk of Bias Tool 2.0 summary.

TABLE LEGENDS

Table 1. Characteristics of the 5 randomized clinical trials included in the qualitative assessment.

Table 2. GRADE Summary of Findings Table.

SUPPLEMENTARY MATERIAL

Supplementary Table 1. Databases and search strategy.

Supplementary Table 2. List of excluded studies with reasons for exclusion (n=6).

Fig. 1

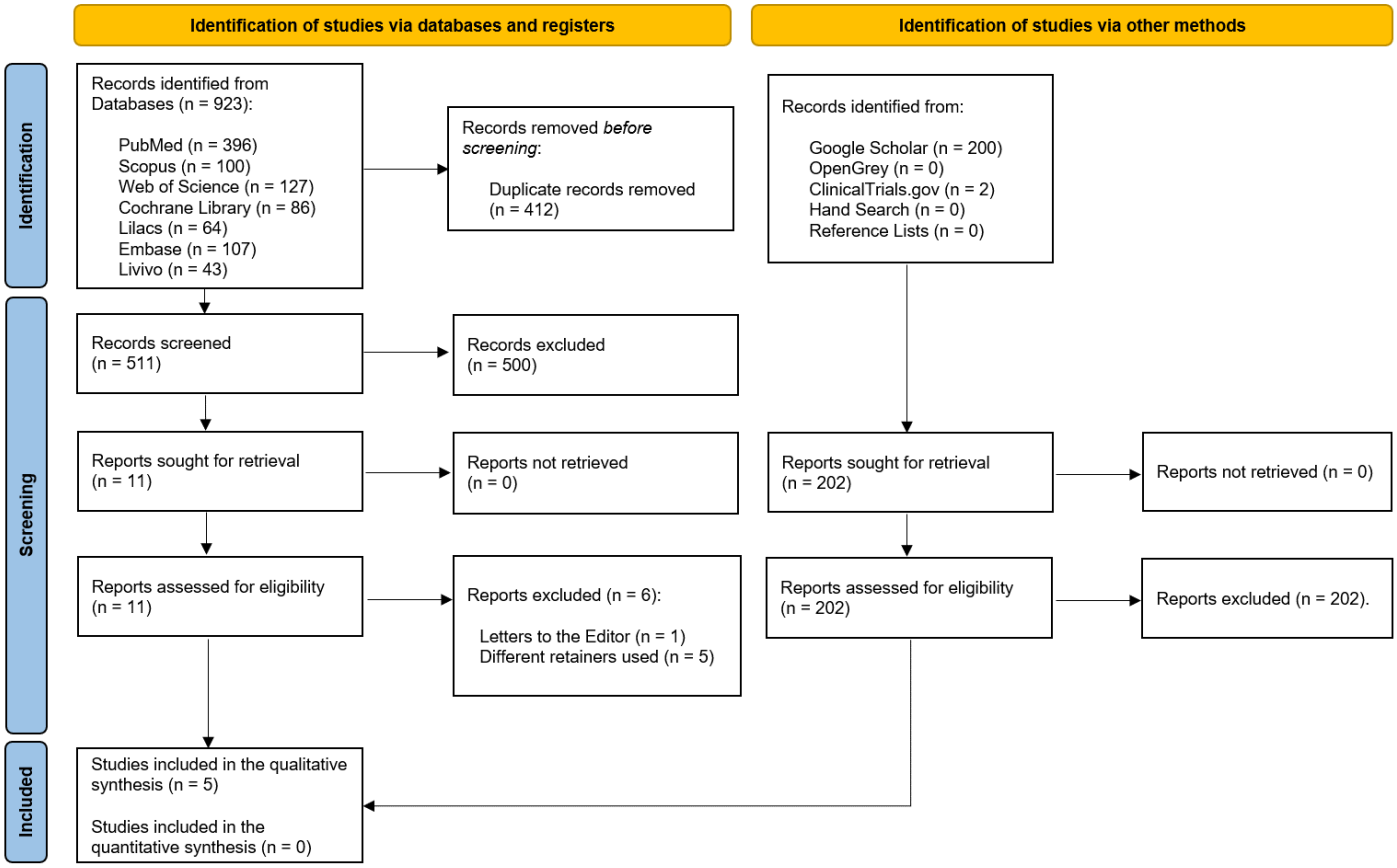
Identification of studies via databases and registers
Identification of studies via other methods
Identification
Screening
Included
Records identified from Databases (n = 923):
PubMed (n = 396)
Scopus (n = 100)
Web of Science (n = 127)
Cochrane Library (n = 86)
Lilacs (n = 64)
Embase (n = 107)
Livivo (n = 43)
Records removed *before screening*:
Duplicate records removed (n = 412)
Records identified from:
Google Scholar (n = 200)
OpenGrey (n = 0)
ClinicalTrials.gov (n = 2)
Hand Search (n = 0)
Reference Lists (n = 0)
Records screened (n = 511)
Records excluded (n = 500)
Reports sought for retrieval (n = 11)
Reports not retrieved (n = 0)
Reports sought for retrieval (n = 202)
Reports not retrieved (n = 0)
Reports assessed for eligibility (n = 11)
Reports excluded (n = 6):
Letters to the Editor (n = 1)
Different retainers used (n = 5)
Reports assessed for eligibility (n = 202)
Reports excluded (n = 202).
Studies included in the qualitative synthesis (n = 5)
Studies included in the quantitative synthesis (n = 0)

Fig. 2

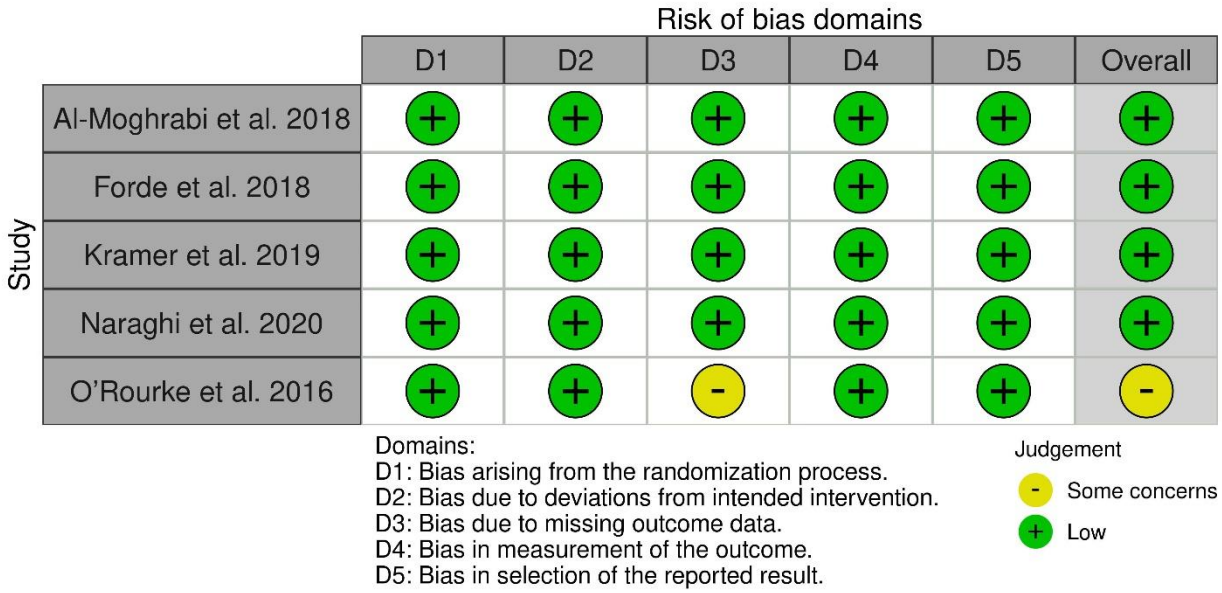
Risk of bias domains
D1
D2
D3
D4
D5
Overall
Study
Al-Moghrabi et al. 2018
Forde et al. 2018
Kramer et al. 2019
Naraghi et al. 2020
O'Rourke et al. 2016
Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.
Judgement
Some concerns
Low

Table I. Characteristics of the 5 randomized controlled trials included in the qualitative assessment.

Authors / Publication Year	Groups (N/sex/age)	Stability assessment	Outcome measures		Retention protocol (Vacuum-formed retainers)	Retainers' failure rates	Main findings
			Debond	Longest follow-up			
Al-Moghrabi et al. 2018	G1 Bonded retainers Coaxial SS wire 21 (18F / 3M) 21.54 years (3.06) G2 Vacuum-formed retainers Essix™ 21 (14F / 7M) 20.77 years (1.49)	Outcomes evaluated: LII, ICW, IMW, AL, extraction site opening Measurements were performed in the lower arches on gypsum study models with a digital caliper at debond and after 48 months	G1 – Lower arch LII: 0.25 (0.47) ICW: 26.90 (1.89) IMW: 42.80 (3.96) AL: 24.45 (3.83) Extraction opening: 0.00 (0.19) G2 – Lower arch LII: 0.42 (0.84) ICW: 26.77 (2.29) IMW: 41.77 (4.03) AL: 22.15 (2.96) Extraction opening: 1.37 (0.72)	G1 – Lower arch LII: 1.23 (1.27) ICW: 26.74 (1.84) IMW: 42.23 (5.82) AL: 25.84 (7.04) Extraction opening: 0.00 (0.00) G2 – Lower arch LII: 3.16 (2.74) ICW: 25.62 (2.51) IMW: 42.66 (4.93) AL: 20.81 (8.33) Extraction opening: 1.65 (1.57)	Full-time basis for the first 6 months, nights only for the following 6 months, and alternate nights from 12-18 months. Thereafter, intermittent nights-only wear (1 to 2 night weekly)	After 48 months: G1 – Lower arch 24% G2 – Lower arch n.r. %	After 48 months, BRs were more effective in retaining lower incisors alignment compared with VFRs (P = 0.02), although some relapse was observed in both groups
Forde et al. 2018	G1 Bonded retainers 3-stranded twistflex SS wire 30 (15F / 15M) 16 years (2) G2 Vacuum-formed retainers Essix™ 30 (18F / 12M) 17 years (4)	Outcomes evaluated: LII, ICW, IMW, AL, overjet and overbite Measurements were performed in the upper and lower arches on digitized study models at debond, 3, 6, and 12 months	G1 – Upper arch / Lower arch LII: 0.00 (0.93) / 0.29 (1.02) ICW: 35.20 (2.83) / 27.53 (1.68) IMW: 50.11 (3.96) / 44.05 (4.64) AL: 73.94 (12.74) / 66.74 (6.00) Overjet: 2.37 (0.70) Overbite: 1.29 (1.22) G2 – Upper arch / Lower arch LII: 0.23 (0.66) / 0.06 (1.23) ICW: 34.09 (2.22) / 26.17 (1.13) IMW: 48.46 (4.24) / 41.34 (5.72) AL: 71.23 (9.67) / 65.53 (12.94) Overjet: 2.38 (2.40) Overbite: 2.00 (1.21)	G1 – Upper arch / Lower arch LII: 1.35 (1.98) / 1.01 (1.28) ICW: 35.08 (2.31) / 27.31 (2.21) IMW: 49.47 (3.88) / 43.90 (4.32) AL: 76.70 (10.81) / 66.97 (8.21) Overjet: 2.26 (1.07) Overbite: 1.59 (0.78) G2 – Upper arch / Lower arch LII: 0.97 (1.68) / 1.73 (2.77) ICW: 33.21 (2.36) / 25.56 (1.39) IMW: 47.70 (3.80) / 41.32 (4.61) AL: 68.86 (10.26) / 62.57 (9.50) Overjet: 2.59 (0.94) Overbite: 2.01 (1.00)	Only at night, every night	After 12 months: G1 – Upper arch / Lower arch 36.7% / 50% G2 – Upper arch / Lower arch 26.7% / 20%	After 12 months, there is no evidence of a significant differences regarding stability (P = 0.61) or retainer survival (P = 0.34) in the upper arch. Nonetheless, in the lower arch, BRs were more effective at maintaining incisors alignment (P = 0.008), but with the cost of a higher failure rate (P = 0.01)

Kramer et al. 2019	G1 Vacuum-formed retainers Essix™ 52 (26F / 26M) 17.1 years (2.4) G2 Bonded retainers Remanium® wire 52 (26F / 26M) 17.1 years (1.9)	Outcomes evaluated: LII, ICW, IMW, AL, overjet and overbite Measurements were performed in the lower arches on digitized study models at debond, 6, and 18 months	G1 – Lower arch LII: 1.33 (0.65) ICW: 26.77 (1.89) IMW: 42.85 (2.96) AL: 58.82 (10.23) Overjet: 3.23 (1.63) Overbite: 1.68 (1.04) G2 – Lower arch LII: 1.53 (1.03) ICW: 27.33 (2.11) IMW: 42.57 (3.10) AL: 54.25 (8.31) Overjet: 3.13 (1.57) Overbite: 1.85 (0.97)	G1 – Lower arch LII: 2.06 (1.52) ICW: 26.63 (1.96) IMW: 43.30 (2.56) AL: 58.48 (9.74) Overjet: 3.12 (1.09) Overbite: 2.17 (1.55) G2 – Lower arch LII: 2.03 (1.40) ICW: 27.28 (1.95) IMW: 42.48 (2.89) AL: 53.22 (7.21) Overjet: 3.03 (1.24) Overbite: 2.06 (1.45)	Full-time the first week and thereafter at night only until 12 months. 12-18 months: intermittent nights 18-24 months: 2 nights per week	After 18 months: G1 – Lower arch 5.8% G2 – Lower arch 5.8%	After 18 months, VFRs and BRs presented the same retention capacity and failure rates in the lower arch
Naraghi et al. 2020	G1 Bonded retainers Penta-One 0.0195 SS wires 30 (17F / 13M) 13.8 years (1.5) G2 Vacuum-formed retainers Essix™ 30 (17F / 13M) 13.9 years (1.9)	Outcomes evaluated: LII, ICW, IMW, AL, overjet, overbite and maximum rotation Measurements were performed in the upper arches on digitized models with the software OnyxCeph™ before treatment, at debond (T1), and after 24 months (T2)	G1 – Upper arch (T2-T1) LII: 0.30 (CI: 0.10; 0.50) ICW: -0.30 (CI: -0.50; -0.10) IMW: -0.30 (CI: -0.70; 0.10) AL: 0.10 (CI: -0.10; 0.30) Overjet: 0.1 (CI: -0.10; 0.30) Overbite: 0.20 (CI: 0.00; 0.40) G2 – Upper arch (T2-T1) LII: 1.00 (CI: 0.40; 1.60) ICW: 0.20 (CI: 0.00; 0.40) IMW: -0.40 (CI: -0.60; -0.20) AL: 0.00 (CI: -0.20; 0.20) Overjet: 0.0 (CI: -0.40; 0.40) Overbite: 0.30 (CI: -0.10; 0.70)		Full-time basis for the first 4 weeks, then every night, and alternate nights from 12-24 months	After 24 months: G1 – Upper arch 23.3% G2 – Upper arch 50%	Both retention methods showed equally effective retention capacity after 2 years and can be recommended as retention methods in the upper arch (P = 0.138)

O'Rourke et al. 2016	G1 Bonded retainers Coaxial SS wire 42 (33F / 9M) 18.47 years (4.41) G2 Vacuum-formed retainers Essix™ 40 (26F / 14M) 16.95 years (2.02)	Outcomes evaluated: LII, ICW, IMW, AL, extraction site opening Measurements were performed in the lower arches on gypsum study models with a digital caliper at debond (T0), 6 (T1), 12 (T2) and 18 (T3) months	G1 – Lower arch LII: (T1-T0) 0.03 / (T2-T1) 0.03 / (T3-T2) 0.03 ICW: (T1-T0) 0.11 / (T2-T1) 0.17 / (T3-T2) 0.17 IMW: (T1-T0) 0.26 / (T2-T1) 0.38 / (T3-T2) 0.18 AL: (T1-T0) 0.19 / (T2-T1) 0.20 / (T3-T2) 0.18 Extraction opening: (T1-T0) 0.00 / (T2-T1) 0.00 / (T3-T2) 0.00 G2 – Lower arch LII: (T1-T0) 0.08 / (T2-T1) 0.08 / (T3-T2) 0.08 ICW: (T1-T0) 0.23 / (T2-T1) 0.20 / (T3-T2) 0.26 IMW: (T1-T0) 0.16 / (T2-T1) 0.25 / (T3-T2) 0.25 AL: (T1-T0) 0.23 / (T2-T1) 0.19 / (T3-T2) 0.19 Extraction opening: (T1-T0) 0.00 / (T2-T1) 0.00 / (T3-T2) 0.00	Full-time basis for the first 6 months, nights only for the second 6 months, and alternate nights from 12-18 months. Thereafter, intermittent nights-only wear (1 to 2 night weekly)	After 18 months: G1 – Lower arch 7.15% G2 – Lower arch 0%	BRs were more effective in their ability to maintain incisor alignment in the lower arch in the first 6 months after debond when compared to VFR (P = 0.008). Nonetheless, some minimal relapse is likely after fixed appliances therapy irrespective of retainer choice. The retention capacity between retainers was similar at 12 and 18 months (P = 0.195 and P = 0.300, respectively)

Table 2. GRADE Summary of Findings Table.

Certainty assessment							Summary of findings	Certainty
N° of studies (Patients)	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication Bias		
3 to 6 Months Stability								
3 (246)	RCTs	Not serious	Serious†	Not serious	Not serious	Not suspected	During the initial 6 months of retention, BRs are more effective than VFRs to maintain the lower incisors alignment. In the upper arch there is no difference between retainers.	⊕⊕⊕◯ MODERATE
12 to 24 Months Stability								
4 (306)	RCTs	Not serious	Serious†	Not serious	Not serious	Not suspected	After 12 to 24 months of retention, BRs and VFRs present the same retention capacity in the upper and lower arches.	⊕⊕⊕◯ MODERATE
48-Month Stability								
1 (42)	RCT	Not serious	Not serious	Serious‡	Serious€	Not suspected	BRs are more effective than VFRs in the long-term (after 48 months).	⊕⊕◯◯ LOW
Periodontal Health Changes								
2 (102)	RCTs	Not serious	Not serious	Not serious	Serious€	Not suspected	BRs are associated with greater plaque and calculus accumulation than VFRs during the initial 12 months of retention. After 48 months both retainers are related to negative periodontal effects. Nonetheless, these effects did not appear to produce any periodontal problem of clinical significance.	⊕⊕⊕◯ MODERATE
Failure Rates (Upper arch)								
2 (120)	RCT	Not serious	Not serious	Not serious	Serious€	Not suspected	BRs and VFRs present similar failure rates after 12 months. Nonetheless, after this period, VFRs present significantly greater failure rates compared to BRs.	⊕⊕⊕◯ MODERATE
Failure Rates (Lower arch)								
3 (246)	RCTs	Not serious	Serious†	Not serious	Not serious	Not suspected	BRs present significantly greater failure rates compared to VFRs after an 18-month period.	⊕⊕⊕◯ MODERATE

Note: for publication purposes the individual GRADE summary of the primary and secondary outcomes evaluated in this systematic review were collated into this single table.
RCT: randomized controlled trial; BRs: bonded retainers; VFRs: vacuum-formed retainers.

†The evidence was downgraded by 1 level because of unexplained heterogeneity in the results of the included RCTs; ‡The evidence was downgraded by 1 level because of the difference in populations and applicability of the results; €The evidence was downgraded by 1 level because the results derived from small studies and few numbers of patients.

Supplementary Table 1. Databases and search strategy.

Database	Keywords
1. PUBMED 2. SCOPUS 3. EMBASE 4. COCHRANE LIBRARY (CENTRAL) 5. LIVIVO	(orthodontics OR orthodontic patients) AND (canine-to-canine retainer OR cuspid-to-cuspid retainer OR lingual retainer OR orthodontic fixed retainer OR 3x3 OR bonded retainer OR fixed retainer OR retention OR contention OR mandibular retainer) AND (removable retainer OR Essix OR vacuum-formed retainer OR thermoplastic retainer OR Vivera OR clear retainer OR plastic retainer)
6. WEB OF SCIENCE	TS=(orthodontics OR orthodontic Patients) AND (canine-to-canine retainer OR cuspid-to-cuspid retainer OR lingual retainer OR orthodontic fixed retainer OR 3x3 OR bonded retainer OR fixed retainer OR retention OR contention OR mandibular retainer) AND (removable retainer OR Essix OR vacuum-formed retainer OR thermoplastic retainer OR Vivera OR clear retainer OR plastic retainer)
7. LILACS (Latin American and Caribbean Health Sciences Literature Resource)	(orthodontics OR ortodontia OR Ortodontia) AND (canine-to-canine retainer OR contenção canino-a-canino OR contencíon de canino-a-canino OR orthodontic fixed retainer OR 3x3 OR bonded retainer OR fixed retainer OR contenção fixa OR contencíon fija OR thermoplastic retainer)
8. GOOGLE SCHOLAR (Grey Literature)	orthodontics AND canine-to-canine retainer OR cuspid-to-cuspid retainer OR 3x3 OR bonded retainer OR fixed retainer AND Essix OR vacuum-formed retainer OR thermoplastic retainer OR Vivera OR clear retainer OR plastic retainer
9. OPEN GREY 10. CLINICALTRIALS.GOV (Grey Literature)	bonded retainer AND vacuum-formed retainer

Supplementary Table 2. List of excluded studies with reasons for exclusion (n=6).

Reasons for Exclusion	Studies
Letters to the Editor	1
Different retainers used	2,3,4,5,6

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2.1 ARTICLE 1

Bellini-Pereira SA, Aliaga-Del Castillo A, Dos Santos CCO, Henriques JFC, Janson G, Normando D. Treatment stability with bonded versus vacuum-formed retainers: a systematic review of randomized clinical trials. Eur J Orthod 2021 (Nov 1), cjab073. Available from: https://doi.org/10.1093/ejo/cjab073

European Journal of Orthodontics, 2021, 1–10
https://doi.org/10.1093/ejo/cjab073
Systematic review

Systematic review

Treatment stability with bonded versus vacuum-formed retainers: a systematic review of randomized clinical trials

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Protocol and registration: The protocol for this systematic review was based on the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 and was registered at PROSPERO database (CRD42020199392). This systematic review is reported according to the PRISMA statement.

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Summary

Background: In orthodontics, the retention phase can be considered challenging and unpredictable. Therefore, evidence obtained from different retention protocols is important to facilitate clinical decision-making.
Objectives: This systematic review aimed to compare the clinical effectiveness of bonded versus vacuum-formed retainers (VFRs) regarding their capacity to maintain treatment stability, periodontal effects, and failure rates.
Search methods and eligibility criteria: Ten databases comprising published and unpublished literature were systematically searched up to August 2021. Randomized clinical trials (RCTs) comparing both retainers were included.
Data collection and analysis: The risk of bias (RoB) evaluation was performed with the Cochrane Collaboration RoB Tool 2.0. All steps of the screening phase and RoB assessment were performed independently by two reviewers. The Grade of Recommendations, Assessment, Development, and Evaluation (GRADE) was used to evaluate the certainty of the evidence.
Results: Initial database search yielded 923 studies. After duplicates removal and full-text assessment, five RCTs remained. Overall, the studies presented Low RoB, except one study judged with 'Some concerns'. Based on the included studies, on a short-term (3–6 months) and long-term (4 years) basis, bonded retainers (BRs) were more effective to maintain treatment stability than VFRs in the lower arch. However, from 12 to 24 months both retainers presented the same efficacy. In the upper arch, the retainers were equally effective. BRs were associated with greater plaque and calculus accumulation than VFRs after 12 months. The retainers' failure rates were similar in the upper arch on the first year of retention; however, after 2 years VFRs showed significantly greater failure rates. Contrarily, BRs presented greater failure rates in the lower arch than VFRs.
Limitations: The findings of the included studies may be influenced by different factors related to the unpredictability of relapse.

Conclusions: Most of the evidence generated in this systematic review derived from a moderate level of certainty. In the lower arch, BRs are more effective than VFRs to maintain treatment stability in the initial 6 months of retention and in the long term. In the upper arch, both retention protocols are equally effective.
Registration: Regist0ration number: PROSPERO CRD42020199392.
Funding: Coordination for the Improvement of Higher Educational Personnel (CAPES, Process code-001).

Introduction

In orthodontics, the possibility of relapse after treatment should always be taken into account (1). Although an accurate diagnosis and adequate mechanics are performed, the results obtained with orthodontic treatment may not be completely stable over time (2). The unpredictable nature of relapse inspired many researchers to investigate the most clinically effective retention protocol to enhance treatment stability. Nonetheless, the ideal retention protocol remains unclear (3, 4).

The retention phase is recognized as the best attempt to maintain teeth in the correct position in the short- and long terms (5). The most frequently used retention appliances are Hawley retainers, bonded retainers (BRs), and vacuum-formed retainers (VFRs) (3). Moreover, the decision-making for each one of them seems to be influenced by a different range of factors such as initial malocclusion, treatment applied, patients' assumptions, and orthodontists' experience (6, 7).

BRs were firstly described in 1973 (8). Basically, this type of retainer consists of solid or braided wires bonded to the lingual surface of the anterior teeth to maintain their alignment (9). Some variations of the retainer exist and its effectiveness is well established in the literature (10, 11). The main advantage of the technique is the minimum requirement of patient compliance when compared with the removable retainers (3). Notwithstanding, BRs have been related to greater plaque and calculus accumulation (12).

Regarding removable retainers, VFRs are currently gaining popularity among patients and orthodontists owing to their ease of production and comfort (13). Interestingly, these plastic retainers were introduced in the same decade as BRs (14). The effectiveness of this kind of retainer has also been proved and is speculated their minor periodontal complications (12). Logically, the greater disadvantage of VFR resides in the entire need for patient compliance.

Previous systematic reviews evaluated the abovementioned retainers individually (10, 11, 15). Nonetheless, a direct systematic comparison between them has not yet been carried out. Recent clinical research compared the retention capacity of both retainers (2, 3, 16–18). However, their findings were controversial. Some of them suggest that BRs are more effective to maintain treatment stability compared with VFRs (3, 16), while others state that no differences between retainers exist (17, 18). Inconsistent evidence is also reported regarding the retainers' survival rates and retention wear time (4, 9). A synthesis of the available evidence from randomized clinical trials (RCTs) would provide relevant information regarding both retainers and improve the orthodontist's decision-making of which retainer is more suitable for each individualized case.

Therefore, the primary aim of this systematic review was to compare the effectiveness of bonded versus VFRs regarding their capacity to maintain treatment stability. The secondary aim was to compare the retainers regarding their periodontal effects and failure rates.

Materials and methods

Protocol and registration

The present review was conducted following the Cochrane Handbook for Systematic Reviews of Interventions (19) and was reported according to the PRISMA statement (20). Furthermore, a pre-existing protocol was registered on PROSPERO (CRD42020199392).

Eligibility criteria

The selection criteria were based on the PICOS strategy:

1. Participants: patients of any age and sex who underwent orthodontic treatment and followed a retention protocol.
2. Intervention: VFRs after active orthodontic treatment.
3. Comparator: BRs after active orthodontic treatment.
4. Outcome: treatment stability evaluated in millimetres with different occlusal variables at any available follow-up. Periodontal changes and failure rates were considered secondary outcomes.
5. Study design: randomized clinical trials.

In summary, RCTs comparing the effectiveness of bonded versus VFRs in maintaining the results obtained with orthodontic treatment were included. Studies were excluded if they not exclusively compared VFRs and BRs; if the patients included presented an initial malocclusion requiring extensive transverse corrections (rapid maxillary expansion or surgical expansion); tooth anomalies of number/form; and craniofacial syndromes.

Information sources, search strategy, and study selection

Seven electronic databases (Pubmed, Scopus, Web of Science, The Cochrane Library, Lilacs, Embase, and Livivo) were searched up to August 2021. Grey literature search included Google Scholar, OpenGrey, and ClinicalTrials (www.clinicaltrials.gov). Overall, 10 databases comprising published and unpublished literature were searched without limitations regarding language, publication year, and status. Detailed search strategies of each database are shown in Supplementary Table 1. Additionally, hand-search was performed in Orthodontic journals to identify any potential article loss.

The search was performed in two phases. Initially, two reviewers (SABP and AADC) screened the titles and abstracts of all retrieved studies. Duplicate records were removed with the reference management software Endnote (Clarivate Analytics, Philadelphia, USA). The remaining studies were transferred for the second phase, where both reviewers assessed the full report of publications and applied the eligibility criteria. Both screening phases were performed independently and any disagreement was resolved by discussion or consulting with a third reviewer (CCOS). Finally, the reference lists of the included studies were searched for additional studies.

Data items and collection

The following qualitative and quantitative data were extracted from the included studies in a piloted electronic spreadsheet (Excel, Microsoft Corporation, 2019): authors; publication year; sample characteristics (sample size, patients' sex, age, type of retainer); stability assessment and outcomes; follow-ups; retention protocol; failure rates and main findings. During the process, if unreported relevant data were noticed, the trial investigators were contacted by e-mail for clarification.

Risk of bias in individual studies

The risk of bias (RoB) of the selected RCTs was assessed with the Cochrane Collaboration RoB Tool 2.0 (21). The tool considers five domains and results in an overall RoB judgement of 'Low RoB' (low risk for all domains), 'Some concerns' (some concerns in at least one domain, but no high risk for any domain), and 'High RoB' (high risk for at least one domain, or some concerns in multiple domains).

Equally to the screening phase (study selection and data extraction), the RoB assessment was performed independently by both reviewers, and the third reviewer acted as a judge to resolve disagreements, if necessary.

Summary measures and approach to synthesis

A qualitative summary of the findings focussing on treatment stability was decided a priori. Moreover, due to the anticipated continuous nature of the outcomes, mean differences and 95% confidence intervals were planned for quantitative synthesis, if possible. Meta-analysis was planned if the included studies presented acceptable homogeneity and reported similar outcomes with appropriate statistical forms. In such case, a random-effects meta-analysis was deemed more suitable considering the possible differences among patients and implementation of interventions (22).

RoB across studies and additional analysis

If feasible, publication bias would be evaluated through the inspection of the contour-enhanced funnel plots (23). The certainty of the evidence was judged with the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach (24) for each outcome and time-point evaluated.

Results

Study selection and characteristics

The database search identified 923 studies. After duplicates removal, 511 studies remained. Grey literature search did not identify any potential study following the eligibility criteria. Moreover, the titles and abstracts were screened and 500 studies were discarded. During the first phase, disagreements were rare between reviewers. Of the 511 titles and abstracts reviewed only 8 presented different judgements and were discussed with the third reviewer. The second phase included 11 studies for full-text evaluation. Of these, 6 were excluded with reasons (Supplementary Table 2). Finally, five studies were included in the qualitative synthesis. Second phase screening was performed with no disagreements between reviewers. The process of identification, screening, and exclusion of studies is described in the PRISMA flow diagram (20) (Figure 1).

The 5 included studies involved 348 patients (60% female/40% male). They presented a two-arm (2, 3, 16, 17) or three-arm (18) RCT design comparing bonded versus VFRs. The mean average age of the patients ranged between 13.8 ± 1.5 and 21.5 ± 3.0 years.

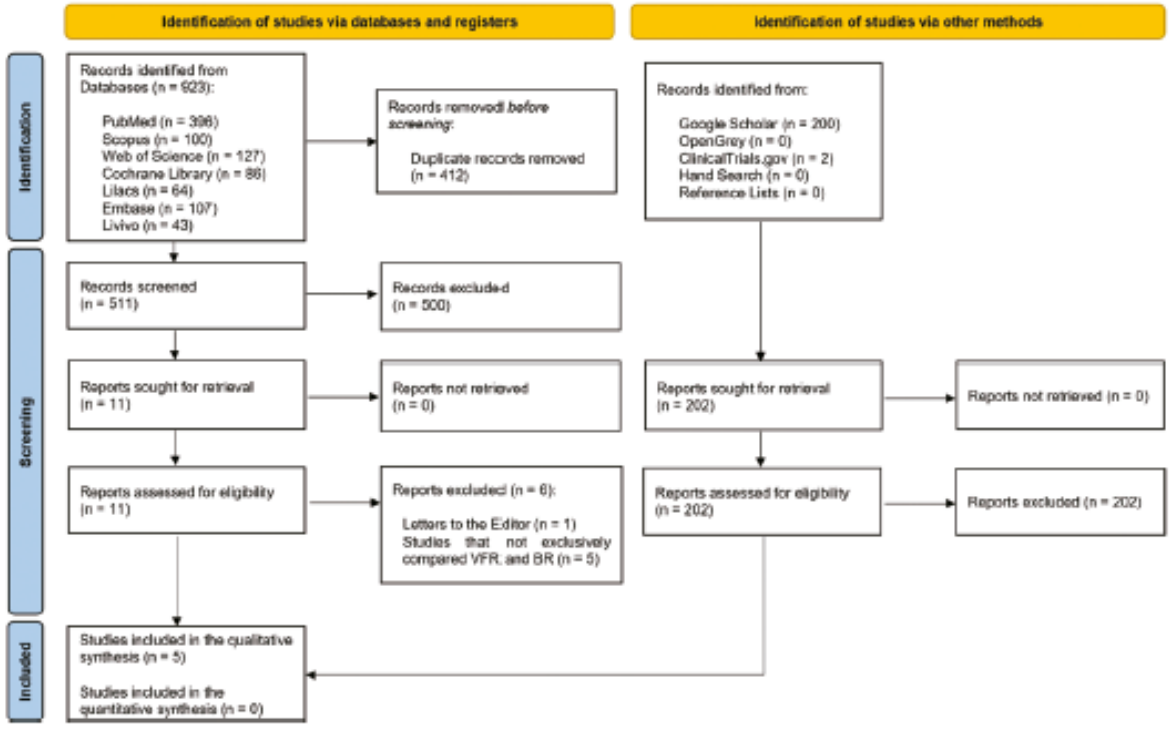

Figure 1. Modified PRISMA flow diagram.

Table 1. Characteristics of the five randomized clinical trials included in the qualitative assessment.

Authors (publication year)	Groups (*N*/sex/age)	Stability assessment	Outcome measures		Retention protocol (vacuum-formed retainers)	Retainers' failure rates	Main findings
			Debond	Longest follow-up			
Al-Moghrabi *et al.* (2018)	G1 Bonded retainers Coaxial SS wire 21 (18F/3M) 21.54 years (3.06) G2 Vacuum-formed retainers Essix™ 21 (14F/7M) 20.77 years (1.49)	Outcomes evaluated: LII, ICW, IMW, AL, extraction site opening Measurements were performed in the lower arches on gypsum study models with a digital calliper at debond and after 48 months	G1—lower arch LII: 0.25 (0.47) ICW: 26.90 (1.89) IMW: 42.80 (3.96) AL: 24.45 (3.83) Extraction opening: 0.00 (0.19) G2—lower arch LII: 0.42 (0.84) ICW: 26.77 (2.29) IMW: 41.77 (4.03) AL: 22.15 (2.96) Extraction opening: 1.37 (0.72)	G1—lower arch LII: 1.23 (1.27) ICW: 26.74 (1.84) IMW: 42.23 (5.82) AL: 25.84 (7.04) Extraction opening: 0.00 (0.00) G2—lower arch LII: 3.16 (2.74) ICW: 25.62 (2.51) IMW: 42.66 (4.93) AL: 20.81 (8.33) Extraction opening: 1.65 (1.57)	Full-time basis for the first 6 months, nights only for the following 6 months, and alternate nights from 12 to 18 months. Thereafter, intermittent nights-only wear (1–2 night weekly)	After 48 months: G1—lower arch 24% G2—lower arch n.r. %	After 48 months, BRs were more effective in retaining lower incisors alignment compared with VFRs ($P = 0.02$), although some relapse was observed in both groups
Forde *et al.* (2018)	G1 Bonded retainers 3-stranded twist-flex SS wire 30 (15F/15M) 16 years (2) G2 Vacuum-formed retainers Essix™ 30 (18F/12M) 17 years (4)	Outcomes evaluated: LII, ICW, IMW, AL, overjet, and overbite Measurements were performed in the upper and lower arches on digitized study models at debond, 3, 6, and 12 months	G1—upper arch/lower arch LII: 0.00 (0.93)/0.29 (1.02) ICW: 35.20 (2.83)/27.53 (1.68) IMW: 50.11 (3.96)/44.05 (4.64) AL: 73.94 (12.74)/66.74 (6.00) Overjet: 2.37 (0.70) Overbite: 1.29 (1.22) G2—upper arch/lower arch LII: 0.23 (0.66)/0.06 (1.23) ICW: 34.09 (2.22)/26.17 (1.13) IMW: 48.46 (4.24)/41.34 (5.72) AL: 71.23 (9.67)/65.53 (12.94) Overjet: 2.38 (2.40) Overbite: 2.00 (1.21)	G1—upper arch/lower arch LII: 1.35 (1.98)/1.01 (1.28) ICW: 35.08 (2.31)/27.31 (2.21) IMW: 49.47 (3.88)/43.90 (4.32) AL: 76.70 (10.81)/66.97 (8.21) Overjet: 2.26 (1.07) Overbite: 1.59 (0.78) G2—upper arch/lower arch LII: 0.97 (1.68)/1.73 (2.77) ICW: 33.21 (2.36)/25.56 (1.39) IMW: 47.70 (3.80)/41.32 (4.61) AL: 68.86 (10.26)/62.57 (9.50) Overjet: 2.59 (0.94) Overbite: 2.01 (1.00)	Only at night, every night	After 12 months: G1—upper arch/lower arch 36.7%/50% G2—upper arch/lower arch 26.7%/20%	After 12 months, there is no evidence of a significant differences regarding stability ($P = 0.61$) or retainer survival ($P = 0.34$) in the upper arch Nonetheless, in the lower arch, BRs were more effective at maintaining incisors alignment ($P = 0.008$), but with the cost of a higher failure rate ($P = 0.01$)
Krämer *et al.* (2019)	G1 Vacuum-formed retainers Essix™ 52 (26F/26M) 17.1 years (2.4) G2 Bonded retainers Remanium® wire 52 (26F/26M) 17.1 years (1.9)	Outcomes evaluated: LII, ICW, IMW, AL, overjet, and overbite Measurements were performed in the lower arches on digitized study models at debond, 6, and 18 months	G1—lower arch LII: 1.33 (0.65) ICW: 26.77 (1.89) IMW: 42.85 (2.96) AL: 58.82 (10.23) Overjet: 3.23 (1.63) Overbite: 1.68 (1.04) G2—lower arch LII: 1.53 (1.03) ICW: 27.33 (2.11) IMW: 42.57 (3.10) AL: 54.25 (8.31) Overjet: 3.13 (1.57) Overbite: 1.85 (0.97)	G1—lower arch LII: 2.06 (1.52) ICW: 26.63 (1.96) IMW: 43.30 (2.56) AL: 58.48 (9.74) Overjet: 3.12 (1.09) Overbite: 2.17 (1.55) G2—lower arch LII: 2.03 (1.40) ICW: 27.28 (1.95) IMW: 42.48 (2.89) AL: 53.22 (7.21) Overjet: 3.03 (1.24) Overbite: 2.06 (1.45)	Full time the first week and thereafter at night only until 12 months 12–18 months: intermittent nights 18–24 months: 2 nights per week	After 18 months: G1—lower arch 5.8% G2—lower arch 5.8%	After 18 months, VFRs and BRs presented the same retention capacity and failure rates in the lower arch

Table 1. Continued

Authors (publication year)	Groups (*N*/sex/age)	Stability assessment	Outcome measures: Debond	Outcome measures: Longest follow-up	Retention protocol (vacuum-formed retainers)	Retainers' failure rates	Main findings
Naraghi *et al.* (2020)	G1 Bonded retainers Penta-One 0.0195 SS wires 30 (17F/13M) 13.8 years (1.5) G2 Vacuum-formed retainers Essix™ 30 (17F/13M) 13.9 years (1.9)	Outcomes evaluated: LII, ICW, IMW, AL, overjet, overbite, and maximum rotation Measurements were performed in the upper arches on digitized models with the software OnyxCeph™ before treatment, at debond (T1), and after 24 months (T2)	G1—upper arch (T2–T1) LII: 0.30 (CI: 0.10; 0.50) ICW: −0.30 (CI: −0.50; −0.10) IMW: −0.30 (CI: −0.70; 0.10) AL: 0.10 (CI: −0.10; 0.30) Overjet: 0.1 (CI: −0.10; 0.30) Overbite: 0.20 (CI: 0.00; 0.40) G2—upper arch (T2–T1) LII: 1.00 (CI: 0.40; 1.60) ICW: 0.20 (CI: 0.00; 0.40) IMW: −0.40 (CI: −0.60; −0.20) AL: 0.00 (CI: −0.20; 0.20) Overjet: 0.0 (CI: −0.40; 0.40) Overbite: 0.30 (CI: −0.10; 0.70)		Full-time basis for the first 4 weeks, then every night, and alternate nights from 12 to 24 months	After 24 months: G1—upper arch 23.3% G2—upper arch 50%	Both retention methods showed equally effective retention capacity after 2 years and can be recommended as retention methods in the upper arch ($P = 0.138$)
O'Rourke *et al.* (2016)	G1 Bonded retainers Coaxial SS wire 42 (33F/9M) 18.47 years (4.41) G2 Vacuum-formed retainers Essix™ 40 (26F/14M) 16.95 years (2.02)	Outcomes evaluated: LII, ICW, IMW, AL, extraction site opening Measurements were performed in the lower arches on gypsum study models with a digital calliper at debond (T0), 6 (T1), 12 (T2), and 18 (T3) months	G1—lower arch LII: (T1–T0) 0.03/(T2–T1) 0.03/(T3–T2) 0.03 ICW: (T1–T0) 0.11/(T2–T1) 0.17/(T3–T2) 0.17 IMW: (T1–T0) 0.26/(T2–T1) 0.38/(T3–T2) 0.18 AL: (T1–T0) 0.19/(T2–T1) 0.20/(T3–T2) 0.18 Extraction opening: (T1–T0) 0.00/(T2–T1) 0.00/(T3–T2) 0.00 G2—lower arch LII: (T1–T0) 0.08/(T2–T1) 0.08/(T3–T2) 0.08 ICW: (T1–T0) 0.23/(T2–T1) 0.20/(T3–T2) 0.26 IMW: (T1–T0) 0.16/(T2–T1) 0.25/(T3–T2) 0.25 AL: (T1–T0) 0.23/(T2–T1) 0.19/(T3–T2) 0.19 Extraction opening: (T1–T0) 0.00/(T2–T1) 0.00/(T3–T2) 0.00		Full-time basis for the first 6 months, nights only for the second 6 months, and alternate nights from 12 to 18 months. Thereafter, intermittent nights-only wear (1–2 night weekly)	After 18 months: G1—lower arch 7.15% G2—lower arch 0%	BRs were more effective in their ability to maintain incisor alignment in the lower arch in the first 6 months after debond when compared with VFR ($P = 0.008$). Nonetheless, some minimal relapse is likely after fixed appliances therapy irrespective of retainer choice. The retention capacity between retainers was similar at 12 and 18 months ($P = 0.195$ and $P = 0.300$, respectively)

AL, arch length; BR, bonded retainer; F, female; G1, group 1; G2, group 2; ICW, intercanine width; IMW, intermolar width; LII, Little Irregularity Index; M, male; n.r., not reported; SS, stainless steel; VFR, vacuum-formed retainer.

Note: All outcomes were evaluated in millimetres and were presented with the median and interquartile range. Except the study from Naraghi *et al.* (18) which presented their results with the mean and 95% confidence intervals (CIs).

Overall, the studies evaluated treatment stability with the following variables: Little Irregularity Index (LII), intercanine and intermolar width, and arch length. Additionally, extraction site opening was assessed in two studies (2, 16), overbite and overjet were evaluated in the other three studies (3, 17, 18). These variables were assessed in digitized (3, 17, 18) or plaster models (2, 16). Only two studies evaluated the upper arch (3, 18).

The outcomes were assessed at debonding and at different follow-ups, which varied among studies. The maximum follow-ups evaluated were 12 (3), 18 (2, 17), 24 (18), and 48 (16) months. In three studies, it was possible to extract data at debonding and the longest follow-up (3, 16, 17), while in two studies only the treatment changes between periods were provided (2, 18).

The retention protocol with VFRs differed among studies. Some authors suggested full-time use for 1 week (17), 4 weeks (18), or 6 months (2, 16), followed by nights-only use for 1 year. Then, intermittent use after this period. Other authors instructed patients to wear the retainers only at night since debonding (3).

The overall retainer failure rates ranged from 5.8% to 50% for both retainers but differed in the upper and lower arches. A detailed description of the study's characteristics can be observed in Table 1.

RoB within studies

In general, all the included studies in this systematic review were well designed and followed the CONSORT guidelines (25). Thus, four included studies (2, 3, 17, 18) presented Low RoB and only one study (16) was judged with 'Some concerns' (Figure 2). The randomization process involving random sequence generation, allocation concealment, and implementation was adequate. Likewise, no signs of deviations from intended interventions were noticed in all studies.

One study (2) presented a great number of drop-outs; therefore, possible bias due to missing outcome data was speculated. Even though the drop-outs were clearly reported and explained, it was decided to judge the study with 'Some concerns' for this domain. The authors reported a considerable drop-out rate of 36% and 48% in the bonded and vacuum-formed groups, respectively.

Two studies (17, 18) presented the trial protocol registration and permitted a direct evaluation of bias in the selection of the reported result. In the remaining studies, the authors were contacted for clarifications and no evidence or suggestion of selection bias were noticed leading to a Low RoB judgement. The RoB assessment occasionally resulted in disagreements between reviewers in two studies (2, 16). However, an agreement was obtained after discussion and contacting the study's authors.

Results of individual studies, meta-analysis, and additional analysis

Initially, the performance of meta-analysis was expected; however, due to the substantial clinical and methodological heterogeneity between studies quantitative analysis was not feasible. Then, for descriptive reasons, findings will be presented regarding treatment stability at 3–6, 12–24, and 48 months to ease understanding. These were the follow-up times during retention provided in the included studies.

3–6 months follow-up: On a short-term basis, two studies (2, 3) stated that BRs were more effective to maintain treatment stability in the lower arch compared with VFRs. Contrarily, one study (17) showed that the retention capacity of both retainers was similar during this period. Concerning the upper arch, no differences were found between retainers in the study of Forde *et al.* (3).

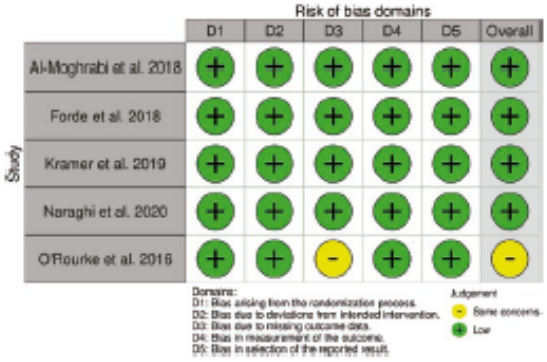

Figure 2. Cochrane risk of bias Tool 2.0 summary.

12–24 months follow-up: After 1 year, two studies (2, 17) observed the same retention capacity between retainers; however, one study (3) suggested that BRs were more effective in the lower arch. Again, no differences were exhibited in the upper arch (3, 18).

48 months follow-up: On a long-term basis BRs were more effective in maintaining treatment stability in the lower arch when compared with VFRs, although some relapse was observed in both groups (16). None of the included studies presented long-term data regarding the upper arch.

Two studies assessed the patient's periodontal health. The first study described that after 1 year BRs were associated with greater plaque and calculus accumulation and gingival inflammation than VFRs (3). Moreover, after 4 years both retainers were associated with plaque accumulation and gingival inflammation without significant differences (16).

Concerning the retainers' failure rates, in the upper arch, both retainers presented similar rates after 1 year in one study (3); however, another study (18) showed significantly greater failure rates with VFRs (50%) compared with BRs (23%) after 2 years (Table 1). In the lower arch, two studies reported significantly greater failure rates with BRs compared with VFRs (2, 3). The study from Krämer *et al.* (17) did not find significant differences between the retainers' failure rates.

The certainty of evidence evaluated through the GRADE approach is described in Table 2. The overall certainty of evidence ranged from low to moderate for the outcomes assessed. In case of low certainty, the confidence in the effect estimated is limited and may be substantially different. Moreover, a moderate judgement suggests that the estimated effect is likely to be close to the true effect. This was the case for the great majority of outcomes. Publication bias was not evaluated because meta-analysis was not undertaken.

Discussion

Summary of evidence

The present systematic review included five RCTs exclusively comparing BRs and VFRs. A broader Cochrane review (4) performed this comparison indirectly, and previous reviews were performed with different retainers (26, 27). However, this is the first systematic review to directly compare these types of retainers.

The study from Al-Moghrabi *et al.* (16) was the long-term (4-year) evaluation of the RCT from O'Rourke *et al.* (2). Nonetheless, they

Table 2. GRADE summary of findings table.

Certainty assessment								
No. of studies (patients)	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Summary of findings	Certainty
3–6-Month stability								
3 (246)	RCTs	Not serious	Serious*	Not serious	Not serious	Not suspected	During the initial 6 months of retention, BRs are more effective than VFRs to maintain the lower incisors alignment. In the upper arch there is no difference between retainers.	⊕⊕⊕○ Moderate
12–24-Month stability								
4 (306)	RCTs	Not serious	Serious*	Not serious	Not serious	Not suspected	After 12–24 months of retention, BRs and VFRs present the same retention capacity in the upper and lower arches.	⊕⊕⊕○ Moderate
48-Month stability								
1 (42)	RCT	Not serious	Not serious	Serious**	Serious***	Not suspected	BRs are more effective than VFRs in the long term (after 48 months).	⊕⊕○○ Low
Periodontal health changes								
2 (102)	RCTs	Not serious	Not serious	Not serious	Serious***	Not suspected	BRs are associated with greater plaque and calculus accumulation than VFRs during the initial 12 months of retention. After 48 months both retainers are related to negative periodontal effects. Nonetheless, these effects did not appear to produce any periodontal problem of clinical significance.	⊕⊕⊕○ Moderate
Failure rates (upper arch)								
2 (120)	RCT	Not serious	Not serious	Not serious	Serious***	Not suspected	BRs and VFRs present similar failure rates after 12 months. Nonetheless, after this period, VFRs present significantly greater failure rates compared with BRs.	⊕⊕⊕○ Moderate
Failure rates (lower arch)								
3 (246)	RCTs	Not serious	Serious*	Not serious	Not serious	Not suspected	BRs present significantly greater failure rates compared with VFRs after an 18-month period.	⊕⊕⊕○ Moderate

BRs, bonded retainers; RCT, randomized clinical trial; VFRs, vacuum-formed retainers.
Note: For publication purposes the individual GRADE summary of the primary and secondary outcomes evaluated in this systematic review were collated into this single table.
*The evidence was downgraded by 1 level because of unexplained heterogeneity in the results of the included RCTs.
**The evidence was downgraded by 1 level because of the difference in populations and applicability of the results.
***The evidence was downgraded by 1 level because the results derived from small studies and few numbers of patients.

were considered independent studies in this systematic review because different research teams performed the outcomes evaluation, and both short- and long-term data would provide clinically relevant findings for the present review.

Overall, during the first 6 months of retention evidence of moderate certainty suggests that BRs are more effective in maintaining treatment stability than VFRs in the lower arch. It could be speculated that the worse performance of VFRs on a short-term basis compared with BRs might be related to the non-compliance of patients regarding the retention regimen rather than a proper failure of the retainer (2). In accordance, the RCT that found no differences between retainers reported minimum failure rates and great patient adherence with the VFR (17). Curiously, in this study, the VFRs were made up to the first premolars. Again, it seems that the possible short-term failure of VFRs in maintaining lower incisors alignment might be more related to the patients' non-compliance than the retainer itself. If the patient is unwilling or unable to wear the retainer as prescribed, some degree of relapse should be expected (1).

Orthodontic studies comparing fixed versus removable appliances are susceptible to this kind of shortcoming because researchers do not know the true amount of time the appliance was wear during the observational period. In this regard, short-term retention remains a controversial topic. Nonetheless, the evidence generated in this review reiterates the greater effectiveness of BRs compared with VFRs in the short term.

The retention capacity of both retainers in the lower arch was similar after 1 and 2 years in most of the included studies (2, 17). This was an interesting finding and may be explained by different aspects of retention. Firstly, the literature describes that relapse mainly occurs in the first 6–12 months of retention; therefore, after this period it should be less expected (17, 28). Additionally, the failure rates of the retainers are also greater in the short-term corroborating with a greater chance of relapse (2, 3, 17). In this regard, the first 12 months of retention are critical. It could be speculated that after this period the chance of relapse might be reduced enhancing the retainers' effectiveness.

The longest follow-up assessed was 4 years. Evidence suggested that BRs were more effective than VFRs to maintain treatment stability in the lower arch in the long term. Nonetheless, these findings are supported by only one study (16), and therefore, represent a low level of certainty. In this study, the authors were contacted for clarifications and confirmed that approximately 70% of the patients in the VFR group stopped wearing the retainers at the 4-year follow-up, probably explaining the greater effectiveness of BRs. Once more, the greater disadvantage of VFRs compared with BRs is the entire need for patient compliance. Although it could be suggested that both retainers present the same retention capacity in the lower arch in the long term, it seems that the patients' responsibility decreases progressively over time, which may lead to relapse. Retention clinical studies are difficult to undertake from a practical and financial perspective, but further long-term studies should be performed for more robust information regarding this subject.

It was possible to gather evidence from two studies regarding the effect of the retainers in the upper arch. In this case, both RCTs indicated that the retainers present the same retention capacity after 1 and 2 years (3, 18). The literature shows considerably smaller relapse in the upper arch when compared with the lower arch in both short- and long terms (29). These findings are in accordance with previous retrospective studies that showed minimum relapse in the upper arch after 5 and 7 years (29, 30). That reduced tendency of relapse in the upper arch might explain the effectiveness of different maxillary retention protocols (3, 18, 29). Overall, there is a lack of sufficient evidence to affirm that one retainer is better than the other on a long-term basis.

The periodontal effects and failure rates of the retainers were secondary outcomes of this systematic review. In this regard, there seems to be a consensus that BRs present greater plaque and calculus accumulation, and consequently cause greater gingival inflammation than VFRs in the short term (3). Logically, these effects are restricted to the canine-to-canine area. Moreover, on a long-term basis, both retainers were related to plaque accumulation and negative periodontal effects. Nonetheless, these effects were not strong enough to be clinically significant (12). It is reasonable to state that orthodontists must follow their patients and control their periodontal health in the long term as part of overall orthodontic treatment.

The survivability of the retainers might be influenced by a different range of factors. Especially when different studies and populations are considered. Likewise, a previous systematic review showed that the failure rate of BRs could range from 11% to 71% (9). Similarly, VFRs can reach important failure rates of 50–70% (16, 18). It seems clear that both retainers are susceptible to failure and require great care from the patient and orthodontist. Based on the RCTs included in this review, it could be considered that after 18 months of retention VFRs present greater failure rates in the upper arch compared with BRs. Contrarily, BRs showed greater failures rates in the lower arch after this period (Table 1). It should be emphasized that these findings are based on a moderate level of certainty, and further studies are required to confirm them.

To date, there is no standardized retention protocol for VFRs. However, high-quality evidence included in this systematic review indicates that VFRs part-time wear is equally effective compared with full-time wear (3, 4, 17). Thus, it is reasonable to affirm that these retainers could be prescribed for night-only use. The part-time wear of the VFR might also be related to the increased longevity of the material. On the contrary, full-time wear could be associated with greater failure rates (31).

From a clinical perspective, the decision-making regarding BRs and VFRs might consider other variables, such as cost–benefit, the differences between upper and lower arches, orthodontist's preferences, quality of life, but more importantly the level of patient compliance/motivation (9). Post-orthodontic appointments for treatment stability assessments are also part of orthodontic treatment. The patient should be followed up regularly after fixed appliances removal independently of the retainer of choice.

Limitations

The results of this review should be interpreted with caution. Even though the studies included were well conducted in a methodological perspective, it should be highlighted that their findings may be influenced by different initial malocclusions included, amounts of tooth movement, the patients' age, the true amount of VFRs wear time, the different materials of BRs, among other factors that are related to the unpredictability of relapse (4). However, these factors are beyond the objectives of this review.

Conclusions

According to the existing evidence found in this systematic review, the following can be concluded based on Low to Moderate level of certainty:

- In the lower arch, BRs are more effective to maintain treatment stability during the initial 6 months of retention compared with VFRs. After 12 months there is a tendency for both retention

protocols to be equally effective. Nonetheless, in the long term, BRs seem to prevail over the VFRs regarding their retention capacity.

- In the upper arch, both retainers are an effective retention protocol to maintain the results obtained with orthodontic treatment.
- BRs are related to greater plaque and calculus accumulation than VFRs in the short term. In the long term, both retainers are associated with negative periodontal effects highlighting the importance of post-orthodontic periodontal control.
- Both retainers present similar failure rates in the upper arch during the first year of retention; however, after this period VFRs present greater failure rates in the upper arch than BRs. In contrast, BRs present greater failure rates in the lower arch when compared with VFRs.

Supplementary material

Supplementary material is available at *European Journal of Orthodontics* online.

Supplementary Table 1. Databases and search strategy.

Supplementary Table 2. List of excluded studies with reasons for exclusion ($n = 6$).

Funding

This work was supported by the Coordination for the Improvement of Higher Educational Personnel (CAPES, Process code—001).

Acknowledgements

We thank the authors' Ama Johal (Queen Mary University of London, London, UK), Dalya Al-Moghrabi (Queen Mary University of London, London, UK), Padhraig Fleming (Queen Mary University of London, London, UK), and Simon Littlewood (St Luke's Hospital, Bradford, UK) for providing clarifications and/or additional data for this systematic review.

Conflicts of interest

None to declare.

Data availability

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

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2 ARTICLES

The second article presented in this thesis was written according to the Consolidated Standards of Reporting Trials (CONSORT) and the American Journal of Orthodontics and Dentofacial Orthopedics instructions and guidelines for article submission.

Treatment stability with bonded versus vacuum-formed retainers after 12 months: A randomized clinical trial

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2.2 ARTICLE 2

TREATMENT STABILITY WITH BONDED VERSUS VACUUM-FORMED RETAINERS AFTER 12 MONTHS: A RANDOMIZED CLINICAL TRIAL

ABSTRACT

Introduction: This single-center 2-arm parallel group randomized clinical trial aimed to compare the clinical effectiveness of V-bend bonded retainers (BR) versus vacuum-formed retainers (VFR) regarding their capacity to maintain treatment stability and survival rates after 12 months. **Methods**: Patients finishing orthodontic treatment were recruited and randomly allocated into two experimental groups. The BR group received upper and lower V-bend BRs bonded in the lingual surfaces of the anterior teeth. The VFR group received upper and lower VFRs right after fixed appliances removal. The patients were evaluated in four time-points: at fixed appliances removal (T0), after 3 months (T1), 6 months (T2), and 12 months (T3). In each time-point digital models were obtained and analyzed with the OrthoAnalyzer™ software. Treatment stability based on occlusal outcomes and retainers' survival rates were the primary and secondary outcomes, respectively. The random sequence was generated using www.randomization.com and allocation was concealed using opaque and sealed envelopes. Intergroup comparisons regarding stability outcomes were performed using Mann-Whitney U-tests ($P < 0.05$). The Kaplan-Meier survival plot and the log-rank test were employed to assess the retainers' survival. **Results**: The BR group included 25 patients (14 female, 11 male; mean age, 16.70 ± 3.21 years) and the VFR group comprised 25 patients (13 female, 12 male; mean age, 16.24 + 2.49 years). The groups were comparable regarding their baseline characteristics. Up to 6 months both retainers were equally effective; however, after 12 months, BRs were more effective in to maintain the incisors' alignment in the maxilla ($P < 0.001$) and in the mandible ($P < 0.006$) compared to the VFRs. No differences were noticed in the intercanine and intermolar widths, overjet and overbite. There were also no differences in the retainers' survival rates in the maxillary and mandibular arches. **Conclusions**: BRs were more effective to maintain the incisors alignment in the maxilla and mandible compared to VFRs after 12 months. Moreover, both retainers present the same survival rates in the maxillary and mandibular arches after the same period. **Registration**: This trial was

registered at ClinicalTrials.gov (Identifier: NCT04847323). **Protocol**: The trial protocol was not published. **Funding**: This study was financed in part by the Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES), Finance Code 001.

Keywords: Orthodontics; Orthodontic Retainers; Randomized Clinical Trial.

INTRODUCTION

Orthodontic treatment should only be considered successful if acceptable treatment stability was ensured at the long-term.[1] The task to obtain treatment stability could seem simple compared to the active phase, but actually is one of the most challenging aspects of orthodontic treatment. Even though proper diagnosis and treatment plan are performed, the results achieved may not be stable due to the unpredictability of relapse.[2]

The causes of relapse are not completely comprehended. The literature suggests some factors that affect the tooth positions such as skeletal and dentoalveolar development;[3] dental factors;[4] treatment mechanics and arch form;[5] and pretreatment malocclusion characteristics.[6] To minimize the possibility of relapse the use of some type of retention is required.[7] Usually, bonded retainers (BRs), vacuum-formed retainers (VFRs) and Hawley retainers are suggested in the attempt to maintain treatment stability.[7]

BRs are commonly used in the mandibular arch in the form of a wire bonded in the lingual surface of the anterior teeth.[8] Different types of BRs exist. The most common is made of multi-strand twistflex wire, but the retainer present some variations with solid wires, wave forms and V-bends.[9] Evidence suggests their superior effectiveness when bonded in all anterior teeth whether only in the canines.[10] The major advantage of these retainers is the reduced need of patient compliance; however, placement of the retainer is technique sensitive and bonding failures may progress unnoticed by the patients.[11] Additionally, BRs have been associated with plaque and calculus accumulation demanding great oral hygiene and periodontal control.[12]

Currently, VFRs are gaining popularity probably because of the greater demand of orthodontic aligners worldwide. Some clinicians and patients are preferring these retainers owing to their ease of fabrication and minor periodontal complications.[12,13] The literature reports the effectiveness of the retainer highlighting the importance of

patient compliance since VFRs are removable.[7,14] Arguably, the greatest disadvantage of this kind of retainers.

Although different retainers exist, there is insufficient evidence to define a retention strategy as the ideal for all cases.[7] Recently, randomized clinical trials (RCTs) compared the clinical effectiveness of BRs and VFRs, but their findings are contradictory.[14-17] Some describe that both retainers are equally effective;[14,17] however, others declare that BRs are more effective to maintain stability in the short- and long-terms.[15,16] A recent systematic review compared both retainers directly.[18] Their findings describe a greater retention capacity with BRs during the initial 6 months after orthodontic treatment. Nonetheless, this review emphasized the need of future RCTs to strengthen the available evidence due to the clinical heterogeneity of the included studies and their inconsistent findings. Further RCTs should be performed to enhance clinical decision-making surrounding treatment stability and orthodontic retention.

SPECIFIC OBJECTIVES OR HYPOTHESES

The aim of this RCT was to compare the clinical effectiveness of V-bend BRs versus VFRs regarding their capacity to maintain treatment stability and survival rates after 12 months. Treatment stability was considered as the primary outcome and retainer survival the secondary outcome.

The null hypothesis tested in this study considered that there were no differences between retainers in their retention capacity and survival rates.

METHODS

Trial design and any changes after trial commencement

This was a single-center 2-arm parallel group RCT with a 1:1 allocation ratio. The study followed the Consolidated Standards of Reporting Trials (CONSORT) statement[19] and guidelines and was registered at ClinicalTrials.gov (Identifier: NCT04847323). Moreover, no changes were required after trial commencement.

Participants, eligibility criteria, and settings

This study was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Bauru, Brazil (Protocol number: 22092919.7.0000.5417/3.835.225).

Patients were recruited while finishing orthodontic treatment at the Orthodontic Clinic of Bauru Dental School, University of São Paulo, Bauru, Brazil, from February to March 2021. The eligibility criteria included patients with satisfactory final occlusion and oral hygiene assessed through clinical examination; presence of all teeth up to the second molars; and acceptable teeth alignment. Treatment protocol performed during fixed appliances therapy was not considered as inclusion criteria. More specifically, patients may have been treated with or without extractions, with removable or fixed functional appliances or any adjunctive treatment.

Patients were excluded for the following reasons: Presence of any medical condition that have an influence in periodontal health; history of periodontal diseases; facial deformities; tooth anomalies of number and form; and initial malocclusion that required remarkable transverse correction with or without orthognathic surgery.

All patients and their parents or legal guardians signed informed consent before recruitment.

Interventions

The overall sample consisted of 50 patients divided into two experimental groups depending on the retainer received. After the end of active orthodontic treatment, one calibrated orthodontist placed the BRs or VFRs in the maxillary and mandibular arches of both groups using the same procedures and materials.

The BR group received upper and lower V-bend BRs (Fig. 1). These retainers were made using 0.024” stainless steel wires (Morelli Ortodontia; Sorocaba, São Paulo, Brazil). The same orthodontist that placed the retainers also shaped the wire using the dental casts. The BRs were built passively against the lingual surfaces of maxillary and mandibular anterior teeth. Differently from the conventional BRs, the V-bend BR present V-bends in a sagittal direction, parallel to the oclusal plane in the interproximal contacts of the anterior teeth. The protocol of installation was performed as follows: Initially, prophylaxis of the dental surfaces was performed, following the enamel etching (37% phosphoric acid) and rinse, and adhesive application (Ambar; FGM, São Paulo, Brazil). Bonding of the retainers was performed with flow composite (Opallis; FGM, São Paulo, Brazil) in all anterior teeth.

The VFR group received upper and lower VFRs (Fig. 2). These retainers were constructed using a vacuum-machine (Bio-Art; São Carlos, São Paulo, Brazil). Likewise, the same orthodontist made the VFRs using the plaster models obtained at

the same appointment of fixed appliances removal. The retainers were made of 1mm thickness acetate (Bio-Art; São Carlos, São Paulo, Brazil) covering the occlusal surface of all teeth up to the second molars. The patients were instructed to wear the retainers only during nights since the first day of retention.

All patients were oriented regarding the use and care of the retainers. Additionally, in the case of problems, concerns, or failed retainers, the patients were advised to contact the orthodontist for resolution as soon as possible.

Outcomes (primary and secondary) and any changes after trial commencement

Treatment stability characterized by the changes in the Little Irregularity Index[20] (LII) was considered the primary outcome of the present study. In view of this, the patients were evaluated in four time-points: at fixed appliances removal (T0), after 3 months (T1), 6 months (T2), and 12 months (T3). In each appointment digital models of all patients were obtained with a 3Shape TRIOS 3 intraoral scanner (3Shape, Copenhagen, Denmark). Therefore, the changes in the LII were compared. Additionally, the changes in arch dimensions, overjet and overbite were also assessed. The digital models were imported to the OrthoAnalyzer™ software (3Shape, Copenhagen, Denmark) where all measurements were performed. A detailed description of the stability outcomes was provided in Table I and depict in Figure 3.

The secondary outcome consisted of the retainers' survival. First, it was necessary to define failure for both retainers. Definitions were based on a previous study.[16] In the case of BRs, failures would be related to adhesive failures between the composite and enamel or detachment from all teeth; and wire fractures. VFRs were associated to failures when the retainer was lost or fractured affecting the full-thickness of the acetate. Smaller fractures, especially in the distal region of the VFRs were not considered failures. The date of retainer failure was recorded at the time the patient became aware and contacted the orthodontist. When an episode of failure occurred, the retainers were repaired or substituted as soon as possible. There were no outcome changes after trial commencement.

Sample size calculation

Considering stability (LII) as the primary outcome, the sample size was calculated to detect a minimum intergroup difference of 0.5mm in the LII with a previously reported standard deviation of 0.5mm.[16] Sample size calculation was

performed to provide 80% test power at a significance level of 5%. Therefore, a minimum of 17 patients was required in each group.

Assuming a possible drop-out rate of 20% in each group, the sample size was increased to 25 patients per group. Thus, resulting in a total of 50 patients in the study.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

Random sequence generation was obtained by using the Web site Randomization.com (http://www.randomization.com).[21] Block randomization was performed to ensure equal distribution of patients in both groups. All fifty patients undergone randomization and were allocated to receive one type of retainer.

Sequentially numbered opaque and sealed envelopes were used to maintain the allocation concealed until implementation of the intervention.[22] Each envelope was prepared with the patients' name on the external surface and a card inside containing the allocated group. The envelopes were torn open just after intervention implementation. All three steps of randomization (random sequence generation; allocation concealment; and implementation) were performed by different persons.

Blinding

Blinding of patients and orthodontist was not possible in this scenario, because both were aware of the intervention received right after the envelopes opening. Moreover, blinding of the outcome assessor was also not possible since the V-bend BRs appeared in the digital impressions obtained with the intraoral scanner.

Statistical analyses (primary and secondary outcomes, subgroup analyses)

After 1-month, digital models from 20% of the sample were randomly selected and remeasured by the same examiner. The intraclass correlation coefficient (ICC) and Bland-Altman plots were used to assess the reliability and precision of the repeated measurements.

Initially, normal distribution of the occlusal measurements was tested with Shapiro-Wilk tests. Data was not normally distributed; therefore, median and inter-

quartile range, and non-parametric statistics had to be performed. Mann-Whitney U-tests were applied for intergroup comparisons between the time-points.

The Kaplan-Meier survival plot and the log-rank test were employed to assess the retainers' survival. All statical analyses were performed using SPSS software (Version 26; IBM, Armonk, NY) with statistical significance at $P < 0.05$.

RESULTS

Participant flow

Overall, 62 patients were assessed for eligibility. Eleven patients did not follow inclusion criteria and one patient opted not to participate. Finally, 50 patients were enrolled to receive either BRs or VFRs. Fortunately, all randomized patients were analyzed and no losses occurred during the 12-month period. The CONSORT flow diagram is shown in Figure 4.

Baseline data

Baseline data were obtained before the retention regimen. The groups were comparable regarding sex distributions, age and initial molar relationship (Table II). Likewise, treatment details such as the type of treatment protocol applied were also similar between groups.

Number analyzed for each outcome, estimation, and precision

The ICC values ranged from 0.976 (95% confidence interval (CI): 0.930-0.992) to 0.999 (CI: 0.997-1.000) indicating excellent intraexaminer reliability.[23] Moreover, reliability and precision of the method were confirmed through Bland-Altman plots for each occlusal outcome (Supplementary Figure 1).

As previously mentioned, the groups were compared regarding the occlusal changes after 3, 6, and 12 months. Up to 6 months both retainers were equally effective to maintain treatment stability regarding all the occlusal outcomes assessed. However, after 12 months of retention, the BRs were more effective to maintain the incisors' alignment in the maxilla ($P < 0.001$) and in the mandible ($P < 0.006$) compared to the VFRs (Table III). No differences were noticed in the intercanine and intermolar widths, overjet and overbite.

There were no significant differences regarding the retainers' survival rates after 12 months. In the maxilla, 92% of the retainers in both groups survived the period of

evaluation; therefore, demonstrating non-significant differences ($P < 0.967$; Figure 5). In the mandible, 92% of the BRs and 88% of the VFRs survived the follow-up period ($P < 0.655$; Figure 5). Including the maxilla and mandible, only 8% of the BRs and 10% of the VFRs failed and had to be repaired or substituted after 12 months (Supplementary Figure 2). Three BRs showed an adhesive failure and one retainer fractured between lateral incisor and canine. In relation to the VFRs, three fractured in the molars' region, and two patients experienced failures because their dogs ate one of the retainers.

Harms

In this study no serious harm or undesirable effect related to the retainers was observed. The amount of relapse was acceptable in a clinical perspective.

DISCUSSION

Main findings in the context of the existing evidence and interpretation

Posttreatment studies evaluating different types of retention protocols represent great importance for the orthodontic literature. This fact is explained because relapse is probably the most common risk of orthodontic treatment and can cause disappointments for both orthodontists and patients.[2] Therefore, this RCT aimed to compare the clinical effectiveness of two different retainers regularly used worldwide regarding their capacity to maintain treatment stability and survival rates.

In this study, the broader concept of treatment stability was depicted in 5 specific outcomes. Among them, the LII was considered primary since patients focus specially on the alignment observed in the anterior teeth.[2] Moreover, intercanine and intermolar widths, overjet and overbite would complement the retainers' capacity to maintain the results obtained with orthodontic treatment.

RCTs occupy a high place in the evidence pyramid due to the randomization process.[24] Randomization is the best attempt to control known and unknown confounding factors. In this trial, randomization worked well; the groups presented great comparability regarding sex distribution, age, initial molar relationship, performance of extraction and orthodontic treatment characteristics (Table II).

The main finding of this study was that BRs were more effective to maintain the incisors' alignment in the maxilla and mandible after 12 months compared to VFRs

(Table III). Thus, the null hypothesis was rejected. The greatest retention capacity of BRs in the anterior teeth of the maxilla was an unexpected finding. Previous RCTs and a recent systematic review demonstrated the similar effectiveness of BRs and VFRs in the maxillary arch.[16-18] It could be speculated that these results might be explained by the patients' adherence to the VFRs, as previously suggested.[14,17]

During the follow-up appointments the patients were interviewed regarding the use and care of the retainers. Barely 40% of the VFR patients reported a strict follow of the retention regimen of using the retainers every day during nights. A reduced compliance rate of less than 50% with removable retainers is generally reported in retention studies.[16,25] Again, this unfortunate adherence to the retention regimen might also explain the greatest effectiveness of BRs in the mandible. Nonetheless, it should be considered that the extent of relapse observed in this study was smaller than previous RCTs.[2,16]

It is worth mentioning that although the VFRs were less effective than BRs, no patient presented a LII greater than 2mm in both arches after 12 months. The literature indicates that LII scores less than 3.5mm are clinically acceptable.[1,26] Therefore, the retention regimen with VFRs still guaranteed satisfactory teeth alignment. From a clinical standpoint, even though statistical differences were verified, posttreatment relapse was minimal with both retainers regarding the incisors' alignment.

In accordance, no differences were observed between retainers in the intercanine and intermolar widths, overjet and overbite (Table III). No differences in the intercanine width were already anticipated; however, small differences in the intermolar width were expected because BRs do not extend to the molars' region. Possibly, the appropriate interdigitation of the buccal segments maintained transversal stability.[2] Since acceptable transversal stability can be obtained even with BRs, perhaps that is the motive that researchers are progressively reducing the VFRs extent to the first premolars.[14] The minimum changes in overjet and overbite corroborate with previous studies.[14,16]

There were no differences regarding the BRs and VFRs failure rates. The BRs failure rates were 8% in the maxilla and mandible. Arguably, greater failure rates were expected with BRs in the maxilla possibly due to occlusal stress;[27] however, this did not happen in this trial. Perhaps, installation of the retainers by an experienced orthodontist following an adequate adhesive strategy may partially explain these findings.[27] These failure rates are in accordance with previous RCTs.[2,14] Additionally,

the Kaplan-Meier plots describe that the majority of BRs failed within the initial 6 months of retention (Fig. 5).

In relation to the VFRs. The failure rates were 8% in the maxilla and 10% in the mandible. Overall, these failure rates can be considered tolerable compared to other published trials.[2,15,16] These reduced failures with the VFRs may be partially explained by the nights-only use wear regimen. Currently, there is no standardized wear protocol for VFRs, but full-time wear is being related to greater VFRs breakages.[7] In this study, the VFRs fractured distally in the first and second molars region (Supplementary Figure 2). That might not be the case if the VFRs is built up to the premolars.[14] Interestingly, the two loses of VFRs in this study were caused by patients' dogs. Most of the failures occurred after the initial 6 months of retention; these findings were contrary to the BRs (Fig. 5).

A viable retention alternative could be associate BRs and VFRs. In this case, if one of the retainers failed the other would maintain treatment results until the next appointment with the orthodontist.[28] Further research evaluating this association would be exciting.

Retention is vital for successful orthodontic treatment; therefore, the use of retainers should be recommended. The ideal retainer for each individualized case, whether fixed, removable, or both, should consider not solely their clinical effectiveness. But more importantly the patients' capacity and desire to comply with the retention protocol.[7,16,29]

There still insufficient evidence about long-term retention. Further long-term studies originated from randomized designs should be performed to increase the robustness of the information regarding this subject. The patients of the present study will be followed over the years with the aim to observe if relapse values progress or remain stable, and if the differences between retainers persist in the long-term.

Limitations

The patients' adherence to the VFRs wear regimen was not assessed in the present study. The patients were only oriented and questioned regarding the use of the retainers during the follow-up appointments, and therefore, this self-assessment by the patient can be inaccurate.[30] That is a limitation frequently reported in retention studies with removable appliances.[2,15,16] Overall, since it is not possible to know the true amount of VFR wear, the slightly significant relapse in the VFRs patients could be

caused by the retainer failure, lack of compliance, or a combination of both. Future studies including a built-in sensor on the retainers may assist to increase the certainty of this kind of study.

Additionally, it was not possible to blind the operators and patients to the treatment allocations due to the nature of the interventions.

Despite the fact some limitations exist, this trial can be considered a “real-life” situation that orthodontists might underwent in their offices, especially regarding removable retainers and compliance.[16] RCTs must be performed to replicate exactly these kinds of situations.

Generalizability

The generalizability of these findings may be limited due to the single center design of this RCT, and only one orthodontist made and installed the retainers. Moreover, the degree of patient compliance might be different in other regions and countries.

CONCLUSIONS

1. The null hypothesis was rejected. In fact, BRs were more effective to maintain the incisors alignment in the maxilla and mandible compared to VFRs after 12 months. During the initial 6 months of retention the retainers were equally effective.
2. Although significant differences existed between retainers, the amount of relapse in both groups was minimal in a clinical perspective.
3. BRs and VFRs present similar survival rates in the maxillary and mandibular arches.

ACKNOWLEDGMENTS

The authors would like to thank all patients and parents for participating in this research. This study was financed in part by the Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES), Finance Code 001.

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FIGURE CAPTIONS

Fig. 1 – Clinical aspect of the V-bend BR after installation.

Fig. 2 – Clinical aspect of the VFR after installation.

Fig. 3 – Occlusal measurements (Software OrthoAnalyzer$^{TM)}$. A) Little Irregularity Index; B) Intermolar (red) and intercanine (blue) widths; C) Overjet and overbite.

Fig. 4 – Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Fig. 5 – Kaplan-Meier survival plots and log-rank *P* values during the 12 months of retention in the maxilla and mandible.

SUPPLEMENTARY MATERIAL

Supplementary Figure 1 – Bland-Altman plots demonstrating acceptable intraexaminer reliability of the occlusal measurements.

Supplementary Figure 2 – Examples of retainers' failures. A) Adhesive failure in the left mandibular canine (The line of fracture between composite and enamel can be observed); B) Fracture of the VFR in the molars' region.

Fig. 1

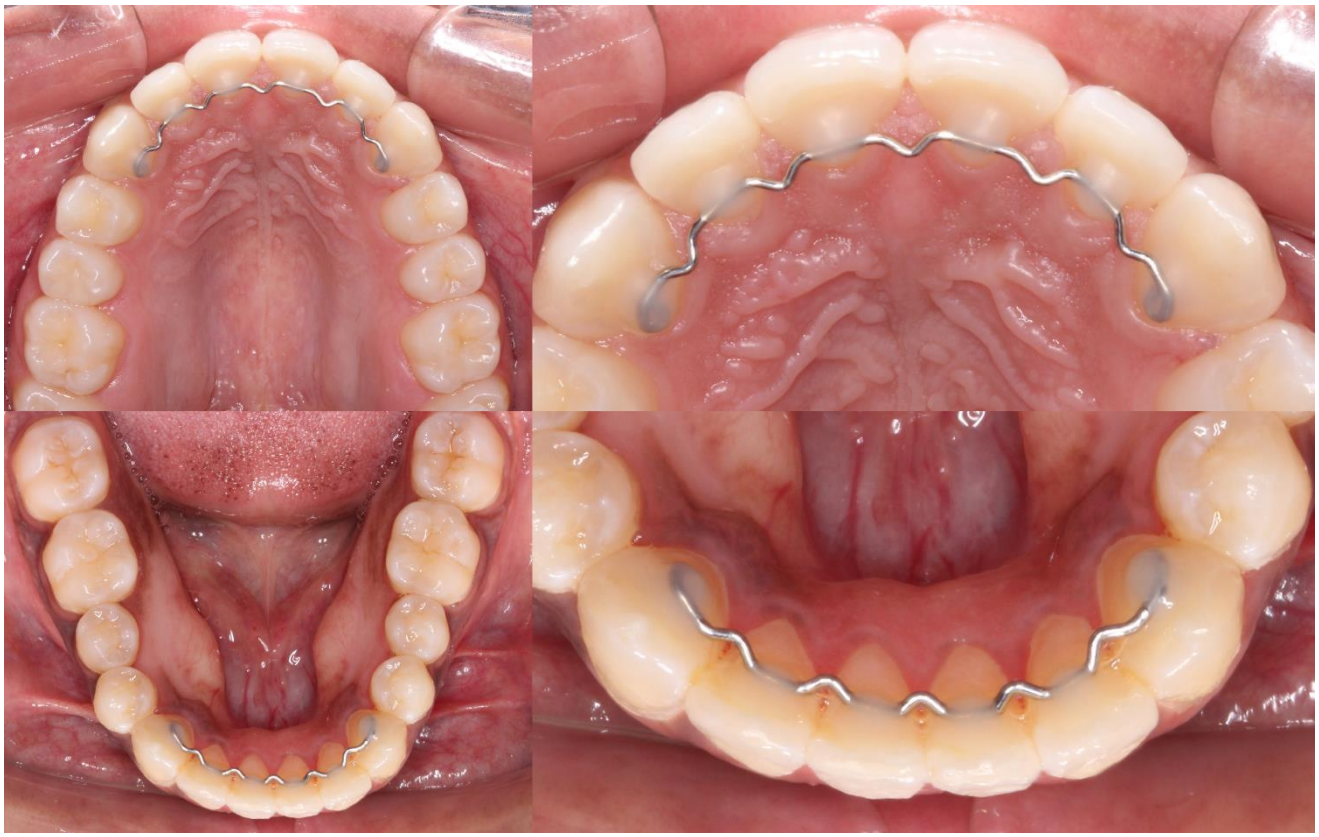


Fig. 2

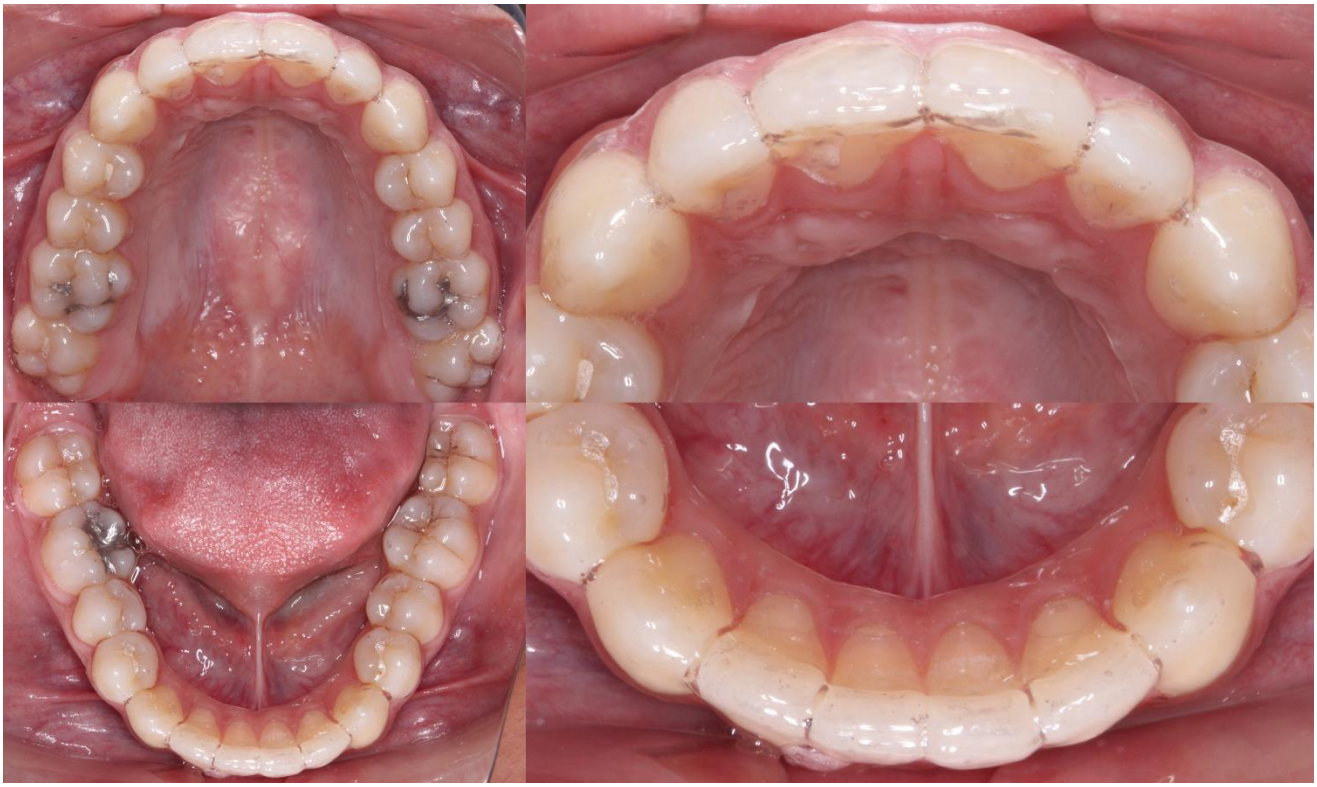


Fig. 3

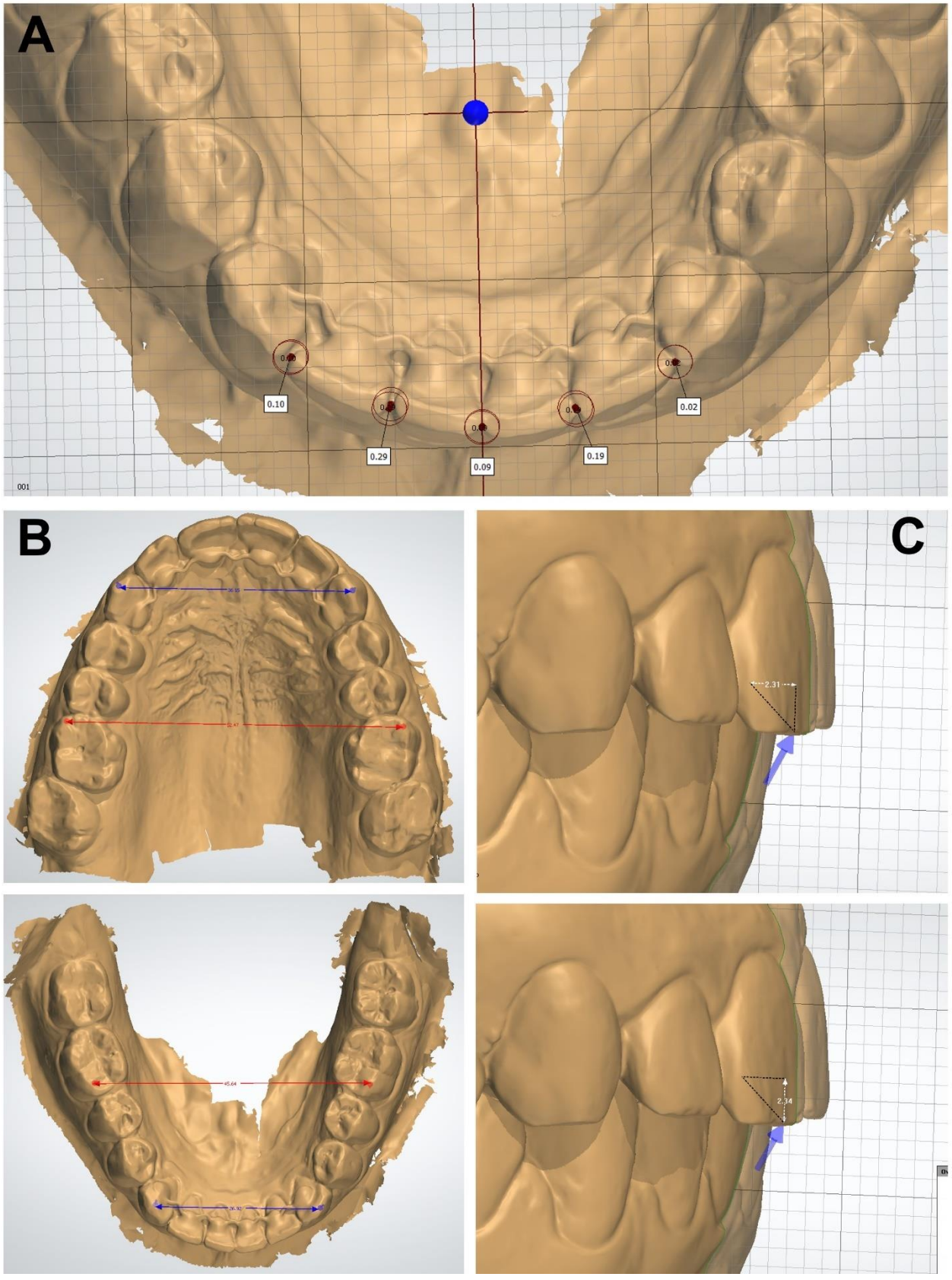


Fig. 4

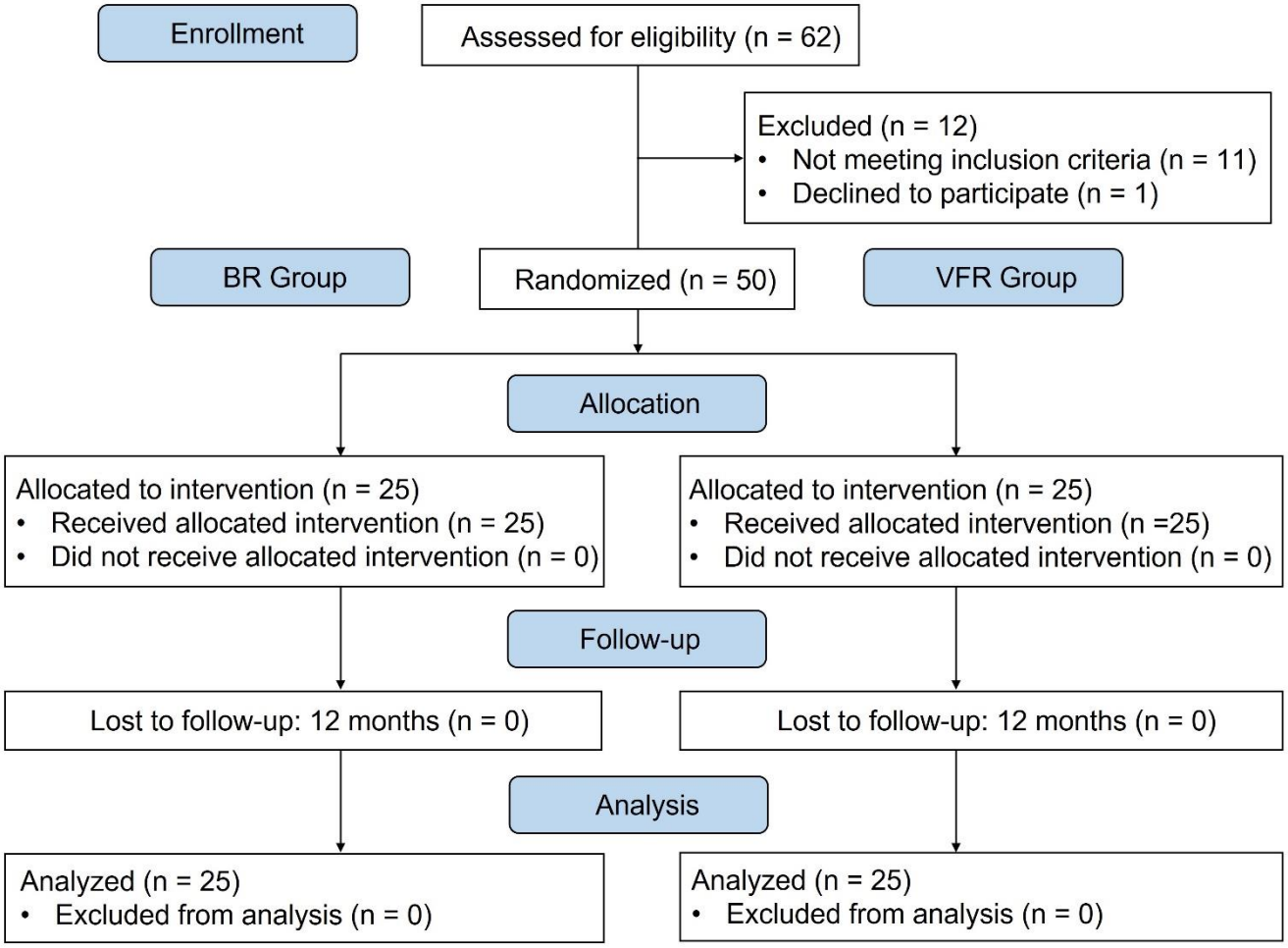
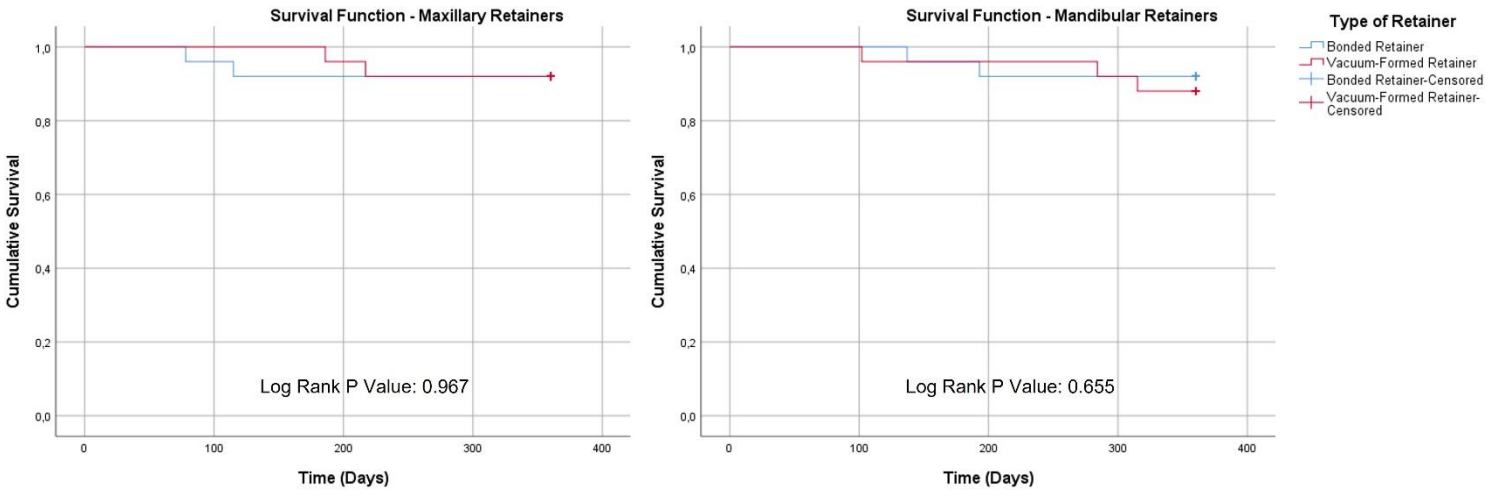
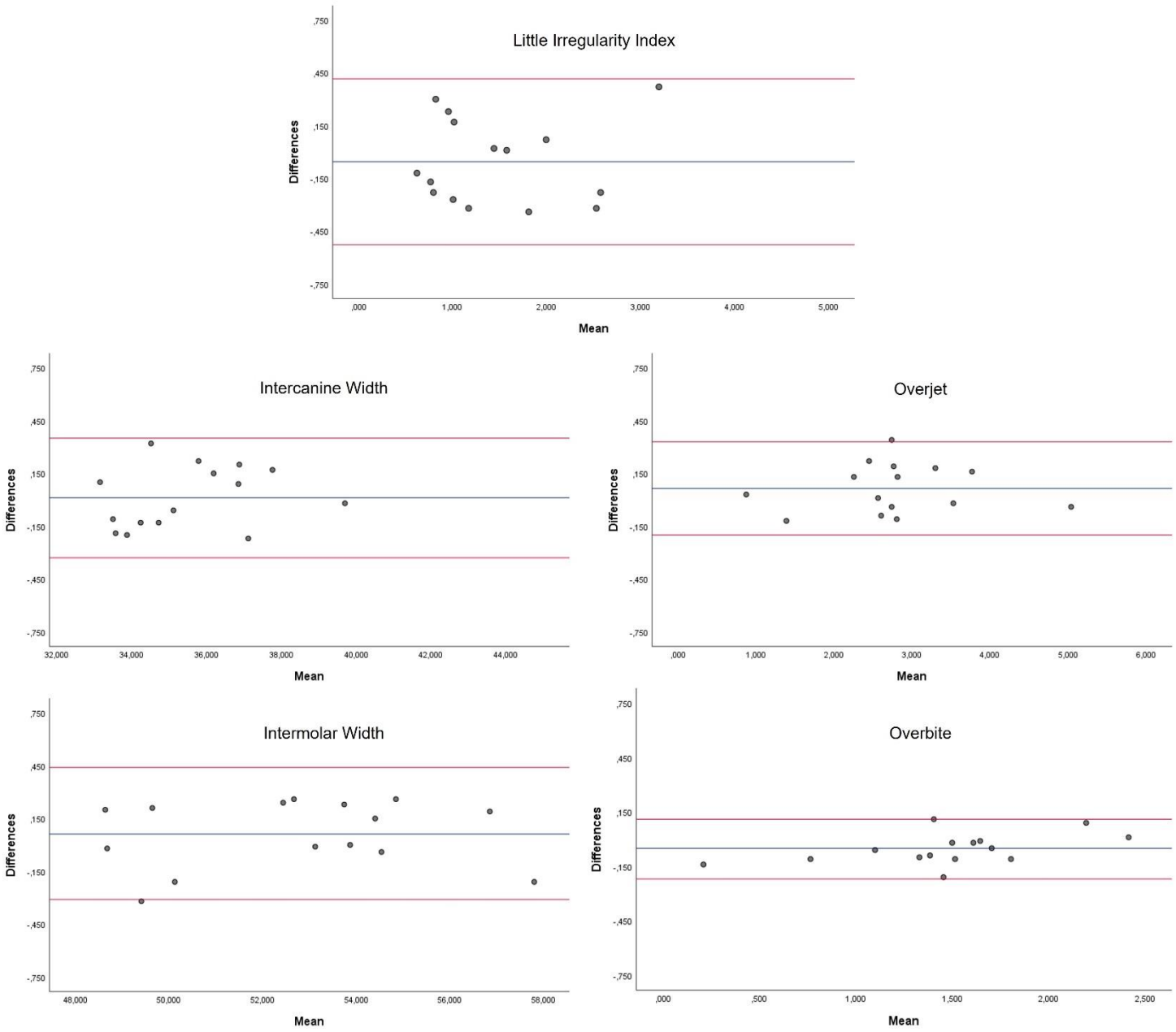

Enrollment
Assessed for eligibility (n = 62)
Excluded (n = 12)
• Not meeting inclusion criteria (n = 11)
• Declined to participate (n = 1)
BR Group
Randomized (n = 50)
VFR Group
Allocation
Allocated to intervention (n = 25)
• Received allocated intervention (n = 25)
• Did not receive allocated intervention (n = 0)
Allocated to intervention (n = 25)
• Received allocated intervention (n =25)
• Did not receive allocated intervention (n = 0)
Follow-up
Lost to follow-up: 12 months (n = 0)
Lost to follow-up: 12 months (n = 0)
Analysis
Analyzed (n = 25)
• Excluded from analysis (n = 0)
Analyzed (n = 25)
• Excluded from analysis (n = 0)

Fig. 5


Survival Function - Maxillary Retainers
Cumulative Survival
1,0
0,8
0,6
0,4
0,2
0,0
0
100
200
300
400
Time (Days)
Log Rank P Value: 0.967
Survival Function - Mandibular Retainers
Cumulative Survival
1,0
0,8
0,6
0,4
0,2
0,0
0
100
200
300
400
Time (Days)
Log Rank P Value: 0.655
Type of Retainer
Bonded Retainer
Vacuum-Formed Retainer
Bonded Retainer-Censored
Vacuum-Formed Retainer-Censored

Supplementary Figure 1



Supplementary Figure 2

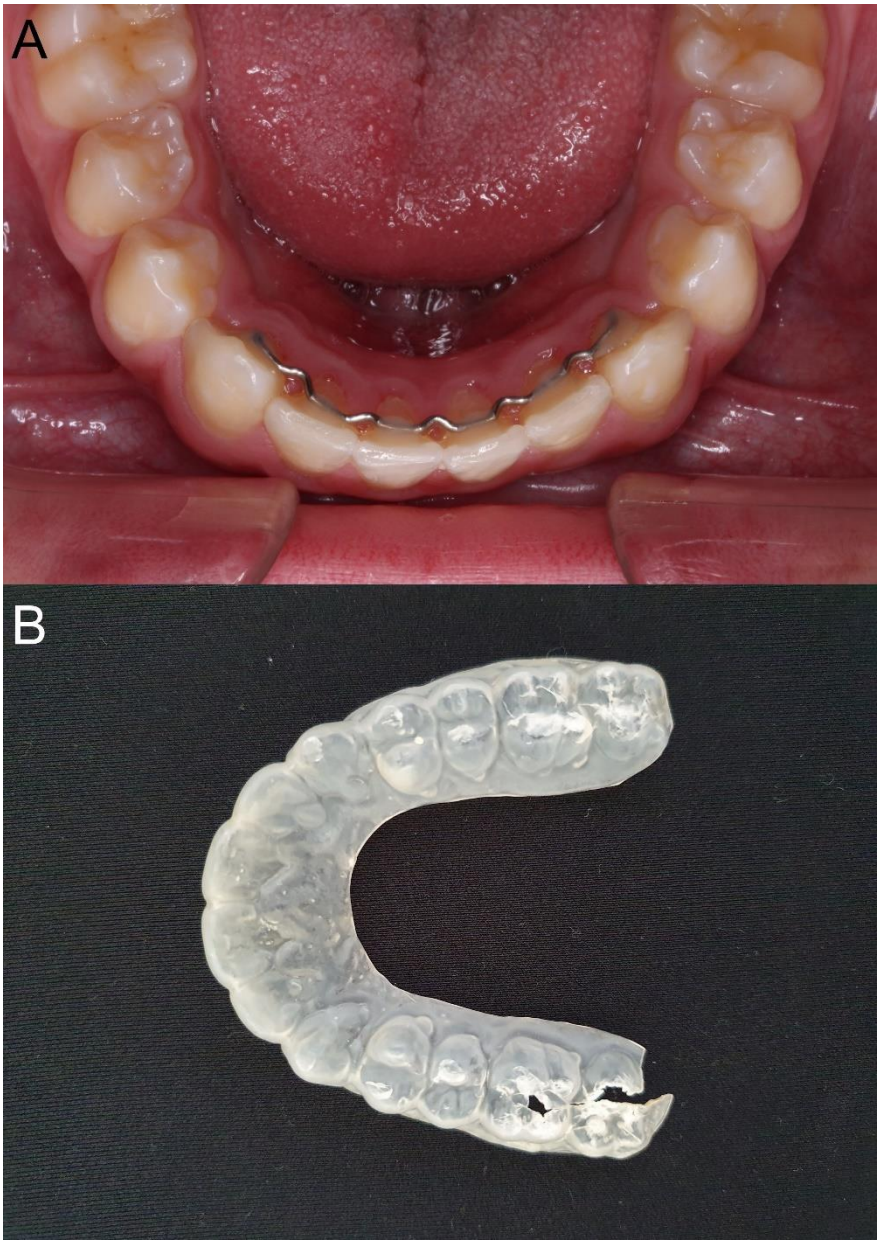


Table I. Occlusal measurements and definitions.

Measurement	Definition
Little's Irregularity Index (LII)	The average of the linear distances between the anatomical contact points of the anterior teeth.
Intercanine Width (ICW)	Distance between the cusp tips of the right and left permanent canines.
Intermolar Width (IMW)	Distance between the tips of the mesiobuccal cusps of the right and left permanent molars.
Overjet	Distance between the incisal edge of the maxillary central incisor and the incisal edge of the mandibular incisor, parallel to the occlusal plane.
Overbite	Distance between the incisal edge of the upper central incisor and the incisal edge of the lower incisor, perpendicular to the occlusal plane.

Note: The measurements were performed in millimeters (mm).

Table II. Baseline characteristics of the groups.

Variable	BR (N = 25)	VFR (N = 25)
Sex		
Female	14	13
Male	11	12
Age (Years)		
Debonding	16.70 ± 3.21	16.24 ± 2.49
Initial Molar Relationship		
Class I	11	10
Class II	11	14
Class III	3	1
Extractions		
Non-extraction	24	24
Mandibular extractions	1	1
Treatment Modality		
Fixed appliances only	18	13
Fixed appliances + mini-implants	7	10
Functional and fixed appliances	0	2

Table III. Intergroup relapse comparisons (Mann-Whitney U-tests).

Changes in each follow-up		Maxilla			Mandible			Interarch	
		LII	ICW	IMW	LII	ICW	IMW	Overjet	Overbite
3-Month relapse (T1-T0)	BRs	0.13 (0.15)	0.05 (0.19)	-0.04 (0.24)	0.09 (0.09)	-0.02 (0.32)	0.05 (0.55)	0.00 (0.21)	-0.05 (0.20)
	VFRs	0.11 (0.12)	0.05 (0.25)	0.15 (0.33)	0.09 (0.10)	-0.03 (0.21)	-0.02 (0.24)	0.08 (0.17)	-0.04 (0.15)
	P value	0.847	0.829	0.220	0.964	0.625	0.352	0.388	0.481
6-Month relapse (T2-T0)	BRs	0.26 (0.13)	0.07 (0.25)	-0.04 (0.43)	0.19 (0.22)	-0.03 (0.24)	0.00 (0.39)	0.05 (0.26)	-0.02 (0.28)
	VFRs	0.30 (0.28)	0.03 (0.32)	0.09 (0.38)	0.18 (0.35)	-0.04 (0.30)	0.09 (0.30)	0.13 (0.32)	-0.04 (0.15)
	P value	0.104	0.247	0.633	0.394	0.517	0.488	0.883	0.874
12-Month relapse (T3-T0)	BRs	0.34 (0.36)	-0.02 (0.19)	0.03 (0.64)	0.27 (0.26)	0.02 (0.25)	0.00 (0.51)	0.09 (0.26)	-0.12 (0.32)
	VFRs	0.68 (0.52)	-0.28 (0.50)	-0.15 (0.37)	0.54 (0.56)	-0.07 (0.38)	0.11 (0.64)	0.05 (0.42)	-0.11 (0.23)
	P value	0.001*	0.069	0.312	0.006*	0.261	0.312	0.959	0.982

*Statistically significant at $P < 0.05$.
BRs: Bonded retainers; VFRs: Vacuum-formed retainers; LII: Little Irregularity Index; ICW: Intercanine width; IMW: Intermolar width.

3 DISCUSSION

3 DISCUSSION

This Ph.D. thesis consisted of two major studies. The first one was a SR including 5 RCTs comparing BRs and VFRs. To our knowledge this was the first SR to compare both retainers directly. (LITTLEWOOD; MILLETT; DOUBLEDAY; BEARN *et al.*, 2016) The second study was an RCT to complement the evidence found in the SR. Overall, stabiliy studies are important for clinical orthodontics because the possibility of relapse is a risk for every orthdontic treatment.(O'ROURKE; ALBEEDH; SHARMA; JOHAL, 2016) We expect that these results might increase the quality of the evidence regarding this subject.

Both SRs and RCTs represent the highest spot in the evidence pyramid due to their sistematic methodology and randomization process, respectively. (MURAD; ASI; ALSAWAS; ALAHDAB, 2016) Thus, the findings of the present research represent evidence of low RoB. In the RCT, both groups presented great comparability at baseline, indicating that the randomization process was well-performed.

Interestingly, the SR and the RCT suggested the greater retention capacity with BRs at 6 and 12 months after fixed appliance removal in the mandible. Based on our results, it could be especulated that the worse performance of VFRs might be related to the patients non-compliance rather than a proper failure of the retainer. (FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018; O'ROURKE; ALBEEDH; SHARMA; JOHAL, 2016) In aggreement, the RCTs included in the SR that reported an equal effectiveness of both retainers declare that the patients adherence to the retention protocol was great. (KRÄMER; SJÖSTRÖM; HALLMAN; FELDMANN, 2020; NARAGHI; GANZER; BONDEMARK; SONESSON, 2021) In our RCT, barely 40% of the VFR patients followed the retention regimen correctly; therefore, this unfortunate adherence might explain the greater effectiveness of BRs over the VFRs, as previously suggested. (FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018; WONG; FREER, 2005)

Studies comparing fixed and removable appliances are prone to this kind of limitations since it is almost impossible to evaluate the true amount of time the patients used the retainers. Moreover, if the patient is unwilling to wear the retainer, relapse in some degree should be taken into account. (LITTLEWOOD; MILLETT; DOUBLEDAY; BEARN *et al.*, 2016)

Regarding the maxilla, the SR and the RCT presented contradictory findings. The SR suggested that no differences between retainer exist; however, in the RCT, again BRs were more effective to maintain treatment stability. When compared to the mandible, the maxillary arch shows significantly smaller relapse in the short- and long-terms. (BJERING; BIRKELAND; VANDEVSKA-RADUNOVIC, 2015) Therefore, it was expected to find non-significant differences with both retainers in the maxillary arch. Nonetheless, once again, it is possible to attribute the greater effectiveness of the BRs in the RCT to the lack of patient compliance. Overall, since both studies were contradictory, there is still a lack of sufficient evidence to affirm that one retainer is better than the other in the maxilla.

It should be highlighted that even though there were significant differences in the RCT, with the BRs being more effective, the LII index presented by the patients was smaller than 2 mm; therefore, indicating acceptable stability based on previous studies. (EDMAN TYNELIUS; PETRÉN; BONDEMARK; LILJA-KARLANDER, 2015; THICKETT; POWER, 2010) Values up to 3.5 should be considered acceptable in a clinical perspective. Based on this values, it is possible to affirm that both retainers were effective to prevent relapse clinically. Likewise, no differences were observed in the other occlusal variables evaluated in the RCT. Some changes in the intermolar distance were expected in the BR group; however, it seems that acceptable transversal stability was obtained with an appropriate interdigitation of the posterior teeth. (O'ROURKE; ALBEEDH; SHARMA; JOHAL, 2016)

All the studies included in the systematic review encountered greater periodontal effects with BRs compared to VFRs. Consequently, greater plaque and calculus accumulation were observed in the canine-to-canine region with these retainers. (STOREY; FORDE; LITTLEWOOD; SCOTT *et al.*, 2018) The orthodontist should be aware that BRs require more attention in a periodontal perspective and probably more appointments to maintain periodontal health.

In relation to the retainers' survival rates. Probably, that was the variable with greater variability. Previous systematic reviews exhibited failure rates of BRs ranging from 11% to 71%. (ILIADI; KLOUKOS; GKANTIDIS; KATSAROS *et al.*, 2015) Likewise, 50% to 70% failure rates have been reported for VFRs. (AL-MOGHRABI; JOHAL; O'ROURKE; DONOS *et al.*, 2018; NARAGHI; GANZER; BONDEMARK; SONESSON, 2021) Based on these increased failure rates, it should be mentioned that both retainers are susceptible to failure and require a great amount of care.

Fortunately, the present RCT showed minimum failure rates compared to previous studies. (AL-MOGHRABI; JOHAL; O'ROURKE; DONOS *et al.*, 2018; FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018; O'ROURKE; ALBEEDH; SHARMA; JOHAL, 2016) Failure rates smaller than 10% were observed after 12 months in this RCT and both retainers demonstrated non-significant differences regarding this outcome. That was an interesting finding and was probably related to the greater experience of the operator while bonding the BRs and the partial wear time of the VFRs. Currently, there is no standardization on the use of VFRs; however, full-time wear is being associated with greater failure rates. (SUN; YU; LIU; CHEN *et al.*, 2011) Moreover, night-only use seems to be equally effective to full-time wear with damage to the retainers. (FORDE; STOREY; LITTLEWOOD; SCOTT *et al.*, 2018; KRÄMER; SJÖSTRÖM; HALLMAN; FELDMANN, 2020; LITTLEWOOD; MILLETT; DOUBLEDAY; BEARN *et al.*, 2016)

The longest follow-up study included in the SR evaluated the patients through 4 years. Retention clinical studies are difficult to undertake from a practical and financial perspective, but further long-term studies should be performed for more robust information regarding this subject. In the case of the RCT, the patients will be followed yearly to observe if the relapse values change, and if the differences between retainers persist. Further studies should also consider the assessment of the combination of BRs and VFRs. It would be interest from a clinical point of view. The tendency of uniting both retainers is increasing especially in the European continent.

4 Final Considerations

4 FINAL CONSIDERATIONS

Based on the evidence found in this systeamtic review and randomized clinical trial, the following could be concluded:

- BRs are more effective to maintain the incisors' alignment during the intial 12 months of retention. Nonetheless, that greater effectiveness compared to VFRs could be related to a reduced level of patient compliance rather than a failure of the VFR itself.
- BRs cause greater calculus and plaque accumulation in the canine-to-canine region compared to VFRs and require greater periodontal control from the patient and orthodontist.
- The failure rates between retainers seems to be similar in the maxillary and mandibular arches; however, the amount of retainers failure is influeced by a different range of factors; therefore, these results might be different in other populations and regions.
- Retention is vital for successful orthodontic treatment; therefore, the use of retainers should be recommended. The ideal retainer for each individualized case, whether fixed, removable, or both, should consider not solely their clinical effectiveness. But more importantly the patients' capacity and desire to comply with the retention protocol.

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REFERENCES

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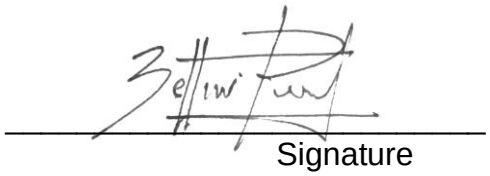
APPENDIX

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

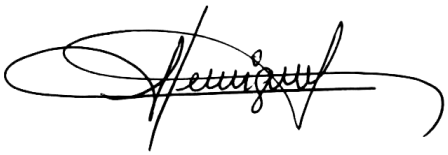
We hereby declare that we are aware of the article “Treatment stability with bonded versus vacuum-formed retainers: A systematic review of randomized clinical trials” will be included in the thesis of the student Silvio Augusto Bellini Pereira and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, January 27th, 2022.



Silvio Augusto Bellini Pereira
Author

Signature



José Fernando Castanha Henriques
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Author

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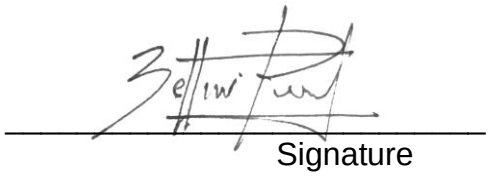
APPENDIX B - DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS

We hereby declare that we are aware of the article “Treatment stability with bonded versus vacuum-formed retainers after 12 months: A randomized clinical trial” will be included in the thesis of the student Silvio Augusto Bellini Pereira and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, January 27th, 2022.

Silvio Augusto Bellini Pereira
Author



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José Fernando Castanha Henriques
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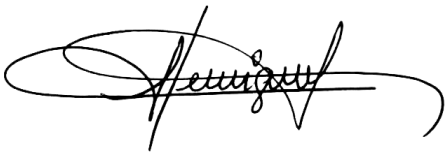
Author



Signature

ANNEXES

ANEXX A. Ethic Committee approval, protocol number 3.835.225 (front).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Efetividade clínica de contenções fixas versus contenções termoplásticas após 18 meses: Um ensaio clínico randomizado

Pesquisador: Silvio Bellini

Área Temática:

Versão: 3

CAAE: 22092919.7.0000.5417

Instituição Proponente: Universidade de Sao Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.835.225

Apresentação do Projeto:

A fase de contenção é um dos mais desafiadores e imprevisíveis estágios de todo tratamento ortodôntico. Mesmo que existam diversas opções de contenções, o protocolo clínico mais efetivo para o uso das mesmas ainda permanece incerto. Objetivo: Comparar a efetividade clínica das contenções fixas versus contenções termoplásticas com relação à estabilidade; saúde periodontal; e taxa de sobrevivência após 18 meses de remoção do aparelho fixo. Material e Métodos: Cinquenta pacientes finalizando o tratamento ortodôntico serão prospectiva e aleatoriamente alocados em dois grupos. O primeiro grupo será composto de 25 pacientes que utilizarão contenções fixas V-bend superiores e inferiores de canino acanino; enquanto o segundo grupo consistirá de 25 pacientes que farão uso de contenções termoplásticas confeccionadas a vácuo. O desfecho primário será a estabilidade pós-tratamento ortodôntico. Os desfechos secundários serão considerados a saúde periodontal, taxa de sobrevivência das contenções e a percepção dos pacientes. Os pacientes serão avaliados no dia da remoção do aparelho fixo (Baseline-T0); após 3 meses (T1); 6 meses (T2); 12 meses (T3) e 18 meses (T4). Em cada consulta de acompanhamento será obtido um modelo de estudo e a saúde periodontal de cada paciente será avaliada tomando como base índices previamente descritos. Os modelos de estudo serão escaneados e analisados pelo Software OrthoAnalyzer®. Os resultados obtidos serão verificados quanto a sua distribuição normal, e as comparações intergrupo serão analisadas pelo teste t para estabilidade, e para as variáveis. periodontais será utilizado o teste de Mann-Whitney. Por fim, as comparações

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ANEXX A. Ethic Committee approval, protocol number 3.835.225 (verse).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 3.835.225

intergrupo para todas as variáveis serão realizadas em todos os tempos de tratamento.

Objetivo da Pesquisa:

Comparar a efetividade clínica das contenções fixas V-Bend versus contenções termoplásticas quanto a sua capacidade de manter estável os resultados obtidos com o tratamento ortodôntico; saúde periodontal; e taxa de sobrevivência após 18 meses de remoção do aparelho fixo. Além disso, avaliar a percepção dos pacientes com relação aos dois protocolos testados.

Avaliação dos Riscos e Benefícios:

Os pesquisadores incluiram a informação sobre risco de exposição de fotos e informações dos participantes na PB, projeto, TCLEs e TALE.

"Vale ressaltar que pelo fato de serem realizadas fotografias e a aplicação de um questionário, existe o risco de exposição da sua imagem e dados pessoais, pois estes dados também poderão ser usados em aulas e publicações científicas. No entanto, o manuseio das fotografias, dados contidos no prontuário e questionário será feito de maneira sigilosa e cuidadosa. O questionário abordará a sua opinião pessoal com relação a vários itens relacionados ao conforto utilizando a contenção durante o período da pesquisa, e se necessário, o pesquisador responsável estará presente para auxiliar no seu preenchimento. Novamente, os pesquisadores envolvidos realizarão todos os procedimentos necessários para minimizar qualquer risco de divulgação inapropriada de imagens e dados pessoais obtidos nas consultas e questionários."

Comentários e Considerações sobre a Pesquisa:

O projeto de pesquisa está adequado e sem impedimento ético.

Considerações sobre os Termos de apresentação obrigatória:

Os termos apresentados estão adequados.

Recomendações:

Todas as solicitações sobre risco foram atendidas e inseridas no projeto, PB, TCLEs e TALE.

Conclusões ou Pendências e Lista de Inadequações:

Nenhuma.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 05/02/2020, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores,

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ANEXX A. Ethic Committee approval, protocol number 3.835.225 (verse).

cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1418649.pdf	08/01/2020 10:07:48		Aceito
Outros	Oficio_Assinado_Projeto_PhD_Silvio.pdf	08/01/2020 10:00:58	Silvio Bellini	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	10_Termo_Assentimento.pdf	08/01/2020 10:00:39	Silvio Bellini	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	9_TCLE_Responsaveis.pdf	08/01/2020 10:00:27	Silvio Bellini	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	8_TCLE.pdf	08/01/2020 10:00:16	Silvio Bellini	Aceito
Projeto Detalhado / Brochura Investigador	4_Projeto_Doutorado_Contencoes_CEP.pdf	08/01/2020 10:00:03	Silvio Bellini	Aceito
Parecer Anterior	Parecer_CEP_2.pdf	08/01/2020 09:59:52	Silvio Bellini	Aceito
Cronograma	6_Cronograma_Silvio.pdf	08/01/2020 09:59:39	Silvio Bellini	Aceito
Outros	1_Carta_de_Encaminhamento_Assinada.pdf	08/11/2019 10:28:23	Silvio Bellini	Aceito
Orçamento	7_Orcamento.pdf	18/09/2019 22:34:24	Silvio Bellini	Aceito
Outros	3_Checklist_Assinado.pdf	18/09/2019 11:53:19	Silvio Bellini	Aceito
Declaração de Pesquisadores	2_Declaracao_de_Compromisso_Pesquisador_Assinada.pdf	18/09/2019 11:52:46	Silvio Bellini	Aceito
Folha de Rosto	5_Folha_de_Rosto.pdf	18/09/2019 11:51:28	Silvio Bellini	Aceito

ANEXX A. Ethic Committee approval, protocol number 3.835.225 (verse).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 3.835.225

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 12 de Fevereiro de 2020

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

Endereço: DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9
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ANEXX B. Informed consent for children.

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e
Saúde Coletiva

Termo de Assentimento

Você está sendo convidado(a) a participar da pesquisa "**Efetividade clínica de contenções fixas versus contenções termoplásticas após 18 meses: Um ensaio clínico randomizado**". Essa pesquisa será realizada pelo Dr. Silvio Augusto Bellini Pereira, nesta faculdade, a Faculdade de Odontologia de Bauru, da Universidade de São Paulo (FOB-USP).

Nesta pesquisa vamos comparar duas "contenções ortodônticas", que são aparelhos usados pelos pacientes depois de remover o aparelho fixo, este que você está usando no momento. Essas "contenções" têm como função manter os dentes alinhados e impedir que eles voltem a sua posição de antes. Elas serão feitas, e colocadas pelo mesmo dentista que vai te atender (Dr. Silvio). É muito importante que você saiba que para colocar as contenções não dói, e elas são praticamente imperceptíveis, ou seja, outras pessoas não percebem que vocês estarão usando. Caso concorde em participar, é importante também que você saiba que os atendimentos serão aqui na clínica de Ortodontia desta faculdade (FOB-USP). Além disso, assim como você, o seu responsável também será informado sobre a sua participação neste estudo.

Depois que as "contenções" forem colocadas é possível que você sinta um mínimo desconforto principalmente para falar, mas pode ficar tranquilo, porque isso é normal, e é um pequeno período de adaptação dos seus músculos e sua língua. Em até dois dias você já estará falando normalmente.

Para verificar se as "contenções" estão fazendo efeito, alguns procedimentos serão realizados, mas todos são muito simples e rápidos. Primeiro vamos tirar algumas fotos do seu rosto e da sua boca. Serão 8 fotos no total. E em seguida vamos "moldar" seus dentes com uma "massinha" utilizada pelos dentistas. Por fim, será feita uma limpeza para tirar a "massinha" entre os dentes, e manter sua boca saudável. Estes procedimentos serão feitos durante um período de 18 meses, em todas as consultas de acompanhamento marcadas pelo Dr. Silvio. É muito importante que as contenções sejam usadas corretamente durante todo esse período e que você siga as instruções do Dr. Silvio com relação à como cuidar da sua "contenção". As consultas de acompanhamento não serão realizadas mensalmente. Você será apenas convidado a retornar após 3 meses da remoção do aparelho, 6 meses, 12 meses e 18 meses, ou seja, durante o período de 1 ano e 6 meses, você será convidado a comparecer somente 5 vezes, com uma duração de consulta de aproximadamente 1 hora.

Além desses procedimentos, nas consultas de acompanhamento com o Dr. Silvio você também será convidado a responder uma escala contendo um questionário com 9 itens. O questionário é muito fácil e simples de você responder. Em apenas 5 minutos é possível realizar o seu preenchimento, e em caso de dúvidas sobre como o questionário funciona, o Dr. Silvio estará por perto para te ajudar. Como vamos tirar algumas fotografias e você vai responder um questionário, existe o risco de exposição da sua imagem e dados pessoais porque muitas vezes usamos essas imagens em aulas e publicações em revistas. Mas, nós vamos cuidar das fotografias, dos seus dados, e das suas respostas do questionário muito bem, e seremos muito cuidadosos. No questionário você vai dar sua opinião pessoal sobre o conforto enquanto usava a contenção durante o período da pesquisa, e se necessário, o Dr. Silvio estará presente para ajudar no seu preenchimento. É muito importante que você saiba que o Dr. Silvio e sua equipe farão todos os procedimentos necessários para minimizar qualquer risco de divulgação inapropriada das suas fotos e dados pessoais obtidos nas consultas e questionários.

Não se esqueça, qualquer problema com a "contenção", como ela quebrar ou descolar, avise o seu responsável para ele conversar com o Dr. Silvio. Dessa maneira o Dr. Silvio poderá fazer uma nova contenção e os seus dentes vão se manter alinhados, bonitos, e na mesma posição. Você deverá usar o aparelho por 18 meses e mesmo após a pesquisa acabar, mas fique tranquilo(a), que o Dr. Silvio explicará em detalhe para você e para o seu responsável tudo relacionado as contenções. Se você tiver alguma dúvida, pode perguntar a qualquer momento. Você não terá nenhum custo, e é responsabilidade do Dr. Silvio e equipe arcar com qualquer possível gasto com relação a alimentação ou transporte que apareça durante a sua participação na pesquisa. Não se esqueça, você não precisa participar da pesquisa se não quiser. Não terá nenhum problema e você receberá atendimento da mesma forma.

Sendo assim, após me explicarem e ter lido e entendido todas as informações deste texto, eu, _____ aceito participar da pesquisa "Efetividade clínica de contenções fixas versus contenções termoplásticas após 18 meses: Um ensaio clínico randomizado".

Entendi que coisas boas que podem acontecer, mas que também posso sentir um pequeno desconforto.

Entendi que posso dizer "sim" e participar, mas que, a qualquer momento, posso dizer "não" e desistir e não acontecerá nenhuma penalidade. Os pesquisadores tiraram minhas dúvidas e conversaram com os meus responsáveis. Recebi uma cópia deste termo de assentimento e concordo em participar da pesquisa.

Bauru, ____ de _____ de _____.

_____
Silvio Augusto Bellini Pereira
Pesquisador Responsável

_____
Assinatura do menor

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ANEXX C. Informed consent for children's legal guardians (front).

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

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

O menor sob sua responsabilidade está sendo convidado a participar como voluntário da pesquisa intitulada "**Efetividade clínica de contenções fixas versus contenções termoplásticas após 18 meses: Um ensaio clínico randomizado**". A pesquisa será realizada por Silvio Augusto Bellini Pereira, Doutorando em Ortodontia na Faculdade de Odontologia de Bauru da Universidade de São Paulo, sob orientação do Prof. Dr. José Fernando Castanha Henriques.

Esta pesquisa tem como objetivo principal comparar dois tipos de contenções (aparelhos usados por pacientes após remover o aparelho fixo) quanto a 4 fatores: 1 – Quanto a sua estabilidade (capacidade de manter os resultados obtidos durante o tratamento ortodôntico); 2 – Quanto a saúde periodontal (saúde da gengiva ao redor do dente); 3- Quanto a sua taxa de sobrevivência (porcentagem de contenções que se mantém sem quebrar ou descolar, por motivos diversos); 4 – Quanto a percepção dos pacientes sobre o uso das contenções no dia-a-dia. Pacientes como o menor sob sua responsabilidade que estão finalizando o tratamento ortodôntico serão convidados a participar desta pesquisa.

Caso você concorde com a participação do menor sob sua responsabilidade nesta pesquisa, saiba que ele(a) poderá ser dividido de maneira aleatória em dois grupos dependendo da contenção que for utilizar. As duas contenções utilizadas nesta pesquisa serão as contenções fixas "V-bend" e "Termoplásticas". A contenção fixa V-bend é composta por um fio de aço inoxidável muito fino colado na parte de trás dos dentes da frente (incisivos e caninos) superiores e inferiores. Ela é colada utilizando resina e praticamente imperceptível durante o sorriso. Já a contenção termoplástica é feita de plástico acetato e pode ser removida durante alimentação e escovação dos dentes, também se apresenta quase imperceptível durante o sorriso.

É importante salientar que independente da contenção que será utilizada pelo menor sob sua responsabilidade, ambas são capazes de manter os resultados obtidos durante o tratamento ortodôntico, e os dentes alinhados, se utilizadas seguindo as instruções adequadas que serão transmitidas pelo pesquisador responsável (Dr. Silvio).

A confecção e instalação das contenções é um método simples, sendo que em uma única consulta o aparelho fixo será removido e a contenção já será instalada. A contenção fixa V-Bend ficará colada na parte de trás dos dentes da frente (incisivos e caninos) e a contenção termoplástica, por ser removível, será usada no período noturno pelos pacientes selecionados. O procedimento de instalação das contenções é completamente indolor (não dói). Entretanto, após sua instalação o paciente pode sentir certo desconforto principalmente para falar, porém suportável, pois é um período de adaptação de até 2 dias para a língua e a musculatura se adaptarem as contenções. Após este curto período, a fala ocorrerá normalmente. Não se pode descartar a possibilidade de as contenções apresentarem o risco de falhar por diversos motivos, sendo os mais comuns a fratura (quebra) ou descolagem das contenções. Por isso, a correta higiene bucal (pela escovação dos dentes e fio dental) e cuidados com alimentos duros serão importantes para a manutenção da saúde bucal e das contenções. O menor e você, responsável, serão orientados quanto a higienização, para manter saúde bucal em níveis ótimos e para evitar alguma intercorrência com relação ao uso das contenções durante todo o período de acompanhamento (18 meses).

Como explicado anteriormente, o uso correto das contenções permitirá que os resultados obtidos pelo tratamento ortodôntico sejam mantidos, evitando dessa maneira, a recidiva (tendência de os dentes voltarem para sua posição original, antes do tratamento).

É importante salientar que o menor sob sua responsabilidade será acompanhado por um tempo total de 18 meses. E em cada consulta de atendimento, o pesquisador responsável realizará fotos da face e da boca, totalizando 8 fotos, e também fará a moldagem da boca (utilização de uma massa odontológica específica para copiar os dentes e gengiva). Ambos os procedimentos são rápidos e fazem parte da rotina odontológica, apresentando apenas mínimo desconforto.

As consultas de acompanhamento não serão realizadas mensalmente. O menor será apenas convidado a retornar após 3 meses da remoção do aparelho, 6 meses, 12 meses e 18 meses, ou seja, durante o período de 1 ano e 6 meses, você e o menor sob sua responsabilidade serão convidados a comparecer somente 5 vezes, com uma duração de consulta de aproximadamente 1 hora.

Além dos procedimentos descritos acima, nas consultas de acompanhamento o menor também será convidado a responder uma escala contendo um questionário com 9 itens. O questionário é de fácil preenchimento e apresenta uma linguagem simples. Em apenas 5 minutos é possível realizar o seu preenchimento, e em caso de dúvidas sobre como o questionário funciona, o pesquisador responsável estará por perto para auxiliar.

Vale ressaltar que pelo fato de serem realizadas fotografias e a aplicação de um questionário, existe o risco de exposição da imagem e dados pessoais do menor, pois estes dados também poderão ser usados em aulas e publicações científicas. No entanto, o manuseio das fotografias, dados contidos no prontuário e questionário será feito de maneira sigilosa e cuidadosa. O questionário abordará a opinião pessoal do menor com relação a vários itens relacionados ao conforto utilizando a contenção durante o período da pesquisa, e se necessário, o pesquisador responsável estará presente para auxiliar no preenchimento. Novamente, os pesquisadores envolvidos realizarão todos os procedimentos necessários para minimizar qualquer risco de divulgação inapropriada de imagens e dados pessoais obtidos nas consultas e questionários.

Todos os procedimentos clínicos serão realizados pelo próprio pesquisador responsável, na clínica de Ortodontia da Faculdade de Odontologia de Bauru, Universidade de São Paulo.

Ao participar desta pesquisa, o menor apresentará como benefícios a gratuidade do acompanhamento para controle ortodôntico (atendimentos após remoção do aparelho) por todo período do estudo (18 meses), onde também

Rubrica do Pesquisador Responsável

Rubrica do Responsável do Menor

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ANEXX C. Informed consent for children's legal guardians (verse).

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

serão realizadas limpezas periódicas e controle da saúde periodontal; e caso apresente a necessidade de algum outro tratamento bucal, o paciente será encaminhado para o sistema de Triagem da Faculdade de Odontologia de Bauru para ser posteriormente encaminhado a outros Departamentos. Lembrando que durante todo período de acompanhamento, o menor poderá ser atendido em âmbito emergencial pelo pesquisador caso ocorra falha em alguma das contenções, independente do motivo. Dessa maneira, será proporcionada uma estabilidade aceitável dos resultados obtidos durante o tratamento ortodôntico, e uma adequada saúde periodontal.

Além disso, ao final do estudo o menor sob sua responsabilidade terá garantido o acompanhamento e/ou tratamento ortodôntico complementar (caso os dentes estejam desalinhados por conta exclusivamente da "recidiva") e estará disposto aos melhores métodos preventivos, diagnósticos e terapêuticos que se demonstrarem eficazes, por parte da Instituição patrocinadora. Você e o menor sob sua responsabilidade não terão nenhum custo, e é responsabilidade do Dr. Silvio e equipe arcar com qualquer possível gasto com relação a alimentação ou transporte que apareça durante a participação na pesquisa. É garantida a indenização em casos de danos que ocorram decorrentes dos procedimentos empregados nesta pesquisa.

É de extrema importância que você saiba que a sua privacidade e do menor sob sua responsabilidade serão respeitadas. Ou seja, o seu nome, o nome do menor, ou qualquer outro dado que possa, de qualquer forma, identificá-los, será mantido em sigilo. O menor poderá deixar de participar da pesquisa a qualquer momento sem sofrer prejuízos, retirando, então, seu consentimento, sem precisar se justificar. Para qualquer questionamento futuro, você também ficará com uma cópia deste termo de consentimento livre e esclarecido.

O **pesquisador responsável** envolvido com a referida pesquisa é **Silvio Augusto Bellini Pereira** e com ele você poderá manter contato via **e-mail** (silvio_abp@hotmail.com) ou **telefone** (11) 99914-2930.

Rubrica do Pesquisador Responsável:

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

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

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

Rubrica do Responsável do Menor:

Bauru, ____ de _____ de _____.

_____ Silvio Augusto Bellini Pereira **Pesquisador responsável**

_____ **Assinatura do responsável pelo menor**

O **Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0698/FOB**), previsto no item VII da Resolução nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.
Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

Horário e local de funcionamento:
Comitê de Ética em Pesquisa
Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das **13h30 às 17 horas**, em dias úteis.
Alameda Dr. Octávio Pinheiro Brisolla, 9-75
Vila Universitária – Bauru – SP – CEP 17012-901
Telefone/FAX(14)3235-8356
e-mail: cep@fob.usp.br

ANEXX D. Informed consent for patients above 18 years (front).

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

Termo de Consentimento Livre e Esclarecido

Você está sendo convidado a participar como voluntário da pesquisa intitulada "**Efetividade clínica de contenções fixas versus contenções termoplásticas após 18 meses: Um ensaio clínico randomizado**". A pesquisa será realizada por Silvio Augusto Bellini Pereira, Doutorando em Ortodontia na Faculdade de Odontologia de Bauru da Universidade de São Paulo, sob orientação do Prof. Dr. José Fernando Castanha Henriques.

Esta pesquisa tem como objetivo principal comparar dois tipos de contenções (aparelhos usados por pacientes após remover o aparelho fixo) quanto a 4 fatores: 1 – Quanto a sua estabilidade (capacidade de manter os resultados obtidos durante o tratamento ortodôntico); 2 – Quanto a saúde periodontal (saúde da gengiva ao redor do dente); 3- Quanto a sua taxa de sobrevivência (porcentagem de contenções que se mantém sem quebrar ou descolar, por motivos diversos); 4 – Quanto a percepção dos pacientes sobre o uso das contenções no dia-a-dia. Pacientes como você que estão finalizando o tratamento ortodôntico serão convidados a participar desta pesquisa.

Caso aceite participar você poderá ser dividido de maneira aleatória em dois grupos dependendo da contenção que for utilizar. As duas contenções utilizadas nesta pesquisa serão as contenções fixas "V-bend" e "Termoplásticas". A contenção fixa V-bend é composta por um fio de aço inoxidável muito fino colado na parte de trás dos dentes da frente (incisivos e caninos) superiores e inferiores. Ela é colada utilizando resina e praticamente imperceptível durante o sorriso. Já a contenção termoplástica é feita de plástico acetato e pode ser removida durante alimentação e escovação dos dentes, também se apresenta quase imperceptível durante o sorriso.

É importante salientar que independente da contenção que será utilizada por você, ambas são capazes de manter os resultados obtidos durante o tratamento ortodôntico, e os dentes alinhados, se utilizadas seguindo as intruções adequadas que serão transmitidas pelo pesquisador responsável (Dr. Silvio).

A confecção e instalação das contenções é um método simples, sendo que em uma única consulta o aparelho fixo será removido e a contenção já será instalada. A contenção fixa V-Bend ficará colada na parte de trás dos dentes da frente (incisivos e caninos) e a contenção termoplástica, por ser removível, será usada no período noturno pelos pacientes selecionados. O procedimento de instalação das contenções é completamente indolor (não dói). Entretanto, após sua instalação o paciente pode sentir certo desconforto principalmente para falar, porém suportável, pois é um período de adaptação de até 2 dias para a língua e a musculatura se adaptarem as contenções. Após este curto período, a fala ocorrerá normalmente. Não se pode descartar a possibilidade das contenções apresentarem o risco de falhar por diversos motivos, sendo os mais comuns a fratura (quebra) ou descolagem das contenções. Por isso, a correta higiene bucal (pela escovação dos dentes e fio dental) e cuidados com alimentos duros serão importantes para a manutenção da saúde bucal e das contenções. Você será orientado quanto a higienização, para manter a sua saúde bucal em níveis ótimos e para evitar alguma intercorrência com relação ao uso das contenções durante todo o período de acompanhamento (18 meses).

Como explicado anteriormente, o uso correto das contenções permitirá que os resultados obtidos pelo tratamento ortodôntico sejam mantidos, evitando dessa maneira, a recidiva (tendência de os dentes voltarem para sua posição original, antes do tratamento).

Você será acompanhado por um tempo total de 18 meses. E em cada consulta de atendimento, o pesquisador responsável realizará fotos da sua face e da boca, totalizando 8 fotos, e também fará a moldagem da boca (utilização de uma massa odontológica específica para copiar os dentes e gengiva). Ambos os procedimentos são rápidos e fazem parte da rotina odontológica, apresentando apenas mínimo desconforto.

As consultas de acompanhamento não serão realizadas mensalmente. Você será apenas convidado a retornar após 3 meses da remoção do aparelho, 6 meses, 12 meses e 18 meses, ou seja, durante o período de 1 ano e 6 meses, você será convidado a comparecer somente 5 vezes, com uma duração de consulta de aproximadamente 1 hora.

Além dos procedimentos descritos acima, nas consultas de acompanhamento você também será convidado a responder uma escala contendo um questionário com 9 itens. O questionário é de fácil preenchimento e apresenta uma linguagem simples. Em apenas 5 minutos é possível realizar o seu preenchimento, e em caso de dúvidas sobre como o questionário funciona, o pesquisador responsável estará por perto para auxiliar.

Vale ressaltar que pelo fato de serem realizadas fotografias e a aplicação de um questionário, existe o risco de exposição da sua imagem e dados pessoais, pois estes dados também poderão ser usados em aulas e publicações científicas. No entanto, o manuseio das fotografias, dados contidos no prontuário e questionário será feito de maneira sigilosa e cuidadosa. O questionário abordará a sua opinião pessoal com relação a vários itens relacionados ao conforto utilizando a contenção durante o período da pesquisa, e se necessário, o pesquisador responsável estará presente para auxiliar no seu preenchimento. Novamente, os pesquisadores envolvidos realizarão todos os procedimentos necessários para minimizar qualquer risco de divulgação inapropriada de imagens e dados pessoais obtidos nas consultas e questionários. Todos os procedimentos clínicos serão realizados pelo próprio pesquisador responsável, na clínica de Ortodontia da Faculdade de Odontologia de Bauru, Universidade de São Paulo.

Ao participar desta pesquisa, você apresentará como benefícios a gratuidade do acompanhamento para controle ortodôntico (atendimentos após remoção do aparelho) por todo período do estudo (18 meses), onde também serão realizadas limpezas periódicas e controle da saúde periodontal; e caso apresente a necessidade de algum outro tratamento bucal, você será encaminhado para o sistema de Triagem da Faculdade de Odontologia de Bauru para ser posteriormente encaminhado a outros Departamentos. Lembrando que durante todo período de acompanhamento, você

Rubrica do Pesquisador Responsável:

Rubrica do Participante da Pesquisa:

Al. Dr. Octávio Pinheiro Brisolla, 9-75 – Bauru-SP – CEP 17012-901 – C.P. 73
e-mail: veragato@fob.usp.br – Fone/FAX (0xx14) 3235-8217
http://www.fob.usp.br

ANEXX D. Informed consent for patients above 18 years (verse).

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Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

poderá ser atendido em âmbito emergencial pelo pesquisador caso ocorra falha em alguma das contenções, independente do motivo. Dessa maneira, será proporcionada uma estabilidade aceitável dos resultados obtidos durante o tratamento ortodôntico, e uma adequada saúde periodontal.

Além disso, ao final do estudo você terá garantido o acompanhamento e/ou tratamento ortodôntico complementar (caso os dentes estejam desalinhados por conta exclusivamente da "recidiva") e estará disposto aos melhores métodos preventivos, diagnósticos e terapêuticos que se demonstrarem eficazes, por parte da Instituição patrocinadora. Você não terá nenhum custo, e é responsabilidade do Dr. Silvio e equipe arcar com qualquer possível gasto com relação a alimentação ou transporte que apareça durante a sua participação na pesquisa. É garantida a indenização em casos de danos que ocorram decorrentes dos procedimentos empregados nesta pesquisa.

É de extrema importância que você saiba que a sua privacidade será respeitada. Ou seja, o seu nome ou qualquer outro dado que possa, de qualquer forma, identificá-lo, será mantido em sigilo. Você poderá deixar de participar da pesquisa a qualquer momento sem sofrer prejuízos, retirando, então, seu consentimento, sem precisar se justificar. Para qualquer questionamento futuro, você também ficará com uma cópia deste termo de consentimento livre e esclarecido.

O **pesquisador responsável** envolvido com a referida pesquisa é **Silvio Augusto Bellini Pereira** e com ele você poderá manter contato via **e-mail** (silvio_abp@hotmail.com) ou **telefone** (11) 99914-2930.

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

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

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

Rubrica do Pesquisador Responsável:

Rubrica do Participante da Pesquisa:

Bauru, ____ de _____ de _____.

_____	_____
Silvio Augusto Bellini Pereira **Pesquisador responsável**	**Participante da Pesquisa**

O **Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0698/FOB**), previsto no item VII da Resolução nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

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

Horário e local de funcionamento:
Comitê de Ética em Pesquisa
Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das **13h30 às 17 horas**, em dias úteis.
Alameda Dr. Octávio Pinheiro Brisolla, 9-75
Vila Universitária – Bauru – SP – CEP 17012-901
Telefone/FAX(14)3235-8356
e-mail: cep@fob.usp.br