

UNIVERSIDADE ESTADUAL DE CAMPINAS FACULDADE DE ODONTOLOGIA DE PIRACICABA

### **GUILHERME ALMEIDA BORGES**

## DESEMPENHO BIOMECÂNICO DE MINI-IMPLANTES COMO RETENTORES DE OVERDENTURES MANDIBULARES: ESTUDO IN VITRO E IN SILICO

## BIOMECHANICAL PERFORMANCE OF MINI-IMPLANTS AS MANDIBULAR OVERDENTURE RETAINERS: *IN VITRO* AND *IN SILICO* STUDY

Piracicaba 2020

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Dissertação apresentada à Faculdade de Odontologia de Piracicaba da Universidade Estadual de Campinas como parte dos requisitos exigidos para a obtenção do título de Mestre em Clínica Odontológica, na Área de Prótese Dental.

Dissertation presented to the Piracicaba Dental School of the University of Campinas in partial fulfillment of the requirements for the degree of Master in Dental Clinic, in Prosthodontics area.

Orientador: Prof. Dr. Marcelo Ferraz Mesquita

ESTE EXEMPLAR CORRESPONDE À VERSÃO FINAL DA DISSERTAÇÃO DEFENDIDA PELO ALUNO GUILHERME ALMEIDA BORGES, E ORIENTADO PELO Prof. Dr. MARCELO FERRAZ MESQUITA.

> Piracicaba 2020

Ficha catalográfica Universidade Estadual de Campinas Biblioteca da Faculdade de Odontologia de Piracicaba Marilene Girello - CRB 8/6159

 Borges, Guilherme Almeida, 1992 B644d Desempenho biomecânico de mini-implantes como retentores de overdentures mandibulares : estudo *in vitro* e *in silico* / Guilherme Almeida Borges. – Piracicaba, SP : [s.n.], 2020.

> Orientador: Marcelo Ferraz Mesquita. Dissertação (mestrado) – Universidade Estadual de Campinas, Faculdade de Odontologia de Piracicaba.

> 1. Boca edentada. 2. Revestimento de dentadura. 3. Implantes dentários. I. Mesquita, Marcelo Ferraz, 1967-. II. Universidade Estadual de Campinas. Faculdade de Odontologia de Piracicaba. III. Título.

Informações para Biblioteca Digital

Título em outro idioma: Biomechanical performance of mini-implants as mandibular overdenture retainers : *in vitro* and *in silico* study Palavras-chave em inglês: Edentulous mouth Overlay dentures Dental implants Área de concentração: Prótese Dental Titulação: Mestre em Clínica Odontológica Banca examinadora: Marcelo Ferraz Mesquita [Orientador] Eduardo Piza Pellizzer Vanessa Cavalli Gobbo Data de defesa: 19-02-2020 Programa de Pós-Graduação: Clínica Odontológica

Identificação e informações acadêmicas do(a) aluno(a) - ORCID do autor: https://orcid.org/0000-0003-4724-9834 - Currículo Lattes do autor: http://lattes.cnpq.br/8324125418593784



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A Comissão Julgadora dos trabalhos de Defesa de Dissertação de Mestrado, em sessão pública realizada em 19 de Fevereiro de 2020, considerou o candidato GUILHERME ALMEIDA BORGES aprovado.

PROF. DR. MARCELO FERRAZ MESQUITA

PROF. DR. EDUARDO PIZA PELLIZZER

PROF<sup>a</sup>. DR<sup>a</sup>. VANESSA CAVALLI GOBBO

A Ata da defesa, assinada pelos membros da Comissão Examinadora, consta no SIGA/Sistema de Fluxo de Dissertação/Tese e na Secretaria do Programa da Unidade.

#### DEDICATÓRIA

A **Deus**, por compreender minhas limitações e assim me capacitar nos momentos difíceis. Além de ser luz e agraciar minha vida com bênçãos das quais permitiram o meu crescimento pessoal e profissional.

Aos meus pais, **Jairo Borges Ferreira** e **Senilda Barbosa de Almeida Ferreira**, por inúmeras vezes pausarem seus sonhos para que os meus pudessem ser realizados. Além disso, por suprirem minha vida com amor, amizade, cuidado e paciência. Agradeço ainda pelas ligações diárias a fim de minimizar a distância durante essa trajetória. Vocês são meu alicerce e palavras jamais serão capazes de traduzir esse sentimento, entretanto ajudam a dizer: obrigado!

Ao meu irmão, **Thales Almeida Borges**, pelo amor, motivação, carinho e por nossa amizade.

#### AGRADECIMENTOS

À Universidade Estadual de Campinas – UNICAMP, na pessoa do Magnífico Reitor, Prof. Dr. Marcelo Knobel, pelo meu mestrado nesta instituição.

À Faculdade de Odontologia de Piracicaba – UNICAMP, na pessoa do seu Diretor, Prof. Dr. Francisco Haiter Neto, pela oportunidade da realização do Programa de Pós-Graduação em Clínica Odontológica.

À Coordenadora Geral da Pós-Graduação **Profa. Dra. Karina Gonzales Silvério Ruiz** e ao Coordenador do Programa de Pós-Graduação em Clínica Odontológica **Prof. Dr. Valentim Adelino Ricardo Barão.** 

Ao meu orientador, **Prof. Dr. Marcelo Ferraz Mesquita**, pela oportunidade de ser um dos seus orientandos e por todo apoio e entusiasmo com que me recebeu. Muito obrigado por sempre ser um exemplo de comprometimento e autenticidade como professor, além de partilhar seus conhecimentos clínicos e no ramo da docência. Agradeço também pela constante paciência, qualidade de orientação e por contribuir significativamente para o meu crescimento e amadurecimento profissional. As oportunidades que o senhor me proporcionou foram únicas e acredito que dificilmente serei capaz de retribuir toda essa confiança, por esse motivo deixo expressa a minha sincera gratidão.

Ao **Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq)**, pela concessão de bolsa de estudo no período de março de 2018 a novembro de 2018, **processo nº 132724/2018-9**, fundamental para o desenvolvimento desta pesquisa.

À Fundação de Amparo a Pesquisa do Estado de São Paulo (FAPESP), pela concessão de bolsa de estudo no período de dezembro de 2018 a fevereiro de 2020, processo nº 2018/03136-4, fundamental para o desenvolvimento desta pesquisa.

À Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES), - Código de financiamento 001, fundamental para o desenvolvimento desta pesquisa. Ao Centro de Pesquisas Renato Archer (CTI), representado por Daniel Takanori Kemmoku pelo suporte na confecção dos protótipos mandibulares utilizados neste trabalho.

À **Estetica Protese Dental Eireli**, representado por **Jorge Antônio Alcarde** pelo suporte na confecção do protótipo da fibromucosa utilizado neste trabalho.

À **Conexão Sistemas de Prótese**, representado por **Jochen Roestel** pelo suporte na disponibilização dos arquivos CAD utilizados neste trabalho.

Aos docentes Prof. Dr. Wander José da Silva, Prof. Dr. Mauro Antônio de Arruda Nóbilo, Prof. Dr. Frederico Andrade e Silva, Prof. Dr. Wilkens Aurélio Buarque e Silva e Prof. Dr. Rafael Leonardo Xediek Consani por todo o conhecimento compartilhado.

À professora **Dra. Altair Del Bel Cury**, por ser sempre uma facilitadora do conhecimento. Todos os momentos de diálogo foram enriquecedores, produtivos e super agradáveis. Agradeço também por auxiliar na disponibilização dos computadores que foram essenciais para a execução da análise de elementos finitos, além da acessibilidade do seu kit de chaves protéticas.

Aos professores **Drs. Americo Bortolazzo Correr, Raissa Micaella Marcello Machado & Renata Cunha Matheus Rodrigues Garcia** por carinhosamente contribuírem e aceitarem o contive de participar no exame de Qualificação da dissertação de Mestrado. A competência científica e clínica das quais vocês possuem, inspiram e guiam os caminhos da pós-graduação.

À professora **Dra. Lucianne Cople Maia**, docente querida da FO-UFRJ, que prontamente se dispôs a compartilhar seus ensinamentos metodológicos sobre revisão sistemática e meta-análise. Obrigado pela amizade, motivação e confiança. Especialmente agradeço por todas as contribuições que culminaram no presente trabalho.

Ao professor **Dr. Pedro Yoshito Noritomi** por cordialmente me recepcionar no Centro de Tecnologia da Informação Renato Archer e proporcionar ensinamentos que foram primordiais para o aprimoramento desse trabalho. Ao professor **Dr. Ricardo Armini Caldas**, docente da FO-UFSC, por gentilmente se disponibilizar em compartilhar seus conhecimentos sobre a metodologia de elementos finitos em 3D.

Ao professor **Dr. Valentim Adelino Ricardo Barão**, por todas as contribuições com esse trabalho e pessoalmente por ser uma inspiração enquanto pesquisador. Agradeço por ser sempre solícito e resolutivo; além de compartilhar seu conhecimento em todas às oportunidades de diálogo que culminaram em aprendizados únicos. Admiro seu senso crítico e dedicação.

Aos técnicos Eduardo Pinez - Laboratório de Prótese Total da FOP-UNICAMP, Renata Maria Dias Groppo – Laboratório de Odonto Infantil da FOP-UNICAMP e Gislaine Regina Alves Piton – Laboratório de Prótese Parcial Removível da FOP-UNICAMP pela solicitude e prontidão em ajudar sempre que necessário.

À secretária do **Departamento de Prótese e Periodontia da FOP - UNICAMP**, **Sra. Eliete Aparecida Ferreira Marin**, pela atenção, solicitude e gentileza.

A todos os meus amigos do Laboratório de Prótese Total, Adaías Oliveira Matos, Anna Gabriella Camacho Presotto, Bruna Egumi Nagay, Carolini Dini, Daniele Valente Veloso, Heloísa Navarro Pantaroto, Jairo Matozinho Cordeiro, João Gabriel Silva Souza, Letícia Del Rio, Raphael Cavalcante Costa, Thamara Beline e Thaís Barbin pela convivência, amizade e conhecimentos compartilhados.

Em especial à **Bruna Egumi Nagay, Carolini Dini, Jairo Matozinho Cordeiro** & Raphael Cavalcante Costa por constantemente motivarem minha busca por novos aprendizados. Além disso, por serem sempre pacientes comigo. Vocês fizeram essa trajetória mais suave, sendo modelo de amizade e companheirismo. Guardarei carinhosamente todos os nossos momentos vividos. Deus confiou em mim todas essas amizades e eu sou/serei eternamente grato!

Em especial à **Daniele Valente Veloso, Letícia Del Rio & Thaís Barbin** pelo carinho e por dividirem comigo mais que um grupo de pesquisa, momentos de felicidade e aprendizado. O tempo nos transformou em uma equipe da qual me orgulho imensamente de fazer parte. Levarei nossas memórias com muito amor em meu coração.

Em especial à **Anna Gabriella Camacho Presotto & Marina Xavier Pisani** por toda gentileza, confiança e ensinamentos durante o desenvolvimento desse trabalho.

Aos amigos conquistados durante a Pós-graduação, em especial Loyse Martorano Fernandes, Mariana Barbosa Câmara-Souza, Olívia Maria Costa de Figueredo, Mariana Marinho Davino de Medeiros, Rodrigo Lins, Catharina Marques Sacramento, Tamires Pereira Dutra & Thayane Cerquiare Businari. Obrigado pela amizade, apoio e bons momentos.

Aos meus amigos da UNIMONTES, **Cláudio Wagnus Xavier Lopes Júnior & Jéssica Rejane Durães Soares**, por acreditarem no meu potencial e sempre me incentivarem durante todo o processo. Agradeço por todos os bons momentos compartilhados em cada retorno à Minas Gerais.

Aos meus amigos **Carlos Alexandre Silva, Felipe Gonçalves Ribeiro & Lucas Ribeiro** por serem a minha família longe de casa. Vocês estavam comigo em cada etapa, feliz ou triste, e se mantiveram sempre de braços abertos. Levarei cada lembrança com muito carinho!

Aos meus **amigos de Salinas** e **Montes Claros** que sempre se fizeram presentes apesar da distância. Serei sempre grato a todos vocês!

Muito obrigado!

#### **RESUMO**

Os implantes dentários utilizados para a reabilitação do tipo overdenture mandibular (OM) são definidos como uma modalidade de tratamento bem estabelecida para pacientes desdentados, especialmente para a restauração estética e funcional. Embora a OM seja eficaz e recomendada amplamente pelos dentistas, limitações baseadas nos custos, múltiplas fases cirúrgicas, morbidade e restrições anatômicas podem dificultar um cenário ideal para os pacientes. Portanto, o uso do protocolo de carga imediato (PCI) e precoce (PCP) podem ser uma alternativa clínica viável, considerando o longo tempo de espera dos pacientes pelas próteses finais. De forma similar, outra possibilidade seria reduzir o plano terapêutico mínimo de dois implantes para apenas um, ou até mesmo substituir os implantes de diâmetro convencional (IDC) para mini-implantes. Assim sendo, foram delineados dois estudos: [1] uma revisão sistemática, para investigar se os protocolos de carregamento (PCI)/ (PCP) atingiriam resultados clínicos semelhantes ao protocolo de carregamento convencional (PCC) em OM com longos períodos de acompanhamento. Os resultados demonstraram que os PCI/ PCP apresentam taxas de sucesso e sobrevivência semelhantes (P>0,05) em comparação com os do PCC. De forma similar, nenhuma diferença estatística (P > 0.05) foi encontrada para o grupo do PCI/ PCP quando se avaliou a perda óssea marginal. Em relação à profundidade de sondagem, valores menores (P <0,05) foram associados ao PCC aos 36 meses de acompanhamento, em comparação ao PCI/ PCP. Quando o índice de placa foi considerado, valores mais baixos (P <0,05) foram observados para o PCC em comparação com o PCI/ PCP. O quociente de estabilidade implantar apresentou valores favoráveis (P <0,05) para o PCC apenas aos 3 meses, considerando que em períodos subsequentes de acompanhamento valores semelhantes (P> 0,05) aos do PCI foram alcançados. O PCI apresentou valores similares (P> 0,05) para o sangramento à sondagem comparados ao PCC; e [2] uma avaliação experimental (in vitro e in silico) para comparar o comportamento biomecânico de OM retidas por um ou dois implantes, utilizando IDC ou mini-implantes. Os resultados mostraram que OM com 2 IDC apresentaram menores valores de força de cisalhamento posterior e total, mesmo para os grupos retidos por 1 e 2 mini-implantes (P< 0,05). Além disso, a tensão de cisalhamento peri-implantar foi semelhante (P > 0.05) para os IDC e mini-implantes, em ambos grupos com 1 ou 2 implantes. Independentemente da aplicação de carga (molar ou incisivo), os grupos com um ou dois miniimplantes apresentaram os menores valores para a tensão de von Misses no implante. Para a carga incisal, o grupo com um mini-implante apresentou os maiores valores de tensão para o housing, em comparação aos outros grupos. A estrutura mais sobrecarregada foi o attachment,

com altos valores sob carga incisal, principalmente nos grupos com dois implantes. Em conclusão, o PCI/ PCP para OM são modalidades de tratamento bem estabelecidas e dignas de consideração na prática clínica. Além disso, independentemente do número dos implantes, os mini-implantes apresentam-se como um método de reabilitação promissor, com baixos valores de tensão de cisalhamento peri-implantar e de tensão de von Misses no implante, em comparação com IDC em OM.

Palavras-chave: Edêntulos. Overdenture. Implantes dentários.

#### ABSTRACT

Dental implants for the rehabilitation with mandibular overdenture (MO) is a welldefined treatment for edentulous patients, regarding the restoration of aesthetics and function. Although MO rehabilitation is effective and recommended throughout the clinician; limitations based on costs, multiple surgical phases, morbidity and anatomical features may hamper an optimal scenario from the patient perspective. Therefore, the use of immediate (ILP) as well as early (ELP) loading protocol might be an alternative for the patients' long waiting time for the final prostheses. Similarly, another possibility it would be to reduce the minimum protocol of two implants for only one; or even to switch the standard implant diameter (SDI) for a miniimplant design. For this purpose, two studies were designs: at first, [1] a systematic review to evaluate whether (ILP)/ (ELP) loading protocols achieve comparable long-term clinical outcomes when compared with a conventional loading protocol (CLP) in edentulous patients rehabilitated with MO. The results showed that the ILP/ELP demonstrated similar success and survival rates (P>.05) compared with those of the CLP. Similarly, no difference between/among groups was found for marginal bone loss (P>.05). With regard to probing depth, lower values (P < .05) were associated with conventional loading at 36 months of follow-up compared with the immediate/early loading protocols. When plaque index was considered, lower indices (P<.05) were assessed for the CLP compared with the ILP/ELP. Implant stability quotient presented favorable values (P<.05) for the conventional loading protocol at only 3 months, since, at subsequent follow-up periods, values similar to those of the ILP were achieved (P>.05). ILP showed the same bleeding (P>.05) on probing than the conventional loading protocol. The second study, [2] it was an experimental study (in vitro and in silico) to assess and compare the biomechanical behavior of MO retained by either one or two implants, using SDI or dental mini-implants. MO with 2 SDI showed the lowest posterior and total shear stress even for the groups retained by 1 and 2 mini-implants. In addition, peri-implant shear stress was similar (P> 0,05) for both SDI and mini-implants, irrespective of the implant number. Irrespective of the loading area (molar or incisor), the groups with one or two mini-implants showed the lowest values of von Misses stress in the implant (P < 0.05). Under incisor loading, the group with one mini-implant presented greatest stress for the housing compared with the other groups. The attachment was the most overloaded structure with high values under incisor loading, especially for the groups with two implants. In conclusion, ILP/ELP for MO is presented as a wellestablished treatment and worthy of consideration in clinical practice. Moreover, regardless of the implant number, MI is a promising rehabilitation method with similar peri-implant shear stress and low von Misses stress to the implant compared to SDI for implant-retained MO.

Keywords: Edentulous. Overdentures. Dental implants.

## SUMÁRIO

1. INTRODUÇÃO	15
2. ARTIGOS	19
2.1 Long-term outcomes of different loading protocols for implant-supported man	ndibular
overdentures: a systematic review and meta-analysis#	19
2.2 Is one dental mini-implant biomechanically appropriate for the retention of a man	ndibular
overdenture? A comparison with Morse taper and external hexagon platforms#	55
3. DISCUSSÃO	79
4. CONCLUSÃO	82
REFERÊNCIAS	83
APÊNDICE 1 - DETALHAMENTO METODOLÓGICO	90
Fotoelasticidade	90
Confecção dos protótipos – mandíbula e fibromucosa	
Obtenção do modelo em gesso e confecção da overdenture	
Obtenção da fibromucosa Torque dos attachments	93
Captura dos attachments	90
Análise em polariscónio	
Preparo das grades	
Análise de elementos finitos 3D	101
Fase de pré-processamento	101
Fase de processamento	102
Fase de pós-processamento	103
ANEXOS	104
ANEXO 1: Verificação de originalidade e prevenção de plágio	104
ANEXO 2: Comprovante de submissão do artigo científico	105
ANEXO 3: Comprovante de aceite do artigo científico	106

#### 1. INTRODUÇÃO

A reabilitação com próteses totais convencionais em pacientes edêntulos é rotineira na prática clínica. Entretanto, problemas funcionais representam uma queixa recorrente dos pacientes, especialmente em relação a prótese inferior (Bakker et al., 2019). Dentre os problemas citados, encontram-se falta de retenção e estabilidade, bem como redução da habilidade mastigatória (van Waas, 1990). Assim sendo, o uso de implantes dentários para reter *overdentures* mandibulares (OM) representa uma excelente ferramenta terapêutica para sobrepor os impasses clínicos com altas taxas de sucesso (> 90%) e satisfação do paciente (Martinez–Lage-Azorin et al., 2013; Schuster et al., 2017; Sivaramakrishnan and Sridharan, 2016). Desse modo, essa categoria de reabilitação é considerada clinicamente segura e previsível, uma vez que apresenta prognóstico favorável.

Brånemark et al. sugeriram em 1983, que para se alcançar a osseointegração, os implantes deveriam permanecer submersos e sem carga por um período de 3-6 meses (Brånemark et al., 1983). Além disso, a micro-movimentação e redução do período de cicatrização levariam à formação de um tecido conjuntivo entre implante e osso, os quais eventualmente levariam também à falha do implante (Romeo et al., 2002). Entretanto, estudos recentes têm demonstrado expressiva melhora nos tratamentos de superfície dos implantes dentários, com período de cicatrização reduzido e melhor previsibilidade da osseointegração (Junker et al., 2009; Nagay et al., 2019; Soares et al., 2018). Assim sendo, o protocolo de carga em reabilitações com OM seria reduzido de 12-24 semanas para 6 semanas, sem prejuízo para a taxa de sucesso dos implantes dentários (Cochran et al., 2004). De forma similar, as definições para os protocolos de carga para implantes dentários receberam modificações. Segundo o último Consenso (Gallucci et al., 2014) de recomendações clínicas, foram estabelecidas três modalidades: [1] protocolo de carga imediato (PCI), definido pelo carregamento do implante em até uma semana após a instalação; [2] protocolo de carga convencional (PCC) com carregamento após dois meses da instalação do implante.

Apesar das limitações anatômicas para a reabilitação de pacientes edêntulos, a utilização de OM apresenta aceitação terapêutica significativa e o uso do PCI e PCP representam opções atrativas para ambos, pacientes e clínicos (Gallucci et al., 2014; Geckili et al., 2011; Passia et al., 2017). Entretanto, a literatura ainda é divergente e os estudos apresentam limitado rigor

metodológico para que conclusões claras possam ser obtidas quanto aos protocolos de carga em OM. Revisões sistemáticas prévias, incluindo estudos com 12 (Schimmel et al., 2014) e 24 (Alsabeeha et al., 2009) meses de acompanhamento avaliaram a sobrevivência dos implantes dentários em OM. Entretanto, observa-se a inclusão de limitado número de artigos e resultados inconclusivos para longos períodos de acompanhamento. Quanto ao sucesso dos implantes dentários em OM, essa variável foi avaliada unicamente por método qualitativo em uma única revisão sistemática, apresentando falta de precisão para a estratégia do PICO e classificação desatualizada para os protocolos de carga (Kawai and Taylor, 2007). Além disso, os parâmetros inflamatórios peri-implantares (perda óssea marginal, sangramento à sondagem, profundidade de sondagem, índice de placa e quociente de estabilidade implantar) não foram sistematicamente avaliados por método quantitativo. Nesse sentido, é de suma importância a avaliação dos estudos disponíveis na literatura para os diferentes protocolos de carga (PCI, PCP e PCC) em longos períodos de acompanhamento implantares e peri-implantares em pacientes usuários de OM.

O número adequado de implantes em reabilitações com OM também é impreciso na literatura, uma vez que é influenciado por aspectos anatômicos, biomecânicos e financeiros. Sugeriu-se que múltiplos implantes em OM fossem utilizados na presença de uma anatomia mandibular favorável, forças oclusais elevadas, necessidade de maior retenção, ou quando fossem utilizados implantes com altura (< 8mm) e diâmetro (< 3.5mm) limitados (Sadowsky, 2001). Entretanto, existem cenários clínicos em que o uso de vários implantes na mandíbula é impraticável, especialmente quando há pouca disponibilidade óssea, além de proximidade com o canal mandibular. Destaca-se também limitações econômicas do paciente, restringindo o acesso ao uso de múltiplos implantes (Cannizzaro et al., 2016). Um estudo de meta-análise elucidou que o uso de 2 ou 4 implantes (2 ou 4) em OM apresentaram resultados satisfatórios na prática clínica (Kern et al., 2016). Além disso, os Consensos de McGill (Feine et al., 2002) e York (Thomason et al., 2009) estabeleceram como modalidade terapêutica padrão para pacientes edêntulos, o uso de dois implantes.

Ensaios clínicos utilizando OM com 2 implantes, demonstraram efeito positivo para os resultados de qualidade de vida (Matthys et al., 2019), função mastigatória (Thomason et al., 2012) e satisfação, além de reduzido número de desfechos desfavoráveis reportados pelos pacientes (Zhang et al., 2019). Entretanto, a contínua reabsorção óssea em indivíduos edêntulos torna-se

condição desafiadora para sua reabilitação, uma vez que apresenta caráter progressivo e fisiológico (Allen and McMillan, 2003). Além disso, o processo de reabsorção progressivo é um fator limitante para indicação de implantes de diâmetro convencional (IDC) (Milinkovic and Cordaro, 2014; Ortega-Oller et al., 2014). À partir deste cenário, surgiram métodos reabilitadores alternativos, destacando-se o uso de implante único ou mini implantes (Enkling et al., 2019; Passia et al., 2017).

As reabilitações com OM utilizando implante único são consideradas modificações da técnica, com baixo custo (Nogueira et al., 2017; Passia and Kern, 2014). Ensaios clínicos prévios comparando o uso de OM com um e dois implantes evidenciaram desfechos clínicos semelhantes para satisfação dos pacientes, qualidade de vida, esforço para manutenção protética, e sobrevivência do implante em um período de 5 anos (Bryant et al., 2015). Clinicamente, a instalação de um único implante requer procedimento cirúrgico simplificado, uma vez que o tempo clínico e o número de componentes necessários será reduzido (Tavakolizadeh et al., 2015). Além disso, na sínfise mandibular o rebordo residual é mais espesso, tornando o procedimento cirúrgico mais seguro e menos oneroso (Srinivasan et al., 2016; Topkaya and Solmaz, 2015). Entretanto, no atual estado da arte o número de estudos biomecânicos investigando os diferentes tipos de plataformas implantares (cone morse e hexágono externo) e as suas implicações em OM utilizando apenas um implante ainda é restrito.

Como alternativa clínica para os indivíduos que apresentam espessura óssea insuficiente, uma proposta simples para reabilitação de pacientes edêntulos seria a indicação de implantes de diâmetro reduzidos (IDR). O Consenso do ITI de 2014 incluiu a categoria 1, que define os mini-implantes ou implantes de peça única como IDR por possuírem diâmetro menor que 3mm (Klein et al., 2014). Em relação a sua aplicabilidade clínica, estudos prévios demonstraram que OM utilizando mini-implantes apresentam perda óssea marginal aceitável, alta satisfação do paciente, elevado índice de sucesso dos mini-implantes, além de melhor função a longo prazo (Enkling et al., 2019, 2017; Mundt et al., 2015; Zygogiannis et al., 2017). Os mini-implantes oferecem ainda benefícios cirúrgicos pelo fato de serem produzidos em peça única, tais como apenas uma sessão clínica e ausência de retalho cirúrgico (Enkling et al., 2019; Ribeiro et al., 2015). Finalmente, os mini-implantes não apresentam micro-movimentos e risco de desrosqueamento e fratura do *abutment*, já que possuem corpo único (Broggini et al., 2003; O'Mahony et al., 2000). Apesar das vantagens destacadas, os estudos clínicos disponíveis na literatura avaliaram apenas OM suportadas por 4 ou 2 mini-implantes (Abou-Ayash et al., 2019; de Souza et al., 2015; Enkling

et al., 2019, 2017; Mundt et al., 2015; Ribeiro et al., 2015; Zygogiannis et al., 2017), não tendo sido observados na literatura pesquisada, estudos avaliando o uso de um mini-implante.

Entender o comportamento biomecânico de diferentes técnicas ou modalidades reabilitadoras para a confecção das OM é o primeiro passo para subsequentemente sugerir sua aplicabilidade clínica. Além disso, a distribuição inadequada das tensões no tecido ósseo pode ocasionar função biomecânica inadequada, podendo causar reabsorções ósseas e insucesso do implante dentário. As avaliações biomecânicas oferecem uma análise conjunta dos diferentes componentes do sistema. Dessa forma, diferentes metodologias podem ser utilizadas para avaliar o comportamento biomecânico em Odontologia, incluindo análise fotoelástica e por elementos finitos em três dimensões. A primeira pode sugerir a tensão interna de diferentes reabilitações, utilizando componentes reais (implante, attachment e matriz), através de franjas isocromáticas obtidas em condições controladas (Presotto et al., 2019). A segunda, pode avaliar o comportamento biomecânico de estruturas dúcteis, através de equações matemáticas (Pisani et al., 2018). Dessa forma, a avaliação do comportamento biomecânico de um ou dois implantes como retentores de OM, utilizando IDC ou mini-implantes não foram explorados experimentalmente. Portanto, nosso objetivo é avaliar: [1] sistematicamente, através de método qualitativo e quantitativo, os estudos disponíveis na literatura para os diferentes protocolos de carga em pacientes reabilitados com OM; [2] o comportamento biomecânico de OM retidas por 1 ou 2 implantes, utilizando IDC ou miniimplantes; através de um estudo in vitro e in silico.

#### 2. ARTIGOS

# **2.1** Long-term outcomes of different loading protocols for implant-supported mandibular overdentures: a systematic review and meta-analysis#

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This study was financed in part by the Conselho Nacional de Desenvolvimento Científico e Tecnológico - Brazil (CNPq) [grant number 132724/2018-9]; by the Fundação de Amparo à Pesquisa do Estado de São Paulo - Brazil (FAPESP), [grant number 2018/03136-4; 2018/04630-2]; and by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES), [grant number 0885/2018].

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#Artigo submetido na revista Journal of Prosthetic Dentistry (IF = 2.787), conforme o Anexo 2.

#### ABSTRACT

**Statement of problem.** Evidence provided by implant-supported mandibular overdentures (MO) research on different loading protocols is important into daily practice. However, methodological inconsistency as well as inadequate reporting of results hampers a consistent decision in terms of clinical applicability.

**Purpose.** This study aimed to evaluate whether immediate (ILP)/early (ELP) loading protocols achieve comparable clinical outcomes when compared with a conventional loading protocol (CLP) in edentulous patients rehabilitated with MO.

**Material and methods.** According to the PICO strategy, prospective clinical studies without restrictions as to language or follow-up period were included. Cochrane Collaboration and ROBINS-I tools were used for quality assessment and risk-of-bias evaluation. The follow-up for the different outcomes ranged from 3 to 168 months, with focus on: (1) implant success and survival rates; (2) marginal bone loss (MBL), bleeding on probing (BOP), probing depth (PD), plaque index (PI) and implant stability quotient (ISQ).

**Results.** The search strategy resulted in 14,234 references. 23 studies fulfilled the inclusion criteria. Meta-analysis showed statistically significant differences for PI at 12 months (SMD 0.284 [0.022, 0.545], P = .033,  $I^2 = 35\%$ ), PD at 36 months (SMD 0.460 [0.098, 0.823], P = .013,  $I^2 = 0\%$ ) and on pooled results for PI (SMD 0.157 [0.031, 0.284], P = .015,  $I^2 = 18\%$ ) in which the CLP presented lower indices compared with those of ILP/ELP. ISQ presented a statistically significant difference only at 3 months (SMD 0.602 [0.309, 0.895], P = .0,  $I^2 = 0\%$ ) with higher values for the CLP. For the other parameters , statistically significant differences (P > .05) were not found.

Conclusions. ILP/ELP for MO is presented as a well-established treatment and worthy of

consideration in clinical practice.

#### **CLINICAL IMPLICATIONS**

Reduction in overall healing time with immediate/early loading protocols of dental implants represented an attractive choice for both clinicians and patients and it is worthy of consideration in clinical practice.

#### **INTRODUCTION**

The rehabilitation of fully edentulous patients with implant-supported mandibular overdentures (MO) has become a well-accepted and predictable treatment in countless clinical trials.<sup>1–5</sup> In addition to having high implant success and survival rates,<sup>2.6</sup> MO also have a positive impact on oral-health-related quality of life, satisfaction and masticatory function in elderly patients.<sup>2.7</sup> In previous clinical trials, those improvements were mainly correlated with the increased retention and stability provided by this rehabilitation.<sup>7,8</sup> Furthermore, one must also consider the importance of achieving an interface between the implant surface and the alveolar bone (i.e. osseointegration) over the healing period after implant placement.<sup>9</sup>

Initially, it was proposed by Brånemark that, for osseointegration to be achieved, the implants should be left submerged and unloaded for a period of 3-6 months.<sup>9</sup> In case of any interference with, micromotion in and avoidance of this healing process, a connective tissue layer would be formed between the implant and the bone, which would eventually cause implant failure.<sup>10</sup> However, recent studies have demonstrated an express improvement in implant surface treatment with a shortened healing period, leading to faster and more predictable osseointegration.<sup>11,12</sup> Thus, the loading protocol would be reduced from 12–24 weeks to at least 6

weeks without impairment of the implant success rate.<sup>13</sup> Similarly, the definitions for loading protocols for dental implants have changed throughout the years and are currently as follows: (I) immediate loading protocol (ILP) is defined as within one week of implant placement, (II) early loading protocol (ELP) between one week and two months after implant placement and (III) conventional loading protocol (CLP) more than two months after implant placement.<sup>14</sup>

Previously, systematic reviews have been performed to evaluate the different loading protocols to support the information published in the literature. A previous meta-analysis was performed for two studies with at least 12<sup>15</sup> and 24<sup>16</sup> months of follow-up for survival rates. Regarding success rates, this outcome has been only qualitatively evaluated without a consistent number of articles and precision to follow the PICO strategy.<sup>17</sup> When it comes to peri-implant inflammatory parameters, those variables have not been quantitatively evaluated. Those outcomes require more clarification for more comprehensive knowledge to support clinicians and patients when choosing loading protocols for dental implants.

Despite the broad scientific evidence for MO rehabilitation and implant loading protocols, treatment outcomes assessing different follow-ups for implant placement and implant and peri-implant variables have not been systematically reviewed. Therefore, the aim of this systematic review and meta-analysis was to assess whether ILP or ELP achieves comparable clinical outcomes related to implant (success and survival rates), peri-implant (MBL, PI, PD, BOP, ISQ) parameters when compared with those of CLP in edentulous patients rehabilitated with MO.

#### **MATERIALS AND METHODS**

This review was registered in the PROSPERO<sup>18</sup> database (http://www.

crd.york.ac.uk/PROSPERO) under the number CRD42018106559. It was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines.<sup>19</sup>

The study included randomized (RCT) and non-randomized (N-RCT) controlled clinical trials comparing the clinical parameters of MO rehabilitations with different loading protocols (ILP/ELP and CLP) in edentulous patients, according to the PICO strategy: population - edentulous patients rehabilitated with mandibular overdentures; intervention - use of immediate/early implant loading; comparison - use of conventional implant loading; and outcomes - (1) survival rate; success rate and other variables (2) [peri-implant complications: marginal bone loss (MBL), bleeding on probing (BOP), probing depth (PD) and plaque index (PI)] as well as implant stability quotient (ISQ).

Articles classified as literature reviews, letters to the editor, in vitro, in silico, observational and descriptive studies, case reports and case series were excluded and not considered for further evaluation.

Two reviewers (G. A. B. and R. C. C.) independently screened all studies by their titles and abstracts for possible inclusion. In cases of any disagreement, a third team member (M. F. M.) was consulted. An extensive search was performed in the following electronic databases: PubMed (MEDLINE), Scopus, Web of Science, Virtual Health Library (VHL) and Cochrane Library . The grey literature was also searched via the System for Information on Grey Literature in Europe (SIGLE) through OpenGrey. The entire electronic strategy was developed with MeSH terms/synonyms and free terms, preventing any restriction of words and enhancing the search for articles (see Appendix A for details on search strategy).

Records identified through all databases were input into reference management

software (Mendeley Desktop 1.19.4, Elsevier). Duplicate entries were excluded according to authors' names, the titles of references and year of publication. Subsequently, two reviewers (G. A. B. and R. C. C.) independently screened all studies by their titles and abstracts for possible inclusion. After selecting potential papers, the same authors reviewed and read the full texts to clearly determine whether or not the articles would be included. In cases of any disagreement, a third team member (M. F. M.) was consulted to reach a consensus about eligibility. Multiple articles from the same study were associated under a single report (the most recent publication).

The quality of the included articles in quantitative synthesis was independently evaluated by two reviewers (G. A. B. and R. C. C.). The RCT were carried out according to the Cochrane Collaboration tool to assess the risk of bias, as recommended in the Cochrane Handbook for Systematic Reviews of Interventions (version 5.1.0)

(http://handbook.cochrane.org). Due to the obvious differences between and among the treatment groups, neither the patient nor the examiner could be blinded, and this section was evaluated as 'not applicable'. The methodological quality for N-RCT studies was assessed according to the ROBINS-I tool (Risk of Bias in Non-randomized Studies of Interventions).<sup>20</sup> Throughout the risk-of-bias evaluation, any disagreements between reviewers were discussed and solved by a third reviewer (L. C. M.).

Data from the studies were analyzed with Comprehensive Meta-Analysis software (version 3.2; Biostat) to evaluate the influence of ILP/ELP and CLP, to calculate the estimated effect and to create the forest and funnel plots. Sub-grouped analyses were conducted based on the follow-up periods evaluated within studies. Since the studies reported different time points for all parameters, the standard mean differences (SMDs) were applied with the 95% confidence interval (CI) when continuous data were included.<sup>21</sup> For dichotomous data, risk difference (RD) was adopted. Heterogeneity was tested with the I<sup>2</sup> index. The random-effects model was used because the studies were not functionally equivalent, in which case the objective was to generalize the results from the meta-analysis.<sup>21</sup>

The certainty of the evidence (certainty in the estimates of effect) was determined for the outcome by means of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.<sup>22</sup>

#### RESULTS

The last search was performed on March 3, 2019, resulting in a total of 14,234 records identified through electronic and manual searches (Fig. 1). After exclusion of duplicates, titles and abstracts were screened, and 56 studies remained for full-text assessment, of which 33 articles were excluded. The hand search did not add any additional references. For this systematic review, 23 studies<sup>23-45</sup> were analyzed for the qualitative synthesis, while 22 studies<sup>23-42,44,45</sup> were included in the quantitative analysis.



Figure 1. Flow diagram of the search results from the databases.

The data extracted from the included studies are detailed in Table 1. The follow-ups of the included articles ranged from: 3 months;<sup>25</sup> 1 year;<sup>23,29,30,33,40,45</sup> 2 years;<sup>24,28,31,34,38,39,41,44</sup> 3 years;<sup>26,32,35,37,42</sup> 7 years;<sup>43</sup> 10 years;<sup>36</sup> to 14 years.<sup>27</sup> At the end of the study, 841 patients were included throughout the articles and 1,874 implants were placed. The study group (ILP/ELP) was represented by 436 patients and 1,046 implants, while the comparison group (CLP) had 381 patients and 780 implants installed. Only one article<sup>43</sup> did not report the specific numbers of patients and implants in each group.

The ILP was tested in 19 papers,<sup>25,26,28–37,39–45</sup> and four studies<sup>23,24,27,38</sup> evaluated the ELP, both compared with CLP. Implant insertion torque was required by 11 studies<sup>25–27,29,30,33,34,40–42,45</sup> in attempts to conduct ILP/ELP, and the values ranged from  $\geq$ 20 Ncm<sup>40</sup> to  $\geq$ 48 Ncm.<sup>30</sup>

However, if insertion torque was not required, two studies<sup>25,26</sup> switched patients for the control group. One<sup>30</sup> replaced the implant for another with a larger diameter; four<sup>29,34,40,42</sup> excluded the patients from the research but kept them under treatment; and the remaining four<sup>27,33,41,45</sup> lacked information regarding the clinical approach.

Among the studies, the overdenture design included the use of one,<sup>34</sup> two,<sup>23–</sup> <sup>25,27,30,32,35,38,40,42–44</sup> three<sup>41</sup> and four<sup>26,28</sup> implants. Two studies<sup>29,45</sup> had additional groups and used two and four implants as MO retainers. Regarding the connection system, different attachments were used: locator,<sup>26,40</sup> equator,<sup>25</sup>, magnetic,<sup>35</sup> bar<sup>27,28,30,31,39,41,42</sup> and ball.<sup>23,24,32,34,37,43,44</sup> Two studies<sup>29,45</sup> had additional groups and used two different attachments, with the first<sup>29</sup> using equator and ball, and the second<sup>45</sup> using ball and bar.

The quality control and risk-of-bias assessments indicated that five RCT<sup>29,33,34,40,45</sup> had low risk of bias, while nine<sup>24–26,32,35,37,42–44</sup> had an unclear risk of bias, due mainly to insufficient information about the randomization, allocation concealment, incomplete outcome data and other sources of bias. Although some minor and major problems were identified, the minority of the studies were assessed as having high risk of bias<sup>28,31,38,39</sup> (Fig. 2). Regarding N-RCT, all four articles<sup>23,27,36,41</sup> presented moderate risk of bias (Fig. 3). This result was attributed mainly to bias in the selection of participants for the study as well as to missing data.

Of the 23 articles included for qualitative analysis, only one<sup>43</sup> lacked sufficient information for further quantitative evaluation. The main reason was the absence of sample numbers in each group. The corresponding author was contacted but the requested information was not forthcoming. In addition, the four articles included, which compared ELP with CLP, did provide sufficient data for the majority of the outcomes; subsequent evaluation only for ISQ and BOP was not possible. For those variables, ILP was the testing group.



**Figure 2.** Quality assessment for risk of bias in randomized studies. Risk of bias explanation: low (green), high (red), or unclear (yellow).



**Figure 3.** Quality assessment for risk of bias in non-randomized studies. Risk of bias explanation: low (blue); moderate (orange); serious (red).

The implants installed with ILP presented similar means of BOP compared with implants installed with CLP at 3 months (SMD -0.077 [-0.615, 0.462], P = .78,  $I^2 = 71\%$ ), 6 months (SMD -0.003 [-0.467, 0.461], P = .991,  $I^2 = 76\%$ ), 12 months (SMD 0.40 [-0.310, 0.389], P = .824,  $I^2 = 58\%$ ), 24 months (SMD 0.021 [-0.257, 0.299], P = .882,  $I^2 = 0\%$ ), 36 months (SMD 0.081 [-0.277, 0.439], P = .659,  $I^2 = 0\%$ ) and pooled results (SMD 0.026 [-0.139, 0.190], P = .760,  $I^2 = 55\%$ ) (Fig. 4A) with low certainty of evidence (Table 2).



**Figure 4.** Forest plot of standard mean difference for clinical outcomes (bleeding on probing and implant stability quotient) in immediate loading protocol vs. conventional loading protocol. A, Forest plot of bleeding on probing. B, Forest plot of implant stability quotient.

# **Table 2.** Evidence profile: Immediate/early compared with conventional loading protocol for peri-implant and implant parameters

		C	ertainty ass	essment		Summary of findings								
							Study even	t rates (%)		Anticipated	l absolute effects			
№ of participants (studies) Follow-up	Risk of bias	Inconsi stency	Indirect ness	Imprecis ion	Publication bias	Overall certainty of evidence	With Conventional loading	With Immediate/e arly loading	Relative effect (95% CI)	Risk with Conventiona I loading	Risk difference with Immediate/early loading			
Bleeding on pr	obing													
325 (4 RCTs)	very serious <sup>a</sup>	serious <sup>b</sup>	not serious	serious <sup>c</sup>	very strong association	⊕⊕⊖⊖ Low	146	179	-	-	SMD 0.026 SD higher (0.139 lower to 0.190 higher)			
Marginal bone loss														
667 (10 RCTs)	serious <sup>d</sup>	very serious <sub>b,e</sub>	not serious	not serious	very strong association	⊕⊕⊕⊖ MODERATE	312	355	-	-	SMD 0.082 SD higher (0.082 lower to 0.247 higher)			
Plaque index		-												
369 (5 RCTs)	serious <sup>d</sup>	not serious	not serious	serious <sup>c</sup>	very strong association	⊕⊕⊕⊕ HIGH	166	203	-	-	SMD 0.157 SD higher (0.031 higher to 0.284 higher)			
Probing depth														
435 (6 RCTs)	not serious	very serious b	not serious	not serious	very strong association	⊕⊕⊕⊕ HIGH	200	235	-	-	SMD 0.140 SD higher (0.060 lower to 0.340 higher)			
Stability														
547 (10 RCTs)	serious <sup>d</sup>	very serious <sub>b,e</sub>	not serious	not serious	very strong association	⊕⊕⊕⊖ MODERATE	288	259	-	-	SMD 0.102 SD higher (0.072 lower to 0.278 higher)			
Success						•								
584 (9 RCTs)	not serious	not serious	not serious	not serious <sup>f</sup>	very strong association	⊕⊕⊕⊕ HIGH	81/284 (28.5%)	84/300 (28.0%)	RD -0.014 (-0.046 to 0.017)	285 per 1.000	289 fewer per 1.000 (298 fewer to 280 fewer)			
Survival														
1002 (15 RCTs)	serious <sup>d</sup>	not serious	not serious	not serious	very strong association	⊕⊕⊕⊕ HIGH	310/469 (66.1%)	315/533 (59.1%)	RD -0.011 (-0.037 to 0.014)	661 per 1.000	670 fewer per 1.000 (687 fewer to 652 fewer)			
CL C	Confiden	ce inter	rval: SN	ID. Stan	dardized r	nean differe	nce: RD. Ri	sk differen	ce. Expla	nations: (a)	) All included			

CI, Confidence interval; SMD, Standardized mean difference; RD, Risk difference. Explanations: (a) All included studies presented some kind of risk of bias; (b) considerable heterogeneity; (c) total number of participants is fewer than 400; (d) the effect estimate change after exclusion of studies with some type of risk of bias; (e) wide variation in the effect estimates across studies; (f) total number of events is fewer than 300.

The MBL means in implants installed with ILP/ELP were similar to those of implants installed with CLP at 6 months (SMD -0.070 [-0.806, 0.667], P = .853,  $I^2 = 91\%$ ), 12 months (SMD -0.338 [-0.612, 0.137], P = .163,  $I^2 = 87\%$ ), 24 months (SMD 0.162 [-0.072, 0.395], P = .176,  $I^2 = 0\%$ ), 36 months (SMD 0.138 [-0.146, 0.422], P = .342,  $I^2 = 0\%$ ) and pooled results (SMD 0.082 [-0.082, 0.247], P = .326,  $I^2 = 85\%$ ) (Fig. 5A) with moderate certainty of evidence (Table 2). No publication bias was detected through the Egger test (P = .10) (Fig. 6A).



**Figure 5.** Forest plot of standard mean difference for peri-implant outcomes (marginal bone loss and plaque index) in immediate/early loading protocols vs. conventional loading protocol. A, Forest plot of marginal bone loss. B, Forest plot of plaque index.



**Figure 6.** Funnel plot calculated for selected studies reporting on immediate/early loading protocols vs. conventional loading protocol. A, Funnel plot of marginal bone loss. B, Funnel plot of success. C, Funnel plot of survival.

Implants installed with CLP presented lower means of PI when compared with implants installed with ILP/ELP at 12 months (SMD 0.284 [0.022, 0.545], P = .033,  $I^2 = 35\%$ )

and on pooled results (SMD 0.157 [0.031, 0.284], P = .015,  $I^2 = 18\%$ ). However, the trends were similar for implants installed with ILP/ELP compared with those installed with CLP at 3 months (SMD 0.158 [-0.122, 0.438], P = .268,  $I^2=0\%$ ), 6 months (SMD 0.72 [-0.318, 0.461], P = .719,  $I^2 = 66\%$ ), 24 months (SMD 0.164 [-0.057, 0.384], P = .145,  $I^2 = 0\%$ ) and 36 months (SMD -0.025 [-0.383, 0.333], P = .89,  $I^2 = 0\%$ ) (Fig. 5B) with high certainty of evidence (Table 2).

The PD in implants installed with CLP presented lower means than implants installed with ILP/ELP at 36 months of follow-up (SMD 0.460 [0.098, 0.823], P = .013,  $I^2 = 0\%$ ). However, in other follow-up periods, implants installed with CLP and ILP/ELP presented similar means of PD at 3 months (SMD -0.128 [-0.493, 0.237], P = .493,  $I^2 = 39\%$ ), 6 months (SMD 0.089 [-0.531, 0.710], P = .778,  $I^2 = 89\%$ ), 12 months (SMD 0.038 [-0.591, 0.667], P = .906, I2 = 90%), 24 months (SMD 0.130 [-0.325, 0.586], P = .575,  $I^2 = 74\%$ ) and on pooled results (SMD 0.140 [-0.060, 0.340], P = .17,  $I^2 = 83\%$ ) (Fig. 7) with high certainty of evidence (Table 2).

Gi	roup by	Study name	Subgroup		Statistics for each study						
Ti	me point		within study	Stand diff	Standard error	Variance	Lower	Upper	Z-Value	<i>p</i> -Value	
03	3 months	Romeo et al., 2002	4 implants	0,014	0,225	0,051	-0,427	0,455	0,062	0,950	
03	3 months	Stephan et al., 2007	3 implants	-0,481	0,241	0,058	-0,954	-0,009	-1,996	0,046	
03	3 months	Zygogiannis et al., 2017	2 implants	0,128	0,293	0,086	-0,446	0,703	0,438	0,662	
03	3 months			-0,128	0,186	0,035	-0,493	0,237	-0,686	0,493	
06	6 months	Elsyad et al., 2014	2 implants	0,758	0,255	0,065	0,258	1,258	2,972	0,003	
06	6 months	Romeo et al., 2002	4 implants	0,016	0,225	0,051	-0,425	0,457	0,072	0,943	
06	6 months	Stephan et al., 2007	3 implants	-1,145	0,255	0,065	-1,645	-0,646	-4,491	0,000	
08	6 months	Zygogiannis et al., 2017	2 implants	0,327	0,295	0,087	-0,250	0,905	1,110	0,267	
06	6 months	Maryod et al., 2014	4 implants	0,478	0,185	0,034	0,115	0,841	2,582	0,010	
06	6 months			0,089	0,317	0,100	-0,531	0,710	0,282	0,778	
12	2 months	Elsyad et al., 2014	2 implants	0,485	0,250	0,062	-0,005	0,975	1,940	0,052	
12	2 months	Payne et al., 2002	2 implants	0,573	0,309	0,095	-0,033	1,178	1,854	0,064	
12	2 months	Romeo et al., 2002	4 implants	0,000	0,225	0,051	-0,441	0,441	0,000	1,000	
12	2 months	Stephan et al., 2007	3 implants	-1,603	0,270	0,073	-2,133	-1,073	-5,929	0,000	
12	2 months	Zygogiannis et al., 2017	2 implants	0,236	0,294	0,086	-0,340	0,812	0,803	0,422	
12	2 months	Maryod et al., 2014	4 implants	0,522	0,186	0,034	0,158	0,886	2,813	0,005	
12	2 months			0,038	0,321	0,103	-0,591	0,667	0,118	0,906	
24	4 months	Payne et al., 2002	2 implants	0,783	0,314	0,099	0,167	1,398	2,493	0,013	
24	4 months	Romeo et al., 2002	4 implants	0,103	0,225	0,051	-0,338	0,544	0,457	0,647	
24	4 months	Stephan et al., 2007	3 implants	-0.512	0.242	0.058	-0.986	-0.039	-2.121	0.034	
24	4 months	Marvod et al., 2014	4 implants	0.237	0.183	0.034	-0.122	0.596	1.293	0.196	
24	4 months	,		0.130	0.232	0.054	-0.325	0.586	0.560	0.575	
36	5 months	Marvod et al 2014	4 implants	0 460	0 185	0.034	0.098	0.823	2 489	0.013	
36	5 months			0.460	0 185	0.034	0.098	0.823	2 489	0.013	
0	verall			0,140	0,100	0.010	-0.060	0.340	1 371	0.170	
0	voran			0,140	0,102	0,010	-0,000	0,040	1,071	0,170	

Figure 7. Forest plot of probing depth.

Implants installed with CLP presented greater means of ISQ than implants installed with ILP at 3 months (SMD 0.602 [0.309, 0.895], P = .0,  $I^2 = 0\%$ ). However, at 6 months and thereafter, implants installed with CLP presented ISQ means similar to those of implants installed with ILP: 6 months of follow-up (SMD -0.109 [-0.781, 0.564], P = .751,  $I^2 = 90\%$ ), 12 months (SMD -0.201 [-0.498, 0.095], P = .183,  $I^2 = 51\%$ ), 24 months (SMD -0.157 [-0.824, 0.510], P = .644,  $I^2 = 80\%$ ), 36 months (SMD -0.161 [-0.609, 0.287], P = .481,  $I^2 = 0\%$ ) and on pooled results (SMD 0.102 [-0.073, 0.278], P = .254,  $I^2 = 80\%$ ) (Fig. 4B) with moderate certainty of evidence (Table 2).

Success rate for implants installed with CLP presented failure incidences similar to those of implants installed with ILP/ELP at 4 months (RD -0.05 [-0.213, 0.113], P = .546,  $I^2 = 0\%$ ), 12 months (RD -0.015 [-0.064, 0.034], P = .55,  $I^2 = 29.5\%$ ), 24 months (RD 0.005 [-0.041, 0.05], P = .839,  $I^2 = 22\%$ ) and 168 months of follow-up (RD -0.105 [-0.213, 0.113], P = .057,  $I^2 = 0\%$ ) and pooled results (RD -0.014 [-0.046, 0.017], P = .366,  $I^2 = 23\%$ ) (Fig. 8A) with high certainty of evidence (Table 2). No publication bias was detected through the Egger test (P = .29) (Fig. 6B).

The implant survival rate with CLP were similar to those of implants installed with ILP/ELP at 3 months (RD -0.050 [-0.213, 0.113], P = .546,  $I^2 = 0\%$ ), 12 months (RD -0.004 [-0.091, 0.083], P = .924,  $I^2 = 58\%$ ), 24 months (RD -0.020 [-0.062, 0.022], P = .352,  $I^2 = 48\%$ ), 36 months (RD -0.006 [-0.046, 0.033], P = .749,  $I^2 = 10\%$ ) and 120 months of follow-up (SMD 0.00 [-0.073, 0.073], P = 1.0,  $I^2 = 0\%$ ) and in pooled results (RD -0.011 [-0.037, 0.014], P = .376,  $I^2 = 24\%$ ) (Fig. 8B) with high certainty of evidence (Table 2). No publication bias was detected through the Egger test (P = .70) (Fig. 6C).

## <u>(A)</u>

Group by	Study name	Subgroup	Statistics for each study							
Time point		within study	Stand diff In means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value	
04 months	Bielemann et al., 2018	2 implants	-0,050	0,083	0,007	-0,213	0,113	-0,603	0,546	
04 months			-0,050	0,083	0,007	-0,213	0,113	0,603	0,546	
12 months	Aunmeungtong et al., 2017	4 and 2 implants	0,000	0,019	0,000	-0,038	0,038	0,000	0,001	
12 months	Zygogiannis et al., 2017	4 and 2 implants	-0,057	0,044	0,002	-0,142	0,029	-1,302	0,193	
12 months			-0,015	0,025	0,001	-0,064	0,034	-0,597	0,550	
24 months	Romeo et al., 2002	4 implants	0,025	0,034	0,001	-0,042	0,092	0,736	0,462	
24 months	Turkyilmaz & Tumer, 2007	2 implants	0,000	0,047	0,002	-0,092	0,092	0,000	1,000	
24 months	Chiapasco et al., 2001	4 implants	0,000	0,035	0,001	-0,068	0,068	0,000	1,000	
24 months	Payne et al., 2002	2 implants	0,083	0,066	0,004	-0,046	0,213	1,259	0,208	
24 months	Tawse-Smith et al., 2002	2 implants	-0,125	0,071	0,005	-0,264	0,014	-1,763	0,078	
24 months			0,005	0,023	0,001	-0,041	0,050	0,204	0,839	
168 months	Alfadda et al., 2019	2 implants	-0,105	0,055	0,003	-0,214	0,003	-1,900	0,057	
168 months			-0,105	0,055	0,003	-0,214	0,003	-1,900	0,057	
Overall			-0,014	0,016	0,000	-0,046	0,017	-0,905	0,366	

Immediate/ Early Loading Conventional Loading

**(B)** 

Group by	Study name	Subgroup			Statistics	for each	study		
Time point		within study	Stand diff In means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
03 months	Bielemann et al., 2018	2 implants	-0,050	0,083	0,007	-0,213	0,113	-0,603	0,546
03 months			-0,050	0,083	0,007	-0,213	0,113	-0,603	0,546
12 months	Elsyad et al., 2014	2 implants	-0,059	0,048	0,002	-0,153	0,035	-1,227	0,220
12 months	Schincaglia et al., 2016	2 implants	-0,063	0,051	0,003	-0,163	0,038	-1,218	0,223
12 months	Zygogiannis et al., 2017	2 and 4 implants	0,200	0,092	0,009	0,019	0,381	2,166	0,030
12 months	Røynesdal et al., 2001	2 implants	0,000	0,051	0,003	-0,100	0,100	0,000	1,000
12 months			-0,004	0,044	0,002	-0,091	0,083	-0,095	0,924
24 months	Kern et al., 2018	1 implant	-0,098	0,037	0,001	-0,171	-0,025	-2,636	0,008
24 months	Stephan et al., 2007	3 implants	0,000	0,028	0,001	-0,056	0,056	0,000	1,000
24 months	Assad et al., 2007	4 implants	0,000	0,026	0,001	-0,050	0,050	0,000	1,000
24 months	Chiapasco et al., 2001	4 implants	0,000	0,035	0,001	-0,068	0,068	0,000	1,000
24 months			-0,020	0,022	0,000	-0,062	0,022	-0,930	0,352
36 months	Acham et al., 2017	4 implants	0,000	0,026	0,001	-0,050	0,050	0,000	1,000
36 months	Elsyad et al., 2012	2 implants	-0,059	0,049	0,002	-0,155	0,037	-1,199	0,231
36 months	Ter Gunne et al., 2016	2 implants	0,025	0,036	0,001	-0,046	0,096	0,690	0,490
36 months	Komagamine et al., 2018	2 implants	0,125	0,095	0,009	-0,062	0,312	1,313	0,189
36 months	Maryod et al., 2014	4 implants	-0,050	0,043	0,002	-0,133	0,033	-1,175	0,240
36 months			-0,006	0,020	0,000	-0,046	0,033	-0,319	0,749
120 months	Kourtis et al., 2018	4 implants	0,000	0,037	0,001	-0,073	0,073	0,000	1,000
120 months			0,000	0.037	0.001	-0.073	0.073	0.000	1.000
Overall			-0.011	0.013	0.000	-0.037	0.014	-0.885	0.376

**Figure 8.** Forest plot of standard mean difference for clinical outcomes (success and survival) in immediate/early loading protocol vs. conventional loading protocol. A, Forest plot of success. B, Forest plot of survival.

Author, Year	Journa l	Study design	Follow -up	Compariso n	No. of patient	Mean Age ± Stand.	Timing of loading	Inserti on		Implant	_	Implan ts/patie	Insertion area	Attachmen t
		ussign	чр		s	Dev. (years)	Tomanig	torque	Length (mm)	Diamete r (mm)	Brand	nt		
Acham et al., 2017	CIDRR	RCT	3Y	G1; ILP G2; CLP	G1; 8 G2; 12	69 ± 5	G1; surgery day G2; At 3 months	G1; ≥ 30 Ncm	3.5 to 4.5	11 to 13	Neoss Implant System	4	Interforaminal	Locator
Alfadda et al, 2019	JPD	N-RCT	14 Y	G1; ELP G2; CLP	G1; 35 G2; 16	G1; 62.41 $\pm$ 11.25 G2; 62.99 $\pm$ 7.86	G1; 10 days G2; 3-4 months	≥ 35 Ncm	3.75	7 to 18	Nobel Biocare	2	Interforaminal	Bar
Assad et al., 2007	ID	RCT	2Y	G1; ILP G2; CLP	G1; 5 G2; 5	48-63	G1; 4 days G2; 4 months	NR	3.7	13	Paragon dental implants	4	Interforaminal	Bar
Aunmeungton g et al., 2017	CIDRR	RCT	1Y	G1 and G2; ILP G3; CLP	G1; 20 G2; 20 G3; 20	$\begin{array}{c} G1; 69.2 \\ \pm 11.2 \\ G2; 66.6 \\ \pm 6.28 \\ G3; 73.8 \\ \pm 10.4 \end{array}$	G1 and G2; surgery day G3; At 3 months	G1; 30- 55 Ncm	G1 and G2; 3 G3; 3.75	G1 and G2; 12 G3; 10	G1 and G2; PW plusVR G3; Type3; PW plus	G1; 4 G2 and G3; 2	G1; Interforaminal G2 and G3; Canine region	G1 and G2; Equator G3; Ball
Bielemann et al., 2018	JPR	RCT	3 M	G1; ILP G2; CLP	G1; 10 G2; 10	66.9 ± 6.61	G1; surgery day G2; 3 months	G1; ≥ 30 Ncm	2.9	10	Neodent	2	Midline	Equator
Cannizzaro et al., 2008	EJOI	RCT	1Y	G1; ILP G2; CLP	G1; 30 G2; 30	G1; 62 G2; 61	G1; surgery day G2; At 3 months	G1; ≥ 48 Ncm	3.7 and 4.8	10, 12 and 14	Zimmer Dental	2	Anterior region	Bar
Chiapasco et al., 2001	IJOMI	RCT	2Y	G1; ILP G2; CLP	G1; 10 G2; 10	58.4	G1; 3 days G2; 4 to 8 months	NR	3.75	13	Nobel Biocare	4	Anterior region	Bar
Elsyad et al, 2012	COIR	RCT	3Y	G1; ILP G2; CLP	G1; 18 G2; 18	G1; 63.2 G2; 64.6	G1; surgery day G2; At 3 months	NR	3.7; 4.7; 5.7	10, 13, 16	Implant s Direct LLC	2	Canine region	Ball
Elsyad et al., 2014	JOR	RCT	1Y	G1; ILP G2; CLP	G1; 18 G2; 18	59.6	G1; surgery day G2; At 3 months	G1; ≥ 35 Ncm	3.7; 4.2; 4.8	11; 13; 15	Tiologic Implant s Dentaur um	2	Canine region	Ball

**TABLE 1.** Summary data from included studies (author, year; journal; study design; follow-up; comparison; no. of patients; mean age; timing of loading)
# Table 1. (Continue)

	Journa	Study	Follow	Compariso	No. of	Mean Age	Timing of	Inserti		Implant		Implan	Insertion	Attachmen
Author, 1 ear	1	design	-up	'n	s s	± Stand. Dev. (years)	loading	on torque	Length (mm)	Diamete r (mm)	Brand	ts/patie nt	area	t
Ter Gunne et al., 2016	IJOMI	RCT	3Y	G1; ILP G2; CLP	G1; 20 G2; 20	NR	G1; 48 hours G2; 6 weeks	≥ 35 Ncm	3.3 or 4.1	8 to 12	Strauma nn	2	Canine region	Bar
Kern et al., 2018	JDR	RCT	2Y	G1; ILP G2; CLP	G1; 81 G2; 77	60–89	G1; surgery day G2; At 3 months	G1 and G2; ≥ 30 Ncm	3.8	11	Camlog Biotech nologies	1	Midline	Ball
Komagamine et al., 2018	CIDRR	RCT	3 Y	G1; ILP G2; CLP	G1; 10 G2; 9	68.4 ± 9.9	G1; surgery day G2; 3 months	NR	4	10 to 18	Nobel Biocare	2	Interforaminal	Magnetic
Kourtis et al., 2018	JERD	N-RCT	10 Y	G1; ILP G2; CLP	G1; 10 G2; 5	61.6	G1; surgery day G2; 3 months	NR	3.5	NR	Dentspl y	4	Interforaminal	Telescopic
Maryod et al., 2014	IJP	RCT	3 Y	G1; ILP G2; CLP	G1; 16 G2; 16	G1; 63.4 G2; 64.8	G1; surgery day G2; 3 months	NR	1.8	15	3М	4	Interforaminal	Ball
Payne et al., 2002	COIR	RCT	2Y and 2M	G1; ELP G2; CLP	G1; 12 G2; 12	55–80	G1; 6 weeks G2; 12 weeks	NR	NR	NR	ITI implants	2	22 mm apart either side of the midline	NR
Romeo et al., 2002	COIR	RCT	2 Y	G1; ILP G2; CLP	G1; 10 G2; 10	63.2	G1; 2 days G2; 3/4 months	NR	3.3 or 4.1	10	ITI implants	4	Interforaminal	Bar
Røynesdal et al., 2001	IJOMI	N-RCT	1 Y	G1; ELP G2; CLP	G1; 11 G2; 10	75.7	G1; 2 to 3 weeks G2; 3 months	NR	3.3 or 4.1	10 to 16	ITI implants	2	Interforaminal	Ball
Schincaglia et al., 2016	IJOMI	RCT	1Y	G1; ILP G2; CLP	G1; 16 G2; 15	66.4 ±9.3	G1; surgery day G2; At 3 months	G1; ≥ 20 Ncm	4	8 to 15	Dentspl y	2	Canine region	Locator
Stephan et al., 2007	JPD	N-RCT	2Y	G1; ILP G2; CLP	G1; 17 G2; 9	63.5 ±8.3	G1; 2 days G2; 3 months	≥ 30 Ncm	3.75	10 to 13	Nobel Biocare	3	Midline and other two were placed 12 to 15 mm distal	Bar

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Author Vear	Journa	a Study design	Follow	Compariso	No. of	Mean Age ± Stand. Dev. (years)	Timing of loading	Inserti	Implant			Implan ts/natie	Insertion	Attachmen
Aution, I car	1		-up	n	s			torque	Length (mm)	Diamete r (mm)	Brand	nt	area	t
Tawse-Smith et al., 2002	CIDRR	RCT	2Y and 2M	G1; ELP G1a; CLP G2; ELP G2a; CLP	G1; 12 G1a; 12 G2; 12 G2a; 12	55-88	G1; 6 weeks G1a; 12 weeks G2; 6 weeks G2a; 12 weeks	NR	G1; 3.8 G1a; 3.8 G2; 3.75 G2a; 3.75	G1; 12 G1a; 12, 14, 16 G2; 10, 13, 15, 18 G2a; 10, 15, 18	Nobel Biocare	2	11 mm apart from midline	Ball
Turkyilmaz & Tumer, 2007	JOR	RCT	2 Y	G1; ILP G2; CLP	G1; 10 G2; 10	62	G1; 1 weeks G2; 3 months	NR	NR	15	Nobel Biocare	2	Canine region	Ball
Turkyilmaz et al., 2012	CIDR R	RCT	7 Y	G1; ILP G2; CLP	G1; NR G2; NR	63	G1; 1 weeks G2; 3 months	NR	3.75	15	Nobel Biocare	2	Canine region	Ball
Zygogiannis et al., 2017	IJOMI	RCT	1 Y	G1; ILP G2a; ILP G2b; CLP	G1; 25 G2a; 15 G2b; 10	67.9 ±7.7	G1; surgery day G2a; 2 days G2b; 3 months	≥ 30 Ncm	G1; 1.8, 2.1, 2.4 G2a; 3.3, 4.1 G2b; 3.3, 4.1	G1; 10, 13, 15, 18 G2a; 10, 12 G2b; 10, 12	G1; 3M ESPE G2a and G2b; Strauma nn	G1; 4 G2a; 2 G2b; 2	G1; Interforaminal G2a; Canine region G2b; Canine region	G1; Ball G2; Bar G3; Bar

The study not included in the meta-analysis is highlighted in bold. CIDRR, Clinical Implant Dentistry and Related Research; JPD, Journal of Prosthetic Dentistry; ID, Implant Dentistry; JPR, Journal of Periodontal Research; EJOI, European Journal of Oral Implantology; IJOMI, The International Journal of Oral & Maxillofacial Implants; COIR, Clinical Oral Implants Research; JOR, Journal of Oral Rehabilitation; JDR, Journal of Dental Research; JERD, Journal of Esthetic and Restorative Dentistry; IJP, The International Journal of Prosthodontics; RCT, randomized clinical trial; N-RCT, non-randomized clinical trial; ILP, immediate loading protocol; ELP, early loading protocol; CLP, conventional loading protocol; NR, not reported.

#### DISCUSSION

Patient preference for minimally long-lasting treatment options such as rehabilitation with ILP/ELP for dental implants is high for esthetic and functional reasons.<sup>46</sup> However, long-term assessment for MO has not been done for success and survival rates related to loading protocols. In addition, the effects of peri-implant variables are also lacking in the literature. Hence, a broad PICO question and search strategy was used to answer the following question: In edentulous patients receiving MOs, what are the clinical effects of ILP/ELP compared with those of CLP?

In the results of our meta-analysis, the ISQ standard mean difference was significantly higher for the CLP at 3 months. A similar result was found by Bielemann et al., who, in a prospective study with MOs retained by two implants, reported lower ISQ values for ILP when compared with those of the CLP up to 3 months of follow-up.<sup>25</sup> However, for other time periods (6, 12, 24 and 36 months), also evaluated in this meta-analysis, no difference was found between ILP and CLP, even for pooled results. These findings may not be surprising, since the interface anchorage between bone and implant seems to be decreased, especially in early phases of implant loading, due to bone remodeling.<sup>47</sup> Conversely, the ISQ values of osseointegrated implants have been proven to increase over time.<sup>26,48</sup>

Regarding the assessment of PI, mean standard differences were higher for the ILP/ELP compared with the CLP in overall and subgroup analyses at 12 months of follow-up. Similar increases in plaque scores for ILP compared with CLP were observed in a clinical trial with MOs at 6 and 12 months of follow-up.<sup>37</sup> These results are in contrast to those of previous studies that demonstrated comparable PI scores in ILP/ELP and CLP for 1,<sup>33,45</sup> 2,<sup>38,41</sup> 3<sup>32</sup> and even 7<sup>43</sup> years of follow-up. We suggest that the PI difference found in this review may not be associated with the loading protocol itself, but rather with the attachment system, specifically the type of matrix used.<sup>47,49</sup> Furthermore, the resiliency in the matrix among

different systems (bar and ball) can be compromised over the years by saliva and also by insertion and removal of the prosthesis. This may increase overdenture movement, leading to food accumulation and plaque formation under the prosthesis. This scenario will require reactivation or even replacement of the matrix; however, this maintenance procedure can be easily accomplished in daily practice.<sup>50</sup>

The peri-implant hard- and soft-tissue indices (PD and MBL) have been previously reported to be correlated.<sup>47</sup> It seems that, in successful implants, the MBL over time is minimal (2 mm at 1 year and 0.2 mm per year) and major changes in the peri-implant hard and soft tissues occur mostly during the healing period and in the early period of loading.<sup>51,52</sup> For this review, no significant difference was found in overall analysis for PD and MBL in both loading protocols (ILP/ELP and CLP). However, for subgroup analysis, only PD had a significant difference at 36 months of follow-up, leading to lower PD for the CLP compared with ILP/ELP. This result may be related to the fact that just one study was available for analysis of the mentioned time point.

The assessment of BOP is a classic indicator for distinguishing between periimplant health and disease, based on mechanical stimulation of the sulcus/pocket.<sup>53</sup> In the present review, meta-analysis indicated similar values of bleeding on probing between ILP and CLP. However, according to the GRADE approach, the evidence was classified as low, which means that the true effect is unlikely to be close to the estimated effect.<sup>22</sup> Thus, the findings suggest that heterogeneity among the studies could have been responsible for the inconsistent results. Two studies included for this review had patients with smoking habits, smoking either 10<sup>41</sup> or 20<sup>39</sup> cigarettes per day. These tobacco-smokers might underestimate the outcome, since nicotine exerts a vasoconstrictive effect on blood flow, which reduces gingival bleeding.<sup>54,55</sup> The findings of the present review should be confirmed by welldesigned randomized clinical trials. Regarding the exclusion section, there were confounders in the included studies, limiting recommendations for the superiority of one loading protocol over the other.

Comprehensive evaluation of implant survival rates is based on the dichotomous nature of this outcome, whether the implant is or is not in the alveolar bone, while the success criteria are based not only on the implant but also on peri-implant hard- and soft-tissue health.<sup>52</sup> Given the different loading protocols reviewed (ILP/ELP and CLP), meta-analysis showed similar results for survival/success rates for initial and long-term follow-up. It appears evident that the loading protocols evaluated have no influential factor driving the outcomes observed. Previous systematic reviews of implant loading for MO acknowledge the results found in this study.<sup>15,16</sup> However, in those reviews, there were limitations of follow-up and methodological issues related to the number of studies included. From the clinical trials standpoint, success<sup>3,27,38,56</sup> and survival<sup>23,25,26,37</sup> rates for ILP/ELP have been further documented, with values comparable to those with CLP.

The present review has revealed a limited number of studies comparing ELP with CLP but was not accompanied by peri-implant assessment, especially for BOP and ISQ. As a consequence, meta-analysis for those outcomes could not be assessed with ELP. An increase in the corresponding papers with well-designed RCT will correctly estimate differences between and among groups. The majority of the studies were included for quantitative synthesis, except for one in which lack of information limited further inclusion. Nevertheless, publication bias (funnel plot asymmetry), as recommended by Egger, Smith, Schneider & Minder (1997),<sup>57</sup> was possible only for marginal bone loss, implant success and survival rates due to insufficient numbers of trials. For that reason, the GRADE approach was used as an alternative strategy to assess inconsistency between and among studies and, whenever data summaries resulted in low certainty of evidence, a more conservative description was used to avoid overestimation of the results.

Quality assessment of the included articles showed a high risk of bias in four studies, which were also included for meta-analysis. However, the certainty of the evidence was granted in each parameter to acknowledge the results in the meta-analysis. The outcomes (success and survival rate; MBL; PI; PD) were downgraded simultaneously in a single group (ILP/ELP), since previous meta-analysis found similar success rates with ILP/ELP when compared with CLP.<sup>16</sup>

Even though there were limitations to reports of insertion torque by some articles, further studies should focus on establishing clear parameters to include patients in either ILP or ELP. Those methodological issues, if present for all included papers, would have increased the power of evidence provided by this review. Thus, clarification of the impact of several features such as parafunction, smoking habits and implant length should be evaluated to guide clinicians when establishing treatment plans. Finally, there is minimal discussion that involves the patient in making the decision process for treatment, which may affect the outcome of therapy.

# CONCLUSIONS

Within the limitation of this systematic review and meta-analysis, the following conclusions were drawn:

1. The different loading protocols (immediate/early) demonstrated similar success and survival rates compared with those of the conventional loading protocol. Similarly, no difference between/among groups was found for marginal bone loss.

2. With regard to probing depth, lower values were associated with conventional loading at 36 months of follow-up compared with the immediate/early loading protocols. Importantly, it must be considered that only one study evaluating this follow-up loading protocol were included due to literature limitations, and further clinical studies should be designed to

enhance the results from the present review.

3. When plaque index was considered, lower indices were assessed for the conventional loading protocol compared with the immediate/early loading protocols.

4. Implant stability quotient presented favorable values for the conventional loading protocol at only 3 months, since, at subsequent follow-up periods, values similar to those of the immediate loading protocol were achieved.

5. Immediate loading protocol showed the same bleeding on probing than the conventional loading protocol.

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# Appendix A. Details on Search strategy (March, 2019)

# PubMed

# Result (n = 3, 161)

Edentulous[MeSH Terms]) OR Mouth. Edentulous[Title/Abstract]) OR Edentulous[Title/Abstract]) OR Complete edentulism[Title/Abstract]) OR Toothless[Title/Abstract]) OR Jaw[MeSH Terms]) OR Jaws[Title/Abstract]) OR Jaws[Title/Abstract]] Edentulous[MeSH Terms]) OR Edentulous Jaw\*[Title/Abstract]) OR Jaw, Edentulous[Title/Abstract]) OR Jaws, Edentulous[Title/Abstract]) OR Mandible[MeSH Terms]) OR Groove\*, Mylohyoid[Title/Abstract]) OR Mylohyoid[Title/Abstract]) OR Mylohyoid Groove\*[Title/Abstract]) Ridge\*, OR Mylohyoid Mandible[Title/Abstract]) OR Ridge\*[Title/Abstract]) OR Mandibles[Title/Abstract]) OR Mandibular[Title/Abstract]) OR Lower Jaw[Title/Abstract]) OR Dental Implants[MeSH Terms]) OR Dental Surgical Implants[Title/Abstract]) OR Prosthesis, Surgical Dental[Title/Abstract]) OR Dental Prostheses[Title/Abstract]) OR Dental Prostheses, Surgical[Title/Abstract]) OR Dental Implantation, Endosseous[MeSH Terms]) OR Dental Implantation, Endosseous[Title/Abstract]) OR Implantation, Endosseous[Title/Abstract]) OR Dental Implantation, Osseointegrated[Title/Abstract]) OR Implantation, Osseointegrated Dental[Title/Abstract]) OR Implantation, Endosseous Dental[Title/Abstract]) OR Dental Implantation[MeSH Terms]) OR Dental Implantation[Title/Abstract]) OR Prosthesis Implantation, Dental[Title/Abstract]) OR Prosthesis Implantations, Dental[Title/Abstract]) Implantation, OR Dental[Title/Abstract]) OR Denture, Overlay[MeSH Terms]) OR Denture, Overlay[Title/Abstract]) OR Overdenture\*[Title/Abstract]) OR Overlay Dentures[Title/Abstract]) OR Overlay Denture[Title/Abstract]) OR Overlay[Title/Abstract]) OR Mandibular overdenture\*[Title/Abstract]) Dentures. OR Implant Loading[MeSH Terms]) OR Dental Implant Loading, Early[Title/Abstract]) OR Dental Implant Loading, Immediate[Title/Abstract]) OR Immediately loaded[Title/Abstract]) OR Immediate functional loading[Title/Abstract]) OR Immediate-loading[Title/Abstract]) OR Loaded immediately[Title/Abstract]) OR Immediate implant loading[Title/Abstract]) OR Early occlusal loading[Title/Abstract]) OR Early prosthetic loading[Title/Abstract]) OR Early implant loading[Title/Abstract]) OR Early-loaded[Title/Abstract]) OR Early implant-loading[Title/Abstract]) OR Immediate nonfunctional loading[Title/Abstract]) OR Immediate functional loading[Title/Abstract]) OR Immediate Load\*[Title/Abstract]) OR Early Load\*[Title/Abstract]))

#### Scopus

#### Result (n = 5,708)

(TITLE-ABS-KEY("Mouth, Edentulous") OR TITLE-ABS-KEY(Edentulous) OR TITLE-ABS-KEY("Complete edentulism") OR TITLE-ABS-KEY(Toothless) OR TITLE-ABS-KEY(Jaw) OR TITLE-ABS-KEY(Jaws) OR TITLE-ABS-KEY("Jaws, Edentulous") OR TITLE-ABS-KEY("Jaw, Edentulous") OR TITLE-ABS-KEY(Edentulous Jaw\*) OR TITLE-ABS-KEY(Mandible) OR TITLE-ABS-KEY(Mandibles) OR TITLE-ABS-KEY(Mylohyoid Ridge\*) OR TITLE-ABS-KEY(Mylohyoid Groove\*) OR TITLE-ABS-KEY(Ridge\*, Mylohyoid) OR TITLE-ABS-KEY("Lower Jaw") OR TITLE-ABS-KEY(Mandibular) OR TITLE-ABS-KEY(Groove\*, Mylohyoid) OR TITLE-ABS-KEY("Dental Prostheses, Surgical") OR TITLE-ABS-KEY("Surgical Dental Prostheses") OR TITLE-ABS-KEY("Prosthesis, Surgical Dental") OR TITLE-ABS-KEY("Dental Implants") OR TITLE-ABS-KEY(Implant\*) OR TITLE-ABS-KEY("Dental Implantation, TITLE-ABS-KEY("Implantation, Endosseous Endosseous") OR Dental") OR TITLE-ABS-KEY("Implantation, Osseointegrated Dental") OR TITLE-ABS-KEY("Dental Implantation, Osseointegrated") OR TITLE-ABS-KEY("Implantation, Endosseous") OR TITLE-ABS-KEY("Dental Implantation") OR TITLE-ABS-KEY("Prosthesis Implantation, Dental") OR TITLE-ABS-KEY("Prosthesis Implantations, Dental") OR TITLE-ABS-KEY("Implantation, Dental") OR TITLE-ABS-KEY("Dental Prosthesis") OR TITLE-ABS-KEY("Prosthesis, Dental") OR TITLE-ABS-KEY("Prostheses, Dental") OR TITLE-ABS-KEY("Dental Prosthesis Retention") OR TITLE-ABS-KEY("Prosthesis Retention, Dental") OR TITLE-ABS-KEY("Dental Prosthesis, Implant-Supported") OR TITLE-ABS-KEY("Dental Prostheses, Implant-Supported") OR TITLE-ABS-KEY("Prostheses, Implant-Supported Dental") OR TITLE-ABS-KEY("Prosthesis, Implant-Supported Dental") OR TITLE-ABS-KEY("Denture, Implant-Supported") OR TITLE-ABS-KEY("Dentures, Implant-Supported") OR TITLE-ABS-KEY("Implant-Supported Dentures") OR TITLE-ABS-KEY("Prosthesis Dental, Implant-Supported") OR TITLE-ABS-KEY("Denture, Overlay") OR TITLE-ABS-KEY("Dentures, Overlay") OR TITLE-ABS-KEY("Overlay Denture") OR TITLE-ABS-KEY("Overlay Dentures") OR TITLE-ABS-KEY(Overdenture\*) OR TITLE-ABS-KEY(Implant overdenture\*) OR TITLE-ABS-KEY(Mandibular overdenture\*)) AND (TITLE-ABS-KEY("Immediate Dental Implant Loading") OR TITLE-ABS-KEY("Dental Implant Loading, Immediate") OR TITLE-ABS-KEY("Dental Implant Loading, Early") OR TITLE-ABS-KEY("Immediately loaded") OR TITLE-ABS-KEY("Immediate functional loading") OR TITLE-ABS-KEY("Immediate-loading") OR TITLE-ABS-KEY("Loaded immediately") OR TITLE-ABS-KEY("Immediate implant loading") OR TITLE-ABS-KEY("Early occlusal loading") OR TITLE-ABS-KEY("Early prosthetic loading") OR TITLE-ABS-KEY("Early implant loading") OR TITLE-ABS-KEY("Early implant loading") OR TITLE-ABS-KEY("Early-loaded") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate functional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate functional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate functional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate functional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate functional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate nonfunctional loading") OR TITLE-ABS-KEY("Immediate functional loading") OR TITLE-ABS-KE

#### Web of Science

# Result (n = 4, 111)

Topic: TS=("Mouth, Edentulous") OR TS=(Edentulous) OR TS=("Complete edentulism") OR TS=(Toothless) OR TS=(Jaw) OR TS=(Jaws) OR TS=("Jaws, Edentulous") OR TS=("Jaw, Edentulous") OR TS=(Edentulous Jaw\*) OR TS=(Mandible) OR TS=(Mandibles) OR TS=(Mylohyoid Ridge\*) OR TS=(Mylohyoid Groove\*) OR TS=(Ridge\*, Mylohyoid) OR TS=("Lower Jaw") OR TS=(Mandibular) OR TS=(Groove\*, Mylohyoid) OR TS=("Dental Prostheses, Surgical") OR TS=("Surgical Dental Prostheses") OR TS=("Prosthesis, Surgical Dental") OR TS=("Dental Implants") OR TS=(Implant\*) OR TS=("Dental Implantation, Endosseous") OR TS=("Implantation, Endosseous Dental") OR TS=("Implantation, Osseointegrated Dental") OR TS=("Dental Implantation, Osseointegrated") OR TS=("Implantation, Endosseous") OR TS=("Dental Implantation") OR TS=("Prosthesis Implantation, Dental") OR TS=("Prosthesis Implantations, Dental") OR TS=("Implantation, Dental") OR TS=("Dental Prosthesis") OR TS=("Prosthesis, Dental") OR TS=("Prostheses, Dental") OR TS=("Dental Prosthesis Retention") OR TS=("Prosthesis Retention, Dental") OR TS=("Dental Prosthesis, Implant-Supported") OR TS=("Dental Prostheses, Implant-Supported") OR TS=("Prostheses, Implant-Supported Dental") OR TS=("Prosthesis, Implant-Supported Dental") OR TS=("Denture, Implant-Supported") OR TS=("Dentures, Implant-Supported") OR TS=("Implant-Supported Dentures") OR TS=("Prosthesis Dental, Implant-Supported") OR TS=("Denture, Overlay") OR TS=("Dentures, Overlay") OR TS=("Overlay") Denture") OR TS=("Overlay Dentures") OR TS=(Overdenture\*) OR TS=(Implant overdenture\*) OR TS=(Mandibular overdenture\*)

#### AND

Topic: TS=("Immediate Dental Implant Loading") OR TS=("Dental Implant Loading, Immediate") OR TS=("Dental Implant Loading, Early") OR TS=("Immediately loaded") OR TS=("Immediate functional loading") OR TS=("Immediate-loading") OR TS=("Immediate-loading") OR TS=("Immediate-loading") OR TS=("Early prosthetic loading") OR TS=("Early implant loading") OR TS=("Early-loaded") OR TS=("Early implant-loading") OR TS=("Immediate nonfunctional loading") OR TS=("Immediate functional loading") OR TS=("Immediate functional loading") OR TS=("Early implant-loading") OR TS=(Early-loaded") OR TS=(Early-loaded") OR TS=(Early implant-loading") OR TS=(Early-loaded") OR TS=(Early-loaded) OR TS

#### Virtual Health Library

#### Result (n = 432)

(mh:("Mouth, Edentulous")) OR (tw:("Mouth, Edentulous")) OR (tw:(Edentulous)) OR (tw:("Complete edentulism")) OR (tw:(Toothless)) OR (mh:(Jaw)) OR (tw:(Jaws)) OR (tw:(Jaw)) OR (mh:("Jaw, Edentulous")) OR (tw:("Jaws, Edentulous" )) OR (tw:("Jaw, Edentulous")) OR (tw:(Edentulous Jaw\$)) OR (mh:(Mandible )) OR (tw:(Mandibles )) OR (tw:(Mandible)) OR (tw:(Mylohyoid Ridge\$)) OR (tw:(Mylohyoid Groove\$)) OR (tw:(Ridge\$, Mylohyoid)) OR (tw:(Groove\$, Mylohyoid)) OR (tw:("Lower Jaw")) OR (tw:(Mandibular)) OR (mh:("DENTAL IMPLANTS")) OR (tw:(Implant\$)) OR (tw:("Dental Prostheses, Surgical")) OR (tw:("Surgical Dental Prostheses")) OR (tw:("Prosthesis, Surgical Dental")) OR (tw:("Dental Implants")) OR (mh:("DENTAL IMPLANTATION, ENDOSSEOUS")) OR (tw:("Implantation, Endosseous Dental")) OR (tw:("Implantation, Osseointegrated Dental")) OR (tw:("Dental Implantation, Osseointegrated")) OR (tw:("Implantation, Endosseous")) OR (tw:("Dental Implantation, Endosseous")) OR (mh:("DENTAL IMPLANTATION")) OR (tw:("Prosthesis Implantation, Dental")) OR (tw:("Implantation, Dental")) OR (tw:("Prosthesis Implantations, Dental)) OR (tw:("Dental Implantation)) OR (mh:("DENTURE, OVERLAY")) OR (tw:("Dentures, Overlay")) OR (tw:("Overlay Denture")) OR (tw:("Overlay Dentures")) OR (tw:(Overdenture\$)) OR (tw:("Denture, Overlay")) OR (tw:(Implant overdenture\$)) OR (tw:(Mandibular overdenture\$)) AND (mh:("Immediate Dental Implant Loading")) OR (tw:("Dental Implant Loading, Immediate")) OR (tw:("Dental Implant Loading, Early")) OR (tw:("Early implant loading")) OR (tw:("Early

#### Cochrane Library

#### Result (n = 818)

#1 MeSH descriptor: [Mouth, Edentulous] explode all trees; #2 (Mouth OR Edentulous OR Edentulous OR Complete OR Edentulism Toothless):ti,ab,kw; #3 MeSH descriptor: [Jaw] explode all trees; #4 (Jaws OR Jaw):ti,ab,kw; #5 MeSH descriptor: [Jaw, Edentulous] explode all trees; #6 (Jaws, Edentulous OR Jaw, Edentulous OR Edentulous Jaw\*):ti,ab,kw; #7 MeSH descriptor: [Mandible] explode all trees; #8 (Mandibles OR Mandible OR Mylohyoid Ridge\* OR Mylohyoid Groove\* OR Ridge\*, Mylohyoid OR Groove\*, Mylohyoid OR Lower Jaw OR Mandibular):ti,ab,kw; #9 MeSH descriptor: [Dental Implants] explode all trees; #10 (Implant\* OR Dental Prostheses, Surgical OR Surgical Dental Prostheses OR Prosthesis, Surgical Dental OR Dental Implants):ti,ab,kw; #11 MeSH descriptor: [Dental Implantation, Endosseous] explode all trees; #12 (Implantation, Endosseous Dental OR Implantation, Osseointegrated OR Implantation, Endosseous OR Dental Implantation, Endosseous):ti,ab,kw; #13 MeSH descriptor: [Dental Implantation, Dental OR Implantation] explode all trees; #14 (Prosthesis Implantation, Dental OR Implantation, Dental OR Dental Implantation, Dental OR Dental Implantation] explode all trees; #14 (Prosthesis Implantation, Dental OR Implantation, Dental OR Dental Implantation, Dental OR Dental Implantation] explode all trees; #14 (Prosthesis Implantation, Dental OR Implantation, Dental OR Dental Implantation, Dental OR Dental Implantation, Dental OR Implantation, Dental OR Dental Implantation, Dental OR Implantation, Dental OR Overlay Denture OR Overlay Dentures OR Overlay OR Overlay OR Overlay Dentures OR Overlay Denture\*):ti,ab,kw

#17 = #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16

#18 MeSH descriptor: [Immediate Dental Implant Loading] explode all trees; #19 (Dental Implant Loading, Immediate):ti,ab,kw; #20 (Dental Implant Loading, Early):ti,ab,kw; #21 (Early implant loading):ti,ab,kw; #22 (Early implant-loading):ti,ab,kw; #23 (Early Load\*):ti,ab,kw; #24 (Early occlusal loading):ti,ab,kw; #25 (Early prosthetic loading):ti,ab,kw; #26 (Early-loaded):ti,ab,kw; #27 (Immediate functional loading):ti,ab,kw; #28 (Immediate functional loading):ti,ab,kw; #29 (Immediate implant loading):ti,ab,kw; #30 (Immediate Load\*):ti,ab,kw; #31 (Immediate nonfunctional loading):ti,ab,kw; #32 (Immediate-loading):ti,ab,kw; #33 (Immediate):ti,ab,kw; #34 (Loaded immediate):ti,ab,kw

#35 = #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34

36 = #17 and #18

#### OpenGrey

#### Result (n = 4)

<sup>(&</sup>quot;Mouth, Edentulous" OR Edentulous OR "Complete edentulism" OR Toothless OR Jaw OR Jaws OR "Jaws, Edentulous" OR "Jaw, Edentulous" OR "Edentulous Jaw" OR Mandible OR Mandibles OR "Mylohyoid Ridge" OR "Mylohyoid Groove" OR "Ridge, Mylohyoid" OR "Lower Jaw" OR Mandibular OR "Groove, Mylohyoid OR "Dental Prostheses, Surgical" OR "Surgical Dental Prostheses" OR "Prosthesis, Surgical Dental" OR "Dental Implants" OR Implant\* OR "Dental Implantation, Endosseous" OR "Implantation, Osseointegrated Dental" OR "Dental Implantation, Osseointegrated Dental" OR "Dental Implantation, Dental" OR "Implantation, Endosseous" OR "Implantation, Osseointegrated Dental" OR "Dental Implantation, Dental" OR "Prosthesis Implantation, Dental" OR "Prosthesis Implantation, Dental" OR "Prosthesis Implantation, Dental" OR "Prosthesis, Dental" OR "Prosthesis, Dental" OR "Prosthesis, Implant-Supported" OR "Dental Prostheses, Implant-Supported" OR "Prostheses, Implant-Supported" OR "Dental" OR "Dental" OR "Prosthesis Dental" OR "Prosthesis, Implant-Supported" OR "Dental Prostheses, Implant-Supported" OR "Dental" OR "Dental" OR "Prosthesis Dental" OR "Prostheses, Implant-Supported" OR "Dental" OR "Dental" OR "Dental" OR "Dental" OR "Dental" OR "Prosthesis Dental" OR "Prostheses, Implant-Supported" OR "Dental" OR "Dental" OR "Prosthesis Dental" OR "Prostheses, Implant-Supported" OR "Dental" OR "Dental" OR "Denture, Implant-Supported" OR "Dentures, Implant-Supported" OR "Dentures, Overlay" OR "Denture" OR "Overlay Denture" OR "Overlay Dentures" OR "Overlay Dentures" OR "Overlay Dentures" OR "Overlay Denture" OR "Dental Implant overdenture") AND ("Immediate Dental Implant Loading, Immediate" OR "Dental Implant Loading, Early" OR "Immediately

loaded" OR "Immediate functional loading" OR "Immediate-loading" OR "Loaded immediately" OR "Immediate implant loading" OR "Early occlusal loading" OR "Early prosthetic loading" OR "Early implant loading" OR "Early-loaded" OR "Early implant-loading" OR "Immediate nonfunctional loading" OR "Immediate functional loading" OR "Immediate Load" OR "Early Load")

# 2.2 Is one dental mini-implant biomechanically appropriate for the retention of a mandibular overdenture? A comparison with Morse taper and external hexagon platforms #

This study was financed by: the Conselho Nacional de Desenvolvimento Científico e Tecnológico - Brazil (CNPq) [grant number 132724/2018-9]; the Fundação de Amparo à Pesquisa do Estado de São Paulo - Brazil (FAPESP) [grant number 2018/03136-4; 2014/19098-3]; and by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) [grant number 0885/2018].

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#### ABSTRACT

**Statement of problem.** Limited information is available to clinicians on the use of dental mini-implants (MI) as opposed to standard-diameter implants (SDIs) for the stabilization of implant-retained mandibular overdentures (MOs).

**Purpose.** The purpose of this in vitro and finite element analysis (FEA) study was to analyze and compare the biomechanical behavior of MOs with either 1 or 2 implants with external hexagon (EH), Morse taper (MT) SDIs, and MIs.

**Material and methods.** Thirty photoelastic models (n=30) of each group (n=5) of SDIs (EH-1, EH-2, MT-1, MT-2) and MI (MI-1, MI-2) were fabricated for posterior, peri-implant, and total maximum shear stress evaluation by quantitative photoelastic analysis. One specimen of each group was further used to create the 6 computational models to be analyzed by FEA. The maximum von Mises values and stress maps were plotted for each ductile component. Two types of load were applied to the overdenture: a150-N load bilaterally and simultaneously on the first molar and a 100-N load on the incisal edge of the central incisors at a 30-degree angle. The data were subjected to the 2-way ANOVA test and the Tukey honestly significant difference test ( $\alpha$ =.05).

**Results.** The EH-2 and MT-2 showed the lowest posterior (P<.001) and total (P<.05) mean shear stress values. For peri-implant shear stress, no difference was found among all groups (P>.05). Regardless of the loading area, the MI-1 and MI-2 groups showed the lowest von Mises stress values. However, for implant housing, the MI-1 group, under incisor loading, presented greater stress, followed by MT-1, EH-1, EH-2, MI-2, and MT-2. The attachment was the most overloaded structure, with high values under incisor loading, especially for the groups with 2 implants (MT-2, EH-2) as compared with the other models.

**Conclusions.** Biomechanically, regardless of the implant number, MI is a promising rehabilitation method with similar peri-implant shear stress and lower von Mises stress on the

implant when compared with SDIs for MOs.

# **CLINICAL IMPLICATIONS**

Mandibular overdentures retained by dental mini-implants are a fairly recent option for the rehabilitation of edentulous patients with limited bone volume. This alternative is biomechanically favorable and less invasive, with a simplified surgical approach that makes it clinically attractive.

# **INTRODUCTION**

In recent decades, oral implants have become part of the clinical routine, especially to stabilize mandibular overdentures (MOs).<sup>1–9</sup> The positive effects of this option led to the McGill Consensus, establishing the use of MOs with 2 implants as the standard treatment for edentulous patients.<sup>10</sup> However, continuous residual ridge resorption in edentulous patients becomes challenging for the placement of standard-diameter implants (SDIs) and the execution of surgical techniques such as bone regeneration.<sup>11,12</sup> Different options have been proposed as alternatives to overcome those limitations with MO-2 using SDIs, such as the use of a single implant and the placement of dental mini-implants (MIs).

In addition to being a low-cost alternative, MO-1 is considered a technique modification of MO-2.<sup>13,14</sup> A previous study comparing MO-2 with MO-1 reported similar clinical outcomes in terms of patient satisfaction, oral-health-related quality of life, effort required for prosthetic maintenance, and implant survival over a period of 5 years.<sup>15</sup> Clinically, the placement of MO-1 requires a simplified surgical approach, since clinical time is reduced and fewer components are necessary.<sup>16</sup> Thus, the residual ridge in the symphysis has a greater thickness, making the surgical procedure safer and less extensive.<sup>17,18</sup> However,

the authors are unaware of biomechanical investigations into different implant platforms, Morse taper (MT) and external hexagon (EH), and their implications for MO-1.

In clinical situations in which edentulous patients have insufficient bone thickness to receive SDIs, narrow-diameter implants present a simpler approach for their rehabilitation. The ITI consensus in 2014 included category 1, which defined implants with a diameter <3 mm as MI or 1-piece implants.<sup>19</sup> Previous studies have reported that MOs with MIs have acceptable marginal bone level changes, favorable patient satisfaction, and high survival rates and that they serve to enhance long-term oral function.<sup>20-23</sup> MIs also offer the benefits of a unibody design, such as single-stage surgery, and can be placed with either flap or flapless surgery.<sup>20,24</sup> Thus, the single-body MIs eliminate micromovement and the subsequent risk of abutment screw loosening and fracture,<sup>25,26</sup> although prospective studies have only evaluated MOs with 4 or 2 MIs.<sup>20-24,27,28</sup>

Clinical studies of the scientific basis for rehabilitation with MOs must consider the influence of different implant designs and numbers because inappropriate stress distribution in the bone tissue can impair proper biomechanical function and lead to implant failure. For this purpose, biomechanical studies based on the same situation as in a clinical trial should be done first. Different methodologies have been used to evaluate biomechanical behavior in dentistry, including photoelasticity and 3D finite element analysis (FEA). Photoelasticity can simulate the internal stress of different rehabilitations, with real components (implant, attachment, and matrix) under isochromatic fringes in controlled conditions,<sup>29</sup> while FEA can be used to analyze the biomechanical behavior of ductile structures by means of a mathematical solver.<sup>30</sup> Therefore, the purpose of this study was to examine the biomechanical behavior of 1- and 2-implant-retained MOs using SDIs or MIs, in terms of peri-implant, posterior, and total mandibular stress through photoelasticity and the implant, attachment, and

housing stress by using FEA. The null hypothesis was that tension would be similar between the MI and SDIs, using 1- or 2-implant-retained MO.

# **MATERIAL AND METHODS**

Two mandibular prototypes (16×8×125 mm) were developed (Fig. 1) to simulate edentulous jaws: one (Fig. 1A) for 2 or 1 MI (Ø 2.0 × 10 mm; Intra-Lock System) (MI-1 and MI-2); and the other for 2 or 1 SDI (Fig. 1B) with EH (Ø 3.75 × 10 mm; Conexão Sistemas de Proteses) (EH-1, EH-2) or MT abutment (Ø 3.75 × 10 mm; Conexão Sistemas de Proteses) (MT-1 and MT-2). For each mandibular prototype, 2 holes were designed in the canines (25 mm apart) and 1 in the midline for placement of the corresponding analogs. The fibromucosa prototype (Fig. 1C) was drawn virtually (exocad DentalCAD) with a 2-mm thickness over the mandibular prototype and printed (MiiCraft printer; Smart Dent) in resin with a digital light projector (DLP). The prototyped fibromucosa was duplicated, both prototypes (mandibular and fibromucosa) were placed in a plastic container, and silicone (Silicone Master; Talmax Produtos de Protese Dentaria Ltd) was poured over the prototypes. After the material had polymerized, the fibromucosa prototype was removed, and its space was filled with silicone (Gingifast; Zhermack Badia Polesine). The mandibular prototype was replaced in position during the polymerization of the fibromucosa resin to achieve precise dimensional replication.

The overdenture was fabricated with the conventional technique with acrylic resin teeth (Trilux; Vipi Produtos Odontológicos). Subsequently, an opening was made from canine to canine on the buccal area of the overdenture (Fig. 1D) for better visualization of the isochromatic fringes around the implants.



**Figure 1.** Prototypes (mandible, fibromucosa), and overdenture design. A, Mandibular prototype for mini-implants. B, Mandibular prototype for standard-diameter implants. C, Fibromucosa prototype. D, Mandibular overdenture.

Five photoelastic models (n=5) for each implant system were made, simulating an MO with 1- or 2-implant designs (Fig. 2). The ball attachment system was used for all models. To obtain the MO-1 photoelastic models, the analog was positioned in the midline hole of the mandibular prototype, and the other 2 holes were covered with wax. For the MO-2 groups, the analogs were positioned in the canine area with the midline hole covered. Subsequently, open tray transfer was tightened on the analog for the EH-1, MT-1, EH-2, and MT-2 groups. To splint the transfers in the MO-2 group, 2 drills were placed and stabilized with low-shrinkage autopolymerizing resin (Duralay II; Reliance Dental Mfg Co). For the MI groups, an abutment was cemented, since the MI did not have transfer abutments. Subsequently, the assembly (analog with transfer or cemented abutment) was centrally placed in a plastic container ( $7 \times 9 \times 14$  cm). The silicone was mixed according to the manufacturer's recommendations and poured over the assembly.



**Figure 2.** Implants (EH, MT, MI) and photoelastic models (EH-1, MT-1, MI-1, EH-2, MT-2, MI-2) designed for each group. EH, external hexagon. MT, Morse taper. MI, dental miniimplant. EH-1/-2, external hexagon model with 1/2 implants. MT-1/-2, Morse taper model with 1/2 implants. MI-1/-2, dental mini-implant model with 1/2 implants.

After 40 minutes, the corresponding implants were positioned in the silicone impression, and the photoelastic resin (Araldite GY279 and hardener Aradur 2963; Araltec Chemicals Ltd) were mixed at a 2:1 ratio and poured. After 72 hours of polymerization, the photoelastic models were analyzed with a circular polariscope with horizontal transmission (developed in the Mechanical Design Laboratory Henner Alberto Gomide; School of Mechanical Engineering of the Federal University of Uberlândia). The ball attachments were tightened on the implant (20 Ncm) by means of a digital torque meter with 0.1-Ncm precision (Torque Meter TQ 8800; Lutron) based on the manufacturer's recommendations.

The artificial fibromucosa was placed over the model, and the matrices were captured by a conventional pick-up technique. Before analysis, the photoelastic models were incubated for thermal relaxation (37 °C for 20 minutes) and evaluated in the polariscope. Also, a layer of mineral oil was applied over the model before the analyses for better visualization of the isochromatic fringes. To record the analysis, a digital camera (EOS Rebel T3i/600d; Canon Inc) was used, and the same position was ensured for all models by crosshatched marks in the platform of the polariscope. Subsequently, a vertical loading of 150 N was applied (75 N in each molar), with a load cell (LD1050 Serie 19878-Lider; School of Mechanical Engineering of the Federal University of Uberlândia) and a digital converter, simulating a bilaterally balanced occlusion.

For measurement of the shear stress ( $\tau$ ) in MPa, the software Fringes (Fringes; Mechanical Design Laboratory, FMEC, Federal University of Uberlândia) was used to quantify the data acquired. A grid with 12 reading points in the peri-implant extension (Figs. 3A, 3B) and 16 points in the posterior area had been previously designed (Figs. 3C, 3D). For each point, the value was based on the optical constant of the photoelastic resin (k=11.271 N/mm), fringe order (N), and thickness of the model (b=12 mm) for calculation of the maximum shear stress ( $\tau = \frac{K \times N}{2 \times b}$ ). The posterior regions, left (L) and right (R), were evaluated, obtaining a posterior average stress value ( $\frac{\text{L region+R region}}{2}$ ). The peri-implant shear stresses for MO-1 groups were computed and were calculated for the MO-2 groups (EH-2, MT-2, MI-2) based on both implants' average stress ( $\frac{\text{L implant+R implant}}{2}$ ). Finally, the total shear stress for each model was achieved based on the average of both analyzed areas.



**Figure 3.** Points of interest (*red*) in the peri-implant and posterior areas. A, Standard-diameter implant. B, Dental mini-implant. C, Posterior area (left). D, Posterior area (right).

All data included in this study were tested for normality by the Kolmogorov-Smirnov method. Two-way ANOVA was used to evaluate the influence of the implant number, implant design, and their interaction in terms of the peri-implant, posterior, and total model maximum shear stress ( $\tau$ ) data. The Tukey honestly significant difference test was used as a post hoc test ( $\alpha$ =.05). All analyses were conducted with statistical software (IBM SPSS Statistics, v20.0; IBM Corp). The power of the sample size was calculated by G\*power 3.1.9.2 (program written, conceived, and designed by Franz, Universität Kiel, Germany; freely available Windows application software) (n=30, n=5 photoelastic models per group; large size effect according to the Partial Eta Squared [ $\eta$ p<sup>2</sup>] test, np<sup>2</sup>=0.416, *P*=.0004). The FEA methodology was performed following protocols from a previous study.<sup>30</sup> The models assessed in the photoelastic methodology were used as data to simulate the FEA models for each group to evaluate the biomechanical behavior of ductile (implant, attachment, housing) structures. In total, 6 computational 3D models, 1 for each group, were simulated. The edentulous mandible was developed virtually (SolidWorks; Dassault-Systèmes SolidWorks Corp), simulating cortical bone with 2-mm thickness surrounding a low-density cancellous bone all covered by a 2-mm constant thickness mucosa.<sup>30</sup> The implants and prosthetic components were obtained from original drawings. The overdenture was also drawn on the prototype and simplified, thereby generating the virtual image file.

After the 3D modeling, the geometries were imported to the FEA software (Ansys Workbench 11; Ansys Inc) for mathematical analysis. The mechanical properties of each material were assigned according to previous studies (Table 1).<sup>30–35</sup> The materials were considered as isotropic, linear, homogeneous, and 100% osseointegrated with the implants.

Two different loading forces were applied, one of 150 N in the axial direction (bilaterally and simultaneously on the first inferior molar) and the other with 100 N in the oblique direction (30 degrees to the incisal edge of the central mandibular incisors).<sup>30,32,36</sup> After the boundary conditions were defined, all 3D models were subjected to a mathematical solver. ANSYS software was also used to assess the von Mises stresses of ductile structures (implant, attachment, and housing). Finally, the von Mises stresses were reported numerically and color-coded (stress maps), allowing a final comparison among all groups.

Material	Young Modulus (MPa)	Poisson Ratio (v)	Reference
Dental mini-implant / housing (Grade 5)	114.000	0.33	Pisani et al, 2018 <sup>30</sup>
Conventional implant/ ball attachment/ housing (Grade 4)	104.500	0.37	de la Rosa Castolo et al, 2018 <sup>35</sup>
Overdenture	8.3	0.28	Daas et al, 2008 <sup>31</sup>
O-ring nylon conventional implant	2.400	0.39	Barão et al, 2013 <sup>33</sup>
O-ring rubber mini-implant	5	0.45	Pisani et al, 2018 <sup>30</sup>
Cortical bone	13.700	0.3	Liu et al, 2013 <sup>32</sup>
Cancellous bone	1.370	0.3	Liu et al, 2013 <sup>32</sup>
Mucosa	340	0.45	Barão et al, 2008 <sup>34</sup>

Table 1. Properties of materials used for finite element analysis

# RESULTS

Two-way ANOVA showed no influence of the implant number, implant design, or their interaction on the peri-implant shear stress values (P>.05) (Table 2). The peri-implant maximum shear stresses (mean ±standard deviation) are presented in Figure 4A. When shear stresses at the posterior region were compared, a statistically significant difference (P<.05) was noted for the implant number, implant design, and their interaction for all groups (Table 2). The EH-2 and MT-2 groups showed the lowest posterior shear stress (P<.001); however, no statistically significant change was noted among the other groups (P>.05) (Fig. 4B). The method of total shear stress evaluation presented similar results for implant number and implant design (Table 2). The EH-2 and MT-2 had the smallest shear stress (P<.05); however, no statistically significant differences were observed among the other groups (P>.05) (Fig. 4C).

	Sum of Squares	df	Mean Squares	F	<b>P*</b>
Peri-implant stress					
Number	13585.95	1	13585.95	2.14	.16
Design	14996.36	2	7498.18	1.18	.32
Number×Design	4875.68	2	2437.84	.38	.69
Total	9564742.57	30			
Posterior stress					
Number	146168.76	1	146168.76	28.52	<.001
Design	169904.39	2	84952.19	16.58	<.001
Number×Design	82905.35	2	41452.68	8.09	.002
Total	12395195.33	30			
Total stress $\left(\frac{\text{Posterior+Peri-implant}}{2}\right)$					
Number	62220.07	1	62220.07	17.11	<.001
Design	28089.73	2	14044.86	3.86	.035
Number×Design	11982.44	2	5991.22	1.65	.21
Total	10778881.07	30			

**Table 2.** Two-way ANOVA results of peri-implant, posterior, and total maximum shear stressfor implant number, design, and their interaction (number x design)

Note: \*Significant P<.05.



**Figure 4.** Scatter plots of maximum shear stress (MPa) of EH-1, MT-1, MI-1, EH-2, MT-2, and MI-2 photoelastic models according to evaluated areas. A, Peri-implant. B, Posterior. C, Total. EH-1/-2, external hexagon model with 1/2 implants. MT-1/-2, Morse taper model with 1/2 implants. MI-1/-2, dental mini-implant model with 1/2 implants.

The values of von Mises stresses for each FEA model, according to the ductile structure evaluated, are presented in Table 3. When the loading areas were compared, regardless of the implant type, the incisor loading generated higher values of stress on the implant, attachment, and housing than the molar loading. Both MI groups showed the lowest stress values for the implant compared with the SDIs. However, the MI housing (MI-1) under incisor loading presented the highest stress value. The attachment was the most overloaded structure, with high values under incisor loading, especially for the groups with 2 implants (MT-2, EH-2) compared with the other models.

	Loading Area	EH-1	EH-2	<b>MT-1</b>	MT-2	MI-1	MI-2
	Molar – 150 N	1.12	1.89	2.14	1.68	0.37	0.32
IMPLANT	Incisor – 100 N	10.1	16.64	14.95	11.01	2.40	4.31
	Molar – 150 N	2.82	2.51	2.21	3.67	*	*
ATTACHMENT	Incisor – 100 N	15.5	22.37	17.89	21.60	*	*
	Molar – 150 N	0.56	0.81	0.63	0.87	0.49	0.8
HOUSING	Incisor – 100 N	17.38	15	19.39	13.64	25.6	14.48

Table 3. Von Mises stress values (MPa) of ductile structures

EH-1/-2, external hexagon model with 1/2 implants; MT-1/-2, Morse taper model with 1/2 implants; MI-1/-2, dental mini-implant model with 1/2 implants; \*data not applied.

In the color-coded view of the implant under incisor loading, greater distribution of stress was observed around the implant platform for the EH (Fig. 5A) and MT groups (Fig. 5B). The same pattern of stress concentration was observed for molar loading, but with lower values. When the stress maps of the MIs were evaluated, the stress concentrations were located throughout the implant body, especially below the MI platform (Fig. 5C). Thus, the MI-1 and MI-2 groups had higher values when evaluated under incisor loading.

The attachments exhibited similar stress patterns for all SDIs under molar loading, with lower values for the MT groups at the neck of the attachment (Figs. 5A, 5B). Conversely, when the incisor loading was evaluated, the stress was found to be concentrated in the attachment's neck followed by the transmucosal area, with higher values in the EH groups (Fig. 5A). Thus, the MT groups also presented stress concentration at the interface between the attachment and implant, especially under incisor loading (Fig. 5B).

In the stress-map of the housing, incisor loading had the highest values, especially for the MI-1 group (Fig. 5C). The locations of stress were similar in all groups, being located at

А



В





**Figure 5.** Von Mises stress maps of prosthetic structures. Molar and incisor loading. A, Groups EH-1 and EH-2. B, Groups MT-1 and MT-2. C, Groups MI-1 and MI-2. EH-1/-2, external hexagon 3D models with 1/2 implants. MT-1/-2, Morse taper 3D models with 1/2 implants. MI-1/-2, dental mini-implant 3D models with 1/2 implants.

# DISCUSSION

С

The association of the 2 methodologies tested in this study supports the hypothesis that either 1 or 2 MIs can be an alternative for MOs. However, 2 SDIs seem to transfer less stress to the edentulous mandible and the posterior region. The null hypothesis was rejected as the biomechanical behavior in both methodologies of the MI was not comparable with that of the SDI under axial (150 N bilaterally and simultaneously on the first inferior molar) and oblique loading (100 N with 30 degrees to the incisal edge of the central mandibular incisors).

The reduced posterior and total shear stress in the MO-2 with SDIs (EH-2, MT-2) may be attributed to the reduced possibility of rotation compared with the groups with 1 implant (EH-1, MT-1).<sup>1,2</sup> Thus, less pressure is transferred to the mucosal tissue and the underlying bone compared with that in groups with 1 implant (EH-1, MT-1).<sup>3</sup> Also, the MO-1

groups have an extended cantilever compared with the MO-2 groups and form a lever which will directly transmit a moment load to the posterior bone, explaining a higher stress for EH-1 and MT-1. Clinically, this would be represented by posterior vertical bone resorption over time.<sup>1</sup>

All the MI groups had similar maximum shear stress values for both posterior and total shear stress analysis, presenting results comparable with those of the MO-1 groups with SDIs. This result may be related to the limited number of MIs, 1 or 2, which would not be enough to reduce the force transferred to the bone through the implants. In addition, the attachment for the MI-1 and MI-2 groups lacks occlusal rest in the female parts for the spherical male parts.<sup>20,21</sup> Thus, the O-ring attachment for the MI has a retentive but not a supportive function to avoid implant overloading, especially in a limited number of MIs with a narrow diameter. The authors are unaware of clinical studies evaluating MO-1 using MIs. However, clinical trials have reported a favorable clinical situation with 4 and even 2 MIs.<sup>20-22,27</sup>

A meta-analysis demonstrated similar clinical outcomes with a low risk of implant failure for MO-1 and MO-2 using SDIs over a mean follow-up period of 37.3 months.<sup>4</sup> Another meta-analysis using MIs in a follow-up period of 3.9 years reported a survival rate of 94.3% and thus an overall favorable prognosis for success.<sup>19</sup> These results may be the main explanation for the absence of statistically significant differences in the peri-implant shear stress analysis for all groups with 1 and 2 implants, regardless of the design (SDI or MI).

The FEA showed the lowest stress for the MI groups, even under incisor loading, compared with the SDIs, regardless of the number of implants. However, the MIs underwent stress distribution throughout the implant body. This finding may be related to the resilient O-ring rubber surrounding the ball connection, acting as a stress breaker and increasing the flexibility of the system.<sup>5,30</sup> Clinically, it could be represented by O-ring wear over time and

the more constant maintenance sessions for this component due to the elastic properties of the O-ring.<sup>6,7</sup> However, O-ring replacement is a relatively straightforward and inexpensive procedure.<sup>28</sup>

Regarding implant housing stress, higher values were represented by the groups with 1 implant under incisor loading. In addition to the proximity to the loading area itself, this result might be better explained by the anteroposterior MO displacement, which has been documented with MO-1 using SDI or MI.<sup>30</sup> Moreover, the greater stress concentration on the top of the housing might be related to implant intrusion. In a clinical situation, patients should be advised to avoid masticating on the anterior teeth, especially because of the continuous increase in maximum occlusal force reported in a clinical study with a 5-year follow-up.<sup>20</sup>

In the present study, the von Mises stress values for the ball attachment were higher than for the other components, indicating it as the first possible ductile component to be damaged. However, the prosthodontic event of attachment replacement has not been reported as the most common in clinical trials with MO-1<sup>14</sup> and MO-2<sup>9</sup>. Previous studies using ball attachments with MO-1 and MO-2 have also advocated a direct (intraoral chairside) pick-up technique instead of an indirect (laboratory) approach in both immediate and longterm aftercare of the attachment.<sup>8</sup> Thus, this would lower the stress in the attachment component and maintenance sections to replace the component in addition to reducing patient cost.

Limitations of the present study were that the evaluation of MI included only category 1; thus, other types of narrow-diameter implants should be further evaluated, such as categories 2 and 3.<sup>19</sup> Additionally, future in vitro studies should assess the retentive properties of the attachments by using a masticatory loading simulator, and well-designed clinical studies should be conducted to evaluate 1 or 2 mini-implant-retained overdentures.
# CONCLUSIONS

Based on the findings of this biomechanical study, the following conclusions were drawn:

1. Mandibular overdentures with 2 standard-diameter implants had the lowest posterior and total shear stress, even for the groups retained by 1 and 2 mini-implants.

2. In addition, peri-implant shear stresses were similar for both standard-diameter and miniimplants, regardless of the implant number.

3. The use of 1 or 2 mini-implants is a valid treatment option, especially when the available residual ridge volume is limited.

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# **3. DISCUSSÃO**

A elevada taxa de sucesso dos implantes dentários na reabilitação de pacientes edêntulos tem sido amplamente reconhecida e é o principal fator que propiciou o desenvolvimento de tratamentos alternativos de protocolos de carga, número e tipo de implantes. Artigos científicos ratificam a aplicabilidade clínica dos PCI/ PCP em reabilitações com OMs, especialmente devido ao desenvolvimento de melhores tratamentos de superfície dos implantes (Chiapasco and Gatti, 2003; Payne et al., 2003). Além disso, alternativas eficazes e simples como uso de implante único e mini-implantes também tornaram-se atrativas, pois reduzem a complexidade e o custo do tratamento (de Souza et al., 2015; Passia et al., 2019; Passia and Kern, 2014; Ribeiro et al., 2015). Para tanto, neste estudo pudemos de forma inédita demonstrar que os PCI/ PCP apresentam-se como modalidades de tratamento estabelecidas e dignas de aplicação clínica. Embora existam revisões sistemáticas prévias (Alsabeeha et al., 2009; Kawai and Taylor, 2007; Schimmel et al., 2014; Sivaramakrishnan and Sridharan, 2016), diferentemente das demais, esta avaliou quantitativamente as variáveis peri-implantares.

A estimativa de previsibilidade para as taxas de sucesso e sobrevivência dos implantes em ambos protocolos de carga (PCI/ PCP) mostraram-se favoráveis, mesmo em longos períodos de acompanhamento (168 e 120 meses). De forma similar, revisões sistemáticas com períodos de acompanhamento menores corroboram os achados deste estudo (Alsabeeha et al., 2009; Schimmel et al., 2014). Quanto à avaliação da estabilidade implantar através do Ostell, foi observado que apenas aos 3 meses o PCC apresentou resultados favoráveis; entretanto, para os períodos subsequentes (6, 12, 24 e 36 meses) os resultados foram similares aos apresentados pelo PCI. Sugere-se assim, que os achados estejam relacionados com o período de osseointegração dos implantes, o qual aumenta com o decorrer do tempo (Acham et al., 2017). Conforme observado em estudos realizados em animais, pode ser explicado como um mecanismo de adaptação óssea em relação à função, à partir da conversão de tecido ósseo imaturo em um tecido lamelar, biomecanicamente mais maduro e eficiente (Berglundh et al., 2003; Duyck et al., 2015).

Para as variáveis peri-implantares, o índice de placa aos 12 meses e de forma geral apresentaram valores mais elevados para o PCI/ PCP quando comparados ao PCC. Sugere-se que a diferença estatística encontrada nestas meta-análises esteja intimamente ligada ao tipo de sistema de retenção e não ao protocolo de carga (Akca et al., 2013; Elsyad et al., 2016), uma vez que a resiliência da matriz entre os diferentes sistemas (barra e bola) pode ser comprometida com o decorrer dos anos em consequência do efeito da saliva, além do ato de inserção/ remoção da prótese. Em relação à perda óssea marginal e profundidade de sondagem, esses índices

mostram-se similares na avaliação geral como esperado, uma vez que as duas variáveis periimplantares mencionadas são correlacionadas (Elsyad et al., 2016). Apesar da correlação, em uma única análise de subgrupo (36 meses) o PCC apresentou menores valores de profundidade de sondagem em comparação aos PCI/ PCP. Desse modo, é necessária a realização de novos ensaios clínicos randomizados, visto que o resultado obtido possivelmente está associado à escassez de estudos.

Em relação ao sangramento à sondagem, a análise quantitativa demonstrou resultado semelhante para os diferentes protocolos de carga (PCC e PCI). Entretanto, conforme os dados obtidos na avaliação qualitativa do GRADE, essa variável apresentou baixa certeza de evidência, indicando que é improvável que o efeito verdadeiro esteja próximo do efeito estimado (Ryan & Hills, 2016). Esse achado sugere que a heterogeneidade entre os estudos pode estar associada à presença de resultados inconsistentes. Durante a avaliação dos artigos, observou-se a presença de indivíduos fumantes na amostra de 2 estudos utilizados na meta-análise (Romeo et al., 2002; Stephan et al., 2007). Entretanto, sabe-se que a presença de fumantes ativos pode subestimar o desfecho avaliado, uma vez que a nicotina reduz o sangramento gengival (Baab and Oberg, 1987; Sakallioğlu et al., 2015). Dessa forma, é necessário realizar estudos com critérios de inclusão e exclusão bem estabelecidos, para remover esse possível viés.

Mesmo frente aos benefícios dos PCI/ PCP, alternativas relacionadas ao ato cirúrgico e planejamento reabilitador devem ser investigados para proporcionar maior conforto ao paciente. Nesse sentido, o estudo experimental relatado no capítulo 2.2 avaliou o comportamento biomecânico de OM confeccionadas com diferentes números (um ou dois) e *designs* (mini-implante ou IDC) de implantes. Diante disso, observou-se redução nos valores de tensão de cisalhamento total e na região posterior das OM confeccionadas com dois IDC (EH-2, MT-2). Esse resultado possivelmente está associado à redução da liberdade de rotação e do cantilever do sistema, quando comparados ao grupo com um IDC (EH-1, MT-1) (Elsyad et al., 2017; Tymstra et al., 2011). Entretanto, para as mesmas análises de tensão (total e posterior) nos grupos com mini-implantes, observou-se resultados semelhantes aos dos grupos com um IDC. Acredita-se que esses resultados estejam relacionados ao limitado número de mini-implantes utilizados (um ou dois), os quais não seriam suficientes para reduzir a quantidade de tensão transferida ao osso.

Um estudo de meta-análise prévio (de Souza Batista et al., 2018), utilizando um ou dois IDC, demonstrou desfechos clínicos similares em reabilitações com OM em um período médio de 37,3 meses. Adicionalmente, outra análise quantitativa, desta vez utilizando miniimplantes (3,9 anos) demonstrou taxa de sobrevivência de 94,3% (Klein et al., 2014). Esses resultados provavelmente justificam a similaridade entre todos os grupos para a avaliação da tensão de cisalhamento peri-implantar, independentemente do número e design do implante.

A análise de elementos finitos em 3D apresentou baixos valores de tensão para os grupos com mini-implantes, independentemente do tipo de carga aplicada, comparados aos IDC. Entretanto, foi possível observar que para os grupos dos mini-implantes houve distribuição de tensão ao longo de todo o corpo do implante. Esse resultado pode estar relacionado à resiliência o O-ring, atuando como redutor de tensões, aumentando a flexibilidade do sistema (Chen et al., 2011; Pisani et al., 2018). Para a avaliação da matriz, os valores mais expressivos da tensão de von Mises foram demonstrados para o grupo com um mini-implante, quando submetido à carga anterior. Apesar da proximidade da estrutura com o local de aplicação da carga, esse resultado provavelmente está relacionado com a possibilidade de deslocamento anteroposterior da prótese, o qual foi previamente relatado para OM retidas por apenas um implante (Pisani et al., 2018). O *attachment* tipo bola foi a estrutura que apresentou maiores valores de tensão dentre todos os componentes, indicando ser a primeira estrutura a sofrer danos por falha. Entretanto, estudos clínicos prévios utilizando OM com um ou dois IDC não documentaram a substituição desse componente como prática frequente durante consultas de proservação (Nogueira et al., 2017; Turkyilmaz and Tumer, 2007).

Nesse sentido, os resultados obtidos neste estudo conciliados com as informações descritas na literatura, demonstram que mini-implantes apresentam características promissoras em um contexto clínico. Assim sendo, implantes com corpo único podem ser uma alternativa biomecanicamente eficaz quando comparados aos IDC, destacando que clinicamente, esperase que as taxas de sobrevivência em reabilitações com um mini-implante sejam comparáveis com outros estudos que utilizaram dois ou quatro mini-implantes. Ensaios clínicos randomizados devem explorar alternativas menos invasivas e considerar a opinião do paciente, uma vez que os resultados avaliados pelos pesquisadores podem não corresponder aos reportados pelo paciente (PROMS). Quanto aos protocolos de carga, a redução do tempo clínico com ambas modalidades (PCI/ PCP) parecem ser soluções válidas, e sua escolha deve levar em consideração os benefícios ao paciente. Finalmente, destaca-se a necessidade da realização de maior número de estudos corretamente delineados para o PCP, especialmente quanto ao sangramento à sondagem e quociente de estabilidade primária, para confirmação dos achados nas pesquisas.

# 4. CONCLUSÃO

Os protocolos de aplicação de carga imediato/ precoce em *overdentures* mandibulares implantossuportadas, apresentaram-se como modalidades de tratamento bem estabelecidas e dignas de consideração na prática clínica. Entretanto, a literatura apresenta limitada informação quanto aos valores do torque de inserção. Assim sendo, pesquisas futuras devem transparecer metodologicamente parâmetros estruturados para incluir os pacientes nos diferentes protocolos de carga. Adicionalmente, devem ser estudados o impacto de tabagismo, hábitos parafuncionais e altura do implante, com a finalidade de guiar os profissionais clínicos durante o estabelecimento do plano de tratamento. Destaca-se também, a restrita discussão no que diz respeito à decisão do paciente em relação ao plano de tratamento o que possivelmente pode afetar os resultados.

Baseado nos achados biomecânicos, pode-se inferir que *overdentures* mandibulares confeccionadas com dois implantes de diâmetro convencional apresentaram os menores valores de tensão de cisalhamento na região posterior, e de forma geral. Além disso, a avaliação periimplantar identificou valores de tensão similares entre ambos grupos (implantes de diâmetro convencional e mini-implates), independentemente da quantidade de implantes utilizados. A avaliação dos elementos dúcteis permitiram concluir que o uso de um ou dois mini-implantes são opções clínicas promissoras, especialmente quando o rebordo residual remanescente apresenta espessura limitada. Finalmente, devem ser delineados ensaios clínicos randomizados, para que possam ser obtidas conclusões mais precisas no futuro.

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<sup>\*</sup> De acordo com as normas da UNICAMP/FOP, baseadas na padronização do International Committee of Medical Journal Editors - Vancouver Group. Abreviatura dos periódicos em conformidade com o PubMed.

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## **APÊNDICE 1 - DETALHAMENTO METODOLÓGICO**

Devido o ineditismo do segundo trabalho apresentado no capítulo 2.2, seguem as metodologias empregadas bem como os materiais necessários para seu desenvolvimento e reprodutibilidade. Além disso, destaca-se que o estudo experimental teve por objetivo avaliar o comportamento biomecânico de *overdentures* mandibulares retidas por um implante na sínfise mandibular, em comparação com dois implantes na região dos caninos, utilizando diferentes designs (mini-implante, cone morse e hexágono externo). As avaliações foram realizadas sob aplicação de carga, através de análise fotoelástica e de elementos finitos em três dimensões.

## Fotoelasticidade

## Confecção dos protótipos – mandíbula e fibromucosa

Os protótipos mandibulares foram desenhados virtualmente no software Rhinoceros 4.0 e assim utilizados como matriz para produção da mandíbula experimental. O arquivo em formato *.stl* foi enviado para a impressora SinterStation 2000 (3D Systems HiQ Dsystems, Hemel Hempstead, UK), onde foi obtido o protótipo em resina à base de PA12 (poliamida 12). Essa etapa foi realizada através da sobreposição de camadas de pó de nylon Duraform PA (à base de PA12) polimerizadas por laser de CO<sub>2</sub> seletivo. Os dois protótipos foram elaborados, sendo um para os grupos com implantes de diâmetro convencional (Figura 1A) e outro para os grupos com mini-implantes (Figura 1B). Juntos, representando uma mandíbula desdentada total simplificada com dimensões padronizadas (1,6 cm altura X 0,6 cm largura X 12,5 cm comprimento), exibindo três orifícios paralelos (dois na região dos caninos inferiores, com distância de 25 mm entre eles, e um na região mediana) (Figura 2). Quanto aos diâmetros e profundidades, eram sutilmente maiores em comparação aos respectivos análogos.



**Figura 1.** Protótipos da mandíbula confeccionados em poliamida. 1A, protótipo para os grupos com mini implantes. 1B, protótipo para os grupos com implantes convencionais.



**Figura 2.** Vista lateral do modelo virtual da mandíbula, demonstrando a distância entre os orifícios posicionados na região de caninos (25 mm).

Foi utilizado o scaner Ceramill<sup>®</sup> Map 400<sup>+</sup> (Amann Girrbach Brasil LTDA; Brasil) para obtenção da imagem digital da mandíbula. Em seguida, a fibromucosa foi desenhada virtualmente (exocad DentalCAD; Darmstadt) com espessura de 2 mm sobre a imagem digital do protótipo mandibular. Para melhor nitidez das franjas isocromáticas, os limites da fibromucosa obedeceram o desenho da *overdenture*, apresentando uma abertura na região anterior. O arquivo CAD (computer-added design) foi assim enviado para uma impressora MiiCraft (Smart Dent; Brasil), obtendo o protótipo da fibromucosa em resina DLP (Figura 3).



Figure 3. Protótipo da fibromucosa impresso em resina DLP.

## Obtenção do modelo em gesso e confecção da overdenture

Um dos protótipos foi moldado com silicone de condensação (Optosil/Xantopren, Heraeus Kulzer South America, SP, Brasil) e duplicado em gesso pedra tipo IV (Herostone, Vigodent, Rio de Janeiro, RJ, Brasil) na proporção recomendada pelo fabricante (23 ml água/100 g pó). Sobre o modelo em gesso, foi preparada uma base de prova inferior com rolete em cera. Foram montados dentes artificiais confeccionados em resina acrílica (Vipi Produtos Odontológicos, Pirassununga, SP, Brasil), e a prótese encerada. Após inclusão, foi realizado um alívio de 2 mm no rebordo, com cera número 7 (Polidental, Cotia, SP, Brasil) para simulação da fibromucosa. A prótese foi confeccionada em resina acrílica incolor (Jet Clássico, Dencor, Artigos Odontológicos Clássico Ltda, SP, Brasil). Após acabamento e polimento da prótese, essa recebeu uma abertura na parte central, para visualização das franjas ao redor dos implantes (Figura 4).



Figura 4. Overdenture mandibular com abertura anterior.

## Obtenção da fibromucosa

A fibromucosa foi confeccionada utilizando um protótipo como base. Primeiro, o conjunto dos protótipos (mandíbula e fibromucosa) foi posicionado, o silicone (Zetalabor; Zhermack, Badia Polesine, Italy) manipulado e então vertido em uma moldeira. Esta etapa permitiu que o espaço da fibromucosa fosse copiado para posterior replicação. Em seguida, após a polimerização do material, foi vertido silicone de adição (Gingifast; Zhermack, Badia Polesine, Italy) na região antes ocupada pelo protótipo. Em seguida, o protótipo mandibular foi reposicionado, até que a posição inicial fosse replicada. Após 10 minutos, a fibromucosa artificial foi removida (Figura 5). Os excessos foram recortados e os orifícios para posicionamento dos *attachments*, confeccionados com broca.



Figura 5. Réplica da fibromucosa em silicone de adição rosa.

## Obtenção dos modelos fotoelásticos

Os protótipos mandibulares foram duplicados através de uma moldagem de transferência para obtenção dos modelos fotoelásticos. Nos modelos com dois implantes, o orifício central do protótipo foi preenchido com cera número 7 e posteriormente os análogos dos implantes foram posicionados com a porção cervical ao nível da superfície superior do protótipo (Figure 6A). O modelo com um implante seguiu o mesmo procedimento para a confecção do modelo fotoelástico, ou seja, os dois orifícios na região dos caninos foram obstruídos, e o análogo colado no orifício central (Figure 6B).



**Figura 6.** Preparo dos protótipos para confecção da moldagem de transferência. A, Modelos com dois implantes. B, Modelos com um implante.

Com os análogos em posição, foram parafusados transferentes para moldeira aberta tanto nos implantes cone morse, como nos de hexágono externo (Conexão - Sistemas de Prótese, Arujá, SP, Brasil) e do tipo munhão (Intra-Lock, São Paulo, SP, Brasil) para os miniimplantes. O conjunto protótipo/análogos/transferentes (Figura 7A) foi então posicionado com sua base colada em um recipiente de acrílico (Figura 7B), para moldagem. O silicone de condensação (Talmax Indústria e Comércio Ltda, SP, Brasil) foi manipulado seguindo as instruções do fabricante e vertido sobre o recipiente, até atingir a altura dos parafusos dos transferentes. Após 40 minutos, obteve-se uma "caixa-molde" (Figura 7C) representando o negativo da mandíbula, com o posicionamento dos implantes. Em seguida, os mini-implantes (Figura 8A) e implantes convencionais (Figura 8B, 8C) foram parafusados nos transferentes e incorporados na caixa-molde, para ambos os casos, com um e dois implantes.



**Figura 7.** Confecção dos modelos fotoelásticos. A, posicionamento do protótipo/ análogo/ transferente. B, posicionamento do conjunto no recipiente de moldagem. C, obtenção da caixa molde em silicone. D, modelo fotoelástico após polimento.



**Figura 8.** Implantes utilizados para ancoragem da *overdenture*. A, mini-implante MDL (Intra-Lock). B, implante convencional hexágono externo (Easy – Conexão). C, implante convencional cone morse (Porous – Conexão).

Para a confecção do modelo fotoelástico (Figura 7D), utilizou-se resina fotoelástica (Araldite GY279, catalisador; Aradur 2963, endurecedor - Araltec Produtos Químicos Ltda,

Guarulhos, SP, Brasil) na proporção recomendada pelo fabricante (100 partes de Araldite para 42 partes de catalisador Aradur). A manipulação foi realizada em béquer de vidro, com auxílio de um bastão de vidro, por aproximadamente um minuto. Para evitar inclusão de ar e formação de estrias, o béquer contendo a resina fotoelástica foi levado em uma panela polimerizadora sob pressão de 60kgf/cm<sup>2</sup> (Protécni, Araraquara, SP, Brasil) por 5 minutos. Em seguida, o molde foi preenchido lentamente com a resina fotoelástica e submetido à pressão novamente, por 48 horas. Esta etapa permitiu proteger o material, de impurezas em recipiente fechado, durante um período de polimerização de 72 horas, recomendado pelo fabricante. Decorrido este período, os parafusos de fixação foram removidos dos transferentes, o modelo fotoelástico retirado do molde para acabamento com lâmina de bisturi e lixa d'água número 1200 (3M do Brasil, Sumaré, SP, Brasil), para remoção de excessos de resina e obtenção de lisura superficial.

#### Torque dos attachments

Após acabamento dos modelos fotoelásticos, os *attachments* do tipo bola dos grupos cone morse e hexágono externo foram parafusados aos implantes, seguindo as recomendações do fabricante (20Ncm). Para esta etapa, foi utilizado torquímetro digital com precisão de 0,1-Ncm (Torque Meter TQ 8800, Lutron, Taipei, Taiwan), com auxílio de uma base para assegurar um único eixo de posicionamento dos encaixes (Figura 8). Os grupos compostos por mini-implantes (MI-1 e MI-2) não receberam torque dos *attachments*, por serem caracterizados como implantes de corpo único.



Figura 8. Torquímetro digital posicionado em uma base estabilizadora para torque dos *attachments*.

## Captura dos attachments

A *overdenture* recebeu alívio interno com dimensão levemente maior que a cápsula para posterior captura do *attachment* pela técnica direta. Posteriormente, a fibromucosa foi posicionada sob o modelo fotoelástico, e a cápsula, sobre o *attachment*. Preparado o conjunto, a *overdenture* foi colocada sobre o modelo fotoelástico até a polimerização da resina, por aproximadamente 10 minutos (Figura 9). Após esta etapa, a prótese foi removida para posterior acabamento e polimento de sua base.



Figura 9. Overdenture em posição no modelo fotoelástico após a captura dos attachments.

## Análise em polariscópio

Os modelos fotoelásticos foram avaliados 72 horas após a confecção e inicialmente mantidos em estufa a  $\pm$  37°C por 20 minutos para eliminação de possíveis tensões residuais. Em seguida, posicionados no polariscópio circular (Laboratório de Design Mecânico Henner Alberto Gomide, Faculdade de Engenharia Mecânica da Universidade Federal de Uberlândia, LPM/FEMEC/UFU, Uberlândia, MG, Brasil) (Figura 11), constituído por dois filtros retardadores de 1/4 de onda e dois filtros polarizadores (polarizador e analisador). Os quatro filtros foram regulados com as respectivas angulações (0°, 45°, 135°, 0°).



Figura 11. Vista lateral do polariscópio de transmissão circular.

Uma carga axial de 150N foi aplicada bilateralmente na região central dos primeiros molares direito e esquerdo, simulando uma oclusão bilateralmente balanceada (Figura 12). Para o carregamento, um dispositivo foi elaborado e parafusado na célula de carga (LD1050 Serie 19878-Lider, Araçatuba, SP, Brasil). Fotografias digitais (Canon SX50HS-Canon Inc) dos modelos foram registradas em 5 posições nos seguintes momentos: (T1) baseline (após eliminação das tensões residuais em estufa); (T2) após a aplicação de carga, com a overdenture em posição.



Figura 12. Célula de aplicação de carga, simulando uma oclusão balanceada bilateralmente.

Foi confeccionado um guia para padronização das posições dos modelos para as fotografias durante a análise fotoelástica, adaptado sobre a plataforma do polariscópio. Os modelos receberam uma camada de óleo mineral em sua superfície, para facilitar a visualização e tomada fotográfica das franjas.

## Preparo das grades

Os resultados de tensão foram examinados pelo método quantitativo das tensões através do software Fringes® (Fringes software, Mechanical Design Laboratory, FMEC, Universidade Federal de Uberlândia, Uberlândia, MG, Brasil). Para tal, foram determinados pontos de interesse ao redor dos implantes convencionais, mini-implantes e na região posterior do rebordo alveolar em ambos lados, direito (D) e esquerdo (E). Para mensurar a tensão de cisalhamento máxima ( $\tau$ ) em megapascal (MPa) estabeleceu-se doze pontos na grade e dezesseis na região posterior do implante. Em cada ponto, o valor foi baseado na constante da resina fotoelástica (k=11.271 N/mm), ordem de franja (N) e espessura do modelo (b=12mm) para calcular a tensão de cisalhamento máxima ( $\tau = K \times N / 2 \times b$ ). Para o implante a tensão de cisalhamento máxima foi calculada através da média dos 12 pontos (Figura 13A, 1B), sendo que para os modelos com dois implantes, utilizou-se uma média de ambos implantes (Figura 13C, 13D, 13E, 13F). Os valores de tensão de cisalhamento no rebordo alveolar posterior foram obtidos através da média de ambas regiões (direita e esquerda) (Figura 13G, 13H).



**Figura 13.** Análise fotoelástica quantitativa. A, modelo com apenas um implante convencional. B, modelo com apenas um mini-implante. C, implante direito do modelo com dois implantes convencionais. D, implante esquerdo do modelo com dois implantes convencionais. E, implante direito do modelo com dois mini-implantes. F, implante esquerdo do modelo com dois mini-implantes. G, região direita da análise posterior. H, região esquerda da análise posterior.

Análise de elementos finitos 3D

A metodologia de elementos finitos em 3D foi realizada seguindo três etapas: fase de pré-processamento, processamento e pós-processamento.

## Fase de pré-processamento

Na fase inicial denominada de pré-processamento foram obtidos os CAD<sub>s</sub> (computer-aided design) dos implantes e componentes protéticos. A empresa Conexão - Sistemas de Prótese gentilmente forneceram os arquivos CAD de todos os implantes e componentes necessários (Figura 14A, 14B, 14C, 14D, 14E). Para o mini-implante e seus respectivos componentes foi utilizado microscópio óptico acoplado à unidade analisadora, para obtenção das medidas do mini-implante e matriz (Figura 15A, 15B, 15C, 15D). Posteriormente, foram realizadas as modelagens (Solidworks 2013; Dassault Systèmes Solidworks Corp) das geometrias de interesse e a verificação de possíveis inconsistências dimensionais ou geométricas em função das possíveis alterações causadas pelos processos de importação dos arquivos CAD que possam dificultar a geração de uma malha de qualidade. Inicialmente, foi realizada a modelagem individual de cada estrutura nas proporções originais e, posteriormente, as peças foram associadas, gerando os modelos tridimensionais simulando situações clínicas.



**Figura 14.** Arquivos CAD utilizados para a análise de elementos finitos em 3D. A, Implante convencional (hexágono externo). B, Implante convencional (cone morse). C, *Attachment* tipo bola (hexágono externo). D, *Attachment* tipo bola (cone morse). E, *Housing*.

Para a análise de elementos finitos, foram confeccionados modelos reproduzindo as situações encontradas nos modelos fotoelásticos seguindo as mesmas dimensões. Entretanto,

para se obter uma análise mais próxima à realidade clínica, foi realizada simulação do osso cortical (2 mm), osso trabecular (10,86 mm), fibromucosa (2 mm), dos implantes e dos encaixes. Os tecidos ósseos foram considerados como isotrópicos, lineares, homogêneos e 100% osseointegrados aos implantes. Durante o desenvolvimento dos modelos, foram realizadas simplificações nas roscas dos implantes e nos dentes da *overdenture*.



**Figura 15.** Mini-implante e *housing* avaliados em microscópio óptico acoplado com uma unidade analisadora para obtenção das medidas. A, *Housing*. B, Terço superior do mini-implante. C, Terço médio do mini-implante. D, Terço inferior do mini-implante.

#### Fase de processamento

A estrutura do modelo durante o processo de geração da malha de elementos finitos foi dividida em um número finito de elementos (discretização) que, posteriormente, foram interconectados por pontos nodais, os quais se encontram no sistema de coordenadas X, Y, Z, onde o conjunto resultante é denominado "malha". Nesta fase, a fim de evitar elementos de elevada distorção, muitas vezes relacionados às instabilidades numéricas durante o processamento da análise do modelo, foi utilizado o elemento sólido tetraédrico parabólico, que se caracteriza geometricamente como uma pirâmide de base triangular, com um nó em cada vértice e um nó no centro de cada aresta, totalizando 10 nós por elemento. As propriedades dos materiais (Módulo de Young e coeficiente de Poisson) e a quantidade de elementos, bem como os nós utilizados na geração de malhas de elementos finitos foram definidos nesta fase.

Por fim, foram delimitadas as condições de contorno (restrição de movimento e carregamento). Na fase de processamento, com as condições experimentais já estabelecidas no pré-processamento, os modelos foram submetidos ao processamento das equações numéricas do programa ANSYS Workbench 11 (Ansys Inc., Canonsburg, Pensylvania, USA). Os resultados das condições experimentais (HE-1, HE-2, MT-1, MT-2, MI-1, MI-2) propostas do campo de tensões foram obtidos e avaliados utilizando-se os critérios da tensão máxima de Von Misses nos sistemas dúcteis.

## Fase de pós-processamento

Na fase final de pós processamento, o resultado do campo de tensão foi avaliado de dois modos: análise qualitativa, obtida pela comparação visual das imagens e seus gradientes de cores geradas pelo software de simulação, onde cores quentes representam maiores valores tensão e cores frias menores valores de tensão, e análise quantitativa ou numérica a qual é avaliada a distribuição e valores das tensões máximas geradas como resposta biomecânica do sistema.

# ANEXOS



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#### ANEXO 2: Comprovante de submissão do artigo científico

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Elsevier Editorial System(tm) for The
Journal of Prosthetic Dentistry
                                  Manuscript Draft
Manuscript Number: JPD-D-19-00652
Title: Long-term outcomes of different loading protocols for implant-
supported mandibular overdentures: a systematic review and meta-analysis
Article Type: Systematic Review
Section/Category:
Keywords: edentulous; overdentures; dental implants; immediate dental
implant loading; meta-analysis
Corresponding Author: Professor Marcelo Ferraz Mesquita,
Corresponding Author's Institution:
First Author: Guilherme A Borges
Order of Authors: Guilherme A Borges; Raphael C Costa; Bruna E Nagay;
Marcela B Magno; Lucianne C Maia; Valentim Barão; Marcelo Ferraz Mesquita
Abstract: Statement of problem. Evidence provided by implant-supported
mandibular overdentures (MO) research on different loading protocols is
important into daily practice. However, methodological inconsistency as
well as inadequate reporting of results hampers a consistent decision in
terms of clinical applicability.
Purpose. This study aimed to evaluate whether immediate (ILP)/early (ELP)
loading protocols achieve comparable clinical outcomes when compared with
a conventional loading protocol (CLP) in edentulous patients
rehabilitated with MO.
Material and methods. According to the PICO strategy, prospective
clinical studies without restrictions as to language or follow-up period
were included. Cochrane Collaboration and ROBINS-I tools were used for
quality assessment and risk-of-bias evaluation. The follow-up for the
different outcomes ranged from 3 to 168 months, with focus on: (1)
implant success and survival rates; (2) marginal bone loss (MBL),
bleeding on probing (BOP), probing depth (PD), plaque index (PI) and
implant stability quotient (ISQ).
Results. The search strategy resulted in 14,234 references. 23 studies
fulfilled the inclusion criteria. Meta-analysis showed statistically
significant differences for PI at 12 months (SMD 0.284 [0.022, 0.545],
                                                                       P
= .033, I<sup>2</sup> = 35%), PD at 36 months (SMD 0.460 [0.098, 0.823], P = .013,
I^2 = 0\%) and on pooled results for PI (SMD 0.157 [0.031, 0.284], P =
.015, I^2 = 18\%) in which the CLP presented lower indices compared with
those of ILP/ELP. ISQ presented a statistically significant difference
only at 3 months (SMD 0.602 [0.309, 0.895], P = .0, I^2 = 0%) with higher
values for the CLP. For the other parameters , statistically significant
differences (P > .05) were not found.
Conclusions. ILP/ELP for MO is presented as a well-established treatment
and worthy of consideration in clinical practice.
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# ANEXO 3: Comprovante de aceite do artigo científico

Re: Your Submission to The Journal of Prosthetic Dentistry					
Mar 02, 2020					
Re: Manuscript # JPD-D-19-01027R5					
Dear Dr. Caldas,					
Thank you for submitting your manuscript # JPD-D-19-01027R5, entitled "Is one dental mini-implant biomechanically appropriate for the retention of a mandibular overdenture? A comparison with Morse taper and external hexagon platforms."					
I am pleased to inform you that your paper has been accepted for publication in The Journal of Prosthetic Dentistry.					
AUDIOSLIDES JPD offers a free service called AudioSlides. These are brief, webcast-style presentations that are shown next to published articles on ScienceDirect and can be viewed for free. This format gives you the opportunity to explain your research in your own words and promote your work by embedding it on your own website and sharing in social media. For more information and examples, please visit https://nam12.safelinks.protection.outlook.com/? url=http%3A%2F%2Fwww.elsevier.com%2Faudioslides&data=02%7C01%7C%7C556df5afe4494d1 dd6fe08d7bec384f6%7C84df9e7fe9f640afb435aaaaaaaaaaa%7C1%7C0%7C637187619260947457&a mp;sdata=%2Bm%2BxYjyJ5QNy%2FbaafftalXtTTInSkHfgMWXzRgQfh44%3D&reserved=0 or watch our webinar: https://nam12.safelinks.protection.outlook.com/? url=https%3A%2F%2Fwww.publishingcampus.elsevier.com%2Fpages%2F206%2FTell-your-research- story-with-					
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