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Dissertação

Avaliação da eficácia do uso de intervenção prévia à reabilitação de usuários de próteses totais durante longos períodos

Rita de Cássia Costa Ribeiro de Almeida

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Resumo

ALMEIDA, Rita de Cássia Costa Ribeiro de. **Avaliação da eficácia do uso de intervenção prévia à reabilitação de usuários de próteses totais durante longos períodos.** 2014. 86f. Dissertação (Mestrado em Prótese Dentária) - Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia Universidade Federal de Pelotas, Pelotas, 2014.

O edentulismo e o uso de próteses totais inadequadas, instáveis e com dentes desgastados durante tempo prolongado, podem levar a um desequilíbrio do sistema estomatognático devido à perda gradual de dimensão vertical de oclusão resultando em movimentos mandibulares inadequados. A realização de reembasamento da base da prótese e o uso de placa oclusal, previamente à nova reabilitação, poderiam ter influência no restabelecimento destes aspectos funcionais. Este estudo foi dividido em dois artigos. Inicialmente, foi conduzida uma revisão sistemática da literatura com o objetivo de avaliar a evidência científica disponível relacionada ao uso de placa oclusal previamente à nova reabilitação de pacientes desdentados totais. Além disso, foi realizado um estudo clínico randomizado e controlado para avaliar se o uso de placa oclusal e do reembasamento das bases das próteses totais, previamente a sua substituição, têm influência na extensão dos movimentos mandibulares e restabelecimento da dimensão vertical de oclusão. Sete bases de dados foram utilizadas no primeiro artigo: MedLine (PubMed), ISI Web of Science, Scopus, Scielo, Lilacs, Ibecs e Cochrane Library. Somente estudos clínicos, sem ano limite de publicação, foram selecionados. A partir de todas as bases de dados foram identificados 1653 estudos potencialmente relevantes. Após remoção das duplicatas e avaliação dos títulos e resumos, 1647 estudos foram excluídos, 6 artigos foram avaliados a partir de leitura completa e apenas 4 estudos foram incluídos na revisão. Para o estudo clínico, 30 voluntários, desdentados e usuários de próteses totais foram distribuídos em três grupos (n=10): **Grupo controle** que não recebeu nenhuma intervenção previamente à substituição das próteses antigas; **Grupo Reebasamento** no qual os voluntários tiveram as bases das próteses reembasadas; e **Grupo Placa Oclusal** que fez uso deste dispositivo previamente a substuição das próteses totais. Inicialmente, a revisão sistemática mostrou que embora o nível de evidência científica encontrado tenha sido fraco, foi possível identificar benefícios do uso de placas oclusais antes da nova reabilitação de usuários de próteses totais durante longos períodos, com relação à redução na sintomatologia da dor e melhora do tônus muscular. No entanto, quanto à extensão dos movimentos mandibulares e espaço intra-articular, essa evidência não foi clara. Adicionalmente, o estudo clínico monstrou que o uso de placa oclusal, previamente a reabilitação de usuários de prótese total durante longos períodos, foi um tratamento efetivo porque restabeleceu a extensão dos movimentos mandibulares e a dimensão vertical de oclusão.

Palavras-chave: dimensão vertical; prótese total; ensaio clínico controlado randomizado; revisão.

Abstract

ALMEIDA, Rita de Cássia Costa Ribeiro de**. Evaluation of the efficacy of the use of intervention prior to rehabilitation of complete denture wearers for long periods.** 86f. Master Thesis - Graduate Program in Dentistry - Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia Universidade Federal de Pelotas, Pelotas, 2014.

The edentulism and the use of inadequate, unstable and with teeth worn complete dentures because long period of usage can lead to an disharmony of the stomatognathic system due to gradual loss of occlusion vertical dimension resulting in inadequate mandibular movements. The reline of the denture base and the use of occlusal splint prior to the new rehabilitation could have influence on these functional aspects. This study was divided into two articles. Initially, the purpose was to conduct a systematic review of the literature to evaluate the avaiable scientific evidence related to occlusal splint before the new rehabilitation of edentulous patients. Furthermore, it was assessed by a randomized clinical trial if the use of occlusal splint and the reline of the denture base, before replacing them, have influence on the extent of mandibular movements and re-establish the occlusion vertical dimension. Seven databases were used in the first article: MedLine (PubMed), ISI Web of Science, Scopus, Scielo, Lilacs, Ibecs and the Cochrane Library. Only clinical studies in humans and unlimited year of publication were selected. From all databases were identified 1653 studies potentially relevant. After removal of duplicates and review of titles and abstracts, 1647 studies were excluded, 6 were completelly evaluated and only 4 articles were inclued in the review. For clinical trial, 30 volunteers, totally edentulous and complete denture wearers were allocated into 3 groups (n=10): **Control group** that not received any intervention prior to replacement of dentures; **Group Reline** in which the volunteers had the dentures bases relined; and **Group Occlusal Splint** in which the voluntters used this device prior to the replacement of old complete dentures. First, the systematic literature review showed that although the scientific evidence level found was weak, it was possible to identify benefits of the use of occlusal splints prior to the new rehabilitation of long-term complete denture wearers with regard to reductions in pain symptomatology and improvement of the muscular tonus. However, regarding the extent of mandibular movements and intra-articular space, this evidence is not clear. Moreover, the clinical study showed that the use of occlusal splint as previous treatment prior to the rehabilitation of long-term complete denture wearers was effective since this intervention re-established the extent of mandibular movement and the occlusion vertical dimension.

Keywords: vertical dimension; complete denture; randomized controlled trial; review.

Sumário

1 Introdução

O edentulismo, que representa a condição de aproximadamente 75% da população brasileira (SB Brasil, 2010), pode resultar em desequilíbrio do sistema estomatognático (GRUNERT; GRUBWIESER; ULMER, 2000; ZARB, 2013). Este desequilíbrio é originado a partir de alterações estéticas e funcionais que ocorrem em função da perda total dos dentes, as quais podem culminar em projeção da mandíbula, devido a perda da dimensão vertical de oclusão (DVO), bem como no deslocamento distal dos côndilos que origina a compressão de estruturas intra-articulares e podem resultar em sintomas como zumbidos, ruídos, sensação de ouvido tapado e perda da coordenação dos movimentos mandibulares (MM) (COSTEN, 1934; CONTI et al., 2006).

A reabilitação de pacientes edêntulos se faz mediante a instalação de próteses totais ou de sobredentaduras implanto-suportadas (VOGEL, SMITH-PALMER, VALENTINE, 2013; THOMASON et al., 2012). No entando, a reabilitação a partir do uso de implantes é um tratamento oneroso e dependente da adequada saúde geral do paciente, o que torna esta modalidade terapêutica, ainda inviável para grande parcela da população (THOMASON et al., 2012).

Neste contexto, é importante pontuar que a perda da dimensão vertical e projeção anterior da mandíbula podem ocorrer não só em indivíduos totalmente edêntulos, mas também em usuários de próteses totais antigas devido ao desgaste progressivo dos dentes artificiais e consequente diminuição da DVO (MATSUDA et al., 2014). Estes aspectos, associados às condições de instabilidade e perda de retenção da prótese, devido, entre outros fatores, a reabsorção óssea do rebordo alveolar (AMORIN et al., 2003; BERSANI et al., 2011), podem propiciar MM inadequados que podem culminar em desconforto e instabilidade na musculatura orofacial e o desenvolvimento de doenças degenerativas assintomáticas e/ou de doenças sintomáticas como a Disfunção Temporomandibular (DTM) (FORGIE; SCOTT; DAVIS, 2005; SUVINEN, KEMPPAINEN, 2007).

Dessa forma, estabelecer a DVO ideal para estes indivíduos têm fundamental importância para a confecção de uma nova prótese total que restabeleça adequadamente a harmonia do sistema estomatognático (ABDUO, LYONS, 2012; MAYS, 2003; MATSUDA et al., 2014). No entanto, se a musculatura

e as articulações estão alteradas, provavelmente o registro de ralacionamento maxilomandibular (RMM) obtido incorporará estas alterações, que serão transmitidas às novas próteses, perpetuando um ciclo de iatrogenias (CASSELI et al., 2007; ZUCCOLOTTO et al., 2007). Dessa forma, a simples substituição de próteses antigas poderia nem sempre representar a única conduta indicada, e nestes casos, seria fundamental oferecer um tratamento que restabelecesse a estabilidade da prótese e gradualmente devolvesse o equilíbrio articular e o recondicionamento tônico-muscular previamente ao novo tratamento reabilitador (DE BOEVER et al., 2000; ZUCCOLOTTO et al., 2007). Provavelmente, em função dos aspectos supra-citados, embora existam vários métodos para obtenção da DVO, o seu correto restabelecimento em pacientes que apresentam grande perda de DVO ainda é um desafio à prática clínica (SILVERMAN, 2001).

Neste contexto, baseado em evidência científica obtida em estudos realizados em indivíduos dentados (ABDUO, 2012; ABDUO; LYONS, 2012), pode-se observar que o restabelecimento da DVO previamente à reabilitação protética definitiva poderia ser instituído a partir da utilização de placas oclusais. Estes dispositivos promovem o restabelecimento da dimensão vertical e do espaço articular propiciando, assim, a liberdade dos movimentos mandibulares e consequente retorno aos parâmetros funcionais de normalidade com o recondicionamento da atividade muscular (CONTI et al., 1998; EKBERG; VALLON; NILNER, 1998; DE BOEVER; CARLSSON; KLINEBERG, 2000; KREINER; BETANCOR; CLARK , 2001).

Por outro lado, os aspectos funcionais negativos, tais como alteração dos MM entre outros, resultantes do uso de próteses totais instáveis e sem retenção, poderiam ser solucionados pelo reembasamento da base da prótese, seja com material macio ou rígido (PISANI et al., 2012). O reembasamento aumenta a retenção e a estabilidade da base da prótese total, o que providencia o restabelecimento do conforto do sistema estomatognático e melhora as atividades funcionais dos usuários (MUTLUAY, et al., 2008; KIMOTO et al., 2010; PISANI et al., 2012).

Com relação a metodologia de avaliação e registro da dinâmica dos MM, (KESHVAD; WINSTANLEY, 2001), destaca-se o registro intraoral, que é um registro mecânico confeccionado a partir de um método clínico simples usado para a avaliação da função muscular e reprodução da relação maxilomandibular (GYSI,

1910; PAIXAO et al, 2007; MYSORE, ARAS, 2012). Este registro projeta no plano horizontal um traçado gráfico dos movimentos funcionais bordejantes da mandíbula, onde os movimentos mandibulares de lateralidade e ântero-posteriores determinam uma configuração angular no traçado obtido, chamado de arco gótico de Gysi (GYSI, 1910). Assim, as alterações gráficas no arco gótico representam as alterações na função muscular (OKESON, 1982; SULUN, 2011). Quanto as metodologias usadas para registrar o restabelecimento de DVO, a literatura relata metodologias que permitem a obtenção de medidas precisas e padronizadas, tais quais aquelas obtidas através do uso de um programa de computador, o Image Tool (CUSI et al., 2000; PAIXÃO et al., 2007).

Finalmente, embora a literatura reporte alterações estéticas e funcionais relacionados aos usuários de próteses totais durante longos períodos, parece ainda não haver suficiente evidência científica, bem como estudos clínicos bem delineados, que sustentem a eficácia do uso de intervenção prévia a realização de nova reabilitação protética nestes indivíduos.

1.2 Objetivos

1.2.1 Objetivo geral

O objetivo desse estudo é avaliar, através da realização de uma revisão sistemática da literatura, a evidência científica disponível acerca da indicação do uso de placa oclusal previamente à nova reabilitação de usuários de próteses totais durante longos períodos. Adicionalmente, será avaliado através de um estudo clínico, controlado e randomizado se o uso de placa oclusal e/ou do reembasamento das bases das próteses totais antigas previamente à nova reabilitação, têm influencia na extensão dos MM e no restabelecimento da DVO destes indivíduos.

1.2.2 Objetivos específicos

A) Avaliar, por meio de uma revisão sistemática da literatura, a influência do uso de placa oclusal na extensão dos movimentos mandibulares, no espaço intra-articular, na dimensão vertical de oclusão, na atividade muscular e na diminuição da sintomatologia dolorosa;
B) Analisar a influência do uso de placa oclusal e reembasamento das bases das próteses totais antigas na extensão dos MM, através do arco gótico de Gysi;

C) Avaliar a influência do uso de placa oclusal e reembasamento das bases das próteses totais antigas no restabelecimento da DVO, através de fotografias digitais padronizadas.

2 Projeto de Pesquisa

2. 1 Caracterização do problema

O uso de dispositivos oclusais ainda está entre as indicações mais frequentes para o tratamento do bruxismo (LOBBEZOO et al., 2008) e dores orofaciais (SUVINEN, KEMPPAINEN, 2007). Porém, não há evidência científica adequada que suporte a indicação do uso destes dispositivos interoclusais previamente a reabilitação de usuários de prótese totais durante longos períodos. Dessa forma, torna-se relevante salientar um recente editorial de um pesquisador que atua com o tratamento de placas oclusais a mais de 40 anos, o qual salienta que caso se deseje realizar tratamentos clínicos baseados em evidência científica, haverá um desafio constante de ultrapassar os conhecimentos básicos, que ficam mais a beira das verdades relativas, baseados somente em prática clínica. Conhecimentos baseados na prática clínica existem e não estão, necessariamente, incorretos. Porém, aceitá-los como se fossem verdades absolutas não seria interessante para os pacientes, devendo ser utilizados apenas em casos nos quais os conhecimentos mais concretos não tenham sido adequadamente comprovados cientificamente. Assim, a obrigação da comunidade científica seria desafiar esse tipo de conhecimento com estudos que ajudem a revelar a verdade, baseada em evidência científica (OKESON, 2014).

Neste contexto, não se pode falaciosamente assumir ou deixar de se avaliar, através de estudos clínicos bem delineados se o uso de placas oclusais constitui um tratamento eficaz no restabelecimento dos MM e da DVO de pacientes que usam próteses totais por muitos anos. A literatura científica tem relatado o restabelecimento do sistema estomatognático devido ao uso de placas oclusais (CONTI et al., 2006; KIDDER, SOLLOW, 2014). Porém, ainda hoje não há estudos clínicos bem delineados que sustentem a relação entre o restabelecimento de DVO e MM e o uso de placa oclusal. Além disso, também não há estudos clínicos desenhados especificamente para avaliar se o uso do reembasamento da base da prótese têm influência no restabelecimento de DVO e MM. Apesar de terem sido propostas várias ferramentas, na forma de diretrizes que orientem o desenvolvimento de ensaios clínicos e providenciem maior força de evidência e

validade aos estudos, até o momento não há uma evidência científica suficiente acerca deste tema.

Neste contexto, as revisões sistemáticas são ferramentas inestimáveis para a prática clínica, proporcionando uma abordagem crítica do conhecimento científico com o objetivo de responder a uma pergunta clínica relevante com base na melhor evidência científica disponível. Além disso, as revisões de literatura podem evidenciar a falta de evidência científica, bem como apontar melhorias e padronização metodológica para futuras pesquisas clínicas (GREENHALGH, 1997; LINDE, WILLICH, 2003). Assim, a realização de uma revisão sistemática e estudo clínico randomizado têm grande relevância científica em virtude da escassez de estudos clínicos avaliando a influência do uso do reembasamento e do uso de placas oclusais no restabelecimento dos MM e DVO, quando usados previamente à realização do novo tratamento reabilitador de indivíduos usuários de prótese total durante longos períodos.

2.2 Parte 1

2.2.1 Delineamento Experimental

Será conduzida uma revisão sistemática com o objetivo de investigar a evidência científica disponível acerca do assunto e/ou apontar melhorias e padronização metodológica para futuras pesquisas clínicas. A revisão sistemática será conduzida seguindo a metodologia do “Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement” (MOHER et al, 2009) e será registrada na base de registros de revisões sistemáticas PROSPERO.

2.2.2 Objetivos

2.2.2.1 Geral

Revisar sistematicamente a literatura disponível acerca da indicação do uso de placa oclusal previamente à nova reabilitação de usuários de próteses totais durante longos períodos, com o objetivo de avaliar se tal intervenção têm influência no restabelecimento dos movimentos mandibulares, dimensão vertical de oclusão, espaço intra-articular, atividade muscular, bem como na diminuição da sintomatologia dolorosa.

2.2.3 Hipóteses

A hipótese testada será que o uso de placa oclusal previamente à nova reabilitação de pacientes usuários de próteses totais durante longos períodos têm influência no restabelecimento dos parâmetros avaliados.

2.2.4 Busca na literatura

A busca será conduzida até maio de 2014 nas seguintes bases de dados: MedLine (PubMed), ISI Web of Science, Scopus, Scielo, Lilacs, Ibecs e Cochrane Library. A estratégia de busca está descrita na Tabela 1. Os critérios de elegibilidade serão: estudo clínico, prospectivo ou retrospectivo, que avalie o uso de placas oclusais em pacientes com próteses totais em pelo menos um arco edêntulo. Artigos em língua diferente do inglês, português e espanhol não serão selecionados.

Tabela 1 – Estratégia de busca a ser utilizada no PubMed (MedLine)

	Search Terms
#4	Search #1 AND #2 AND #3
#3	Search Retrospective Studies OR Studies, Retrospective OR Study, Retrospective OR Retrospective Study OR Prospective Studies OR Prospective Study OR Studies, Prospective OR Study, Prospective OR Clinical Trial OR ((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading]) OR (randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract]))
#2	Search "Occlusal Splints"[Mesh] OR Occusal Splints OR Splints, Occlusal OR Occlusal Splint OR Splint, Occlusal OR Interocclusal appliance OR Interocclusal Splint OR Splint Therapy OR Acrylic Splint OR occlusal device OR Device, occlusal OR Interocclusal Device OR Device, Interocclusal
#1	Search “Dentures”[Mesh] OR Dentures OR Denture, Complete OR Complete Denture OR Complete Dentures OR Dentures, Complete OR Denture, Complete, Lower OR Denture, Complete, Upper OR Prosthesis total OR Total, prosthesis OR Mouth, Edentulous OR Edentulous Mouth OR Edentulous Mouths OR Mouth, Toothless OR Toothless Mouth OR Jaw, Edentulous OR Edentulous Jaw OR Edentulous Jaws OR Jaws, Edentulous OR Denture wear OR Wear, denture OR "Dental Restoration Wear"[Mesh] OR Wear, Dental Restoration OR Occlusal Wear, Restoration OR Restoration Occlusal Wear OR Wear, Restoration Occlusal OR Restoration Wear, Dental OR Denture, Partial OR Dentures, Partial OR Partial Denture OR Partial Dentures OR Dental Bridgework OR Dental Bridgeworks OR Bridgeworks, Dental OR Bridgework, Dental OR Denture, Partial, Removable OR Removable Partial Denture OR Denture, Removable Partial OR Dentures, Removable Partial OR Partial Denture, Removable OR Partial Dentures, Removable OR Removable Partial Dentures

Para formular a questão de pesquisa será utilizado o formato PICOT: (i) **População:** usuários de prótese total, em pelo menos um arco; (ii) **Intervenção**: uso de placa oclusal; (iii) **Comparação**: antes e após a nova reabilitação com prótese total; (iv) **Desfechos:** extensão dos movimentos mandibulares, sintomatologia dolorosa, espaço intra-articular, dimensão vertical de oclusão e atividade muscular; (v) **Tipo de estudo**: prospectivo ou retrospectivo. **Questão de pesquisa determinada:** O uso de placas oclusais seria benéfico no restabelecimento do sistema estomatognático antes da nova reabilitação de pacientes usuários de próteses totais durante longos períodos?

A busca na literatura, bem como a coleta de dados, será feita independentemente por dois revisores e quaisquer dúvida a respeito de algum artigo

será realizada baseada na opinião, também, de um terceiro revisor. Se possível será conduzida uma meta-análise dos artigos incluídos visando a estimativa do efeito comum entre os estudos.

2.3 Parte 2

2.3.1 Delineamento Experimental

Será realizado um estudo clínico controlado, randomizado e duplo-cego (examinador e estatístico).

Serão selecionados 30 pacientes usuários de prótese total superior e inferior por um período superior à 5 anos. O desenho deste estudo clínico será realizado conforme o CONSORT (SCHULZ, ALTMAN, MOHER, 2010). Os voluntários serão distribuidos aleatoriamente em 3 grupos (n=10): um grupo controle que não receberá nenhuma intervenção previamente à substituição das próteses antigas; um grupo em que os voluntários terão as bases das próteses reembasadas; e outro grupo que fará uso de placa interoclusal previamente a substuição das próteses totais. Os voluntários alocados nos grupos que receberão tratamento serão avaliados quanto à extensão dos MM e DVO em 3 períodos de tempo: T0 (*baseline*), T1 (após a aplicação do tratamento aleatorizado, reembasamento ou uso de placa) e T2 (após a nova reabilitação). O grupo controle será avaliado apenas nos períodos T0 e T2.

O projeto será submetido ao Comitê de Ética em Pesquisa da Faculdade de Odontologia da Universidade Federal de Pelotas e todos os voluntários que atenderem os critérios de inclusão e concordarem em participar do estudo após terem sido informados acerca dos objetivos e metodologias que serão usadas assinarão um Termo de Consentimento Livre e Esclarecido (Apêndice 1). Este termo será confeccionado em duas vias, uma ficará com o pesquisador e a outra com o voluntário.

2.3.2 Objetivos

2.3.2.1 Geral

Este estudo tem como objetivo avaliar a influência do uso de placas oclusais e reembasamento da base da prótese total na extensão de MM e OVD em indivíduos usuários de próteses totais durante longos períodos.

2.3.2.2 Específicos

1. Avaliar, intra e intergrupos, por meio do registro gráfico do arco gótico de Gysi, a extensão dos MM nos seguintes tempos: T0, T1 e T2;
2. Avaliar intra e intergrupos, através de registro fotográfico, a DVO nos tempos T0,

T1 e T2.

2.3.3 Hipóteses

As hipóteses testadas serão que os MM e a DVO serão influenciados pelo uso de placa oclusal e pelo reembasamento da base da prótese, previamente à nova reabilitação protética de pacientes usuários de próteses totais duplas durante longos períodos.

2.3.4 Cálculo amostral

O tamanho da amostra foi determinado com o objetivo de detectar uma diferença de 20% na média do valor obtido quando avaliado o restabelecimento da extensão dos MM e da DVO em função dos períodos de avaliação, com um poder de 80% e nível de significância de 5%. Foi realizado um cálculo a partir de publicação prévia que avaliou os MM através do arco gótico de Gysi em desdentados totais (CASSELI et al., 2007). Este cálculo determinou que em cada grupo deveriam estar alocados 8 voluntários. Entretanto, considerando-se futuras perdas no decorrer da pesquisa foi estipulado para a condução deste estudo clínico um n=10.

2.3.5 Seleção dos voluntários

Inicialmente este estudo será submetido à avaliação do Comitê de Ética em Pesquisa da Faculdade de Odontologia da Universidade Federal de Pelotas (Apêndice C). Depois, a partir da lista de espera de pacientes do Departamento de Odontologia Restauradora da Área de Prótese Dentária da Faculdade de Odontologia (FO) da Universidade Federal de Pelotas (UFPel), serão selecionados indivíduos que buscaram a Faculdade de Odontologia com o intuito de trocar suas próteses e que preencham os seguintes **Critérios de inclusão: (i)** Adultos saudáveis com pelo menos 50 anos, de ambos os gêneros, usuários de prótese total superior e inferior durante pelo menos 5 anos; (ii) Usuários de próteses com instabilidade, falta de retenção, perda de DVO e com alteração de posicionamento maxilomandibular; (iii) Indivíduos com habilidade para realizar os protocolos da pesquisa; (iv) Indivíduos com ausência de DTM; (v) Indivíduos com ausência de doenças na mucosa oral; (vi) tenham disponibilidade para comparecerem a FO/UFPel nos dias pré-determinados e (vii) que concordem em assinar o termo de

consentimento livre e esclarecido, após terem sido informados dos objetivos do estudo, riscos e benefícios associados aos procedimentos experimentais. Os **Critérios de exclusão** serão: (i) Indivíduos não usuários de prótese total superior e inferior; (ii) Indivíduos usuários de prótese total durante períodos inferiores a 5 anos; (iii) Indivíduos que apresentem DTM, doenças neurológicas e na mucosa oral.

2.3.6 Randomização

A randomização dos procedimentos experimentais será realizada com auxílio de tabela computadorizada de números randômicos, emitida por planilha eletrônica no software Microsoft Office Excel 2013 (Microsoft Corporation, Redmond, WA, EUA). O resultado da randomização será mantido em envelopes selados e opacos para garantir a ocultação da seleção.

2.3.7 Procedimentos clínicos

Os voluntários selecionados serão convidados a responder a um questionário para a coleta de dados sócio-demográficos como gênero, idade, escolaridade, estado civil, profissão e tempo de uso das próteses atuais (Apêndice 2). A presença e severidade de sinais e sintomas de DTM serão determinadas usando-se um questionário composto por questões relacionadas a sintomas comuns de DTM, baseados no índice anamnésico modificado de Helkimo, previamente utilizado em outros estudos (CONTI et al., 2006; HELKIMO, 1976, BOSCATO et al., 2013; DALLANORA et al., 2012). Adicionalmente, um examinador conduzirá uma avaliação clínica intra e extraoral dos tecidos orais e da prótese de todos os voluntários. Assim, os voluntários selecionados (n=30) serão inseridos em três grupos (n=10): O **Grupo contole** no qual as próteses dos voluntários não receberão nenhuma intervenção antes da nova reabilitação; O **Grupo reembasamento das bases das próteses totais** no qual as próteses totais dos voluntários serão reembasadas a fim de que sejam reajustadas aos rebordos residuais. Neste grupo, a parte interna de cada prótese será desgastada e preenchida com resina acrílica macia (TruSoft^{TM}, Bosworth Company, EUA), seguindo as recomendações do fabricante; O **Grupo placa oclusal** no qual os voluntários receberão tratamento com placas oclusais planas, sem guias de desoclusão, as quais serão adaptadas sobre as próteses superiores (CASSELI et al., 2007). A superfície plana de cada placa terá como referencial o plano oclusal e cada aparelho intraoral será obtido a partir de

moldagem das próteses totais antigas com hidrocolóide irreversível (Hydrogum – Zhermack, Badia Polesine, Itália). Tais moldagens originarão a confecção dos respectivos modelos em gesso pedra tipo III (Herodent – Vigodent, RJ, Brasil). Estes modelos serão montados em articulador semi-ajustável (Model-400-S, BIO-ART, São Carlos, SP, Brasil) e a placa oclusal será encerada (Cera rosa número 7, Clássico, SP, Brasil), obtendo-se o máximo de contatos com os dentes inferiores, sem, contudo, alterar a configuração plana da superfície oclusal do aparelho e mantendo a dimensão vertical de oclusão prévia determinada (CASSELI et al., 2007).

A inclusão da placa oclusal será realizada de maneira convencional em mufla metálica, indicada para a cocção da resina acrílica termicamente ativada (JET, Clássico, SP, Brasil). Após a demuflagem, serão realizados os procedimentos de acabamento e polimento e, então, as placas serão instaladas, observando-se sua estabilidade sobre a prótese total superior e a observação da DVO previamente determinada. Ajustes oclusais serão executados em todas as placas, nos períodos de 7, 14 e 21 dias, utilizando-se papel articular (Accufilm II – Parkell, Nova Iorque, EUA). Cada voluntário será recomendado a usar a placa, retirando-a apenas para as principais refeições.

Após o término da pesquisa todos os voluntários receberão novas próteses totais confeccionadas pela técnica convencional (ZARB et al., 2012), preservando-se um espaço funcional livre de 3 mm. No relacionamento maxilomandibular a DVO de cada voluntário será obtida, por meio do plano de cera, segundo os métodos métrico, estético e fonético (PLEASURE, 1951, FAYZ; ESLAMI, 1988, LYONS, 1988, SILVERMAN, 2001) e a relação cêntrica será obtida através da técnica bimanual de Dawson (DAWSON, 1979). Após instalação, os voluntários serão instruídos a retornar para realizar possíveis ajustes após 24 horas, 7, 14 e 21 dias. Além disso, é importante salientar que as novas próteses serão confeccionadas a partir do registro de DVO obtido após os tratamentos experimentais (reembasamento e uso de placa), para os grupos que receberão intervenção.

2.3.8 Avaliação da extensão dos movimentos mandibulares (MM)

A extensão dos MM será avaliada através do traçado do registro intraoral do arco gótico de Gysi. Para a obtenção do registro intraoral, os modelos de trabalho de cada paciente serão montados em articulador semi-ajustável (Model 4000-S, BIO-ART, São Paulo, Brasil) e sobre estes modelos serão construídas bases de prova

em resina acrílica quimicamente ativada (JET, Clássico, SP, Brasil), sobre as quais os dispositivos para o registro gráfico intraoral serão fixados. No centro da base de prova superior será instalada uma pua registradora que é constituída de um parafuso com ponta romba e uma porca utilizada para sua fixação. A pua é fixada o mais próximo possível da linha média do paciente, buscando um ponto de equilíbrio para a inscrição do arco gótico de Gysi. Para o correto posicionamento da pua registradora, realizar-se-á um traçado no modelo superior onde é determinado o ponto de intersecção da rafe palatina com as linhas que se estendem da bossa dos caninos à tuberosidade da maxila. Na placa base inferior será adaptada uma plataforma com uma placa metálica utilizada para o registro do arco gótico, observando o paralelismo entre as placas base superior e inferior.

Para realizar o registro do arco gótico de Gysi, o paciente será posicionado confortavelmente em uma cadeira odontológica, com o encosto posicionado em um ângulo de 90° em relação ao plano horizontal. A cabeça será posicionada de forma que o plano de Frankfurt se localize o mais próximo possível do plano horizontal. O paciente será instruído para que faça os MM horizontalmente à frente, para trás, para a direita e para a esquerda, executando-os de forma ampla e sempre com a pua em contato com a placa metálica durante dez minutos (CASSELI et al., 2007). Quando necessário, serão realizados ajustes para eliminar interferências que possam comprometer a livre excursão da pua sobre a placa metálica e, assim, o arco gótico seja obtido com absoluta liberdade.

Dessa forma, poderão ser realizadas as medidas pertinentes aos movimentos mandibulares a partir do traçado do arco gótico de Gysi. A extensão dos movimentos será obtida através de duas medidas: uma no eixo X que registra a extensão do movimento mandibulares no sentido látero-lateral, outra no eixo Y que registra no sentido ântero-posterior (Figura 1).

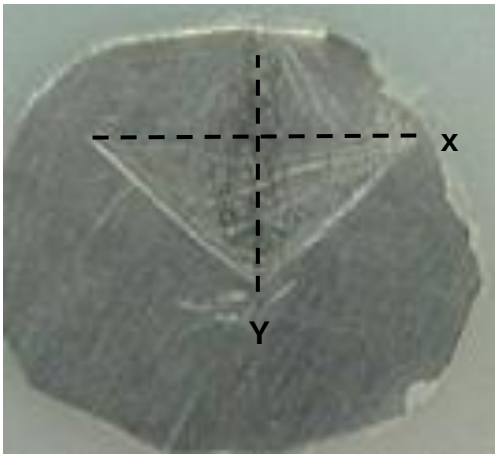

Figura 1 – Mensuração da extensão dos MM no arco gótico de Gysi. Eixo **X**: avalia a extensão do MM no sentido látero-lateral. Eixo **Y**: avalia a extensão do MM no sentido ântero-posterior.

Será utilizada uma câmera fotográfica (Canon EOS Rebel XTi, Tokio, Japão) fixada a um tripé para padronização de distância (CHOU et al., 2014), com padronização quanto ao foco (2,8) e abertura (105 mm), para a obtenção das images dos MM (eixos X e Y) obtidos pelo traçado do arco gótico. Para padronização das medidas obtidas em cada registro fotográfico dos MM, será incluido uma régua milimetrada em cada imagem digital obtida dos registros (DESAI, UPADHYAY, NANDA, 2009). Posteriormente, as imagens dos MM serão levadas para um programa de computador (Image Tool version 3.0, University of Texas Health Science Center, San Antonio, TX, US) (CHOU et al., 2014) para que as medições dos MM sejam realizadas.

2.3.9 Avaliação da dimensão vertical de oclusão (DVO)

As fotografias serão realizadas por um único operador pelo método de posição natural de cabeça (PNC) e a partir da observação de um plano fixo horizontal de referência (Plano de Frankfort) (VAN DER GELD, OOSTERVELD, KUIJPERS-JAGTMAN, 2008). Será utilizada uma câmera fotográfica (Canon EOS Rebel XTi, Tokio, Japão) fixada a um tripé para padronização de distâncica (CHOU et al., 2014), com padronização quanto ao foco (2,8) e abertura (105 mm). Cada paciente será instruído a sentar-se com a coluna ereta, pés ligeiramente afastados e cabeça posicionada paralela ao Plano de Frankfort. Para identificação e padronização das medidas em cada registro fotográfico, será inserido na glabella do

paciente uma marca de referência (DESAI, UPADHYAY, NANDA, 2009). Posteriormente, as imagens de DVO serão levadas para um programa de computador (Image Tool version 3.0, University of Texas Health Science Center, San Antonio, TX, US) (CHOU et al., 2014) e a medida de DVO será avaliada através de uma medida vertical realizada entre duas linhas horizontais localizadas entre dois pontos anatômics da face, uma na base do nariz e outra na base do mento.

2.3.10 Medidas dos MM e da DVO

As medidas em milímetros (mm) a respeito da MM e DVO serão obtidas em diferentes períodos. Para os grupos que receberão os tratamentos (reembasamento e uso de placa oclusal), as medidas serão obtidas antes dos tratamentos (T0); 30 dias após os tratamentos experimentais (T1); e 30 dias após a nova reabilitação (T2). O grupo controle será avaliado somente em dois períodos (T0 e T2). Além disso, as diferenças entre os períodos para a DVO e os MM serão obtidas a partir de T2-T0 e T1-T0. Após a tomada das imagens digitais, um examinador calibrado e cego quanto a alocação dos voluntários de cada grupo executará as medições no programa de computador Image Tool (version 3.0, University of Texas Health Science Center, San Antonio, TX, US).

2.3.11 Análise estatística

Os dados obtidos em relação aos MM e DVO serão submetidos à análise estatística adequada, a qual será realizada no programa estatístico STATA (STATA, version 13.0; Chicago, EUA), assumindo um nível de significancia de 5% para todas as comparações.

4 Cronograma

As etapas de execução do presente estudo serão:

1. Levantamento bibliográfico inicial;
2. Elaboração do projeto de dissertação;
3. Qualificação do projeto;
4. Submissão ao Comitê de Ética em Pesquisa da Faculdade de Odontologia – UFPel;
5. Seleção de pacientes e início da revisão sistemática;
6. Seleção de estudos da revisão;
7. Recolhimento e análise estatística dos resultados obtidos;
8. Desenvolvimento do estudo clínico;
9. Levantamento bibliográfico adicional;
10. Redação de relatórios e artigo para publicação;
11. Defesa da Dissertação;
12. Correções e envio do artigo para publicação.

Tabela 1 - Cronograma de execução das etapas

2012											
Jan	Fev	Mar	Abr	Mai	Jun	Jul	Ago	Set	Out	Nov	Dez
		1	1	1	2	2	2	3	4	5	6

2013											
Jan	Fev	Mar	Abr	Mai	Jun	Jul	Ago	Set	Out	Nov	Dez
6	6	6	8	8	8	9	9	10	10	10	11

5 Relatório do Trabalho de Campo

Este trabalho foi conduzido em duas etapas principais: primeiro, foi realizada uma revisão sistemática da literatura com o objetivo de avaliar a evidência científica disponível acerca da indicação do uso de placa oclusal para o restabelecimento do sistema estomatognático de usuários de próteses totais por longos períodos. Porém, esta revisão foi também conduzida com o objetivo de providenciar o melhor delineamento, e metodologia apropriada para a realização do estudo clínico. Então, a segunda etapa do nosso estudo foi a realização de um ensaio clínico randomizado e controlado com o intuito de avaliar a eficácia clínica do uso de placa oclusal em pacientes desdentados totais. Outro foco do nosso estudo clínico foi avaliar a efetividade do reembasamento das bases das dentaduras antigas no restabelecimento da DVO e extensão dos movimentos mandibulares. A concepção de avaliar o reembasamento das próteses totais baseou-se no fato de que a literatura reporta que este procedimento clínico, relativamente barato e de fácil execução, mostra-se eficaz em promover maior retenção e, consequente, promover maior conforto aos usuários de dentadura. Assim, optamos em testar também a eficácia do reembasamento das bases das próteses no restabelecimento da DVO e extensão dos MM.

Nosso principal percalço na realização do estudo clínico, inicialmente, foi o tempo de espera de 11 meses para a aprovação deste projeto de pesquisa pelo Comitê de Ética em Pesquisa (CEP) da Faculdade de Odontologia da Universidade Federal de Pelotas. Este longo tempo de espera resultou no atraso do início do estudo clínico e, consequentemente, atraso na finalização do trabalhoe não cumprimento do cronograma inicialmente estipulado no projeto. Além disso, o atraso do CEP, resultou na desistência de voluntários que optaram em realizar o tratamento em instituições privadas.

Outra dificuldade que tivemos na condução do nosso estudo clínico foi o adoecimento dos pacientes, uma vez que alguns apresentavam idade avançada. Um paciente sofreu um acidente vascular cerebral, outro teve que ser submetido a uma cirurgia para instalação de um marcapasso e outro teve pneumonia. Porém, as dificuldades na condução do trabalho foram contrabalanceadas com o aprendizado

pessoal e profissional destes últimos meses. A confecção dos 30 pares de próteses totais, a comunicação com o laboratório, o contato com as diferentes personalidades e expectativas dos voluntários, contribuíram para o meu amadurecimento profissional e pessoal.

6 Artigo 1*

Would the use of occlusal splints be beneficial prior to the new rehabilitation of complete denture wearers for longer periods? – A systematic review

Short title: Rehabilitation of complete denture wearers for long periods.

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Keywords: complete dentures, facial pain, occlusal splints, systematic review.

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Would the use of occlusal splints be beneficial prior to the new rehabilitation of complete denture wearers for long periods? – A systematic review

Abstract

***Objective*:** A systematic review was conducted to determine whether the use of occlusal splints before the replacement of a new prosthesis in complete denture wearers for longer periods had an influence on the extent of mandibular movements, pain symptomatology, intra-articular space, vertical dimension and muscle activity.

Sources: This report followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (Prisma) statement. Searches were performed until May 2014 in seven databases: MedLine (PubMed), ISI Web of Science, Scopus, Scielo, Lilacs, Ibecs and the Cochrane Library.

Study selection: As eligibility criteria, any clinical trial, prospective or retrospective, and that evaluated the use of occlusal splints in patients with complete dentures in at least one edentulous arch was selected. A total of 1653 potentially relevant records were identified from all databases.

Data: After title and abstract examination, 1647 studies were excluded because they did not meet the eligibility criteria. Only 4 studies fulfilled all of the selection criteria. All studies were longitudinal, and the period using the occlusal splints ranged from 30 to 360 days. Electromyography was the main evaluation method used, but pain scales and electrognathography were also used in two studies.

Conclusions: Although the scientific evidence level found was weak, it was possible to identify benefits of the use of occlusal splints prior to the new rehabilitation of long-term complete denture wearers with regard to reductions in pain symptomatology and improvement of the muscular tonus. However, regarding the extent of mandibular movements and intra-articular space, this evidence is not clear.

Prospero number: CRD42014009919

Keywords: complete dentures, facial pain, occlusal splints, systematic review

1. Introduction

Despite the improvements observed in oral health conditions, the need for rehabilitation has tended to increase with the increase in life expectancy.[1] Although mortality is decreasing around the world, owing to the implementation of several public health policies, studies have indicated that the increase in life expectancy at birth has been accompanied by a high prevalence of tooth loss and/or lower numbers of teeth in the oral cavity at older ages.[2] Regarding the rehabilitation of these people, prosthodontists' interests have been very much focused on implant-supported prostheses, which could be described as the first choice for the treatment of this condition.[3] However, these implants are indicated for well-selected patients and not for individuals with poor general health status or low incomes.[3,4] For these reasons, conventional complete dentures could have a positive impact on the oral health-related quality of life and satisfaction of edentulous patients, and this treatment tend to still be widely used, with considerable implications for public health and oral health care planners.[1,5]

As a result, the use of inadequate complete dentures (i.e., with instability, lack of retention, loss of vertical dimension and alterations in maxillomandibular positioning) has been linked with functional and aesthetic disharmonies of the stomatognathic system.[6,7] These disharmonies can result of incorrect manufacturing of complete dentures, of wear of artificial teeth, or of oral alterations because of long-term use and bone resorption. In fact, individuals who wear poorly fitted dentures for long periods of time deserve attention because improper integrity of the intra-articular space, occlusal changes and alterations in muscle function could culminate in the symptomatic or asymptomatic clinical manifestations of orofacial pain or degenerative diseases.[8-10] It is important to note that clinical, asymptomatic episodes can remain untreated for long periods of time,[11-13] thus jeopardizing the clinical scenario, muscles and orofacial structures.

Temporomandibular disorder (TMD) is the most common cause of orofacial pain, and it is characterized by painful symptoms of facial and temporomandibular joint (TMJ) pain, uncoordinated and limited mandibular movement, presence of joint sounds and an altered occlusal relationship.[7,14] The etiologic factors for this disorder, in edentulous patients, can include the reduced sensory perception and motor control; the impaired adaptive capacity of the individual;[15] the incorrect vertical dimensions and maxillomandibular relationships, as well as the old age, which triggers degenerative metabolic changes.[16,17]

Despite these findings, when complete denture wearers are rehabilitated improperly and without prior treatment of occlusal disharmony and intra-articular space, they can present gradual loss of specific control of mandibular movements, which can also perpetuate

asymptomatic pathologies.[12] Thus, offering treatment to re-establish the stomatognathic system before submitting an individual to any definitive restorative treatment should be imperative.[7] In this context, occlusal splints constitute the most used treatment in patients with signs and symptoms of TMD because they are considered a conservative, reversible and non-invasive treatment.[13,18] These devices are designed to re-establish intra-articular space and maxillomandibular relationships (Figure 1), as well as to reduce or eliminate pain symptoms by decreasing muscle hypertonicity.[13,16] Nonetheless, the use of this treatment has yet been poorly assessed in edentulous patients and this statement has been based mainly on results obtained from assessments conducted in dentate individuals.

Thus, there are many factors that are still not completely elucidated that can influence the rehabilitation of edentulous patients with complete dentures, particularly in denture wearers for longer periods of time. Therefore, the aim of this study was to systematically review the literature to analyze the effectiveness of using occlusal splints in complete denture wearers prior to the new rehabilitation based on the following outcomes: the extent of mandibular movements, pain symptomatology, intra-articular space, vertical dimension and muscle activity. The hypothesis tested was that these outcomes would be influenced by the use of occlusal splints.

2. Methods

This systematic review was performed according to the PRISMA statement[19] and was registered with the international prospective register of systematic reviews of the PROSPERO network (registration number: CRD42014009919). To formulate question in evidence based practice it was used the following PICOT format: (i) Population: complete denture wearers in at least one arch; (ii) Intervention: the use of occlusal splints; (iii) Comparison: before and after treatment; (iv) Outcomes: the extent of mandibular movements, pain symptomatology, intra-articular space, vertical dimension and muscle activity; (v) Type of study: prospective or retrospective clinical trials. The research question was: Would the use of occlusal splints be beneficial prior to the new rehabilitation of complete denture wearers for longer periods?

2.1. Systematic literature search

The literature search was performed by two independent reviewers until May 2014 (without limit for start date). Seven databases were screened: MedLine (PubMed), ISI Web of Science, Scopus, Scielo, Lilacs, Ibecs and the Cochrane Library. The keywords related to the search strategy are listed in Table 1. The references cited in the included papers were also checked.

After the identification of articles in the databases, the articles were imported into Endnote X7 software (Thompson Reuters, Philadelphia, PA, USA) to remove duplicates.

2.2. Study selection

Two review authors independently assessed the titles and abstracts of all of the documents. Any clinical trial, prospective or retrospective, and that evaluated the use of occlusal splints in complete denture wearers with at least one edentulous arch was selected. Studies published in a language other than English, Spanish or Portuguese were excluded; however, no limit of publication year was applied. The eligibility criteria are described in Figure 2.

Full copies of all of the potentially relevant studies were identified. Those appearing to meet the inclusion criteria or for which there were insufficient data in the title and abstract to make a clear decision were selected for full analysis. The full-text papers were assessed independently and in duplicate by two review authors (Figure 3). Any disagreement regarding the eligibility of included studies was resolved through discussion and consensus or by a third reviewer. Only papers that fulfilled all of the eligibility criteria were admitted.

2.3. Data extraction

The data were extracted using a standardized form in Microsoft Office Excel 2013 software (Microsoft Corporation, Redmond, WA, USA). If there was some information missing, the authors of the included papers were contacted via e-mail to retrieve any missing data. If no answer was received within 2 weeks after the first e-mail message was sent, then a second e-mail was sent.

The reviewers tabulated data of interest for the composition of a spreadsheet in Excel format, with all of the trial documents containing demographic data (year, type of study), type of edentulism, and length of follow-up after intervention (Table 2). The characteristics of the included studies, such as the period using occlusal splints, the evaluation method used and the main conclusion, were also tabulated (Table 3). Additionally, the reviewers analyzed the scientific evidence regarding the use of interocclusal devices in denture wearers based on the following outcomes: pain symptomatology, extent of mandibular movements, intra-articular space, vertical dimension, and muscle activity (Table 4). Due to the high degree of heterogeneity in terms of different studies, a meta-analysis was considered to be inappropriate.

2.4. Quality assessment

The methodological quality of each included study was independently assessed by the two

reviewers (RCCRA and WLOR) based on the checklist created by Downs and Black.[20] The studies were evaluated to provide a framework for judging the methodological quality of the clinical trials and the power of the scientific evidence. This checklist assessed the quality of both randomized and non-randomized studies of health care interventions, and it consisted of 27 questions divided into 5 sections: reporting, external validity, internal validity–bias, internal validity–confounding, and power. According to previous systematic reviews,[21-23] the scoring for question 27, which addresses statistical power, was simplified to a choice of awarding either 1 point or 0 points, depending on whether there was sufficient power to detect a clinically important effect. The scores of the Downs and Black checklist can be grouped into four quality levels[21-23]: ≤14; poor; 15–19, fair; 20 –25, good; and 26 –28, excellent (Table 5).

3. Results

3.1. Search strategy

A total of 1653 potentially relevant records were identified from all of the databases. Figure 2 is a flowchart that summarizes the article selection process according to the Prisma Statement.[19] After the title and abstract examination, 1647 studies were excluded because they did not meet the eligibility criteria. Of the 6 studies retained for detailed review, 2 were not included because one did not use occlusal splints,[24] and in the other, the patients were not edentulous in at least one arch.[18] A total of 4 studies fulfilled all of the selection criteria and were included in this review.

3.2. Characteristics of included studies

A total of 50 patients were evaluated in this review, considering all of the included clinical trials. The participants of all of the studies had a median age between 52 and 61 years old. All of the studies were longitudinal, and there were no controlled and/or randomized clinical trials (Table 2). The period of using occlusal splints ranged from 30 to 360 days. Electromyography, electrognathography and pain scales were the evaluation methods used. In addition, there was heterogeneity in the results provided, and these results were classified according to the previously planned outcomes that are presented in Table 4.

3.3. Quality assessment

The articles included in this review scored between 13 and 15 on the Downs and Black[20] scale, with a mean of 14.5 ± 0.96 (Table 5). The agreement between the 2 authors was substantial (Kappa = 0.9076). The results indicate that the quality of the studies varied among

poor[16,25] and fair.[6,7] The studies scored particularly poorly on the following items: descriptions of adverse events, sample representativeness, patient and assessor blinding, adjustment for confounding factors in the analysis, and power.

1. Discussion

All of the studies analyzed and included in this review showed that there is scientific evidence supporting the recommendation of the use of occlusal devices prior to the new rehabilitation of complete denture wearers for long periods, with regard to reductions in pain symptomatology[25] and improvement of the muscular tonus.[6,7,16] However, regarding the extent of mandibular movements[7] and intra-articular space, this evidence is unclear. Thus, our hypothesis was partially accepted. Nonetheless, the results obtained in this review should be interpreted with caution because only 4 longitudinal clinical studies were included, and each analyzed only one or two possible outcomes of interest. Moreover, one limitation of this review was the degree of scientific evidence obtained by non-randomized and contolled clinical trial. None of the included studies was considered to have good or excellent quality, corroborating the poor quality levels obtained by the Downs and Black Scale.

Based on studies included in this review, it was possible to note that long-term complete denture wearers could adapt themselves to their unsatisfactory prostheses. Therefore, they needed additional time and previous treatment, such as treatment with occlusal devices, prior to new rehabilitation to re-establish their orofacial musculature adequately, as well as, to obtain therapeutic horizontal and vertical mandibular positioning. In fact, it was the intervention used in the majority of the included studies.[6,7,16,25] Additionally, other studies also reported that these devices provided an alternative to re-establish the stomatognathic system.[7,8,13,26,27] Thus, it seems that the use of occlual devices is the first logical step toward rehabilitating individuals with clinical signs that might suggest articular, muscular and occlusal changes.[25,28,29]

Nonethelles, it is also very important to emphasize that there is a lack of homogeneity in the reporting of treatment with occlusal splints in the current dental literature. This heterogeneity could culminate in several findings regarding the efficacy of this treatment, thus, jeopardizing comparisons due to differing methodologies (type of edentulism, age, sex, study design, sample size) and clinical scenarios, as well as differing periods of examination and re-examination. In this way, further studies should be performed with standardized methodologies to assess the outcomes, thereby allowing future comparisons between studies.

In this context, regarding the methodologies used in the included studies, it should also be

noted that the evaluation of pain symptomatology[25] is one method that does not necessarily reflect the efficacy of the rehabilitation implemented because the alterations of the stomatognathic system are often asymptomatic once the muscles present physiological adaptations and great capacity to alter their longitudinal height, thus adapting to conditions of vertical dimension, regardless of whether such conditions are clinically favorable or not.[1] Moreover, although some authors have indicated the use of occlusal splints as the first option to facilitate diagnosis and control of painful symptomatology,[26,30,31] the assessment of the effectiveness of this intervention has been clinically obtained based on the subjective quantification of the intensity and frequency of the related signs and symptoms.

In contrast, the graphic records of Gysi's gothic arch were used for one study[6] to identify the centric relation position. The layout of the Gothic arch is a very simple clinical method for assessing muscle function, and the graphics of the gothic arch tracings represent occlusal alterations.[6] Furthermore, electrognathography (EGN) was conducted to corroborate the neuropsychological analysis of the factors linked to prosthetic rehabilitation procedures.[6] This is an easily completed examination for quantifying jaw movements using numeric values, thus making the functional diagnosis and the evolution of the applied therapeutics more precise. However, the useful application of EGN on the diagnostic and therapeutic problems that affect stomatognathic system is still rare.[32] Another study[16] used electromyography (EMG), which is a graphic recording of the electrical potential of muscles that is used to evaluate muscle activity. The basic EMG technique involves the insertion of either surface or intramuscular electrodes into the muscles being studied and the detection and amplification of the motor unit action potentials of the muscles.[9,33] Nonetheless, there is still only limited knowledge regarding the causes of variations in both static and dynamic muscle function and other related parameters of the stomatognathic system. It has been reported that the limitations and the sensitivity of EMG measurements must be understood when collecting and analyzing data. Because of these requirements, it is necessary to correlate muscle testing with other objective and subjective and particularly pain-related assessments, thereby observing the multifactorial principle.[9]

Finally, it is important to point out that the systematic reviews are invaluable tools for the clinical practice, providing a critical approach of the scientific knowledge regarding to some subjects, with the aim of either answering a clinically relevant question based on the best scientific evidence available or the lack of it, and finally to point out improvement and standardization methodological for further research.[34,35] Thus, it is possible to evaluate that considerable improvements must be made in terms of the quality of research regarding the

topic of this review, particularly regarding the means of assessing clinical outcomes after using occlusal splints. Further researchs are recommended to address specifically the outcomes and benefits related to using any previous interventions performed prior to the new rehabilitation of long-term complete denture wearers and for more concrete evidence, it is critical to conduct randomized, controlled trials with appropriate designs.

Conclusions

This systematic review showed that although the scientific evidence level found was weak, it was possible to identify benefits of the use of occlusal splints prior to the new rehabilitation of long-term complete denture wearers with regard to reductions in pain symptomatology and improvement of the muscular tonus. However, regarding the extent of mandibular movements and intra-articular space, this evidence is not clear. However, the quality of the included studies emphasized the need for well-designed, randomized and controlled clinical trials to highlight the real benefits of using occlusal splints in these clinical situations.

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Tables and Figures

Table 1 – Search strategy used in PubMed (MedLine).

	Search Terms
#4	Search #1 AND #2 AND #3
#3	Search Retrospective Studies OR Studies, Retrospective OR Study, Retrospective OR Retrospective Study OR Prospective Studies OR Prospective Study OR Studies, Prospective OR Study, Prospective OR Clinical Trial OR ((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading]) OR (randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract]))
#2	Search "Occlusal Splints"[Mesh] OR Occusal Splints OR Splints, Occlusal OR Occlusal Splint OR Splint, Occlusal OR Interocclusal appliance OR Interocclusal Splint OR Splint Therapy OR Acrylic Splint OR occlusal device OR Device, occlusal OR Interocclusal Device OR Device, Interocclusal
#1	Search “Dentures”[Mesh] OR Dentures OR Denture, Complete OR Complete Denture OR Complete Dentures OR Dentures, Complete OR Denture, Complete, Lower OR Denture, Complete, Upper OR Prosthesis total OR Total, prosthesis OR Mouth, Edentulous OR Edentulous Mouth OR Edentulous Mouths OR Mouth, Toothless OR Toothless Mouth OR Jaw, Edentulous OR Edentulous Jaw OR Edentulous Jaws OR Jaws, Edentulous OR Denture wear OR Wear, denture OR "Dental Restoration Wear"[Mesh] OR Wear, Dental Restoration OR Occlusal Wear, Restoration OR Restoration Occlusal Wear OR Wear, Restoration Occlusal OR Restoration Wear, Dental OR Denture, Partial OR Dentures, Partial OR Partial Denture OR Partial Dentures OR Dental Bridgework OR Dental Bridgeworks OR Bridgeworks, Dental OR Bridgework, Dental OR Denture, Partial, Removable OR Removable Partial Denture OR Denture, Removable Partial OR Dentures, Removable Partial OR Partial Denture, Removable OR Partial Dentures, Removable OR Removable Partial Dentures

Table 2 - Demographic data of the included studies.

Author	Year	Type of study	Number of patients	Sex		Age	Median Age	Type of edentulism	
				Male	Female			Maxillary	Mandibular
Casseli[6]	2007	LCT	16	6	10	NS	53	Edentulous	Edentulous
Fonseca-Silva [16]	2007	LCT	8	1	7	45-60	54	Edentulous	Edentulous
Zanatta[25]	2006	LCT	16	13	3	33-67	52	Edentulous	Partly edentulous
Zuccolotto[7]	2007	LCT	10	1	9	NS	61	Edentulous	Edentulous

LCT, longitudinal clinical trial; NS, not specified

Table 3 - Characteristics of the included studies and related outcomes.

Characteristic	Casseli [6]	Fonseca-Silva [16]	Zanatta [25]	Zuccolotto [7]
Intervention	Occlusal splints	Occlusal splints	Occlusal splints	Occlusal splints (sliding plates)
Evaluation method	Electromyography and Gysi's gothic arc	Electromyography	Pain scale	Electromyography
Period using occlusal device	30 days	70 days	150 days	360 days
Evaluation periods	30 days after occlusal splint installation; 60 days after new denture installation; and 60 days after occlusal vertical dimension increase	Before and 70 days after using occlusal splints	Fortnightly consultations from the installation of the occlusal splints up to 150 days of treatment	Before insertion of the complete dentures with sliding plates and at 4, 9 and 12 months following insertion
Main conclusion	The presence of a free-way space at the end of the treatment confirmed the importance of its existence for maintaining the balance of the masticatory system, assuming the occurrence of postural repositioning.	The use of occlusal splints promoted a significant increase in the electrical activity of the orbicularis oris.	The therapy used was effective in decreasing painful symptomology over 150 days of treatment.	The intervention contributed to muscular balance of the masticatory system and could be indicated for use before the fabrication of definitive complete dentures in patients with TMD.

Table 4 – Scientific evidence for possible outcomes related to interventions with occlusal splints in complete denture wearers.

Outcomes	Characteristics of clinical trial	Scientific evidence
Pain symptomatology	A study evaluated the evolution of painful symptomology in patients submitted to treatment with flat occlusal appliances with fortnightly consultations.[25]	The pain scale recorded a significant reduction in the signs and symptoms of temporomandibular disorders initially recorded.[25]
The extent of mandibular movements	One study evaluated the cycle of maximal mouth opening and closure and final mandibular closing. The patients were instructed to remain at rest for a period of approximately seven seconds. After this period, the operator asked the patient to perform three subsequent movements of mandibular closing, from rest to maximum intercuspidation covering all of the dimensions of the free-way space, and finally returning to rest.[6]	No significant differences were found during opening and closing. When the cycle of maximal opening and closing was observed, the maintaining of a constant vertical dimension opening, considering an occlusal vertical dimension increase of approximately 8-10 mm (clinically measured), revealed the great capacity that the muscles had to alter their longitudinal height. Hence, they had the capacity to adapt to a condition of vertical dimension, regardless of whether it was clinically favorable or not.[6]
The intra-articular space	No clinical trials included evaluated this outcome.	No scientific evidence was available.
The vertical dimension	The mandibular movement pattern was investigated in this study. The patients used occlusal splints and were rehabilitated with new dentures, preserving a free-way space of 3 mm. After 60 days, the occlusal vertical dimension was increased, and the modified inferior dentures were used for another 60 days.[6]	A significant decrease in free-way space between the first and the last evaluations was observed. The free-way space attempted to establish itself within the most economical and healthy dimension for every established occlusal vertical dimension. In addition, it was not a safe reference for determining occlusal vertical dimension, and its maintenance at the end of the treatment emphasized the occurrence of postural repositioning.[6]
Muscle activity	One clinical trial analyzed the influence of occlusal splints on the electromyographic activity of two portions — the upper and lower orbicularis oris muscles — during yogurt suction.[16] Another study investigated the electromyographic (EMG) activity of the anterior temporalis and masseter muscles in edentulous individuals with temporomandibular disorder before and after using sliding plates on complete dentures in the mandibular rest position.[7]	The use of occlusal splints promoted a significant increase in the electrical activity of the orbicularis oris.[16] The study that evaluated the temporalis and masseter muscles demonstrated that the temporalis exhibited an increase in EMG activity, and the masseter showed significantly lower mean values, compared with the initial values. Neuromuscular reprogramming was demonstrated, which contributed to the muscular balance of the masticatory system.[7]

Table 5 – Quality assessment using the Downs and Black Scale.

Author	Reporting										External validity			Internal validity													Power	Total
														Bias							Confounding							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Casseli[6]	1	1	1	1	0	1	1	0	1	1	0	0	1	0	0	1	1	1	1	1	0	0	0	0	0	1	0	15
Fonseca-Silva[16]	1	1	1	1	0	1	1	0	1	1	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	1	0	13
Zanatta[25]	1	1	1	1	0	1	1	0	1	1	0	0	1	0	0	0	1	1	1	1	0	0	0	0	0	1	0	14
Zuccolotto [7]	1	1	1	1	0	1	1	0	1	1	0	0	1	0	0	1	1	1	1	1	0	0	0	0	0	1	0	15

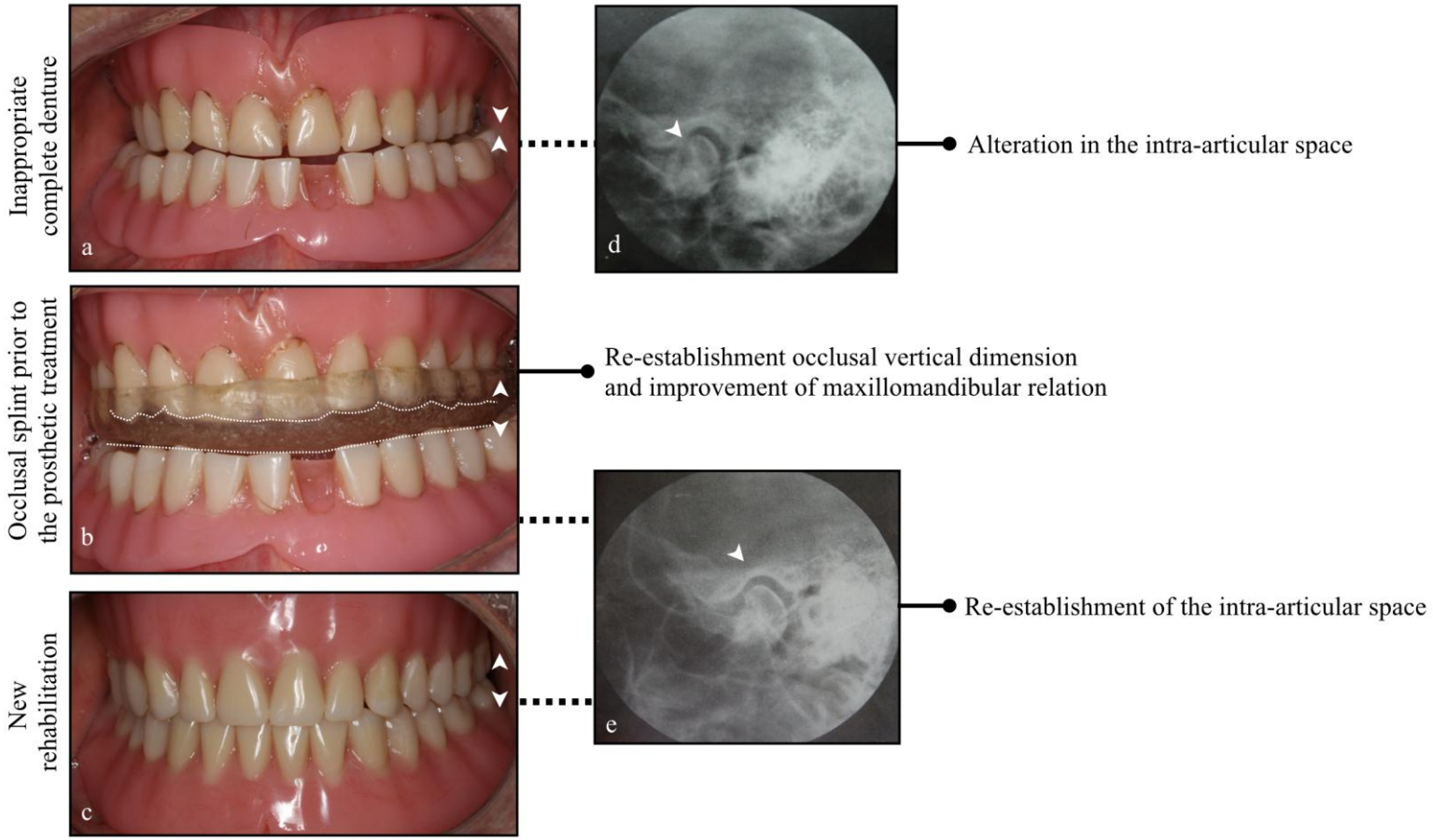

Figure 1 – Use of occlusal splints prior to definite prosthetic rehabilitation for the re-establishment of intra-articular space and occlusal vertical dimension (OVD): **a)** A complete denture wearer for long periods of time with an alteration in maxillomandibular position and decrease in OVD (white arrows); **b)** Occlusal splints over old complete dentures to increase OVD (white line and arrows); **c)** New rehabilitation after re-establishment of maxillomandibular position and an increase in OVD (white arrows); **d)** Computed tomography image showing inadequate position of the condyle-fossa (white arrow); **e)** Computed tomography image showing adequate positioning of the condyle-fossa (white arrow).

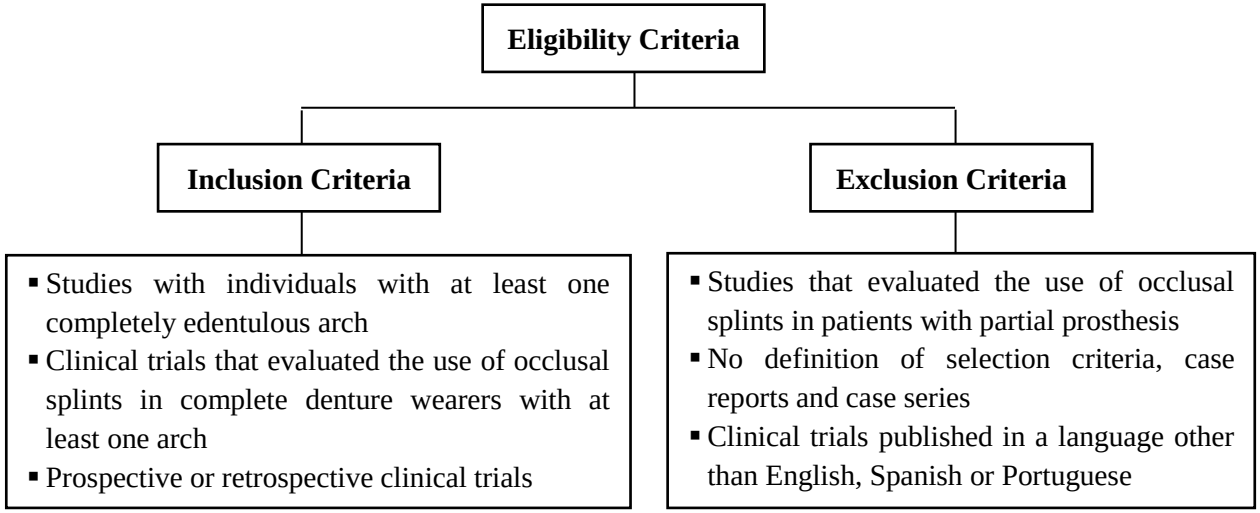

Figure 2 – Eligibility criteria.

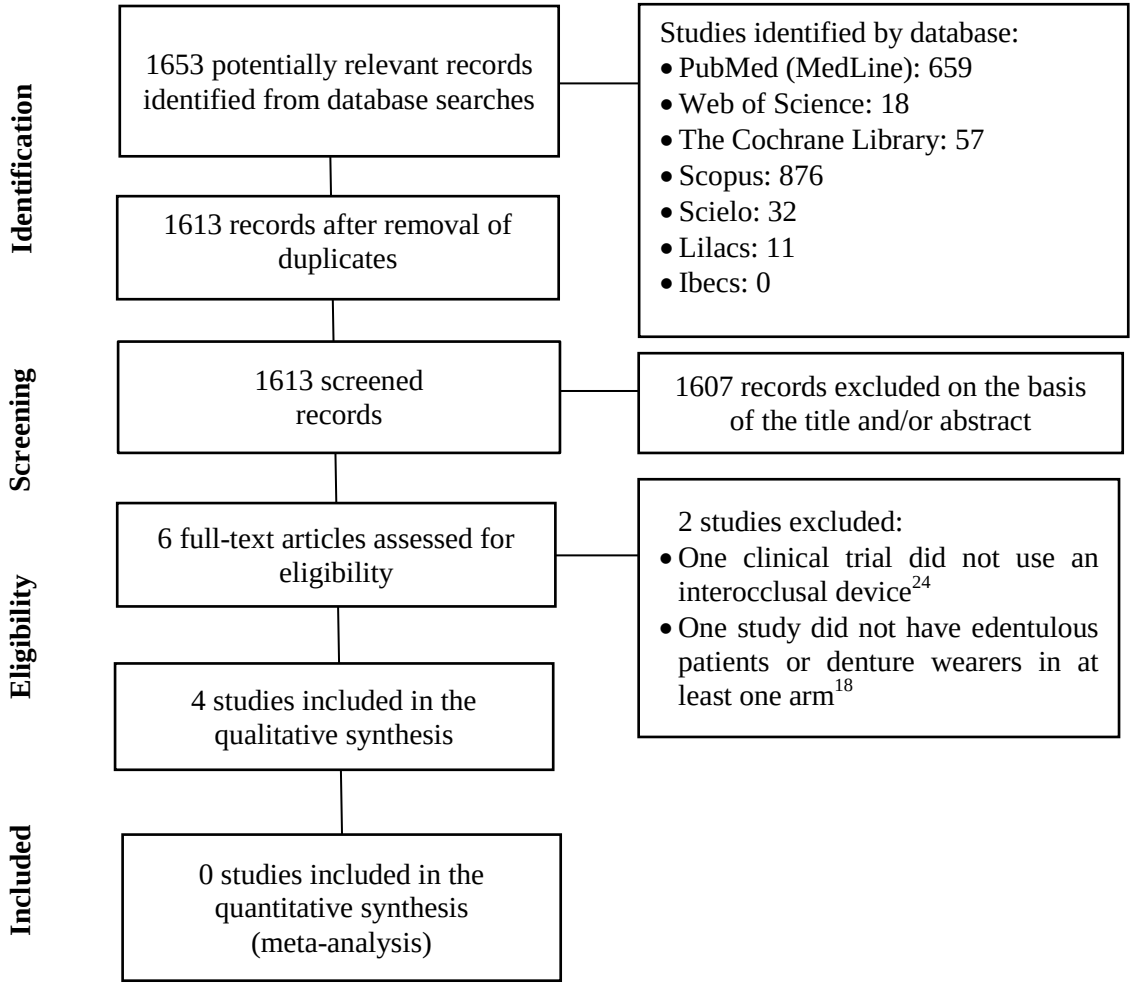

Figure 3 – Search flowchart according to PRISMA Statement.[19]

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Would be beneficial the use of occlusal splints prior to definitive rehabilitation of complete denture wearers for longer periods? – A systematic review

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7 Artigo 2*

Is it necessary to re-establish the stomatognathic system prior to the rehabilitation of long-term complete denture wearers? A randomized controlled clinical trial.

Short title: Stomatognathic re-estabilishment of complete denture wearers.

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Keywords: gothic Gysi arch, temporomandibular disorders, occlusal splints, vertical dimension, edentulous patients, complete denture, treatment outcome.

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Is it necessary to re-establish the stomatognathic system prior to the rehabilitation of long-term complete denture wearers? A randomized controlled clinical trial.

Abstract

Objective: The aim of this clinical trial was to evaluate whether the relining of the denture base and the use of occlusal splints prior to rehabilitation have an influence on mandibular movements (MM) and occlusal vertical dimension (OVD) in long-term complete denture wearers.

Methods: In this randomized controlled clinical trial, thirty complete denture wearers were distributed into three groups (n=10): control (C), without any previous intervention; relining denture (RD) and occlusal splints (OS). Volunteers were evaluated regarding the extent of MM by their intraoral Gothic Gysi arch record; and OVD was evaluated by a standardized digital photograph recorded at three periods: baseline (T0), 30 days after the initiation of the randomized treatment (T1), and after the new rehabilitation (T2). The statistical analyses were performed by one-way (ANOVA) with a post hoc Bonferroni and paired t-test (α=0.05).

Results: In the intragroup analysis for OVD, all groups showed statistically significant differences between baseline (T0) and (T2) periods. In the intergroup analysis for OVD and MM, the OS showed statistically significant differences when compared to the RD and C groups. The OS group revealed a greater increase of OVD (T2-T0 5.6±1.4) and extension of MM in both axes, X (XT2-T0 1.0±0.14) and Y (YT2-T0 1.2±0.11), ($p< 0.05$).

Conclusion: The use of occlusal splints as previous treatment prior to the rehabilitation of long-term complete denture wearers was effective because it improved the extent of MM and OVD.

Clinical significance: Inadequate OVD and integrity of the intra-articular space could result in the alteration of MM and degenerative diseases; thus, previous treatment should be considered for the long-term use of a complete denture.

1. Introduction

The predictability of the successful rehabilitation of elderly edentulous patients is still uncertain, especially when patients suffer damage to supporting tissues, leading to morphological and functional compromise.[1] In fact, long-term complete denture wearers exhibit prostheses with instability and lack of retention resulting from worn artificial teeth, alteration of the maxillomandibular position, or bone reabsorption.[2-5] These factors have been linked with functional and esthetic disharmonies with significant deterioration in clinical oral health conditions.[5-7] Moreover, these alterations can culminate in pain and tenderness in the temporomandibular joint (TMJ), which can progress to temporomandibular disorders (TMD).[8,9]

Psychological conditions and occlusal force as well as mandibular movement (MM) are influenced by immediate changes in the occlusal vertical dimension (OVD) of complete denture wearers.[7] Thus, the long-term use of a complete denture has been linked with symptomatic or asymptomatic clinical conditions originated from alterations in maxillomandibular positioning and due to hypoactivity of the masticatory muscles that may result in uncoordinated and limited mandibular movement (MM), and sometimes, orofacial pain.[10-13] When these conditions remain untreated, they may cause oral degenerative and/or systemic disease.[14,15] In this way, many studies have investigated the treatment of symptomatic orofacial pain.[4,10,16] However, the previous treatment for complete denture wearers with an imbalance of the stomatognathic system has not been adequately investigated, and therefore there is a lack of scientific evidence supporting the recommendation of any previous intervention prior to the replacement of their new prostheses.

Treatment with occlusal splints has been recommended to re-establish the maxillomandibular positioning and tonic muscle prior to any definitive treatment.[5,8,17] This recommendation has been used for dentate individuals who report signs and symptoms of TMD,[5,10,18] because their application has shown a decrease in the hyperactivity of the orofacial muscles and re-establishing the lost OVD.[2,4,10,19] Additionally, another treatment used for this purpose has been the relining of the complete denture base.[20] Usually, this procedure has been carried out with soft denture liners either due to their ability to improve the distribution of the occlusal functional load in the bone support area[20] or to re-establish MM lost due to denture instability and lack of retention.[21,22] In this context, it is very important that edentulous patients not receive treatment based on clinical practice or scientific evidence obtained from studies performed in dentate individuals,[23] since to re-establish an

appropriate OVD in the patient who has used the same complete dentures for long periods can be challenging.[13]

Based on the above, the aim of this study was to evaluate the influence of the use of occlusal splints and denture relining on the extent of MM and OVD in long-term complete denture wearers. The hypothesis tested was that the use of these treatments prior to the new complete denture rehabilitation leads to an adequate re-establishment of OVD and MM when compared to rehabilitation without previous treatment.

2. Materials and Methods

2.1 Experimental Design

This prospective, double-blinded (examiner and statistic), parallel-group and randomized controlled trial (RCT) was registered at ClinicalTrials.gov (NCT02915585). This study was approved by the Local Research and Ethics Committee (protocol n^{o}.32/2013) and followed the CONSORT recommendations.[24] All volunteers signed a statement of informed consent before enrolling in the study, and the volunteers' oral health was assessed. Inclusion criteria were: (i) adults and elderly totally edentulous with at least 50 years old of both genders and complete dentures wearers who had not changed their dentures for at least a period of five years; (ii) dentures with instability, lack of retention, loss of vertical dimension and alterations in maxillomandibular positioning; (iii) volunteers with the ability to comply with the experimental protocol; (iv) absence of TMD; (vi) absence of disease in healthy mucosa; and (v) good general health. The other volunteers were excluded because of the following: (i) presented systemic or neurological disease; (ii) complete denture wearers for less than five years; (iii) volunteers with disease in healthy mucosa (i.e., signs of inflammation, traumatic lesion, candidiasis, or hyperplasia) and (iv) presence of TMD. Thus, thirty volunteers were distributed into 3 groups (n=10): without and with previous intervention with a duration of 30 days, which were evaluated regarding the extent of MM and OVD at three periods of evaluation. Figure 1 is a flowchart that summarizes the study design.

2.2 Sample size calculation

The sample size was calculated presuming that statistical tests would be performed with 80% power and $\alpha = 0.05$. For this, data from previous publications[2] determined that eight volunteers were required for experimental treatments and control group, under the assumption of differences between the groups. However, considering losses during the experiment, it was

considered that ten volunteers would be needed per group.

2.3 Randomization

The volunteers (6 male and 24 female, mean age 70.4 years old, and mean use of complete denture of 14 years) were randomly allocated according to the experimental treatment and/or control groups using a computer generated allocation program. For treatment randomization, a person not involved in the study wrote the group (control or experimental) on slips of paper and inserted them into plain brown envelopes that were used to conceal the allocation. Thirty volunteers without TMD were distributed into three groups (n=10): one control group (C) with individuals without any previous intervention; and two intervention groups, who either received a Relined Denture (RD) or received treatment by the use of Occlusal Splints (OS). In both groups, the experimental treatment had duration of 30 days prior to the onset of replacement of the old complete denture.

2.4 Clinical procedures

Between September 2013 and December 2013, a total of one hundred and thirty-one complete denture wearers (49 male and 82 female) requiring new rehabilitation were screened in the Dental School. According to pre-determined inclusion criteria and the sample size calculation, thirty patients were included in this study and one hundred and one were excluded because they did not meet the inclusion criteria (n=97), declined to participate (n=3) or other reasons (n=1). One examiner administered one questionnaire and carried-out the intra-oral clinical examination of oral tissues and complete dentures of all volunteers. Data on age, gender and time of use of the complete dentures were collected to determine whether volunteers satisfied the study inclusion criteria. The presence and severity of signs and symptoms of TMD in the sample were determined using a questionnaire about common TMD symptoms based on the modified Helkimo's anamnestic index, which has been previously used in other studies.[10,11,25,26]

All clinical procedures were performed following the same standardized procedures and all materials were used according to the manufacturers' instructions. The volunteers allocated in the relining denture group (RD) received a reline of their old complete denture base and used it during a period of 30 days before the replacement of their old prostheses. For the relining procedure, the dentures were removed from the oral cavity, cleaned by brushing and the inner denture surface of both the maxillary and mandibular dentures were reduced by 1.5 mm with drills, taking care to preserve the borders. Then, the soft resilient acrylic reline

(Trusoft, Bosworth Company, Illinois, USA) was applied according to the manufacturer's instructions. The retention, support, stability and occlusal interferences of the denture were verified. Volunteers returned for adjustments after 24 hours and, if necessary, again after 48 hours. In the occlusal splints group (OS), the volunteers received treatment by using occlusal splints, which were used over the old complete denture, for a period of 30 days. Participants were also instructed to remove the appliance only during meals and to return for possible occlusal adjustment after 7, 14 and 21 days. The upper and lower arches of each volunteer were molded for the manufacture of an occlusal splint with a flat occlusal surface, contact with the antagonist teeth, and without the presence of canine and protrusive guides. The occlusal splint was built in a semi-adjustable articulator (Model 4000-S, BIO-ART, São Paulo, Brasil) in centric relation. The material used was thermopolymerized acrylic resin (JET, Clássico, SP, Brazil) with 3 mm thickness, respecting the configuration of the occlusal plane in the antero-posterior and latero-lateral directions. The appliances were constructed with the smallest thickness possible to prevent interference with the values of vertical dimension. Finally, the control group (C) not received any treatment.

After the end of the study, all volunteers received new complete dentures manufactured using the conventional technique[27], preserving a freeway space of 3 mm.[2] In maxillomandibular relationship, the OVD of each volunteer was obtained by means of wax-up, according to the metric, aesthetic and phonetic method[28-31]; and the centric relation was achieved by Dawson bimanual technique method.[32] After installation, they were instructed to return for possible adjustments after 24 hours, 7, 14 and 21 days. It is important to highlight that the new complete dentures were made from record of OVD obtained after experimental treatment for the OS and RD groups.

2.5 Evaluation of Occlusal Vertical Dimension (OVD)

Posed frontal images at occlusal vertical dimension were made with a digital single lens reflex camera (Canon EOS Rebel XTi, Tokio, Japan), with a macro lens (105 mm f/2.8VR; Canon), mounted on a tripod at a fixed distance from the patients. For accurate positioning of the tripod between sessions, the tripod was secured to the floor with a hot glue gun adhesive.[33] A fixed reference plane (Frankfort Horizontal)[34] was used to stabilize the head position, allowing accurate repositioning. The lens camera was adjusted for the fixed reference plane and face. For identification and standadization of measurements in each photographic record was inserted in patient's glabella a numered reference markers (One centimeter) (Figure 2).[35] After, the OVD digital images were imported into software (three

measures in each image were made) and the vertical distance measures between two horizontal line, inserted in anatomical and selected point (base nose and base of the chin), were made with a computer software (Image Tool version 3.0, University of Texas Health Science Center, San Antonio, TX, US).[33] The measures regarding the OVD were expressed as mean values and standard deviation (SD) in milimeters (mm).

2.6 Evaluation of Mandibular Movements (MM)

The intraoral record was made from the casts, which were mounted on a semi-adjustable articulator from interocclusal distance and OVD previously obtained with base plates and wax planes.[2] On these casts, base plates were constructed in acrylic resin (JET, Clássico, SP, Brazil) and the intra-oral record was made. In the center of the acrylic base, a pua register that consisted of a screw with blunt tip was installed. In the lower base plate a platform with a metal plate was adapted and used to record the arch form, noting the parallels between the upper and lower baseplates. Devices were inserted into the oral cavity. The volunteer was positioned at an angle of 90° to the horizontal plane and instructed to close his/her mouth until the blunt tip of the pua register touched the metal platform and mandibular movements horizontally; anteroposterior (Y axis: protrusion and retrusion), and latero-lateral excursion (Y axis: to right and left) for ten minutes.[2]

Images of the MM (X and Y axes) obtained by gothic arch tracing were made with a digital single lens reflex camera (Canon EOS Rebel XTi, Tokio, Japan), with a macro lens (105 mm f/2.8VR; Canon), mounted on a tripod at a fixed distance from the records.[33] For standadization of measurements in each MM photographic record was included a millimeter ruler (one centimeter) attached to each Gothic arch tracing records to provide reliability in digital images measurements.[35] After, the MM digital images were imported into software and Gothic arch tracing (X and Y axes) measurements were made (three measures in each image were made) with a computer software (Image Tool version 3.0, University of Texas Health Science Center, San Antonio, TX, US) [36] The measures regarding the MM were expressed as mean values and standard deviation (SD) in milimeters (mm).

2.7 Measurements of MM and OVD

The measurements in millimeters (mm) regarding MM and OVD were obtained at different periods. For groups that received treatments, RD and OS, the measurements were obtained in (T0) at baseline, before any procedure and with the current complete denture in the oral cavity; (T1) 30 days after experimental treatment with a relined denture or occlusal

splints; and (T2) after new rehabilitation, 30 days after the delivery of a new complete denture. The C group was only evaluated at 2 periods (T0 and T2), with a 6-week interval between evaluations. Therefore, the following measurements were obtained in milimeters: T0, T1, T2 and (T2-T0) and (T1-T0) that showed the differences found between means of OVD and MM measures obtained for different periods. After the OVD and MM photograph records were taken, the same calibrated examiner, blinded regarding the allocation of the volunteer in each group, performed the measurements with the Image Tool software.

2.8 Statistical analyses

Statistical analyses were performed using STATA (STATA, version 13.0; Chicago, IL), employing a significance level fixed at 5% for all comparisons. The hypothesis assumed differences between the experimental treatments and outcomes (MM and OVD) assessed. A randomized block design was used for the statistical analysis, considering the experimental treatments and control group as statistical blocks and MM and OVD measurements as the factors under study. The Shapiro-Wilk test was used to determine the normality of the data. One-way analysis of variance (ANOVA) with a post hoc Bonferroni test was used for intergroup comparisons and paired t-test for intragroup comparisons.

3. Results

3.1 Occlusal Vertical Dimension (OVD)

Table 1 displays the OVD measurement obtained from the periods evaluated (T0, T1 and T2) in the 3 groups. In the intragroup analysis, with paired T-test, a significant increase in OVD was found between (T0) and (T1 and T2) measures for the occlusal splint and reline groups and between (T0) and (T2) for the control group ($p<0.05$ for all pairs). Table 2 shows the OVD measurement obtained from the periods evaluated (T2-T0) and (T1-T0) in the groups. In the intergroup analysis, with post hoc Bonferroni test, statistically significant differences in OVD were found between the occlusal splint and reline groups for (T1-T0) and between the occlusal splint and other groups for (T2-T0), ($p<0.05$). Nonetheless, the denture reline group was statistically similar to the control group ($p>0.05$).

3.2 Mandibular Movements (MM)

Table 3 shows the clinical effect size of the application of the treatment protocols in the extension of latero-lateral (axis X) and antero-posterior (axis Y) MM measures obtained

from the periods evaluated (T0, T1 and T2) in the 3 groups. In the intragroup analysis, Paired T-test reveled a significant increase in the extension of MM when evaluated differences between the (T0) and (T1 and T2) measures for the occlusal splint and reline groups ($p<0.05$). However, for the control group a significant difference was not found between the (T0) and (T2) periods, when the extension of MM measures were observed. Additionally, there was a decrease of the mandibular movements for both axes X and Y, in this later group.

In Table 4 shows the extension of laterolateral (axis X) and anteroposterior (axis X) MM measures obtained from the periods evaluated (X and Y, T2-T0) and (X and Y, T1-T0) in the 3 groups. Bonferroni test for intergroup comparisons found, statistically significant differences between occlusal splints and other groups for (X and Y, T2-T0) and (X and Y, T1-T0) MM measures ($p<0.05$). However, the reline group was statistically similar to the control group ($p>0.05$).

4. Discussion

The MM and ODV outcomes evaluated in this study have been related to imbalance of the stomatognathic system, which could culminate in local or systemic diseases over extended periods of time, and interesting results have been found. Our hypothesis was accepted because significant differences were observed for outcomes obtained from volunteers rehabilitated either using the traditional technique (without any intervention prior to the new rehabilitation) or after receiving previous intervention (occlusal splints or relining of their old dentures). Based on the above, although the protocol used for the manufacture of complete dentures is already well established and is conventionally used, our results indicate that previous therapeutic treatment should be considered for long-term use of complete dentures to re-establish MM and OVD.

In this context, it is important to highlight that the aging stomatognathic system is frequently associated with the prevalence of complete and partial edentulism for long periods because the lost teeth and the use of inadequate prostheses provides consequently adverse biomechanical loading and aging's role becomes significant this correlation.[12] Thus, older denture wearers may suffer age-related morphologic changes, such as decreased OVD as a result of mandibular ridge reabsorption, or due to the wear of artificial teeth and[3,37] progressive forward posturing of the mandibular denture that can lead to a reduced horizontal MM.[38] In this context, it should be noted that patients who have been edentulous for long periods, although adapted to their unsatisfactory prosthesis and with or without orofacial pain symptomatology, could require previous treatment to re-establish their musculature before

receiving new rehabilitation.[2-5]Additionally, it is important to note that functional imbalance of the stomatognathic system is an age-dependent alteration[38] and that a prevalence of edentulism of up to 84% has accompanied the increase in life expectancy of those aged 60 years and above.[39] Moreover, the rehabilitation of these individuals due to systemic, financial and/or psychological reasons with conventional complete dentures is still widely used.[20]

In this study, the OVD intragroup analysis demonstrated that all the groups evaluated showed statistically significant differences when observing measures obtained at baseline and the T1 and T2 periods, with higher or lower increases of OVD. This finding demonstrated that any treatment influenced the increase of OVD. Moreover, statistical differences were not found between T1 and T2 periods, what represent that there was not alteration between the OVD previously obtained with base plates and wax planes, and the OVD obtained after new complete denture manufacturing, demonstrated standardized clinical and laboratory procedures. On the other hand, regarding OVD intergroup comparisons, in the (T2-T0) periods, it is possible to observe, that the C group re-established a lower OVD (1.5 mm), which may not be sufficient for proper re-establishment of the stomatognathic system of long-term complete denture wearers. However, in this same period, the OS group showed the higher OVD increase (5.6 mm) with statistically significant differences regarding other groups evaluated.

In this way, it seems that the intervention in the OS group provided an adequate muscular re-establishment since the individuals allocated to this group reported greater comfort after rehabilitation and finally, it was observed greater ODV increase. Thus, it is possible conclude that the diagnostic splint placed over the old complete denture to restore the OVD[40], provided stability of the stomatognathic system.[16,19,41] Our findings corroborate with other studies that report that an increase of up to 5 mm[38,42] in a reduced interocclusal space is a safe and predictable procedure when new complete dentures were constructed, without any report of TMD or detrimental consequences, probably because the OVD was not increased, but rather was restored.[38,42,43] Nonetheless, same authors revealed that patients can adapt to increase of ODV of 3 mm to 16 mm[43], however, it is impossible to determine the upper limit since there is a lack of evidence in relation to a greater increase in the ODV due to its significant impact on the horizontal relationship of the teeth.[13] In contrast, the results of other study has shown that the use of occlusal splints did not provide increases in free-way space and MM.[2] However, this latter study used different methodology for the evaluation, sample size and experimental design. On the other hand, the denture relining intervention showed no great influence in restoring OVD (2.1 mm) because the DR group showed OVD mean values

that were statistically similar to those of the C group when evaluated before and after treatment (T0 and T2) periods.

With respect to the extension of MM measures obtained in the T0, T1 and T2 periods for the X and Y axes, the intragroup comparison showed that only the C group did not show statistically significant differences between baseline and the T1 and T2 periods and that the OS group revealed the higher MM means values in both axes Y (antero-posterior MM) and X (latero-lateral MM). This result could be linked to the lower values of the re-establishment of OVD obtained in the group of volunteers rehabilitated using the traditional technique because limited MM may indicate alterations in the muscles of mastication or in the intra-articular space, which are strongly linked to OVD.[12] Thus, the increase of OVD obtained in the C group may not have been adequate to re-establish the integrity of the intra-articular space or to allow muscle relaxation.[5] In this way, it should be highlighted that the groups that showed the lower means values of OVD were also those that showed the lower increase of MM mean values. Moreover, it was possible to note that the C and RD groups presented similar statistical significance when observing MM measures at the (X and Y T2-T0) period, although the RD group showed a greater increase in the extension of MM when compared with C group. These results most likely occurred because, although the reline of the old denture had improved the denture's stability, it was not sufficient to improve significantly the MM. Thus, it is necessary to note that the intervention with resilient denture liners has a smaller influence on MM and OVD when compared with the OS group. However, the reline of the old denture should be used as a previous treatment for complete denture wearers because it is not a present limitation for use as it is a non-surgical intervention and cost-effective treatment.[20] In addition, these materials have the ability to restore the inflamed mucosa, distribute the functional load in the support area of the prostheses and improve their adaptation and retention. [22,44]

Based on the above, our findings corroborate with the literature that reports that the evidence suggests that occlusal splint therapy may be associated with the re-establishment of OVD and the integrity of intra-articular space[8,18] because the articular mechanic optimization can also offer a better muscular response by the liberation of the disc.[7] Thus, the decrease of orofacial pain obtained by occlusal splints as a therapy for TMD[16,19] is most likely linked to the best results observed in MM and OVD outcomes evaluated in the volunteers that received treatment prior to the new rehabilitation.[28,31,45,46] Therefore, when the patient does not have a physiologic OVD for proper masticatory function, should be determined that it is improper to

fabricate a new denture at a determined vertical dimension without diagnostically evaluating the patient's ability to adapt to it.[47]

With respect to results obtained in this study, the variability of the data reported in the current dental literature most likely occurs because there is still a lack of homogeneity regarding both MM and ODV measures, which could culminate in contrasting findings regarding these outcomes and therefore jeopardize comparisons. In this way, different methodologies, clinical scenarios, experimental treatments, sample sizes, and time periods of evaluation are reported.[2-4] Moreover, there are differences regarding the technologies and accuracy used to take measures from different outcomes.

Regarding the methodologies used in this study one positive aspect is related to the MM and OVD measures and digital images, which were obtained from standardized OVD frontal photograph and Gothic arch tracing records. Additionally, the measures from digital images were obtained in Image Tool, software that exhibits a high accuracy and precision for the measurements.[48,49] and finally, the millimeter ruler attached to the photographic records was used to verify the camera positioning and calibration of the each photographs and, thus to provide reliability in digital images measurements. In addition, arch tracing can be used as a standard protocol that has been acknowledged as one of the most reliable means of recording centric relation and to determine the centric relation or for purposes of education and research[50,51] as well as to record the extent of antero-posterior and lateral-lateral MM. Thus, the graphic records of Gysi's arch were used because it is a simple clinical method for assessing muscle function because the graphics of the arch tracings represent occlusal alterations.[2,51,52] Electromyography (EMG) is an easily completed examination for quantifying jaw movements using numeric values; however, there is still only limited knowledge regarding the data obtained from EMG about variations in both static and dynamic muscle function and other related parameters of the stomatognathic system[53], and thus this methodology was not used in this study.

Finally, although the occlusal splint showed a positive clinical outcome, several factors have been related to the re-establishment of the stomatognathic system. Thus, it is important that the clinical practice and treatment concepts are constantly based on scientific evidence to provide better and more effective treatments for our patients.[23] In this way, the outcomes obtained from these clinical trials should be interpreted with caution because, to our knowledge,[2-4] this is the first randomized controlled clinical trial that evaluates MM and OVD under the influence of the use of occlusal splints and denture relining prior to the new rehabilitation of complete denture wearers. Moreover, one of the limitations of this study was

that we tested only the immediate effects of the treatments in the outcomes evaluated, but a long-term effect is more clinically relevant. Additionally, further research should be performed to evaluate factors associated with aging and edentulism, which are predisposing factors for oral diseases because both the frequency and severity of this disease appear to increase with age.

Conclusions

Within the limitation of this clinical trial, it is possible to conclude that the use of occlusal splints prior to the new rehabilitation of complete denture wearers for long periods provide higher re-establishment of extent of MM and ODV. Thus, this previous treatment should be performed for these individuals.

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Tables

Table 1. Intragroup comparison of OVD measures obtained in the T0, T1 and T2 periods.

	Means of OVD measures and (SD)		
	T0	**T1**	**T2**
C	68.4 (6.8)a	-	69.9 (7.2)b
RD	68.6 (7.1)a	70.63 (7.40)b	70.7 (7.3)b
OS	69.3 (8.1)a	74.68 (8.79)b	74.9 (8.7)b

The means followed by different letters in the line show significant differences ($p < 0.05$). Paired t-test.

Data expressed as the mean values in millimeters (mm) and standard deviation (SD) of the occlusal vertical dimension (OVD) measures. **T0:** Baseline; **T1:** After application of randomized treatment, relined denture and interocclusal appliance; **T2:** After final rehabilitation. **C:** Control Group; **RD:** Relined Denture Group; **OS:** Occlusal splint group.

Table 2. Intergroup comparisons of OVD measures obtained in the (T2-T0) and (T1-T0) periods.

Means of OVD measures and (SD)		
	T2-T0	**T1-T0**
C	1.5 (1.1)a	
RD	2.1 (1.1)ab	1.9 (1.0)a
OS	5.6 (1.4)c	5.3 (1.4)b

One-way ANOVA and post hoc Bonferroni tests. The means followed by different letters in the column, show significant differences ($p < 0.05$). Data expressed as the mean values in millimeters (mm) and standard deviation (SD) of occlusal vertical dimension (OVD) measures.

T2-T0: Difference between the means of the OVD measures obtained for the T2 and T0 periods; **T1-T0:** Difference between the means of the OVD measures obtained for the T1 and T2 periods. **C:** Control Group; **RD:** Relined Denture Group; **OS:** Occlusal splint group.

Table 3. Intragroup comparisons of the extension of MM measures obtained in the T0, T1 and T2 periods for X and Y axes.

Extension of MM measures (X and Y axes) and SD						
	XT0	**XT1**	**XT2**	**YT0**	**YT1**	**YT2**
C	8.1 (2.0)a		7.7 (2.0)a	8.6 (2.4)a		7.9 (1.7)a
RD	8.6 (2.4)a	9.0 (2.2)b	9.1 (2.1)b	8.8 (3.7)a	9.2 (3.7)b	9.1 (3.7)b
OS	8.5 (1.5)a	9.9 (1.5)b	9.8 (1.6)b	8.6 (2.6)a	9.8 (3.3)b	9.9 (3.2)b

The means followed by different letters in the line show significant differences ($p < 0.05$). Paired t-test.

Data expressed as the mean values in millimeters (mm) and standard deviation (SD) of the extension of the mandibular movements (MM) measures.

T0: Baseline; **T1:** After application of the randomized treatment, relined denture and interocclusal appliance; **T2:** After final rehabilitation. **Y:** Extension of the anteroposterior (protrusion and retrusion) and **X:** Extension of the latero-lateral (right and left lateral excursion) MM obtained using the intraoral record of the Gysi arch tracing. **C:** Control Group; **RD:** Relined Denture Group; **OS:** Occlusal splint group.

Table 4. Intergroup comparisons of the extension of MM measures obtained in the (T2-T0) and (T1-T0) periods for X and Y axes.

Extension of MM measures (X and Y axis) and SD				
	XT2-XT0	**YT2-YTO**	**XT1-XT0**	**YT1-YTO**
C	0.4 (0.8)a	0.4 (0.1)a		
RD	0.6 (0.6)ab	0.5 (0.4)ab	0.4 (0.5)a	0.4 (0.4)a
OS	1.0 (0.14)c	1.2 (0.11)c	1.1 (0.13)b	1.2 (0.12)b

One-way ANOVA and post-hoc Bonferroni tests. The means followed by different letters in the column present significant differences ($p < 0.05$). Data expressed as the mean values in millimeters (mm) and standard deviation (SD) of the extension of the mandibular movements (MM) measures.

(X and Y T2-T0): Difference between the means of the MM measures obtained for the T2 and T0 periods; (X and Y **T1-T0):** Difference between the means of the OVD measures obtained for the T1 and T2 periods; **Y:** Extension of the anteroposterior (protrusion and retrusion) and **X:** Extension of the latero-lateral (right and left lateral excursion) mandibular movements obtained using the intraoral record of the Gysi arch tracing. **C:** Control Group; **RD:** Relined Denture Group; **OS:** Occlusal splint group.

Figures

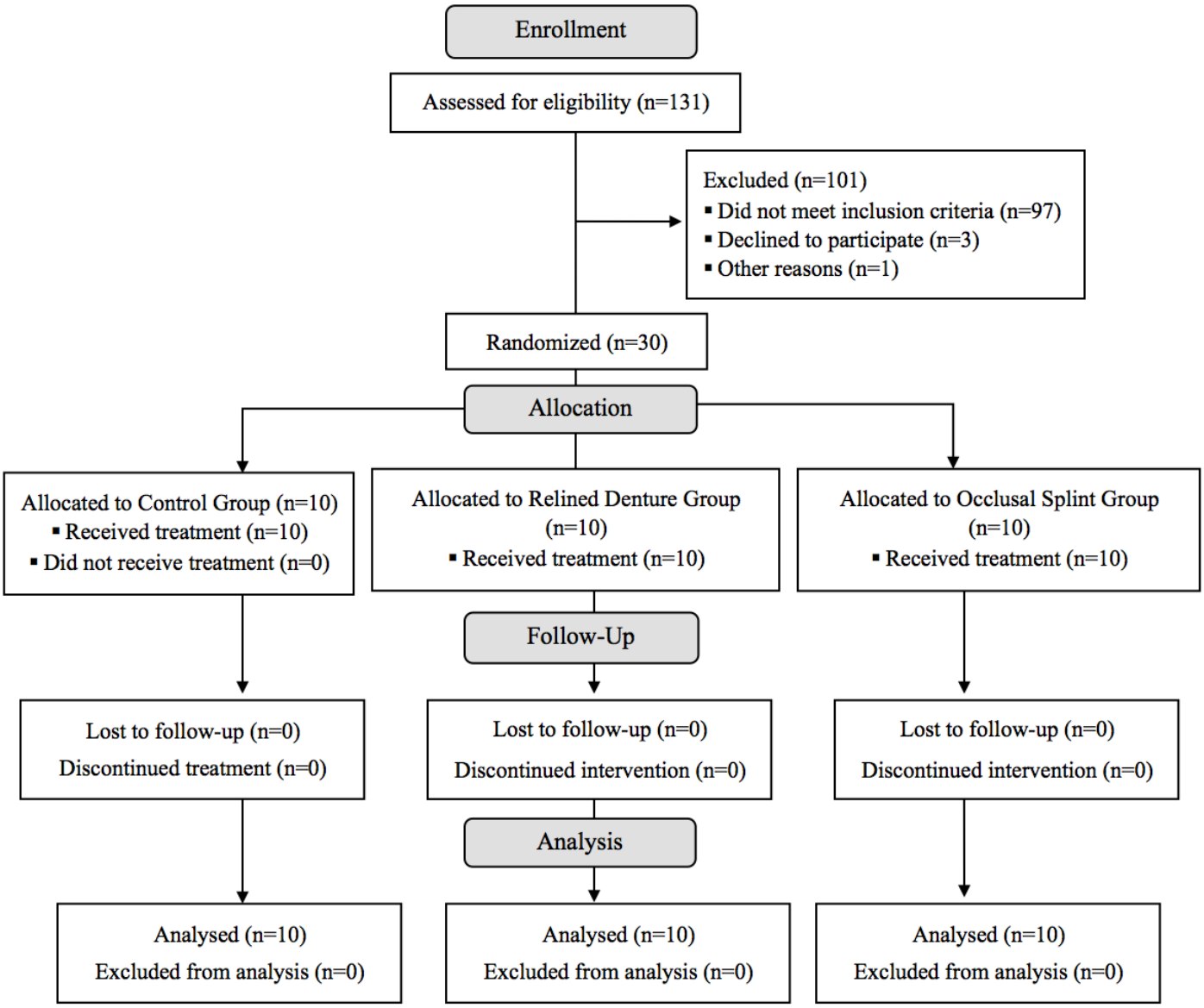

Figure 1. Study design according to CONSORT Statement.

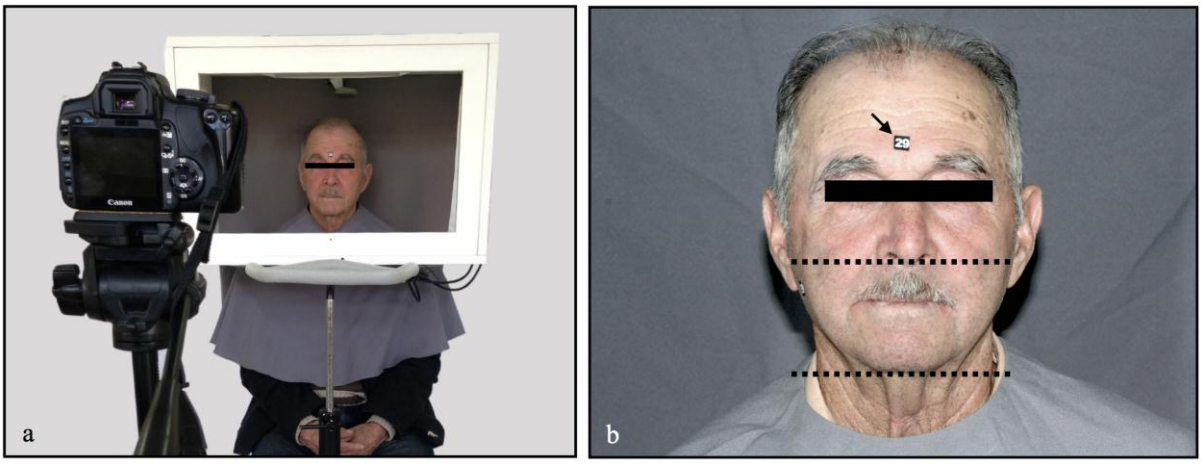

Figure 2. a) Display a posed frontal images of the OVD made with a digital single lens reflex camera mounted on a tripod at a fixed distance from the volunteer; **b)** The black arrow indicates the mark of 1cm inserted as reference for identification and standadization of measurements in each photographic record, and the dotted black lines indicate the two anatomical points (base nose and base of the chin) used to evaluate the vertical distance.

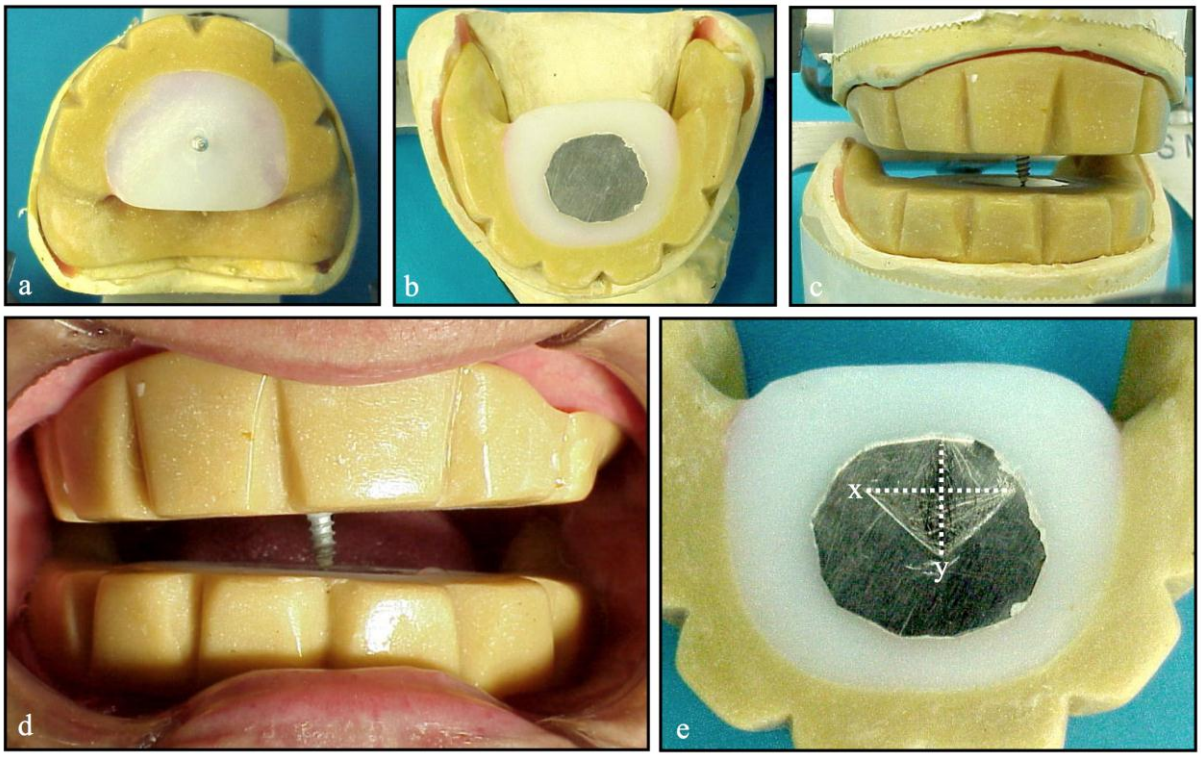

Figure 3. Displays the following images regarding to Gothic arch tracing. **a)** Upper acrylic resin base and one pua register installed in center that consists of a screw with blunt tip; **b)** In the lower base plate was adapted a platform with a metal plate, used to record the Gothic arch; **c)** Parallelism between the upper and lower baseplates; **d)** Devices were inserted into the oral cavity; **e)** MM anteroposterior (Y axis: protrusion and retrusion) and latero-lateral excursion (X axis: to right and left) record of the Gothic arch.

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8 Considerações finais

Dentro das limitações deste estudo é possível relatar as seguintes conclusões:

(i) Após a condução da revisão sistemática é possível concluir que embora o nível de evidência científica encontrado tenha sido fraco, foi possível identificar benefícios do uso de placas oclusais antes da nova reabilitação de usuários de próteses totais durante longos períodos, com relação à redução na sintomatologia da dor e melhora do tônus muscular. No entanto, quanto à extensão dos movimentos mandibulares e espaço intra-articular, essa evidência não é clara.

(ii) A partir dos resultados do estudo clínico, é possível concluir que o uso de placa oclusal, previamente à substituição das antigas próteses totais, promove um aumento da extensão dos movimentos mandibulares e dimensão vertical de oclusão, parecendo, portanto, ser um tratamento efetivo para o tratamento de pacientes que usam próteses totais inadequados durante longos períodos de tempo.

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Apêndices

Apêndice A – Termo de Consentimento Livre e Esclarecido

PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA

Título da Pesquisa: Avaliação dos movimentos mandibulares e do relacionamento côndilo-fossa mandibular, a partir de dois protocolos de tratamento. Estudo clínico randomizado.

Pesquisadores: Prof[a]. Dr[a]. Noéli Boscato, Wellington Luiz de Oliveira da Rosa e Rita de Cássia Costa Ribeiro de Almeida.

Objetivos: A proposta deste trabalho será avaliar a influência do tratamento com placas oclusais planas e reembasamento da base da dentadura, sobre a função muscular por meio do arco gótico de Gysi obtido com o registro intraoral e avaliação da dimensão vertical de oclusão através e fotografias, em pacientes portadores de próteses totais duplas.

Procedimentos: Será realizada terapia com placas interoclusais, reembasamento das próteses totais e confecção de novas dentaduras.

Riscos: É de extrema importância que o paciente esteja ciente que as duas tomografias computadorizadas que serão realizadas, de forma desnecessária, emitem certa dose de radiação podendo causar algum dano eventual a sua saúde.

Benefícios: Os pacientes serão avaliados quanto a presença de disfunção temporomandibular, além de receberem dentaduras novas.

Custos: O paciente não terá nenhum custo inerente a pesquisa, apenas arcará com o custo laboratorial para confecção da prótese total.

Remuneração: Não haverá nenhum tipo de remuneração para os pacientes participantes da pesquisa.

Atendimento: Os atendimentos serão realizados a partir de fevereiro de 2013. Mesmo que o paciente não opte em participar da pesquisa, receberá igualmente o tratamento necessário. Além disso, o paciente pode retirar consentimento para a participação na pesquisa a qualquer momento sem nenhum custo e sem perda de nenhum dos direitos e benefícios que estiver gozando ou dos que lhe foram prometidos. Caso seja diagnosticado qualquer alteração na articulação têmporo-mandibular, o paciente será tratado e acompanhado pelos pesquisadores do estudo.

Assinatura do termo: Este termo será impresso em duas vias, sendo uma destinada ao pesquisador e a outra ao voluntário que aceitar participar do estudo.

Eu,_____, RG n°_____, abaixo assinado, tendo recebido todos os esclarecimentos acima citado e ciente dos meus direitos, aceito, de forma livre e esclarecida, participar desta pesquisa, bem como autorizo a utilização dos dados clínicos e imagens dele resultantes para fins didático-científicos, desde que minha identidade seja preservada. Foi-me assegurado, também, que posso retirar a permissão para utilização deste material com fins didáticos, a qualquer tempo e por qualquer motivo por mim determinado, sem nenhum prejuízo ao tratamento a ser realizado.

Pelotas, _____ de _____ de 20____.

_____

Assinatura do Paciente

Apêndice B - Questionários dos dados sócio-demográficos

Ficha de Anamnese

Nome:_____

Endereço:_____

Bairro:_____ **CEP:**_____

Tel. residencial:_____ **Celular:**_____

Data de nascimento:_____ **Idade:**_____

Estado Civil:_____ **Profissão:**_____

RG:_____ **CPF:**_____

História Médica

1) **Está ou esteve recentemente sob cuidados médicos?**
   ( ) Não ( ) Sim Por quê?_____
2) **Mesmo não estando em tratamento, está tomando algum medicamento?**
   ( ) Não ( ) Sim Qual (is)?_____
3) **Já foi acometido por alguma dessas doenças?**

( ) Anemia	**( ) Hepatite**	**( ) Diabete**	**( ) Nefrite**
( ) Úlcera	**( ) Tuberculose**	**( ) Febre Reumática**	**( ) Epilepsia**
( ) Sífilis	**( ) Doença de Chaga**	**( ) Hemofilia**	**( ) Hipertensão**
( ) Problemas cardía	**( ) Distúrbios psíqui**	**( )Problemas hepáti**	**( ) Sinusite**
( ) AIDS	**( ) Câncer**	**( ) Osteoporose**	

4) **Você tem alguma outra doença, condição ou problema não citado acima?**_____
5) **Toma abitualmente bebidas alcoólicas? ( ) Sim ( ) Não**
6) **Sente frequentes náuseas? ( ) Sim ( ) Não**
7) **A salivação é abundante? ( ) Sim ( ) Não**
8) **Sente frequentemente falta de ar? ( ) Sim ( ) Não**
9) **Tem alguma alergia? ( ) Sim ( ) Não Qual (is)?**_____
10) **Já teve problemas hemorrágicos? ( ) Sim ( ) Não**
11) **Já teve problemas de cicatrização? ( ) Sim ( ) Não**
12) **Seus tornozelos incham? ( ) Sim ( ) Não Quando?**_____
13) **Quando recebe anestésicos para tratamento odontológico sente-se mal? ( ) Sim ( ) Não**
14) **É fumante? ( ) Sim ( ) Não Quantos por dia?**____
15) **Está grávida? ( ) Sim ( ) Não Quantos meses?**____
16) **Alguma outra informação que você considere importante e que não foi citada?**

Exame da Cavidade Oral

1) **Alterações em Tecidos Moles? ( ) Não ( ) Sim**

   Local?_____

   Descrição da lesão?_____

   Diagnóstico/ Hipótese Diagnóstica?_____

   Conduta:_____

Apêndice C – Parecer do Comitê de Ética em Pesquisa

MINISTÉRIO DA EDUCAÇÃO

UNIVERSIDADE FEDERAL DE PELOTAS

FACULDADE DE ODONTOLOGIA

COMITÊ DE ÉTICA E PESQUISA

PELOTAS, 18 de novembro de 2013

PARECER Nº 63/2013

O projeto de pesquisa intitulado **"Avaliação dos movimentos mandibulares e do relacionamento côndilo-fossa mandibular, a partir de dois protocolos de tratamento. Estudo clínico randomizado"** está constituído de forma adequada, cumprindo, nas suas plenitudes preceitos éticos estabelecidos por este Comitê e pela legislação vigente, recebendo, portanto, PARECER **APROVADO**.

Prof. Dr. Renato Fabrício de Andrade Waldemarin

Coordenador do CEP- FOP/UFPel