



**UNIVERSIDADE ESTADUAL DE CAMPINAS  
FACULDADE DE ODONTOLOGIA DE PIRACICABA**

**MAYARA ABREU PINHEIRO**

**REABILITAÇÃO ORAL DE IDOSOS COM OVERDENTURES RETIDAS POR UM  
IMPLANTE: ESTUDO LONGITUDINAL**

**ORAL REHABILITATION OF ELDERLY WITH OVERDENTURES RETAINED BY  
ONE IMPLANT: LONGITUDINAL STUDY**

Piracicaba

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

Thesis presented to the Piracicaba Dental School of the University of Campinas in partial fulfillment of the requirements for the degree of Doctor in Clinical Dentistry, in Prosthodontics area.

Orientadora: Prof<sup>ª</sup>. Dr<sup>ª</sup>. Renata Cunha Matheus Rodrigues Garcia

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DA TESE DEFENDIDA PELA ALUNA MAYARA ABREU  
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A Comissão Julgadora dos trabalhos de Defesa de Tese de Doutorado, em sessão pública realizada em 17 de fevereiro de 2020, considerou a candidata MAYARA ABREU PINHEIRO aprovada.

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## RESUMO

A overdenture mandibular retida por um implante (OMRI) é um tratamento simplificado e que melhora a retenção e a estabilidade da prótese inferior. No entanto, aspectos relacionados a mastigação e limitações no tratamento a longo prazo, como os altos índices de manutenção e fratura, precisam ser investigados. Este estudo teve os seguintes objetivos: avaliar através de uma revisão sistemática da literatura, a função mastigatória antes e após a instalação da OMRI (capítulo 1); examinar a mastigação e a qualidade de vida relacionada à saúde oral (QVRSO) em idosos com baixa altura de rebordo, reabilitados com a OMRI, em 24 meses de acompanhamento (capítulo 2); e, avaliar em um período de 24 meses, a necessidade de manutenções e complicações protéticas da OMRI, contendo uma infraestrutura metálica na região anterior e verificar a sua influência na autopercepção do indivíduo com a prótese (capítulo 3). Para a revisão sistemática, buscas de estudos comparando a função mastigatória antes e após a instalação da overdenture foram realizadas. No estudo clínico pareado foram selecionados 15 idosos ( $68,27 \pm 4,77$  anos) com rebordos residuais classes III e IV. Os participantes receberam novas próteses totais (PTs) com uma infraestrutura metálica na região anterior. Após 2 meses de uso, as seguintes variáveis foram avaliadas: performance mastigatória, força máxima de mordida (FMM), espessura do masseter, e QVRSO. Seguindo, os voluntários receberam um implante na região central mandibular. Após a osseointegração, foi realizada a captura por meio de *attachment* do tipo perfil baixo e a PT inferior foi transformada em OMRI. Nos tempos de 2, 12 e 24 meses de uso, as variáveis foram novamente mensuradas. Todas as manutenções e complicações protéticas foram documentadas durante os 24 meses e analisados descritivamente. O teste de ANOVA de medidas repetidas e testes de post hoc foram utilizados a uma significância de 5%. Onze estudos foram incluídos na revisão, com indivíduos edêntulos, acima de 60 anos, e usando PT antes da OMRI. A função mastigatória melhorou após o uso da overdenture e os parâmetros mais investigados foram performance e eficiência mastigatórias. A maioria dos estudos incluídos apresentou baixo risco de viés e uma baixa força de evidência. No estudo clínico, todas as variáveis melhoraram após os 2 meses de uso da OMRI comparando com a prótese total ( $P < 0,05$ ). As variáveis de FMM e espessura muscular aumentaram até 12 meses ( $P < 0,05$ ). Na avaliação de 24 meses nenhuma alteração ocorreu, em relação a 12 meses. Com relação as manutenções, a troca da matriz foi a mais incidente e nenhuma prótese fraturou. A satisfação com a estabilidade da OMRI diminuiu com o tempo ( $P < 0,05$ ), apesar QVRSO não ter sido afetada. Diante dos achados, este estudo pode concluir que a OMRI melhora a função mastigatória, em termos de performance, FMM e

espessura muscular, podendo ser uma alternativa para indivíduos idosos edêntulos com reduzida altura do rebordo mandibular. Ainda a inclusão de uma infraestrutura metálica e a elevada manutenção devem ser consideradas quando a OMRI for o tratamento de escolha.

**Palavras-chave:** Idoso. Mastigação. Arcada edêntula. Próteses e Implantes.

## ABSTRACT

Mandibular single-implant overdenture (SIO) is a simplified treatment that improves retention and stability in the lower prosthesis. However, aspects related to mastication and limitations in long-term treatment, such as, high maintenance rate and fracture index, need to be investigated. Thus, this study had the following purposes: to perform a systematic review to assess masticatory function before and after SIO installation (chapter 1); to verify mastication and oral health-related quality of life (OHRQoL) in elderly people with loss of residual bone height, rehabilitated with SIO, at 24-month follow-up; and finally, to evaluate maintenance and prosthetic complications of the SIO, containing a metal framework in the anterior region, and verify its influence on the individuals self-perception with the prosthesis, during 24 months follow-up period (chapter 3). For the review, searches were performed to collect studies comparing masticatory function before and after SIO installation. For the paired clinical study, 15 elders ( $68.27 \pm 4.77$  years) with Class III and IV residual ridge were selected. Participants received a new set of complete dentures with a metallic framework in the region corresponding to the anterior mandible. After 2 months of use, the following variables were measured: masticatory performance, maximum bite force, masseter thickness and OHRQoL. Following, the volunteers received a single-implant in the midline mandibular region. After osseointegration, low-profile attachments were installed, and the lower dentures were converted into SIO. At 2, 12 and 24 months of SIO use variables were re-measured. All prosthetic maintenance events and clinical complications were registered throughout a 24-months period. Repeated measures ANOVA test and post hoc tests were applied at a significance level of 5%. Eleven studies were included in the systematic review with edentulous subjects, mostly over 60 years and using conventional complete dentures before SIO. Masticatory function improved after SIO use and the most investigated parameters were masticatory performance and efficiency. The majority of included studies had a low risk of bias, but also a low level of evidence was observed. In the paired clinical study, all variables improved after 2 months of SIO use, comparing to complete denture ( $P < 0.05$ ). Maximum bite force and muscle thickness increased until 12 months of use ( $P < 0.05$ ). At the 24-month evaluation no changes occurred. Regarding prosthetic events findings, matrix replacement was the most incident maintenance and no prosthesis fractured. Satisfaction with SIO stability decreased over time ( $P < 0.05$ ), although OHRQoL was not affected. Considering the findings, this study can conclude that SIO improves masticatory function in terms of masticatory performance, maximum bite force and muscle thickness, and may be an alternative for edentulous elderly individuals with loss of

residual bone height. Also, the inclusion of a metallic framework and the high maintenance level should be considered when SIO is the treatment of choice.

**Key words:** Elderly. Mastication. Mouth, edentulous. Prostheses and Implants.

## SUMÁRIO

<b>1 INTRODUÇÃO.....</b>	<b>16</b>
<b>2 ARTIGOS.....</b>	<b>19</b>
2.1 Artigo: Masticatory function improvement with the use of mandibular single- implant overdentures in edentulous subjects—A systematic literature review	20
2.2 Artigo: Mastication and quality of life of elderly people using a mandibular single-implant overdenture: a two years evaluation.	50
2.3 Artigo: Prosthodontics events and self-reported outcomes of a mandibular single-implant overdentures containing a metallic framework: a 24-months follow-up.	73
<b>3 DISCUSSÃO.....</b>	<b>95</b>
<b>4 CONCLUSÃO.....</b>	<b>98</b>
<b>REFERÊNCIAS.....</b>	<b>99</b>
<b>ANEXOS</b>	<b>103</b>
ANEXO 1 - Certificado de aprovação do Comitê de Ética em Pesquisa da Faculdade de Odontologia de Piracicaba.	103
ANEXO 2 – Protocolo de submissão Minerva Stomatologica	104
ANEXO 3 – Relatório de Originalidade	105

## 1. INTRODUÇÃO

Com o aumento da expectativa de vida em todo o mundo, a população idosa apresenta-se como o grupo etário de maior crescimento demográfico (United Nations, 2007). No Brasil, a população com 60 anos ou mais deve atingir um contingente 41,5 milhões, em 2030, e 73,5 milhões, em 2060 (IBGE, 2015). Em contrapartida, segundo o último levantamento de saúde bucal realizado no país (Ministério da Saúde, 2011), apenas 7,3% da porção de indivíduos de 65 a 74 anos, não necessita de algum tipo de prótese dentária.

Os altos níveis de perda dentária em idosos estão relacionados a uma precária saúde bucal, prejudicando a mastigação e a nutrição (Petersen et al., 2010), além de afetar a qualidade de vida desses indivíduos (Petersen et al., 2010). Uma recente revisão sistemática (Roberto et al., 2019) demonstrou que fatores demográficos e socioeconômicos estão fortemente associados a prevalência do edentulismo. A situação econômica, idade e nível educacional da população idosa estão entre os fatores mais frequentemente associados ao edentulismo, sendo o primeiro considerado o principal determinante para a condição (Roberto et al., 2019).

Dessa forma, próteses totais (PTs) convencionais são amplamente utilizadas devido ao baixo custo e a maior acessibilidade. Entretanto, nem sempre é possível atender às expectativas dos pacientes com tal procedimento (Muller et al., 2014), uma vez que, a prótese tem a função de restabelecer a função das estruturas perdidas. A ausência de retenção e estabilidade, principalmente da PT mandibular, resulta em diversos problemas, como dificuldades na mastigação e diminuição da qualidade de vida e satisfação dos idosos com o tratamento, culminando em limitação dos contatos sociais (Grover et al., 2014) destes indivíduos.

Em contrapartida, os avanços no cuidado em saúde bucal dos idosos estão relacionados ao uso de implantes dentais como componente efetivo na reabilitação oral (Nogueira et al., 2018a). Entretanto, esta população pode encontrar dificuldades no acesso ao tratamento, especialmente por restrições financeiras (Nogueira et al., 2018a) e por conseguinte, muitos optam por uma PT mandibular convencional em detrimento de uma prótese sobre implantes. Assim, o uso de múltiplos implantes para reter uma overdenture, pode influenciar negativamente na decisão pelo tratamento (Carlsson & Omar, 2004, Alsabeeha et al., 2009).

O protocolo e o tratamento considerado de primeira escolha para reabilitação de pacientes edêntulos mandibulares é a overdenture retida por dois implantes osseointegrados (Feine et al., 2002), posicionados na região de caninos inferiores. No entanto, além do custo, a



técnica cirúrgica invasiva é um fator limitante para a maior difusão das overdentures retidas por dois implantes (Cordioli et al., 1997).

Dessa forma, a reabilitação com a overdenture mandibular retida por um implante têm ganhado popularidade nos últimos anos (Nogueira et al., 2018b, Paleari et al., 2018, Passia et al., 2019). Foi proposta em meados dos anos noventa para pacientes geriátricos, que, devido à senilidade, necessitavam de procedimentos pouco invasivos que obtivessem uma efetividade quanto a estabilidade e a retenção de suas próteses (Cordioli et al., 1997). Além disso, possui custo reduzido (Walton et al., 2009) e oferece mínimo trauma tecidual, fato que diminui a morbidade do implante e necessidade de manutenção pós-cirúrgica (Cordioli et al., 1997, Grover et al., 2014, Alqutaibi et al., 2017), favorecendo assim, a aplicação desse tratamento para populações com baixo nível econômico ou ainda sua inserção em políticas públicas, especialmente em países subdesenvolvidos ou em desenvolvimento.

Nos últimos anos, a overdenture retida por um implante vem sendo estudada com relação aos parâmetros mastigatórios como performance mastigatória, força de mordida e atividade muscular (Cheng et al., 2012, Grover et al., 2014, Passia, et al. 2017, Amaral et al., 2018, Nogueira et al., 2019, Amaral et al., 2019) demonstrando uma melhora após os primeiros meses de uso quando comparada a PT. A autopercepção dos pacientes e qualidade de vida relacionada ao tratamento protético também apresenta melhores resultados após o tratamento com a overdenture (Nogueira et al., 2017, Policastro et al., 2019, Amaral et al., 2018). No entanto, os estudos que realizaram avaliações da função mastigatória, em sua maioria (Cheng et al., 2012, Grover et al., 2014, Passia, et al. 2017, Amaral et al., 2018, Amaral et al., 2019), o fazem em caráter transversal, sem acompanhamento ao longo do tempo. O período de avaliação mais longo reportado foi de um ano e apenas a performance mastigatória foi usada como parâmetro de avaliação da mastigação (Paleari et al., 2018, Nogueira et al., 2019).

Além do déficit de estudos que avaliem os efeitos do tratamento na mastigação de idosos a longo prazo, o comportamento biomecânico da overdenture é outro ponto que deve ser considerado. Apesar da simplicidade técnica, por não necessitar de paralelismo e pela facilidade de captura durante a conversão da overdenture (Cheng et al., 2012, Passia & Kern, 2014), o direcionamento das forças oclusais para a região implantar, pode levar ao estresse ao redor do implante e a fratura da prótese (Gonda et al., 2010, Bryant et al., 2015). Achados clínicos têm apontado como principais limitações do tratamento a elevada taxa de manutenção das próteses, em termos de trocas de matriz e *attachments*, além de um alto índice de fraturas das overdentures nos primeiros anos de acompanhamento (Gonda et al., 2010, Harder et al., 2011, Nogueira et al., 2018, Passia et al., 2019).

Nesse sentido, a inclusão de uma infraestrutura metálica na região anterior da prótese inferior pode contribuir para a diminuição deste índice de fratura (Gonda et al., 2007, Grageda & Rieck, 2014). Em uma análise de elementos finitos observou-se que a inclusão de uma infraestrutura metálica de Co-Cr na região anterior da prótese mandibular melhora a distribuição de forças e não acarretou nenhum prejuízo nos demais componentes da overdenture (Amaral et al., 2018). No entanto, nenhum estudo acompanhou a longo prazo o comportamento de uma overdenture retida por um implante com uma infraestrutura incluída na região central.

Desta forma, este estudo teve como objetivo avaliar, em caráter longitudinal, a função mastigatória e manutenção protética, além da autopercepção com o tratamento de indivíduos idosos edêntulos, com rebordos reabsorvidos, reabilitados por meio de uma overdenture mandibular retida por um implante, com uma infraestrutura metálica na região anterior. Os objetivos específicos desse estudo foram: 1) avaliar por meio de uma revisão sistemática da literatura, o quanto a função mastigatória pode ser melhorada com a instalação de uma overdenture mandibular retida por um implante; 2) examinar a função mastigatória, em termos de performance mastigatória, força máxima de mordida e espessura do masseter e a qualidade de vida relacionada à saúde bucal em idosos edêntulos reabilitados com overdenture mandibular sobre um implante em um acompanhamento de 24 meses; 3) avaliar a necessidade de manutenção e reparo, além das complicações clínicas da overdenture mandibular retida por um implante, contendo uma infraestrutura metálica na região anterior, como tratamento reabilitador de idosos edêntulos com rebordos reabsorvidos, em um período de 24 meses, e verificar se essa modalidade de tratamento pode influenciar na autopercepção do paciente com a prótese.

## 2 ARTIGOS

Este trabalho foi realizado no formato alternativo, conforme a Informação CCPG/001/2015, da Comissão Central de Pós-Graduação (CCPG) da Universidade Estadual de Campinas.

O artigo 1, intitulado “Masticatory function improvement with the use of mandibular single-implant overdentures in edentulous subjects—A systematic literature review”, foi submetido no periódico *Minerva Stomatologica*.

O artigo 2, intitulado “Mastication and quality of life of elderly people using a mandibular single-implant overdenture: a two years evaluation”, será submetido no periódico *European Journal of Oral Sciences*.

O artigo 3, intitulado “Prosthodontics events and self-reported outcomes of a mandibular single-implant overdentures containing a metallic framework: a 24-months follow-up”, será submetido no periódico *Journal of Prosthodontics*.

**2.1 Artigo: Masticatory function improvement with the use of mandibular single-implant overdentures in edentulous subjects—A systematic literature review. \***

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## ABSTRACT

**INTRODUCTION:** In this systematic review, several masticatory function parameters assessed during mandibular single-implant overdenture (SIO) use were compared to pre- SIO placement values in edentulous patients with aim of contributing to a consensus regarding denture treatment options.

**EVIDENCE ACQUISITION:** This study was registered a priori in the PROSPERO database (CRD42018106567). Two independent reviewers carried out electronic searches in eight databases, without language or time frame limitations, to collate studies comparing masticatory function of edentulous patients before versus after SIO installation with the implant placed on the mandibular midline. Risk of bias was assessed with a before-and-after tool and evidence certainty level was evaluated with the Grading of Recommendations Assessment, Development and Evaluation program.

**EVIDENCE SYNTHESIS:** Eleven studies were included in this review (1 prospective, 3 crossover trials, 4 randomized clinical trials, 2 paired clinical trials, and 1 pilot). Enrolled patients were mostly over 60 years old; all patients were using conventional complete dentures (CD) prior to SIO installation. Masticatory performance, masticatory efficiency, bite force, and muscle activity were improved after the SIO placement compared to during mandibular CD use. Mandibular movement and masticatory ability data were inconclusive. Most of the studies had low risk of bias, but all had very low certainty level ratings due to methodological heterogeneity.

CONCLUSIONS: Placement of SIO improves masticatory function, as reflected mostly by masticatory performance and efficiency data, relative to CD use. Further studies comparing dental rehabilitation options, including SIOs, are needed to improve the quality of evidence in the literature.

Key words: Mouth, Edentulous; Denture, Overlay; Dental Prosthesis, Implant-Supported; Mastication.

## INTRODUCTION

Elderly patients are often rehabilitated with conventional complete denture (CD) prostheses, but many report difficulties adapting to their use, including difficulty chewing foods with hard or inconsistent textures.<sup>1</sup> These problems have the potential to compromise nutrition.<sup>1,2</sup> In addition, over time, patients using conventional CDs are prone to losing residual bone height, which results in poor denture stability<sup>3</sup>, speech impedance<sup>4,5</sup>, limited masticatory function<sup>4,6</sup>, and reduced quality of life.<sup>6,7</sup> It has been suggested that fixation of overdentures with two implants can improve denture retention and stability while increasing overall oral comfort, function, and psychosocial wellbeing.<sup>1</sup> The mandibular single-implant overdenture (SIO) was introduced as a lower-cost, simplified alternative for oral rehabilitation in edentulous elderly people that could be placed with a less invasive surgery than a two-implant denture.<sup>3,8</sup> Relative to two-implant dentures, SIOs have been reported to result in similar marginal bone loss and implant survival outcomes.<sup>9,10</sup> Relative to conventional CDs, SIO users have been reported to have better self-perception, quality of life, and denture satisfaction than conventional CD users.<sup>11</sup>

Although a number of studies have collected data for several parameters of masticatory function in patients rehabilitated with SIOs<sup>7,12-18</sup>, the impact of SIOs on masticatory function is not yet well understood. The available evidence needs to be summarized to clarify the reliability of SIOs, particularly with respect to masticatory function outcomes. The aim of this systematic review was to assess whether and to what extent masticatory function can be improved by replacing a conventional CD with an SIO. Our study sought to answer the following PICO question: Does mandibular SIO rehabilitation improve mastication in edentulous patients compared to conventional CD use before implant installation?

## EVIDENCE ACQUISITION

## **Protocol and registration**

This systematic review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.<sup>19,20</sup> It was registered a priori in the PROSPERO (International Prospective Register of Systematic Reviews) network (CRD42018106567).

## **Eligibility criteria**

Our search strategy was based on a PICO framework: edentulous subjects (P); mandibular SIO (I); conventional CD before implant installation (C); and improvement of masticatory function (O). Clinical studies were considered potentially eligible for inclusion in our analysis if they met the following criteria: prospective paired design (at least one evaluation before and one after SIO installation); conducted in humans; a well-defined objective to assess masticatory parameters (e.g. masticatory performance and efficiency, bite force, muscle activity, mandibular movements, and masticatory ability); and comparison of conventional CD versus SIO use outcomes. Subjective variables, such as quality of life and patient satisfaction, were included as secondary parameters if present. Case reports, review articles, editorials, opinions and studies without a comparison between conventional CD and SIO treatments were ineligible.

## **Information sources and search**

A detailed search, without language restrictions, was conducted to identify studies focused on SIO effects on masticatory parameters. MEDLINE via PubMed, Scopus, Web of Science, LILACS, and Cochrane database were searched (final searches completed in June of 2019). Specific search strategies were developed for each database (Table 1) with the guidance of an experienced librarian (HMC). In addition, the grey literature was searched using



OpenGrey ([www.opengrey.eu](http://www.opengrey.eu)) and the clinical trial protocol databases Clinical Trials ([clinicaltrials.com](http://clinicaltrials.com)) and Rebec ([www.ensaioclinicos.gov.br/](http://www.ensaioclinicos.gov.br/)) were explored. Electronic searches were complemented with a manual search of the reference lists in the included articles. Authors were contacted when it was necessary to obtain more details regarding study design, clarify data, or verify whether they have ongoing studies.

### Study selection and data collection process

Study selection screening was performed independently by two reviewers (MAP and IAM). Citations were first screened based on their titles and abstracts. Full articles of studies determined to be eligible based on their titles or abstracts were then retrieved, and papers determined to be not sufficiently related to the review's aim were excluded (Fig. 1). Disagreement between reviewers was solved by discussion toward reaching consensus and, if appropriate, consultation with a third reviewer (LCM).

**Table 1.** Electronic databases and search strategies according to the PICO question components Database.

Database	Search strategy
Pubmed	(P) #1 Mouth, edentulous [MeSH Terms] OR Edentulous Mouth* [Title/Abstract] OR Mouth, Toothless [Title/Abstract] OR edentulous patient* [Title/Abstract] OR edentulousness [Title/Abstract] OR edentulous mandible [Title/Abstract] OR Mouth, edentulous [Title/Abstract] OR Jaw, Edentulous [MeSH Terms] OR Jaws, Edentulous [Title/Abstract] (I) #2 AND Denture, overlay [MeSH Terms] OR Overdenture* [Title/Abstract] OR Denture, overlay [Title/Abstract] OR Single mandibular implant [Title/Abstract] OR Dental Prosthesis, Implant-supported [MeSH Terms] OR Dental Prostheses, Implant-Supported [Title/Abstract] OR Prostheses, Implant-Supported Dental [Title/Abstract] OR Prosthesis, Implant-Supported Dental [Title/Abstract] OR Denture, Implant-Supported [Title/Abstract] (C) #3 AND Denture, Complete [MeSH Terms] OR Denture, Complete [Title/Abstract] OR Denture

		<p>[Title/Abstract] OR Dental Prosthesis [MeSH Terms] OR Prosthesis, Dental [Title/Abstract] OR Protheses, Dental [Title/Abstract] OR Dentures [MeSH Terms] OR Dentures[Title/Abstract]</p> <p>#1 AND #2 AND #3</p>
Scopus		<p>(P) #1 TITLE-ABS-KEY "Mouth, edentulous" OR TITLE-ABS-KEY "Edentulous Mouth" OR TITLE-ABS-KEY "Edentulous Mouths" OR TITLE-ABS-KEY "Mouth, Toothless" OR TITLE-ABS-KEY "edentulous patient" OR TITLE-ABS-KEY "edentulous patient" OR TITLE-ABS-KEY edentulousness OR TITLE-ABS-KEY "edentulous mandible" OR TITLE-ABS-KEY "Jaw, Edentulous" (I) #2 AND TITLE-ABS-KEY "Denture, overlay" OR TITLE-ABS-KEY overdenture* OR TITLE-ABS-KEY "Single mandibular implant" OR TITLE-ABS-KEY "Dental Prosthesis, Implant-supported" OR TITLE-ABS-KEY "Dental Protheses, Implant-Supported" OR TITLE-ABS-KEY "Protheses, Implant-Supported Dental" OR TITLE-ABS-KEY "Prosthesis, Implant-Supported Dental" OR TITLE-ABS-KEY "Denture, Implant-Supported" (C) #3 AND TITLE-ABS-KEY "Denture, Complete" OR TITLE-ABS-KEY denture OR TITLE-ABS-KEY "Dental Prosthesis" OR TITLE-ABS-KEY "Prosthesis, Dental" OR TITLE-ABS-KEY "Protheses, Dental" OR TITLE-ABS-KEY dentures</p> <p>#1 AND #2 AND #3</p>
Web of Science	of	<p>(P) #1 TS=("Mouth, edentulous" OR "Edentulous Mouth" OR "Edentulous Mouths" OR "Mouth, Toothless" OR "edentulous patient" OR "edentulous patients" OR "edentulousness" OR "edentulous mandible" OR "Jaw, Edentulous") (I) #2 AND TS=("Denture, overlay" OR overdenture* OR "Single mandibular implant" OR "Dental Prosthesis, Implant-supported" OR "Protheses, Implant-Supported Dental" OR "Prosthesis, Implant-Supported Dental" OR "Denture, Implant-Supported" OR "Dental Protheses, Implant-Supported") (C) #3 AND TS=("Denture, Complete" OR denture OR "Dental Prosthesis" OR "Prosthesis, Dental" OR "Protheses, Dental" OR dentures)</p> <p>#1 AND #2 AND #3</p>
Lilacs		<p>(P) #1 tw:(mh:(Mouth, edentulous)) OR tw:(Mouth, edentulous) OR tw:(Edentulous mou*) OR tw:(Mouth, Toothless) OR tw:(edentulous patien*) OR tw:(edentulousness) OR tw:(edentulous mandible) OR mh:(Jaw, Edentulous) OR tw:(Jaws, Edentulous) (I) #2 AND mh:(Denture, overlay) OR tw:(Denture, overlay) OR tw:(Overdenture*) OR tw:(Single mandibular implant) OR mh:(Dental Prosthesis, Implant-Supported) OR tw:(Protheses, Implant-Supported Dental) OR tw:(Prosthesis, Implant-Supported Dental) OR tw:(Denture, Implant-Supported) OR tw:(Dental Protheses, Implant-</p>

Supported) (C) #3 AND mh:(Denture,Complete) OR tw:(Denture,Complete) OR mh:(Dentures) OR tw:(Dentures) OR mh:(Dental Prosthesis) OR tw:(Prosthesis, Dental) OR tw:(Prostheses, Dental) OR tw:(Denture)

#1 AND #2 AND #3

Cochrane Library (P) #1 MeSH descriptor: [Mouth, Edentulous] OR (Edentulous Mouth\* OR Mouth, Toothless OR Mouth, Edentulous OR edentulous patient\* OR edentulousness OR edentulous mandible):ti,ab,kw OR MeSH descriptor: [Jaw, Edentulous] OR (Jaw, Edentulous):ti,ab,kw (I) #2 AND MeSH descriptor: [Denture, Overlay] OR (Overdenture\* OR Denture, overlay OR Single mandibular implant):ti,ab,kw OR MeSH descriptor: [Dental Prosthesis, Implant-Supported] OR (Dental Prosthesis, Implant-supported OR Dental Prostheses, Implant-Supported OR Prostheses, Implant-Supported Dental OR Prosthesis, Implant-Supported Dental OR Denture, Implant-Supported):ti,ab,kw (C) #3 AND MeSH descriptor: [Denture, Complete] OR (Denture, Complete OR Denture):ti,ab,kw OR MeSH descriptor: [Dental Prosthesis] OR (Prosthesis, Dental OR Prostheses, Dental OR Dental Prosthesis):ti,ab,kw OR MeSH descriptor: [Dentures] OR (Dentures):ti,ab,kw

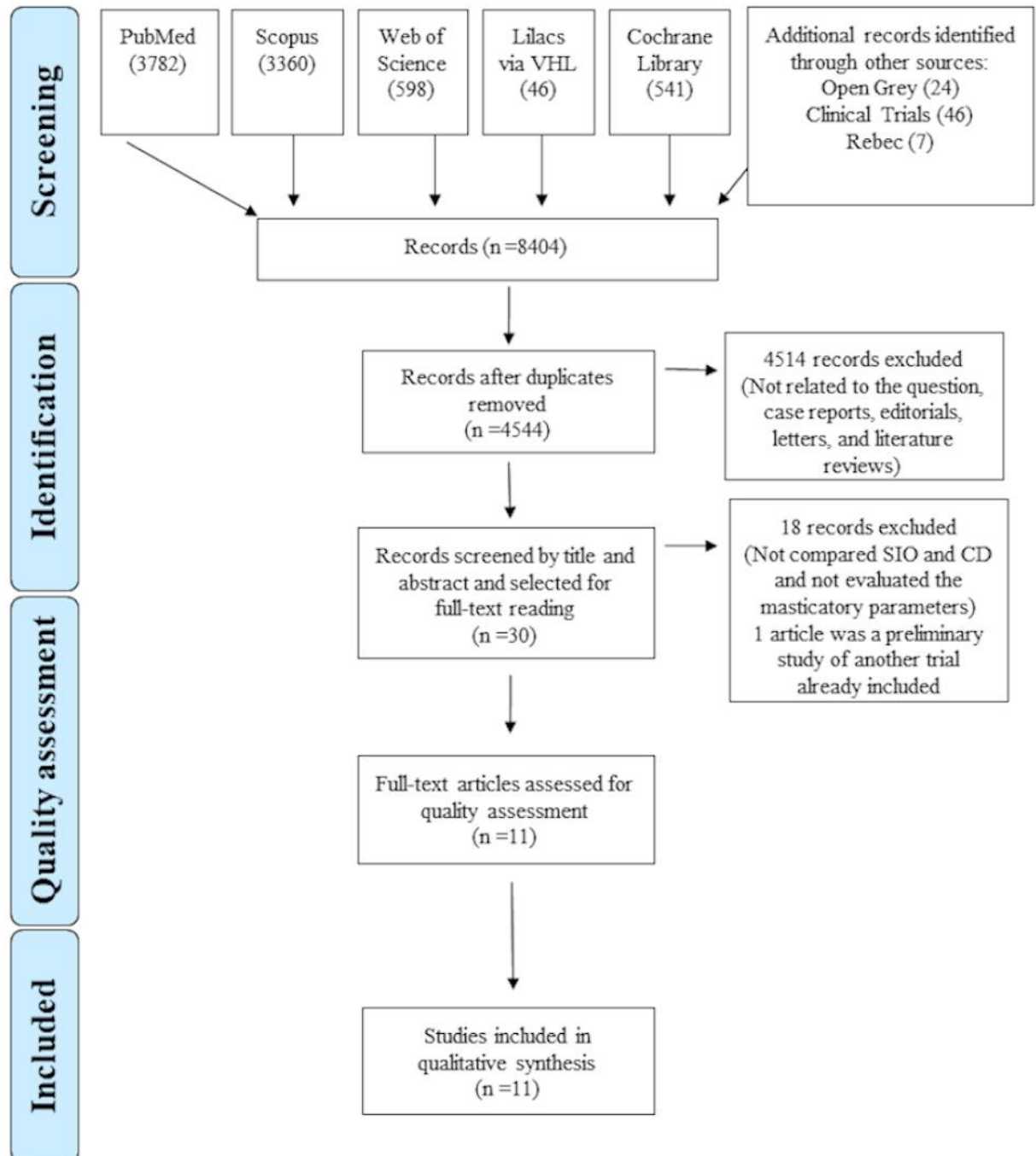
#1 AND #2 AND #3

Open grey (P) #1 "Mouth, Edentulous" OR "Edentulous Mouth" OR "Mouth, Toothless" OR "Mouth, Edentulous" OR "Edentulous Mouths" OR "edentulous patient" OR "edentulous patients" OR "edentulousness" OR "edentulous mandible" OR "Jaw, Edentulous" (I) #2 AND "Denture, Overlay" OR "Overdenture" OR "Overdentures" OR "Single mandibular implant" OR "Dental Prosthesis, Implant-Supported" OR "Dental Prosthesis, Implant-supported" OR "Dental Prostheses, Implant-Supported" OR "Prostheses, Implant-Supported Dental" OR "Prosthesis, Implant-Supported Dental" OR "Denture, Implant-Supported" (C) #3 AND "Denture, Complete" OR "Denture" OR "Dental Prosthesis" OR "Prosthesis, Dental" OR "Prostheses, Dental" OR "Dental Prosthesis" OR "Dentures"

#1 AND #2 AND #3

Clinical trials Overdenture

Rebec Overdenture



**Figure 1.** Flow diagram of the study selection process (VHL, Virtual Health Library).

## **Data items**

Data extracted included the following items: author and year of publication, study design, sample size, gender and age characteristics of participants, follow-up period, variables analyzed, methodology and statistical settings and outcomes.

## **Risk of bias in individual studies**

After final determination of the eligible studies based on reviewing the full texts of the retrieved reports, the researchers analyzed the individual studies for bias risk using the before-and-after checklist.<sup>21</sup> Nine items were considered: (1) clearly established issue or purpose of the study; (2) pre-specified and clearly described eligibility criteria; (3) participants representative of the target population; (4) enrollment of all eligible participants who met the entry criteria; (5) sample size calculation performed at least for the main outcome [articles lacking sample size calculation were designated as not reported (NR)]; (6) clear description and consistent delivery of the intervention; (7) outcome measures were pre-specified, clearly defined, valid, reliable, and assessed consistently; (8) <20% sample loss in the follow-up period (vs. first evaluation); and (9) statistical analysis performed to assess changes in outcome measures before versus after the intervention with resultant p-values reported. The following scoring categories were established: 8–9 “yes” answers, “good” (low risk of bias); 5–7 “yes” answers, “fair” (moderate risk of bias); and  $\leq 4$  “yes” answers, “poor” (lack of information/uncertain risk of bias or high risk of bias).

The certainty of evidence level for each outcome was assessed with the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. Certainty of evidence was rated on scale ranging from high to very low in accordance with level of concern related to each of the following GRADE criteria: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Baseline ratings of high and low were given to

randomized controlled trials (RCTs) and non-RCTs, respectively. The rating was then downgraded one level for each serious concern. Conversely, an upgrade of the rating was considered if there was a large magnitude of effect, of dose response data were included, or if all confounding factors had effects counter to the direction of the observed effect.<sup>22</sup> Certainty in effect estimates were determined for outcomes related to masticatory function (masticatory performance, masticatory efficiency, mandibular movements, maximum bite force, muscle activity and masticatory ability).

## EVIDENCE SYNTHESIS

A PRISMA flow diagram of the study selection process is presented in Figure 1. Briefly, of 8,404 records retrieved in our searches, 3,860 duplicates were excluded. Of the remaining 4,544 records, 4,514 were excluded because they were case reports, editorials, letters, or literature reviews or they did not address our PICO question. The remaining 30 articles were read completely. Eighteen articles were excluded because they did not compare SIO and CD conditions and/or did not assess masticatory parameters. One article<sup>4</sup> was excluded because it was a preliminary study for another trial that was already included<sup>24</sup> in this review. Finally, 11 studies<sup>7,12-18,23-25</sup> fulfilled the inclusion criteria.

Information about, participants, interventions, follow-up periods, measures, statistical analyses, and outcomes of the studies<sup>7,12-18,23-25</sup> are provided in Table 2. The following types of studies were represented: prospective<sup>25</sup>, crossover<sup>7,23,24</sup>, RCT<sup>13,14,16,17</sup>, paired clinical trial<sup>15,18</sup>, and pilot<sup>12</sup>. Participants in the selected studies ranged in age from 51 to 89 years old. With respect to implant size, the ranges of implant length and diameter were 10–13 mm and 3.0–4.1 mm, respectively. The majority of studies<sup>12-18,23-25</sup> used conventional loading with the ball attachment type<sup>12,13,16,17,25</sup> and performed evaluations of masticatory parameters in a short-term follow-up.<sup>7,12, 13,14,18,23-25</sup>

**Table 2.** Data extracted from the studies descriptive of their enrolled patients, interventions, and analyses.

Study		Volunteers					Intervention				Software and statistic test
Author, year	Country	Type of study	N and sex	Age range, y (mean)	Posterior Alveolar ridge evaluation	CD	Type of implant (l × d, mm)	Loading	Type of attachment	Follow-up, mos.	
Harder et al., 2011 <sup>25</sup>	Germany	PS	11 and 5 F 6 M	66.7 (51–86)	NR	Old / new if unacceptable	Titanium Camlog screw line; air-abraded, acid-etched surface (11–13 × 3.8)	CL (after 2 mos.)	Ball	1	NR and Friedman, followed by Wilcoxon
Cheng et al., 2012 <sup>24</sup>	China	CO	15 and 10 F 5 M	NR (53–83)	NR	New	Straumann standard (10 or 12 × 4.1)	CL (after 10 wks)	Magfit and locator	3	SPSS, Wilcoxon
Grover et al., 2014 <sup>7</sup>	India	CO	10 and 4 F 6 M	70 (62–77)	NR	≤6 mos.	Zimmer tapered Swiss Plus SPB12 (12 × 3.7)	IL (after 7 d)	Magfit	3	SPSS, Wilcoxon
Bhat et al., 2016 <sup>12</sup>	India	PL	10 and NR	NR	NR	NR	Endosseous (13 × 3.0)	CL (after 3 mos.)	Ball	1	NR, Wilcoxon
Passia et al., 2017 <sup>13</sup>	Germany	RCT	163 and NR	NR (60–89)	Class II/III* Pan radiograph	Old	Camlog implant (11 × 3.8)	IL(after 4 wks)/ CL (after 4 mos.)(after 4 months)	Ball	1 and 4	SPSS, Wilcoxon
Alqutaibi et al., 2017 <sup>14</sup>	Egypt	RCT	28 and 15 F 13 M	59 (NR)	NR	New	Root-form self-tapping implant	CL (after 3 mos.)	Locator	3, 6, and 12	SPSS, paired t
Amaral et al., 2018 <sup>15</sup>	Brazil	PC	12 and 8 F 4 M	68.6 (±5.2)	Class III/IV* Pan radiograph	New	Titamax HE (11 × 3.75)	CL (After 3 mos.)	Equator	2	SAS, Paired <i>t</i> test and Wilcoxon
Paleari et al., 2018 <sup>16</sup>	Brazil	RCT	11 and 6 F 5 M	64 (±8.3)	NR	New	Internal hexagon (11.5 × 3.75)	CL (After 4 mos. and 2 wks)	Ball	3, 6, and 12	PASW, Friedman, Mann-Whitney or owANOVA, Bonferroni

Policastro et al., 2019 <sup>17</sup>	Brazil	RCTP	11 and 6 F 5 M	64.4 (± 8.3)	NR	New	Internal hexagon (11.5 × 3.75)	CL (After 4 mos. and 2 wks)	Ball	3, 6, and 12	PASW, paired sample owANOVA, Bonferroni.
Amaral et al., 2019 <sup>18</sup>	Brazil	PC	12 and 8 F 4 M	68.6 (± 5.2)	Class III/IV* Pan radiograph	New	Titamax HE (11 × 3.75)	CL (After 3 mos.)	Equator	2	SAS, Paired <i>t</i> test and Wilcoxon
Lam Vo et al., 2019 <sup>23</sup>	Japan	CO	22 and 12 F 10 M	75.6 (±1.8)	NR	New	SLA Ti BLT (10 × 4.1)	CL (After 3 mos.)	Locator	2	SPSS, Wilcoxon

CL, conventional loading; CO, crossover study; d, day(s); F, female; HE, implant hexagon extern; HI, implant hexagon intern; IL, immediate loading;  $l \times d$ , length and diameter; M, male; mo., month; owANOVA, one-way analysis of variance; Pan, panoramic; PC, paired clinical study; PL, pilot study; PS, prospective study; RCT, randomized clinical trial study; RCTP, randomized clinical trial study with two parallel groups; wk, week; y, year(s). \*McGarry et al., 1999.



In addition, all studies were evaluated in the quality assessment (Table 3). With respect to risk of bias, 9 of the 11 selected articles<sup>13-18,23-25</sup> received a ‘good’ score, 1 article<sup>7</sup> received a ‘fair’ score, and 1 article<sup>12</sup> received a ‘poor’ score. All 11 studies reported their purposes unambiguously, described the interventions examined in the study clearly, and delivered the intervention consistently across the study participants. The outcomes were pre-specified, clearly defined, valid, reliable, and consistently evaluated across participants in all 11 studies. Statistical tests with reported p values were applied for pre- versus post-intervention comparisons in all 11 studies. One study<sup>7</sup> did not provide detailed information about the characteristics of its participants. Two studies<sup>7,12</sup> did not describe their eligibility/selection criteria, did not indicate whether all eligible participants met pre-specified entry criteria, and three studies<sup>7,12,25</sup> did not report sample size calculation. One study<sup>12</sup> did not explain its sample losses. All analyzed masticatory function parameters had very low GRADE certainty of evidence levels (Table 4).

**Table 3.** Results of the methodological quality (risk of bias) assessment by before-and-after tool.

<i>Autor, year</i>	Harder et al, 2011 <sup>25</sup>	Cheng et al, 2012 <sup>24</sup>	Grover et al, 2014 <sup>7</sup>	Bhat et al, 2016 <sup>12</sup>	Passia et al, 2017 <sup>13</sup>	Alqutaibi et al, 2017 <sup>14</sup>	Amaral et al, 2018 <sup>15</sup>	Paleari et al, 2018 <sup>16</sup>	PolICASTRO et al, 2019 <sup>17</sup>	Amaral et al, 2019 <sup>18</sup>	Lam Vo et al, 2019 <sup>23</sup>
1. Was the study question or objective clearly stated?	yes	yes	yes	yes	yes	Yes	yes	yes	yes	yes	yes
2. Were eligibility/selection criteria for the study population prespecified and clearly described?	yes	yes	NR	NR	yes	Yes	yes	yes	yes	yes	yes
3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?	yes	yes	yes	NR	yes	Yes	yes	yes	yes	yes	yes
4. Were all eligible participants that met the prespecified entry criteria enrolled?	yes	yes	NR	NR	yes	Yes	yes	yes	yes	yes	yes
5. Was the sample size sufficiently large to provide confidence in the findings at least for main outcome?	NR	yes	NR	NR	yes	Yes	yes	yes	yes	yes	yes



**Table 4.** Certainty of evidence according GRADE approach.

Certainty assessment						No. patients		Certainty
No. studies	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	SIO	CD	
Masticatory ability								
2	Not serious	Serious <sup>a</sup>	Not serious	serious <sup>b</sup>	None	23	23	⊕○○○ VERY LOW
Observational								
Masticatory efficiency								
2	Not serious	Not serious	Not serious	serious <sup>b</sup>	None	27	27	⊕○○○ VERY LOW
Observational								
Masticatory performance								
4	Not serious	Not serious	Not serious	serious <sup>b</sup>	None	196	196	⊕○○○ VERY LOW
Observational								
Mandibular moviments								
2	Not serious	Not serious	Not serious	serious <sup>b</sup>	None	23	23	⊕○○○ VERY LOW
Observational								
Masticatory force								
2	Not serious	Not serious	Not serious	serious <sup>b</sup>	None	32	32	⊕○○○ VERY LOW
Observational								
Muscle activity								
1	Not serious	Not serious	Not serious	serious <sup>b</sup>	None	28	28	⊕○○○ VERY LOW
Observational								

CI, confidence interval. <sup>a</sup>Amaral et al., 2018a and Harder et al., 2011 report different results and conclusions for some fibrous aliments. <sup>b</sup>Total number of patients <300.

Masticatory performance was the main outcome parameter; it was evaluated by a sieve system in 4 studies<sup>7,13,16,18</sup> (Table 5). Masticatory efficiency<sup>16,24</sup>, mandibular movements<sup>17,18</sup>, bite force<sup>12,23</sup>, and masticatory ability<sup>15,25</sup>, were evaluated in 2 studies. Muscular activity was analyzed in 1 study<sup>14</sup>. Regarding secondary outcomes, patient satisfaction with the prostheses<sup>12,15,16,24</sup> and oral health-related quality of life (OHRQoL)<sup>7,17,25</sup> were commonly evaluated (Table 5).

**Table 5.** Data extracted from the studies and outcomes.

Study	Outcomes				
	<i>Variables of masticatory function</i>	<i>Failure/success rate(s)</i>	<i>Sample loses</i>	<i>Prosthetic maintenance (no. events)</i>	<i>Other variables</i>
Harder et al., 2011 <sup>25</sup>	SMA: Significant SIO vs. CD differences for bread, apples, meat, fish, and carrots; not for soft food (potatoes, mashed potatoes, and soup).	Survival rate, 100%	1 male patient died 35 mos after implantation.	Matrix (12)/contour (9) readjustment, abutment loosening (3). Broken midline dentures (6). Replaced abutment (2), attachment (2).	OHIP total scores with SIO significantly different vs baseline. OHIP subscales (except pain) significantly reduced with SIO.
Cheng et al., 2012 <sup>24</sup>	ME (peanuts) with SIO improved significantly after placement of both types of attachment.	NR	3 patients dropped out during follow up for reasons not related to the study.	NR	Patient SAT improved significantly after placement of both types of attachment.
Grover et al., 2014 <sup>7</sup>	SIO improved MP (peanuts) significantly, both arches (conventional and shortened).	NR	NR	Fracture of two mandibular protheses at midline region.	OHIP scores significantly better after SIO.
Bhat et al., 2016 <sup>12</sup>	Bite force of SIO significantly improved compared to CD.	NR	NR	NR	No statistical difference in patient SAT.
Passia et al., 2017 <sup>13</sup>	MP (Optocal) of patients using SIO was significantly increased, 4 mos. after implant loading, compared to CD.	During the first 4 mos., 12 implants failed.	One patient was excluded due to medical conditions before second stage surgery.	NR	None
Alqutaibi et al., 2017 <sup>14</sup>	MA was statistically different between CD and SIO. Lower muscle activity was observed in the SIO users.	Survival rate = 100%	None	NR	No implant or denture fracture at 12 mos.
Amaral et al., 2018 <sup>15</sup>	Transition to SIO greatly increased ME (optocal). SMA, no significant difference between CD and SIO.	NR	3	NR	SAT of volunteers increased with stability of their SIO vs. CD. Aesthetic SAT decreased when mandible CD converted to SIO.
Paleari et al., 2018 <sup>16</sup>	MP (almonds) with SIO significantly increased 3/6/12 mos. after implant loading compared to baseline	90.9%	None	Fracture of two mandibular protheses at midline	SAT obtained from SIO at 3 and 6 months, overall SAT with dentures remained high. At 12 mos., participants experienced SAT decrease vs. prior periods.

Policastro et al., 2019 <sup>17</sup>	HO improvement emerged in SIO users at 6-mo. and 12-mo. follow-ups. Increased LO in SIO users observed at 6-mo. follow-up vs. other periods.	1 implant failed.	None	NR	Overall OHRQoL improved after insertion of SIO, all periods, vs. CD.
Amaral et al., 2019 <sup>18</sup>	SIO increased MP (Optocal), OV, CVC.	None	NR	NR	None
Lam Vo et al., 2019 <sup>23</sup>	MBF of SIO significantly higher vs. CD	NR	None	NR	None

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SMA, Subjective masticatory ability; CVC, closing velocity during chewing; HO, horizontal opening; LO, lateral opening; MA, muscle activity; ME, masticatory efficiency; MM, mandible movements; mo., month; MP, masticatory performance; OV, opening velocity during chewing; SAT, satisfaction, MBF, maximum bite force.

Notably, all 11 studies included in this review reported improvements in masticatory performance, masticatory efficiency, maximum bite force, and muscular activity after SIO placement compared with results obtained during use of a conventional CD, the reference condition. Likewise, improvements in patient satisfaction with dentures and quality of life ratings were improved after SIO installation compared to the reference condition. Because these measures were not standardized, we conducted a descriptive analysis.

## DISCUSSION

The present systematic review showed consistent improvements in masticatory function parameters, as well as subjective measures related to satisfaction and OHRQoL, in edentulous patients following SIO installation, relative to when they were using conventional CDs. Meta-analysis comparisons between conventional CD and SIO conditions have been impaired by methodological differences among studies.<sup>11,26</sup> In this report, we provide descriptive summaries of the included studies that investigated masticatory parameters, in addition to analyzing the methods used for obtaining their outcomes.

The majority of the 11 studies included with subjects older than 60 years of age, consistent with earlier SIO studies,<sup>3,8,25</sup> whose study cohorts include generally older edentulous patients who usually complain of discomfort and functional difficulties with mandibular CD. Most of those investigations used new CDs<sup>14-18,23,24</sup> and conventional implant loading<sup>12-18,23-25</sup>. The ball attachment was the connection more used by researchers<sup>12,13,16,17,25</sup>. Although the ball attachment was widely used, all retention systems must ensure the long-term success of rehabilitation.<sup>27</sup> Besides, only 3 studies included in this review considered alveolar ridge height<sup>13,15,18</sup>, which is an important factor for implant therapy success in elderly people.<sup>28</sup> It has been suggested that edentulous patients with severe alveolar bone loss (i.e. Class IV)<sup>29</sup> are not



suitable candidates for SIO rehabilitation.<sup>28</sup> Thereby, it is not known if this aspect was overlooked during the selecting the sample and / or writing the papers.

Concerning the quality assessment by the before-and-after tool, the lowest scores<sup>7,12</sup> were mainly related to the lack of sample information (characteristics of participants, if all of them met pre-specified entry criteria and sample size calculation). On the other hand, according to the GRADE approach, the certainty of evidence levels of the parameters was very low, mainly due to the inclusion of non-RCTs, which were initially classified as low quality.<sup>22</sup> The levels were downgraded to very low quality due to methodological heterogeneity.

The mastication improvements following SIO insertion was mostly reported by studies that assessed masticatory performance<sup>7,13,16,18</sup> and efficiency<sup>16,24</sup>, however, these researches had used different methodologies. The sieve system was adopted by all studies, nevertheless, 3 of them<sup>13,15,18</sup> employed an artificial material test (Optocal), while the others used natural food as material test.<sup>7,16,24</sup> Although natural food has the advantage of being commonly consumed by subjects, the artificial material test provides more favorable physical properties for analysis, such as a standardized hardness, consistent anisotropy, and resistance to saliva dilution.<sup>30-33</sup> In addition, artificial materials fulfill the need for standardization of masticatory performance and efficiency tests.<sup>32</sup> Regardless, both types of material tests showed improvements in mastication after SIO installation in presently reviewed studies.

Concerning mandibular movements during chewing, Policastro et al.<sup>17</sup> showed larger vertical opening after SIO insertion, and Amaral et al.<sup>18</sup> found greater opening and closing velocities after SIO insertion. Other studies (not included in this review) examining implant-based prostheses showed similar post-treatment increases in masticatory cycle velocity.<sup>34,35</sup> SIO use was shown to result in greater bite force 2 months post-SIO placement<sup>23</sup> and 1 month post-SIO placement.<sup>12</sup> Moreover, implant rehabilitations have been demonstrated to increase bite force.<sup>26,36</sup> Hence, these findings support the notion that dentures stabilized by implants should

allow patients to chew more liberally and to press their mandibular and maxillary dentures together with greater force and control than can be done when wearing conventional CDs.

The last objective masticatory parameter investigated in this review was the muscular activity, evaluated by only 1 study.<sup>14</sup> Its findings demonstrated significantly decreased on masseter and temporalis activity, relative to the conventional CD, throughout the study follow-up period (3 months, 6 months, and 12 months). Notably, that study<sup>14</sup> showed that those decreases correlated with improvement in denture stability achieved by implant use. The authors attributed these effects to patients no longer needing to exert effort to stabilize or retain their prostheses, and therefore requiring less muscle activity during chewing.<sup>14</sup>

Our review also showed contrasting results on masticatory ability of edentulous subjects after using conventional CD or SIO.<sup>15,25</sup> Harder et al.<sup>25</sup> noted a significant difference in masticatory ability between conventional CD and SIO wearers for hard foods (bread, apples, meat, carrots, and fish). However, Amaral et al.<sup>15</sup> showed no differences in ability to chew any type of food between patients using both denture types. This disagreement may be related to different questionnaires used by the referred studies,<sup>15,25</sup> which did not evaluate the same foods.

Finally, in terms of secondary parameters, patients reported better satisfaction and OHRQoL after using SIO.<sup>7,12,15-17,24,25</sup> These positive outcomes are likely consequent to the improved retention and stability provided by SIOs.<sup>14,37</sup> Consistent with these findings, SIOs have been associated with increased self-perception of oral health<sup>11</sup> and improved patient self-reported outcomes<sup>26,38</sup> in other studies (not included in the present review).

## CONCLUSION

Most of the studies included in this review, mainly, evaluated masticatory performance and efficiency and presented low risk of bias. The methodological heterogeneity among them impaired the meta-analysis, as well as reduce the certainty level of parameters included. It was

showed considerable improvement in masticatory function after SIO installation, mainly represented by performance and efficiency measures. Therefore, further studies are needed to fully understand the impact on masticatory function of CD users after rehabilitation with SIO.

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## NOTES

*Conflicts of interest.*— There is no conflicts of interest.

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## **2.2 Artigo: Mastication and quality of life of elderly people using a mandibular single-implant overdenture: a two years evaluation. \***

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**Abstract**

The aim of this clinical study was to prospective evaluate the masticatory function and oral health-related quality of life (OHRQoL) of edentulous elders before and up to two years after single-implant overdenture installation. Fifteen class III/IV edentulous elderly were enrolled. They received a new set of conventional complete dentures (CDs) and after 2 months, masticatory performance, maximum bite force (MBF), masseter thickness and OHRQoL were assessed. Mandibular CD was converted into an overdenture by inserting one external hexagon implant. Variables were reevaluated 2, 12 and 24 months after SIO installation. Masticatory performance was determined by the sieving method, MBF was evaluated with pressure sensors and masseter thickness was measured by ultrasonography. The Geriatric Oral Health Assessment Index (GOHAI) was applied to measure the OHRQoL. Masticatory performance was improved 2 months after overdenture insertion and remained better over time, when compared to baseline ( $P < 0.05$ ). MBF and masseter thickness increased through the 24 months ( $P < 0.05$ ). GOHAI index were higher during overdenture use than during CD use ( $P < 0.05$ ). In conclusion, masticatory function parameters and OHRQoL increased after SIO installation and remained stable through 24 months of follow-up, relative to CD values.

**Key words:** complete denture, dental implants, overdenture, mastication, quality of life.

## INTRODUCTION

Conventional complete denture (CD) remains a frequent treatment option for the edentulous elders (1). However, residual bone height loss can cause difficulties with mandibular CDs (2,3), including discomfort, loss of retention, and poor stability (4), which impair masticatory function and quality of life (5). In this context, overdentures retained by two implants have been a standard treatment for mandibular edentulous patients (3). However, the cost of a two-implant overdenture may be prohibitive for economically disadvantaged populations. Moreover, patients with anatomical impairments may be contraindicated for two-implant installation (2).

Thus, in the 1990s, a single-implant overdenture (SIO) protocol for the mandible emerged as a less invasive alternative procedure for geriatric patients (2). Thereafter, some studies have demonstrated improvements in masticatory function within the first months of SIO installation (4,6-10). Longest period evaluations also reported mastication enhancement after 6 (9) or 12 (8) months of SIO use. Nevertheless, the last studies have evaluated masticatory performance by the mixing ability of a two-coloured chewing gum (9), or by the sieve method using almonds as natural test food (8). However, tests using coloured chewing-gum measure a subject's ability of mixing a semi-solid artificial test food between the teeth, or between tongue and palate, rather than an integrated functioning of all oral structures which are involved in the breakdown of solid foods (11). Besides, natural foods are susceptible to softening in saliva and had high variation in force for breaking and deformation (12), impairing the sieve method accuracy. Thus, evidence of sustained long-term chewing with SIOs is still lacking.

The capacity to grind food is highly dependent on the available bite force (13). Meanwhile, masticatory-muscle thickness significantly declines with age (14), impairing the maximum bite force (MBF) for food comminution over the course of one's lifetime (15). Overdentures supported by two or more implants have been reported to prevent or even reverse

muscular atrophy in elderly patients in short period of time (16,17). SIO can also improves bite force and masseter thickness just after two months of its use (18,19). In contrast, it is still unknown whether muscular thickness obtained by SIO use remains increased over time. In addition, mastication of CDs wearers also depends on the mandibular bone height, once individuals with regular residual bone height have greater masticatory performance than those with mandibular bone resorption (20), However, many studies (4,6,9) have not standardized the posterior bone height of their subjects, which may mask differences in treatment outcomes (9), exposing the needs for further studies.

Besides objective evaluations of masticatory function after prosthetic therapies, subjective measures assessing the individual oral health related quality of life (OHRQoL) including functional, emotional and social well-being, are important because are related to success of dental rehabilitation treatments (21). Several studies have shown a positive effect of SIO on the individual's OHRQoL (5,6,19,22,23) by applying the Oral Health Impact Profile index, which measures changes in the OHRQoL after the insertion of new prostheses (24). On the other hand, the subjective oral health regarding functional problems, pain and discomfort as determined by the Geriatric Oral Health Assessment Index (GOHAI) (25) has not yet been assessed for long term elderly people with SIO. Thus, the aim of this paired clinical study was to compare masticatory function in terms of masticatory performance, MBF and masseter thickness in elderly people with loss of residual bone height, firstly rehabilitated with a conventional CDs and after with a mandibular SIO in a 24-month follow-up period. The OHRQoL evaluated by the GOHAI index was also investigated.

## **METHODS**

Edentulous elderly subjects who lived in the community of Piracicaba city and those seeking oral rehabilitation at the Piracicaba Dental School clinic were eligible for this study.

Each participant first received new conventional maxillary and mandibular CDs (26) with a metallic (cobalt-chromium) framework in the anterior region (27) to prevent early fracture (27,28).

To be included, completely edentulous elderly people with 60 years or older must present the following criteria: (1) mandibular residual ridges classified as Class III or IV, according to the Classification System for Complete Edentulism from the American College of Prosthodontics (29), (2) bone volume and height in the anterior mandibular region that allowed implant insertion without need for major bone augmentation procedures, evaluated by panoramic radiography, (3) a regular salivary flow rate (30), as measured by MUDDUGANGADHAR *et al.* (30), (4) good general health or adequately-controlled systemic disease, and (4) making use a set of clinically unsatisfactory CD (31). Elderly people with parafunctional behavior, orofacial pain, in head and neck radiotherapy treatment, smokers, alcoholics and those with cognitive limitations (evaluated by the Mini-Mental State Examination) (32) were excluded. In addition, elderly people diagnosed with systemic or neurological diseases that would contraindicate implant surgery or those with physical limitations that may prevent parameter evaluations were also excluded.

Upon installation in the mouth, each CD was adjusted according to a bilateral balanced occlusion scheme. Additional adjustments for individual needs were performed until each volunteer affirmed no complaints. Then, all patients wore their new CD for a 2-month period before undergoing baseline assessments. After completing the baseline assessments, one external hexagon implant (11-mm length, 3.75-mm wide; Titamax-ticortical; Neodent, Curitiba, Brazil) was inserted in the mandibular symphysis region of each volunteer and remained covered during the osseointegration process. All surgeries were carried out by using tomographic guides and computed tomography images (27). The conventional mandibular denture was relined with resilient material and used during the osseointegration period. Three

months later, a small incision was made to access the implant platform, and an equator attachment was adapted (Equator; Neodent). The mandibular conventional CD was relieved in the denture base and the conversion to a SIO occurred when the matrix was affixed intraorally with self-curing acrylic resin (27). All prosthetic treatments were made by a single specialized dentist and the same dental technician. Variables were re-evaluated 2, 12, and 24 months after SIO installation.

The study protocol was submitted and approved by the local Ethics Committee (#087/2015) and registered in the Brazilian Registry of Clinical Trials (ReBEC RBR-3kgttj). Study participation was voluntary, and all procedures were performed free of charge for the patients. All participants provided written informed consent, in compliance with the Helsinki Declaration.

Sample size calculation based on previous study (33) indicated that 12 participants would yield 80% power ( $\beta = 0.8$ ) at  $\alpha = 0.05$  based on a difference of 0.5 points in masticatory performance values, considered as the main outcome of this study. In expectation of a 25% withdrawal rate, we enrolled a sample of 15 volunteers, being part of them participants of previous studies (10,19).

### **Masticatory performance**

The sieving method was used to measure masticatory performance with an Optocal material test. After 40 masticatory cycles (34), each subject was instructed to expectorate the comminuted particles onto a paper filter. After drying for 7 days, the particles were submitted to 2-Hz vibration for 20 min in a sieving machine (Bertel Industria Metalurgica, Caieiras, Brazil) with a stack of 10 mesh sieves ranging in passage size from 5.6 mm to 0.5 mm and a bottom plate (34). Particles on each sieve, including the bottom plate, were weighed on an analytical balance.

Masticatory performance was determined according to median particle size ( $X_{50}$ ), calculated with the Rosin-Rammler cumulative function (nonlinear regression analysis)  $Q_w - (X) = 1 - (2 - X/X_{50})^b$ , wherein  $Q_w$  is the percentage by weight of particles with a diameter smaller than  $X$  (measure of sieve opening),  $X_{50}$  is the aperture of a theoretical sieve through which 50% of the chewed particles could pass, and  $b$  is the particle size distribution amplitude (34). Thus, lower  $X_{50}$  values were taken to represent better masticatory performance.

### **Maximum bite force**

MBF was measured with a Quantum X MX840A bite force transducer (Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany) and pressure sensors (diameter, 18.28 mm; thickness, 0.45 mm; FSR 402, Interlink Electronics Inc., Camarillo, CA) (35). Two sensors were placed in the bilateral first artificial molar regions, and signals were recorded and analyzed by Catman Easy software (35). Subjects were requested to occlude with maximum force for 7 s, and the procedure was repeated after a 5-min rest period. The highest measurement obtained was the MBF (36), recorded in Newtons (N).

### **Masseter thickness**

Real-time imaging of masseter muscle thickness was performed bilaterally with a JustVision 200 device (Toshiba®, Tokyo, Japan) at a frequency of 8 Hz (37). Muscle thickness was measured directly on the instrument screen with an accuracy of  $\pm 0.01$ -mm (38). Participants were instructed to sit upright, maintaining their heads in a natural position with the Frankfort plane parallel to the ground (38). Each trial was conducted in a darkened room with the subject seated in an upright position. Measurements were performed by a single examiner who had evaluated the masseter thickness of five edentulous elderly patients previously within a 2-week interval ( $K = 0.967$ ) (39). A standardized protocol was used to establish the correct



location of the muscle site. Initially, the muscle was identified by palpation (area of greatest lateral distention, ~2 cm above the inferior mandibular border) (38) and a line was drawn on the subject's skin marking the site where the transducer should be placed. After applying a conductor gel, the probe was held perpendicular to the muscle, avoiding excessive pressure on the tissue, until the reflection of the bone was depicted as a sharp white line. The thickest part of the muscle was measured perpendicular to the muscle's long axis (38). Two measurements were performed for each muscle at rest and during maximum voluntary clenching. The mean of these two measurements was taken as the final muscle thickness value (38).

### **OHRQoL**

Finally, the OHRQoL was measured by applying a validated Portuguese-language version of the Geriatric Oral Health Assessment Index (GOHAI) (25,40). This index is composed by 12 questions about oral problems that evaluate three dimensions: physical, pain/discomfort and psychosocial. Subjects were asked to respond using a 3-point scoring scale (always, sometimes, or never). The final GOHAI score could range between 12 and 36 and was classified as high (34–36), moderate (31–33), or low ( $\leq 30$ ) (41). Elderly presenting higher GOHAI scores indicated a positive self-rated oral health, as those with lower scores had more self-reported oral health problems (25).

### **Statistical analysis**

Data distributions were assessed with Shapiro-Wilk tests. A mixed generalized linear model of rank-based variance analysis, treated as a repeated measure, was used to examine the hypothesis of a time effect. Repeated measures ANOVA were performed to masticatory performance, MBF and masseter thickness and, when significant results were found, Student's t-tests were applied to compare means, two by two, at different times. A Spearman correlation

was performed between MBF and masseter thickness during contraction. Fisher's Exact Test were applied to GOHAI Index. All statistical analysis was performed in SAS software (version 9.13; SAS Institute Inc., Cary, NC), considering  $P$  values  $\leq 5\%$  statistically significant.

## RESULTS

The study cohort of 15 elderly people (mean age  $68.3 \pm 4.7$  years old; 10 female and 5 male) with normal salivary flow rates ( $1.63 \pm 0.36$  g/mL). However, 2 female participants were lost due to death and personal decision, and consequently 13 participants completed the entire follow-up. Most patients had a low educational level (mean years of education,  $4.47 \pm 2.17$ ) and belonged to the middle socioeconomic class (2.54 Brazilian minimum wage). The average time of edentulousness was  $21.87 \pm 9.25$  years, with 11 subjects having Class III edentulism and 2 having Class IV edentulism (29).

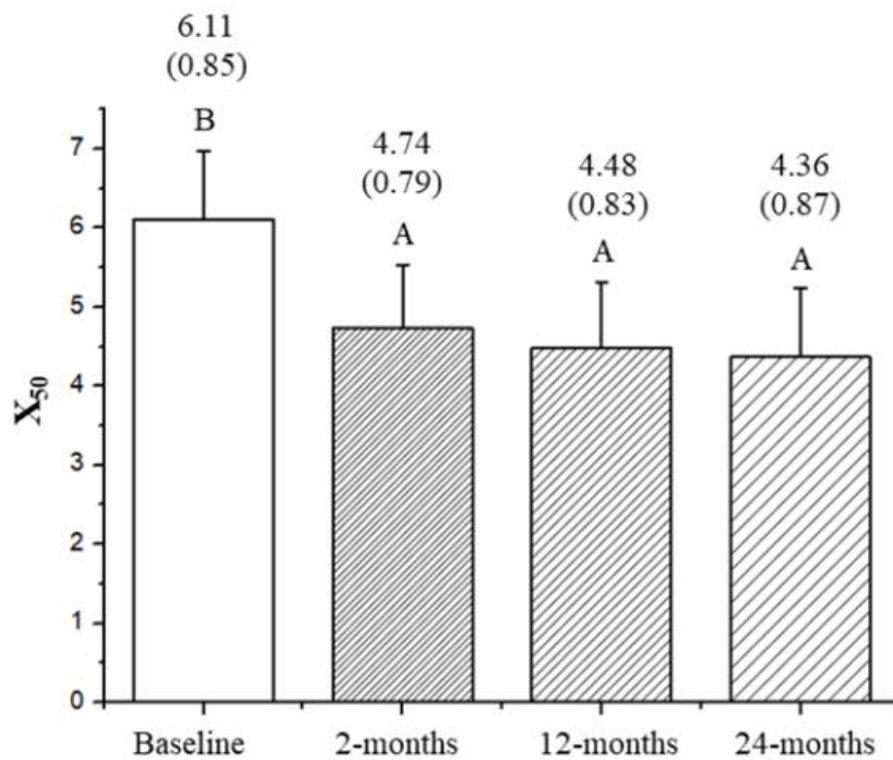
Repeated-measures ANOVA revealed differences ( $P < 0.01$ ) among the evaluation time points for masticatory performance, MBF and masseter thickness (Table 1).

**Table 1** Repeated measures ANOVA testing the time effect hypothesis of  $X_{50}$ , MBF, and masseter thickness

<b>Variable</b>	<b>df</b>	<b>F</b>	<b>P</b>
$X_{50}$	3	15.74	0.0001
MBF	3	26.40	0.0001
Masseter thickness			
At rest, right	3	3.51	0.0241
At rest, left	3	2.96	0.0438
In contraction, right	3	11.77	0.0001
In contraction, left	3	15.21	0.0001

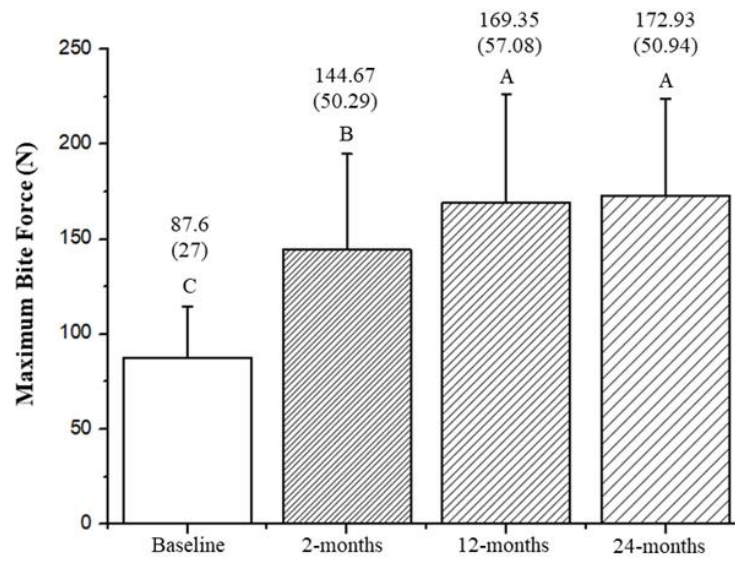
$X_{50}$ , median particle size, MBF, maximum bite force, Df, degrees of freedom.

According to Student's t-test, considering SIO use over time, the comminution capacity remained better when compared to the conventional CD, with no differences among SIO follow-up periods. (*Figure 1*).



*Fig. 1.* Mean values (SDs) of median particle size ( $X_{50}$ ) after conventional complete dentures (baseline) and SIO use.

Student's t-test showed that MBF values were higher ( $P < 0.01$ ) after 12 months (post hoc power = 0.58) and 24 months (post hoc power = 0.72) of using SIOs than they were after 2 months of using SIOs and at baseline (*Figure 2*).



*Fig. 2.* Mean values (SD) of MBF after conventional complete dentures (baseline) and SIO use

Masseter thickness on the right and left sides was also increased during contraction after 12 months and 24 months of SIO use ( $P < 0.001$ , post hoc power= 0.80). On the right side was increased at the 12- and 24-month post-SIO installation time points (*Figure 3*).

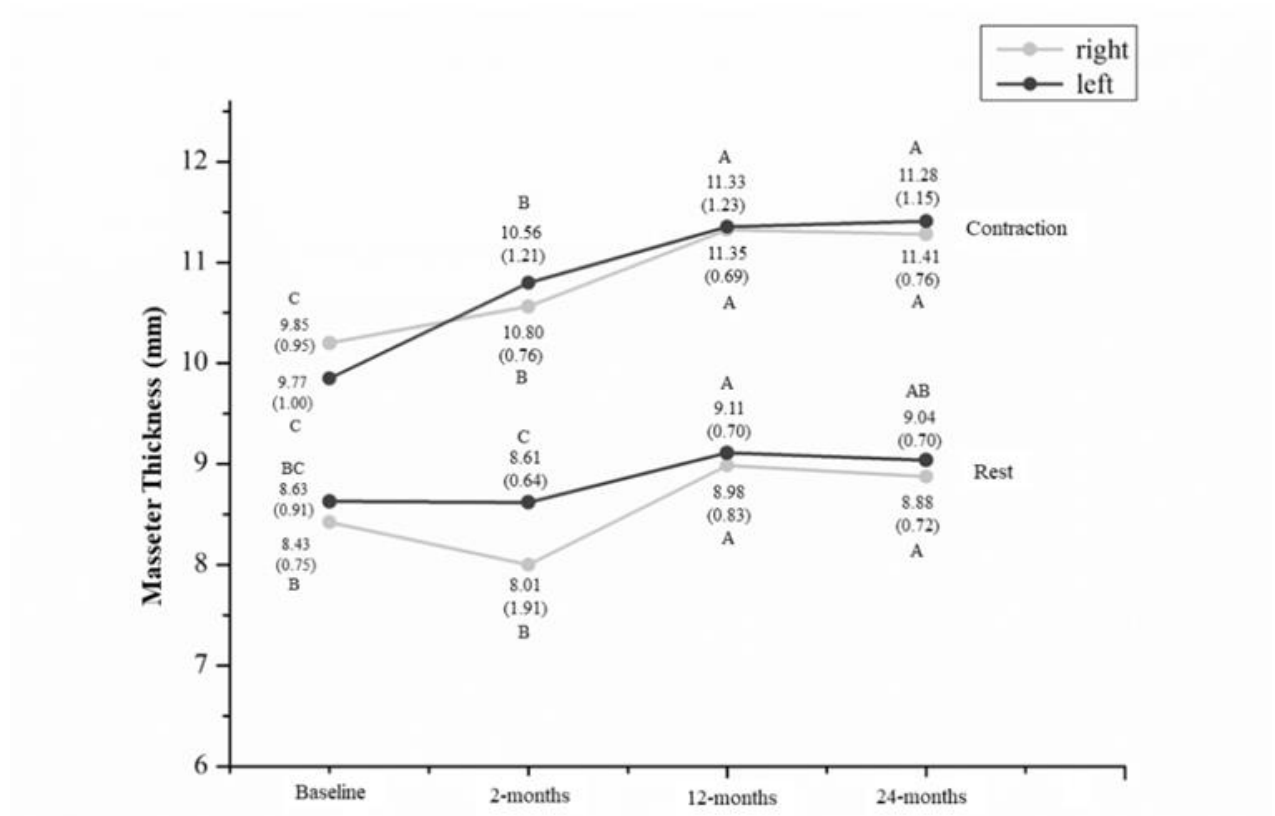


Fig. 3. Mean values (SD) of right and left sides of masseter thickness after conventional complete dentures (baseline) and SIO use

MBF were correlated with masseter thickness during contraction with positive moderate strength on the right and left sides ( $R = 0.525$ ,  $P < 0.001$ ;  $R = 0.634$ ,  $P < 0.001$ , respectively), indicating that these variables increase in tandem. Fisher's Exact Test revealed significant differences over time ( $P < 0.05$ ) for GOHAI Index and improved patients' perceptions on oral functioning after SIO use compared to the conventional CD (Table 2).

**Table 2** Distribution of GOHAI index (%) after conventional complete dentures (baseline) and SIO use.

GOHAI index	Baseline	SIO follow-up		
		2-months	12-months	24-months
Low	1 (6.67%)	0	0	0
Moderate	3 (20.0%)	0	0	0
High	11 (73.33%)	15	14	13
	B	A	A	A

\* Fisher's Exact Test,  $p=0.029$ ; Distinct letters indicate differences among the periods of evaluation.

## DISCUSSION

The present study showed that installation of SIOs improves mastication and OHRQoL of elderly subjects with reduced residual bone height and these enhancements persisted through 24-months of follow-up. Edentulous elders with reduced bone height were selected due their prolonged period of edentulism, which hamper satisfactory recovery of masticatory function with conventional CDs (42). Use of SIOs could improve mastication in these patients, as has been observed with other types of implant-retained overdentures (43).

Masticatory performance was improved after only 2 months of SIO installation. Consistent with previous report (10), this variable was probably improved by SIOs being associated with implant retention in the midline region (4,9). The observed improvement indicate that patients had better comminution of solid materials after SIO installation, which would be expected to imply better food preparation for swallowing. After 12 months and 24 months of SIO use, masticatory performance remained steady, suggesting that once subjects

have adapted to their SIOs, the comminution process did not evolve further over time, remaining greater than with conventional CDs.

Several studies (4,6-8,10) have shown short-term improvements in masticatory performance. In contrast, a recent parallel clinical trial (9) showed similar mixing ability between subjects using conventional CD and those using SIOs at the 12-month follow-up. However, different from the sieve method, the mixing ability test depends less on the crushing and grinding of test foods and more on the coordination and sensitivity of the soft tissues to form boli (44,45), which could explain this disagreement. In addition, the authors (9) did not consider posterior bone height to standardize sample selection.

In the present study, MBF had improved 1.6-times after only 2 months of SIO use and increased almost twice after 12 months of SIO use. These findings agree with previous studies have also shown increased bite force after others implant prosthesis treatments (46,47). Moreover, masseter thickness at contraction was also enhanced following 2 months of SIO installation and continued to increase on both sides until the 12-month time point. These data may reflect implant-retained dentures in edentulous patients supporting masseter muscle training (46). Thus, by increasing muscle thickness it would be expected to consequently increase bite force. It is important to highlight that the MBF post hoc power was greater in the period of 24 months; therefore, even with a statistical difference in 12 months, the strongest improvement occurred in 24 months. At rest, a more pronounced increase in masseter thickness was observed on both sides at the 12- and 24-month time points. Unexpectedly, after 2 years, masseter thickness on the left side returned to baseline values, perhaps due to chewing side preferences.

It is important to note that it was found a moderate positive correlation between MBF and masseter thickness during contraction for both sides, affirming that bite force and masseter activity increased in tandem, supporting a positive effect of using SIOs over time. These



observations could be related to neuroplasticity, wherein behavioral adaptation processes and structural and functional neural circuitry changes occur over a period of time (48). Although this potential may decrease with aging, the elderly remains capable of neuroplasticity (48). Thus, the SIO may improve the action of masticatory muscles, increasing MBF and masseter thickness, similar to training effects on other muscles of the body, which increase in strength and thickness when stimulated.

The OHRQoL was improved after SIO treatment, as evidenced by all elderly subjects having positive GOHAI scores, presumably because the physical, pain/discomfort and psychosocial dimensions were improved after increase in prosthesis retention. This finding is in accordance with the masticatory function outcomes of this study that improved following commencement of SIO use. It is corroborated by prior studies reporting positive effects of SIO treatment on quality of life (5,6, 19, 22,23), which are justified by improvement on mastication (4,7,10) and self-confidence (6).

In summary, all objective parameters of masticatory function, as well as the OHRQoL of elderly people with loss of residual bone height were significantly improved by inserting one implant to retain a mandibular CD. All improvements were sustained even after 24-month follow-up period. In spite of subjects with residual bone height classified as Class IV, which represent the poor edentulous status, should receive a two implants overdentures (49), they were included in our study because they present the least favorable condition for complete dentures use (29).

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*Conflict of Interest*

All authors declare no conflict of interest.

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 I, MUNDT T, MALTZAHN NF, WOLFART S, KERN M. Single Mandibular Implant Study:  
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**2.3 Artigo: Prosthodontic events and self-reported outcomes of the use of a mandibular single-implant overdenture with a metal framework: a 24-month follow-up study. \***

Running title: Long-term reinforced single-implant overdenture use

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## ABSTRACT

**Purpose:** This paired study investigated the maintenance/repair needs and clinical complications of edentulous elderly patients using a single-implant overdenture (SIO) with a metal framework for 24 months. In addition, patients' treatment-related perceptions were examined.

**Materials and Methods:** Edentulous elderly people ( $n = 15$ , mean age  $68.3 \pm 4.8$  years) received sets of new conventional complete dentures (CDs); each mandibular CD had a metal framework in the anterior region. After osseointegration, 1 implant was placed in the central symphyseal region and the mandibular CD was converted to an SIO. Prosthodontic events, such as the need for SIO maintenance, denture fracture, and oral and implant complications, occurring over 24 months were registered. Self-reported patient satisfaction with the SIO was assessed using a 100-mm visual analog scale and oral health-related quality of life (OHRQoL) was measured using the Oral Health Impact Profile for edentulous patients. Assessments were made after 2 months of SIO adaptation (baseline), and after 12 and 24 months of SIO use. Data were analyzed using repeated-measures analysis of variance and Bonferroni post-hoc tests ( $P < 0.05$ ).

**Results:** Matrix exchange was the prosthodontic maintenance event with the highest incidence (83.6%). No implant was lost and no overdenture fracture occurred during follow-up. Three SIOs developed cracks in the anterior regions after 18 months of use. Regarding patients' satisfaction, only satisfaction with SIO stability had reduced after 12 and 24 months ( $P < 0.05$ ); no significant difference in any other measure of satisfaction or OHRQoL was detected over the follow-up period.

**Conclusions:** The increased number of matrix exchanges needed and the need to insert a metal framework to prevent prosthesis fracture should be included in consideration of the use of this

prosthetic treatment. Patients' satisfaction with SIO stability decreased over time, while OHRQoL remained good.

**Keywords:** Prosthetic maintenance; dental implants; implant retained protheses; patient satisfaction; quality of life.

## INTRODUCTION

Advances in oral health care for elderly patients are related to the use of dental implants, which are effective components of oral rehabilitation.<sup>1</sup> However, elderly populations face difficulties with access to such treatments, due mainly to financial constraints.<sup>1</sup> Thus, although implant-retained devices are the gold standard for the rehabilitation of edentulous mandibles,<sup>2</sup> especially for patients with reduced alveolar bone height, conventional mandibular complete dentures (CDs) remain the most commonly used prosthetics for elderly patients.<sup>3</sup>

The mandibular single-implant overdenture (SIO) opposing a maxillary CD has been investigated as an alternative to the mandibular CD.<sup>1,4,5</sup> Recent studies have shown that the SIO improves masticatory performance and efficiency,<sup>4,6-8</sup> maximum bite force,<sup>9,10</sup> and muscular activity<sup>10,11</sup> compared with the CD. In addition, implant survival rates exceeding 95% after conventional loading have been reported.<sup>4,11-13</sup> However, the survival rate may decline to <88% 2 years after immediate loading.<sup>13,14</sup>

In addition to implant survival, the long-term effects of the SIO on functional and self-perceived parameters should be better understood, especially considering that treatment success is defined according to SIO and implant maintenance and failure rates.<sup>15</sup> Mandibular overdentures are known to need repeated matrix exchange, irrespective of the number of implants.<sup>16-18</sup> For the SIO, an incidence rate of 1.46 has been reported for matrix replacement using a ball attachment at 2 years;<sup>19</sup> this procedure entails additional costs and clinical time. This rate is in accord with that for ball attachment maintenance procedures for 2-implant overdentures (~3.5/5 years).<sup>20</sup>

Denture fracture is a frequent SIO-related problem, including in the first year of use.<sup>5,12,19</sup> Of concern for clinical routine, 50% of SIOs have been reported to fractured within 3 years.<sup>12,19</sup> SIO fracture can be explained by the greater concentration of compressive stress near the implant and attachment area,<sup>21</sup> in addition to the creation of a relief chamber in the inner part

of the CD to house the matrix.<sup>5,12,19,22</sup> To delay or prevent SIO fracture, some authors have suggested the inclusion of a framework in the anterior region of the overdenture,<sup>23-25</sup> to better dissipate mechanical forces and reinforce the denture base.<sup>26</sup> A cobalt-chromium (Co-Cr) framework to reinforce the SIO can be manufactured efficiently and inexpensively.<sup>25</sup> Nevertheless, no longitudinal investigation has been performed to verify the benefit of the inclusion of such a metal framework in the SIO.

As modification of the prosthesis-manufacturing technique may influence device acceptance and consequently treatment success,<sup>27</sup> individuals' preferences and self-perceived needs<sup>28</sup> should be evaluated when a denture is produced using a modified method. Thus, the aim of this prospective clinical study was to assess the need for and number of maintenance events (adjustments and repairs) performed on SIOs with metal frameworks during 24 months of use. In addition, clinical complications, patient satisfaction, and oral health-related quality of life (OHRQoL) after long-term SIO use were investigated. The null hypothesis was that the metal framework inserted into the SIO base to prevent fracture would not affect prosthodontic maintenance or the self-reported assessments of SIO wearers.

## **MATERIALS AND METHODS**

This paired clinical trial was approved by the Ethics Committee of Piracicaba Dental School, University of Campinas (protocol no. 087/2015), and was registered in the Brazilian Registry of Clinical Trials (no. RBR-3kgttj), which is linked to the World Health Organization's International Clinical Trials Registration Platform. Elderly people seeking CD treatment at the Piracicaba Dental School were recruited as voluntary study participants. All participants provided written informed consent in accordance with the 1964 Helsinki Declaration and its latter amendments.

Eligible patients were aged  $\geq 60$  years, had good general health or medication-controlled systemic diseases (e.g., hypertension and diabetes), were completely edentulous and using unsatisfactory maxillary and mandibular CDs,<sup>29</sup> and had mandibular posterior bone heights of 10–15 mm with sufficient bone in the symphyseal region for the placement of an 11-mm-long implant (as measured by panoramic radiography). Elderly patients presenting signs and symptoms of temporomandibular disorder, uncontrolled systemic diseases, or osteoporosis; smokers and alcoholics; and those who had undergone head and neck radiotherapy were excluded. Sample size calculation was performed as described elsewhere.<sup>7</sup>

### ***Clinical procedures***

The medical and dental histories of recruited individuals were evaluated, and the individuals were clinically examined. Those selected to participate in the study received new maxillary and mandibular CDs constructed using standard techniques.<sup>30</sup> All dentures were adjusted to a bilaterally balanced occlusal scheme. To dissipate forces and prevent prosthesis fracture, a Co-Cr framework was inserted in the acrylic denture base in the anterior region (canine–canine) of each mandibular CD using a previously described technique.<sup>25</sup> During CD placement, participants received verbal and written instructions on how to use and clean the new dentures. Over the next 3 weeks, according to individual needs, the patients returned to the clinic for adjustments.

After CD use for a 2-month adaptation period, an osseointegrated implant was placed in each participant's central mandibular symphyseal region. Two expert dental surgeons (CSVS and MM) performed all surgeries at the Piracicaba Dental School; the procedures were planned with the aid of computed tomography and multifunctional guides. Under local anesthesia, a conventional 2-stage technique was used to place 1 external hexagonal implant (Titamax-ticortical, 11-mm length, 3.75-mm width; Neodent, Curitiba, Brazil) in the midline of each

edentulous mandible with 45 N/cm torque. Then, the mandibular CD was relined with resilient soft material (Soft Confort; Dencril, Pirassununga, Brazil); this device was used during the 3-month osseointegration period.

Periapical radiographs were obtained using a long-cone paralleling technique to evaluate osseointegration; when this process had been completed, the mandibular CD was converted to an overdenture. The hexagonal implant platform was exposed and a low-profile attachment patrix (Equator; Neodent, Curitiba, Brazil) was attached using 32 N/cm torque, according to the manufacturer's instructions. The height of the Equator attachment was selected to achieve a distance of 1 mm above the gingival margin. The central region of the mandibular denture base was relieved, and the matrix/housing was captured intraorally using self-curing acrylic resin (VipiFlash; Vipi, Pirassununga, Brazil). The acrylic base was polished, and adjustments were made to maintain the previously established bilaterally balanced occlusion. Participants received verbal and written instructions about SIO cleaning and maintenance.

### ***Prosthodontic events and self-reported assessments***

The incidence of maintenance events and clinical complications was registered throughout the 24-month follow-up period, according to patients' needs or scheduled returns for evaluation. The participants were instructed to contact the researchers whenever necessary or in case of any doubt. Prosthodontic maintenance events comprised all SIO and retention system adjustments and repairs, such as those performed to eliminate mucosal sore points, attachment loosening and replacement, and denture relining. Clinical complications included implant failure, the need for postsurgical peri-implant tissue intervention, and overdenture fracture.

Patients reported their satisfaction with the dentures and OHRQoL after 2 months of SIO adaptation (baseline) and after 12 and 24 months of SIO use. Patient satisfaction with the SIO (general, stability, comfort, mastication ability, speaking ability, ease of cleaning, and esthetic

appearance) was determined according to Awad and Feine<sup>31</sup> using a 100-mm visual analog scale (0, totally dissatisfied; 100, completely satisfied). OHRQoL was assessed in 7 domains (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicaps) using the 19-item Oral Health Impact Profile for edentulous patients (OHIP-Edent).<sup>32,33</sup> OHIP-Edent items address factors such as masticatory capacity, eating pleasure, levels of comfort and assuredness while wearing the prosthesis, and social problems to determine the impact of oral health on the quality of life of patients using CDs.<sup>33</sup> Item responses are structured by a 3-point Likert-like scale (2, almost always; 1, sometimes; 0, never); total scores range from 0 to 38, with lower scores indicating better OHRQoL.<sup>33</sup>

### ***Statistical analysis***

The incidence of prosthodontic maintenance events and clinical complications was reported as absolute frequencies. Data on patient satisfaction with the SIO and OHRQoL were tabulated and analyzed to verify the normality of distributions and variance homogeneity of outcomes using the Shapiro–Wilk and Levene tests, respectively. Then, repeated-measures analysis of variance was performed with time serving as the factor. The Bonferroni post-hoc test was applied for multiple comparisons of means among pairs to identify differences within evaluation periods. The statistical analyses were performed using SPSS software (ver. 21.0 for Windows; IBM, Chicago, IL, USA with a significance level of 5%).

## **RESULTS**

Fifteen edentulous elderly patients (10 women, 5 men; mean age,  $68.3 \pm 4.7$  years) participated in the study. Posterior residual bone heights were 15 mm in 6 patients, 14 mm in 4 patients, 12 mm in 2 patients, 11 mm in 1 patient, and 10 mm in 2 patients. No implant failure occurred



during the 24-month period; however, one participant decided to stop using the SIO after the 6th month due to recurrent mucosal inflammation adjacent to the implant. In this case, the low-profile attachment was removed, and a cover screw was connected to the implant; the female part was detached from the denture and the hole was filled with self-curing acrylic resin. One participant died after 18 months.

Matrix exchange (nylon) was the maintenance event with the highest incidence (83.6%). Forty-six matrix replacements were performed, ranging from 1 to 6 per participant (mean,  $3.1 \pm 1.9$ ), including the 2 patients who did not complete the 24-month follow-up period (Table 1).

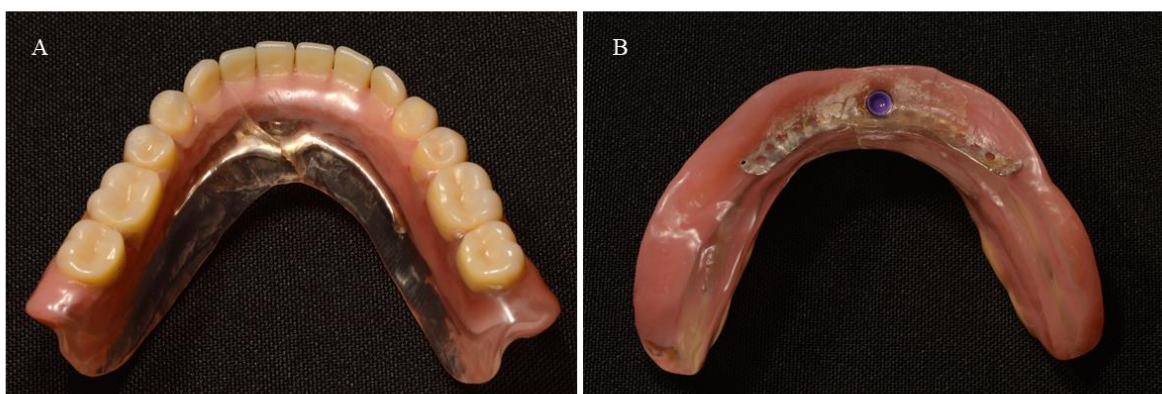
No SIO fractured during the follow-up period, but three SIOs developed cracks in the anterior region (Fig 1). Two cracks occurred when the patients dropped the prostheses into the sink, and the third occurred without the patient's perception (Table 1).

Concerning clinical complications, 1 participant presented mucosal hyperplasia after 3 months of SIO use. Two others (including the patient who discontinued SIO use) had recurrent gingival inflammation in the attachment area, resulting in the application of connective tissue grafts (Table 1).

**Table 1** Repairs, adjustments and clinical complications occurring during 24 months of single-implant overdenture use

Event	Time period		Total	Intervention
	0–12	13–24		
	months	months		
Repair				
Matrix exchange (nylon)	23 <sup>a</sup>	23	46	Replacement
Attachment patrix	0	1	1	Replacement
Matrix/housing	1	1	2	Replacement
Adjustment				
Crack in denture base	0	3	3	Polishing
Clinical complications				
Hyperplasia (mandibular mucosa)	1	0	1	Removal
Recurrent gingival inflammation (attachment area)	2	0	2	Connective tissue graft

<sup>a</sup>Four events occurred before 6 months.



**Figure 1.** A single-implant overdenture with a crack in the anterior region.

Repeated-measure ANOVA applied to evaluate patient satisfaction and OHRQoL by applying OHIP-Edent data are presented in Table 2.

**Table 2** Results of repeated-measures ANOVA for patient satisfaction and oral health–related quality of life

Variable	SS	df	<i>F</i>	<i>P</i>
Patient satisfaction with SIO				
General satisfaction	62.21	2	1.932	0.167
Stability	204.97	1.27	8.34	0.008*
Comfort	50.67	2	1.61	0.220
Ability to chew	0.36	2	0.37	0.96
Ability to speak	46.77	2	2.61	0.094
Ease of cleaning	1.59	2	0.05	0.948
Esthetics	14.31	1.32	1.15	0.318*

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OHIP-Edent scores				
Functional limitation	1.08	2	1.05	0.364
Physical pain	0.18	2	0.20	0.820
Psychological discomfort	2.00	1.29	2.27	0.055*
Physical disability	0.05	2	0.24	0.792
Psychological disability	0.21	1	2.18	0.165*
Social disability	0.51	1	1.00	0.337*
Handicap	0.51	1	1.00	0.337*
Overall	0.359	2	0.06	0.936

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SS, sum of squares; df, degrees of freedom; SIO, single-implant overdenture; OHIP-Edent, Oral Health Impact Profile for edentulous patients. \*Greenhouse-Geisser correction.

Satisfaction with overdenture stability ( $P = 0.008$ ) showed difference between time. Bonferroni's test revealed a decreased from baseline in the SIO stability at 12 ( $P = 0.005$ ) and 24 months ( $P = 0.011$ ) (Table 3). Moreover, Table 4 displays the means of OHIP-Edent domains, analyzed by the Bonferroni test, showing no differences ( $P > 0.05$ ) over the entire follow-up period.

**Table 3** Mean (standard deviation) scores for patient satisfaction with the single-implant overdenture

Domain	2 months	12 months	24 months
General satisfaction	97.40 (4.89) <sup>a</sup>	96.50 (4.20) <sup>a</sup>	94.23 (6.07) <sup>a</sup>
Stability	98.40 (1.54) <sup>a</sup>	95.57 (3.08) <sup>b</sup>	92.54 (5.43) <sup>b</sup>
Comfort	96.47 (6.04) <sup>a</sup>	97.50 (2.79) <sup>a</sup>	94.54 (5.78) <sup>a</sup>
Ability to chew	96.00 (4.05) <sup>a</sup>	96.64 (2.56) <sup>a</sup>	96.46 (2.90) <sup>a</sup>
Ability to speak	98.93 (1.51) <sup>a</sup>	96.86 (4.11) <sup>a</sup>	96.31 (4.15) <sup>a</sup>
Ease of cleaning	97.13 (3.95) <sup>a</sup>	96.71 (3.97) <sup>a</sup>	96.85 (4.02) <sup>a</sup>
Esthetics	98.93 (1.44) <sup>a</sup>	97.64 (3.27) <sup>a</sup>	97.69 (3.88) <sup>a</sup>
Mean	97.82 (1.77) <sup>a</sup>	96.54 (3.79) <sup>a</sup>	95.84 (3.02) <sup>a</sup>

Distinct letters indicate differences among evaluation periods (Bonferroni post-hoc test,  $P < 0.05$ ).

**Table 4** Mean (standard deviation) OHIP-Edent scores

Domain (range)	2 months	12 months	24 months
Functional limitation (0–6)	0.67 (0.62) <sup>a</sup>	1.14 (1.10) <sup>a</sup>	1.08 (0.76) <sup>a</sup>
Physical pain (0–8)	0.33 (0.72) <sup>a</sup>	0.21 (0.80) <sup>a</sup>	0.08 (0.28) <sup>a</sup>
Psychological discomfort (0–4)	0.33 (0.50) <sup>a</sup>	0.21 (0.43) <sup>a</sup>	0.69 (0.75) <sup>a</sup>
Physical disability (0–6)	0.13 (0.36) <sup>a</sup>	0.07 (0.27) <sup>a</sup>	0.08 (0.28) <sup>a</sup>
Psychological disability (0–4)	0.13 (0.36) <sup>a</sup>	0.00 (0.00) <sup>a</sup>	0.00 (0.00) <sup>a</sup>
Social disability (0–6)	0.07 (0.27) <sup>a</sup>	0.00 (0.00) <sup>a</sup>	0.00 (0.00) <sup>a</sup>
Handicap (0–4)	0.00 (0.00) <sup>a</sup>	0.07 (0.27) <sup>a</sup>	0.00 (0.00) <sup>a</sup>
Overall (0–38)	1.67 (1.17) <sup>a</sup>	1.60 (2.26) <sup>a</sup>	1.67 (1.40) <sup>a</sup>

OHIP-Edent, Oral Health Impact Profile for edentulous patients. Distinct letters indicate differences among evaluation periods (Bonferroni post-hoc test,  $P < 0.05$ ).

## DISCUSSION

In the present study, prosthodontic maintenance events, self-reported assessments, and clinical complications of the use of an SIO with an anterior metal framework among edentulous elderly patients were investigated over a 24-month period. Matrix exchange was the most frequent repair needed, with more events occurring after 10 months of SIO use. To promote better resistance against horizontal forces and prevent dislodgement, the matrix considered to have the greatest retention, according to the manufacturer, was used in this study. Despite this effort, the frequency of matrix exchange was greater than reported previously for SIOs.<sup>5,19</sup> Previous studies of implant-retained overdentures, irrespective of the number of implants or type of connection (ball, locator, equator, or magnet) used, have also revealed high frequencies of matrix exchange.<sup>16-18,34,35</sup> Thus, the inclusion of a midline metal framework in the SIO in this study does not seem to have influenced the matrix exchange rate. In agreement with some

authors,<sup>36,37</sup> this high rate could be explained by denture rotation due to differences in height between the anterior and posterior regions, which could affect matrix replacement; we selected subjects with posterior bone heights of 10–15 mm.

Another relevant finding was the lack of SIO fracture during the 2-year follow-up period. Mandibular overdenture fracture is a recurrent problem, mainly for single implant–supported devices.<sup>5,12,19</sup> The metal reinforcement of the SIO in this study prevented denture fracture without impairing other components. Thus, we achieved treatment success with the use of this prosthesis for edentulous elderly people with loss of posterior residual bone height.

We used a conventional loading protocol in this study, as the immediate loading of a single implant in an edentulous mandible should be considered only in exceptional cases.<sup>13</sup> Follow-up complications were mucosal hyperplasia in 1 patient after 3 months of SIO use, treated by tissue removal with no recurrence, and recurrent painful gingival inflammation in the attachment area in 2 patients after 6 months of SIO use, treated by connective tissue grafting to improve mucosal thickness. This procedure eliminated the symptoms in 1 patient, whereas the other patient decided to return to conventional CD use. In the latter case, we believe that the inflammation was attributable to the reduced thickness of the keratinized mucosa remaining after SIO capture; keratinized mucosa is considered to be a barrier contributing to the maintenance of implant stability and function, preventing soft-tissue recession and facilitating oral hygiene.<sup>38</sup>

Patient satisfaction with SIOs has been investigated extensively, with contrasting results reported. Some studies have revealed better satisfaction with stability, comfort, and speech after SIO use,<sup>19,39</sup> whereas others have shown little difference in satisfaction, or increases in the initial months of SIO use followed by declines to values comparable to CD satisfaction over time.<sup>4,40</sup> In the present study, almost all measures of patient satisfaction were high and remained stable; satisfaction with SIO stability decreased during the follow-up period, possibly reflecting

greater stability of the mandibular denture immediately after installation, followed by the loss of matrix retention and need for maintenance.

OHRQoL did not change during the follow-up period in this study, supporting the ideas that SIO treatment positively affected individuals' quality of life and that the inclusion of a metal framework did not affect patients' treatment-related perceptions. Although previous studies showed an improvement after SIO use,<sup>19,41</sup> the overall OHIP-Edent score obtained in the present study was 3 times lower than scores reported by Nogueira et al.<sup>19</sup> and Policastro et al.<sup>41</sup> (means of 1.67, 4.0, and 6.45, respectively), obtained in the first months of SIO use. Although the OHIP-Edent score was low and OHRQoL did not increase over time in this study, the preserved lower scores could be considered as a positive impact of this rehabilitation on self-perceived quality of life.

Despite our attempt to conduct a well-designed clinical trial, the results of this research should be interpreted carefully. The absence of a control group of elderly patients using an SIO without the metal framework should be considered. Moreover, the production of a Co-Cr framework for insertion into the CD could be considered to increase costs and laboratory and/or clinical time. However, as reported previously,<sup>25</sup> each framework cost <\$20 dollars; the lack of SIO fracture with framework use could be considered to overcome the increased cost and processing time. As clinicians and patients seek treatments that combine the least invasive and most economical approaches with favorable biomechanical behavior, the results of this study suggest that the SIO with a midline Co-Cr framework is an alternative to mandibular CDs for edentulous elderly patients.

## CONCLUSIONS

The inclusion of a metal framework to reinforce an SIO is a promising treatment option for elderly edentulous patients, as it could prevent fracture and does not influence patients'



perceptions. The need for frequent maintenance interventions must be considered when making decisions about the use of this treatment modality.

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### 3 DISCUSSÃO

O presente estudo teve por objetivo analisar sistematicamente a mastigação de idosos reabilitados por meio de overdentures mandibulares retidas por um implante, além de verificar por meio de um estudo clínico pareado, a mastigação, os achados clínicos e a autopercepção de idosos reabilitados pela overdenture mandibular durante 24 meses de acompanhamento.

O prejuízo causado na função mastigatória devido à perda dentária e a reabsorção do rebordo alveolar muitas vezes não pode ser restaurada com o tratamento através de PTs convencionais. A adição de um implante na região central da mandíbula favorece a mastigação no que diz respeito a performance e eficiência mastigatórias, os dois parâmetros mais investigados na literatura, logo após os primeiros meses de uso da overdenture. A melhora na mastigação está relacionada a retenção e estabilidade promovida pelo implante instalado, que promove uma diminuição nos movimentos horizontais da prótese (Cheng et al., 2012) e permite aos indivíduos uma maior capacidade de trituração. Entretanto, a evidência científica demonstrou-se insuficiente no que diz respeito às demais variáveis da função mastigatória, como força de mordida e espessura muscular, especialmente quando o aspecto longitudinal do tratamento é requerido.

Por outro lado, um dos maiores problemas relacionados à overdenture retida por um implante é a fratura da prótese (Gonda et al., 2010, Harder et al., 2011, Nogueira et al., 2018, Passia et al., 2019). Dessa forma, realizou-se um estudo clínico que além de analisar diferentes aspectos da mastigação em idosos por um período prolongado, também observou o comportamento clínico de uma overdenture mandibular com uma infraestrutura metálica na região anterior, em termos de manutenções e reparos protéticos. Em adição verificou-se como a inclusão da infraestrutura influencia a autopercepção dos idosos com o tratamento.

A overdenture mandibular retidas por um implante demonstrou ser efetiva na melhora da função mastigatória, quando comparada a PT, no período de 24 meses de acompanhamento. Corroborando os achados prévios da revisão sistemática, a variável de performance mastigatória melhorou significativamente nos dois primeiros meses de uso da overdenture. Durante o período de acompanhamento, nenhuma mudança significativa ocorreu nos valores, portanto, a performance mastigatória permaneceu constante e melhor que a PT. Desta forma, acredita-se que a partir do momento que o indivíduo está adaptado a nova prótese, ocorre também uma estabilização no processo de trituração do alimento durante o ciclo mastigatório, não ocorrendo maiores mudanças com o passar do tempo.

Em adição, as variáveis de força máxima de mordida e espessura do músculo masseter tiveram um aumento significativo até os 12 meses de uso da overdenture, não ocorrendo alterações na avaliação de 24 meses. Além disso, observou-se uma correlação positiva entre as duas variáveis. Assim, o tempo de uso da prótese teve influência nos resultados desses parâmetros, uma vez que da mesma forma que nos demais músculos do corpo, o maior estímulo tende a aumentar a atividade e a espessura muscular. Ademais, a reabilitação com overdentures mandibulares retidas por um maior número de implantes também foi relacionada a uma melhora na atividade dos músculos da mastigação (Muller et al., 2014, Melo et al., 2018).

Além disso, a qualidade de vida relacionada a saúde oral avaliada pelo GOHAI melhorou após a inserção da overdenture, o que corrobora tanto com a melhora na mastigação observada em nosso estudo, como com diversos estudos na literatura que reportam uma melhora na qualidade de vida após o tratamento com overdenture (Nogueira et al., 2017, Nogueira et al., 2018, Policastro et al., 2019).

A inserção de uma infraestrutura metálica na região anterior da prótese mandibular partiu da necessidade de prevenir ou retardar a ocorrência de fraturas relatadas em estudos prévios (Gonda et al., 2010, Harder et al., 2011, Nogueira et al., 2018, Passia et al., 2019). Optou-se por uma infraestrutura em Co-Cr, que proporcionaria uma maior dissipação das forças, sem prejudicar os demais componentes da prótese (Amaral et al., 2018), além de não aumentar em demasia o custo do tratamento (Amaral et al., 2019).

Nenhuma fratura ocorreu no período de 24 meses, e apesar de três próteses apresentarem uma trinca, nenhum reparo foi necessário, realizando-se apenas o polimento da superfície. Um elevado índice de manutenção no que diz respeito a troca da matriz (*o'ring*) foi observado, quando comparado a estudos com overdenture retida por dois implantes (Mathias et al., 2019) ou mesmo com outros estudos de overdenture retida por um implante (Nogueira et al., 2018, Passia et al., 2019). Este achado pode estar relacionado ao fato de termos incluído idosos com altura de rebordo residual classificados como Classes III e IV (McGarry et al., 1999), ou seja apresentando uma altura de 15 a 10 mm, o que favorece a rotação posterior e pode comprometer a durabilidade da retenção proporcionada pela matriz, mesmo sendo usada a de maior retenção segundo o fabricante. Apesar disso, o *attachment* do tipo perfil baixo foi de fácil uso e proporciona conforto e retenção para a overdenture mandibular.

O elevado índice de manutenção e reparo requerido pelo tratamento ressalta a necessidade de avaliação do custo da overdenture mandibular retida por um implante, em caráter longitudinal, a fim de identificar o relação custo-benefício e a efetividade do tratamento. Uma vez que se confirmado o baixo custo mesmo, a simplicidade técnica facilita a inserção



desta modalidade de reabilitação em políticas públicas de países em desenvolvimento, como é o caso do Sistema Único de Saúde no Brasil, onde é possível o financiamento de próteses associadas a implantes, com o custo de aproximadamente R\$260,00 por implante e R\$300,00 por prótese (Brasil, 2017).

Durante os meses de acompanhamento, três pacientes necessitaram de intervenção cirúrgica. O primeiro devido a uma hiperplasia na região anterior da mandíbula, solucionada com a remoção do tecido hiperplásico. Outros dois participantes apresentaram uma mucosite na região peri-implantar devido provavelmente a fina espessura de mucosa queratinizada remanescente após a captura. Um enxerto de tecido conjuntivo (proveniente da região de túber maxilar do próprio paciente) foi realizado no local. Em um dos casos a intervenção foi bem-sucedida, entretanto no outro o participante decidiu voltar a usar a PT mandibular.

A diminuição da satisfação com a estabilidade da overdenture pode estar relacionada à recorrente necessidade de manutenção, uma vez que, apenas essa característica teve alteração significativa, sem interferir, entretanto, na satisfação geral com o tratamento. A qualidade de vida associada a saúde oral, avaliada pelo OHIP-Edent não sofreu alteração durante os 24 meses, e quando os valores são comparados a outros estudos clínicos com overdenture retida por um implante, os escores encontrados no presente estudo foram menores (Nogueira et al., 2018, Policastro et al., 2019). Assim, uma autopercepção positiva da qualidade de vida pode ser uma característica inerente a amostra utilizada.

Desta forma, a overdenture mandibular retida por um implante com uma infraestrutura na região central, foi capaz de promover uma melhor função mastigatória quando comparada a PT convencional, além de prevenir a fratura da prótese. Apesar da satisfação com o tratamento ter diminuído, no que diz respeito a estabilidade da overdenture, a qualidade de vida relacionada a saúde oral permaneceu alta e inalterada durante o período observado. No entanto, ao decidir-se por essa modalidade de tratamento, alguns pontos devem ser levados em consideração. Primeiro, a altura do rebordo residual, uma vez que esta característica pode estar relacionada ao maior índice de manutenção observado. Em casos de rebordos menores ou iguais a 10 mm, talvez um maior número de implantes seja requerido. Outro fator é a quantidade de mucosa queratinizada na região do implante, que deve ter pelo menos 2 mm de espessura para não causar uma mucosite, recorrente. Apesar da elevada manutenção o *attachment* do tipo perfil baixo parece ser uma boa escolha de uso e deve ser associado a matriz de maior retenção. E finalmente, o uso da infraestrutura em Co-Cr fornece uma maior segurança quanto a prevenção de fratura da overdenture.

## 4 CONCLUSÃO

A evidência científica demonstra melhora na função mastigatória, representada pelas medidas de performance e eficiência, após uso da overdenture mandibular retida por um implante, quando comparada ao uso das próteses totais convencionais.

Em 24 meses de acompanhamento, a função mastigatória permaneceu estável e superior à PT convencional, em termos de performance mastigatória, força máxima de mordida, espessura do masseter, além da qualidade de vida relacionada a saúde oral ter melhorado após o uso da overdenture.

A overdenture mandibular sobre um implante com uma infraestrutura metálica na região anterior pode ser considerada como uma alternativa viável para idosos edêntulos, uma vez que, nenhuma fratura foi observada nos 24 meses de acompanhamento. O elevado índice de manutenções da prótese deve ser levado em consideração quando a overdenture for escolhida como a opção de tratamento.

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\*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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## ANEXOS

### ANEXO 1 – Certificado de aprovação do Comitê de Ética em Pesquisa da Faculdade de Odontologia de Piracicaba.



**COMITÊ DE ÉTICA EM PESQUISA**  
**FACULDADE DE ODONTOLOGIA DE PIRACICABA**  
**UNIVERSIDADE ESTADUAL DE CAMPINAS**



## CERTIFICADO

O Comitê de Ética em Pesquisa da FOP-UNICAMP certifica que o projeto de pesquisa "Função mastigatória e qualidade de vida de idosos reabilitados com overdenture sobre implante central mandibular único", protocolo CEP/FOP nº 087/2015, CAAE-46547715.0.0000.5418, dos pesquisadores **RENATA CUNHA MATHEUS RODRIGUES GARCIA, CAMILLA FRAGA DO AMARAL e MAYARA ABREU PINHEIRO**, satisfaz as exigências do Conselho Nacional de Saúde – Ministério da Saúde para as pesquisas em seres humanos e foi aprovado por este comitê em 20/09/2016.

The Ethics Committee in Research of the Piracicaba Dental School, University of Campinas, certify that the project "Ancestry Estimate from Face Linear and Angular Measures", register number CEP/FOP nº 087/2015, CAAE-46547715.0.0000.5418 of **RENATA CUNHA MATHEUS RODRIGUES GARCIA, CAMILLA FRAGA DO AMARAL e MAYARA ABREU PINHEIRO**, comply with the recommendations of the National Health Council – Ministry of Health of Brazil for research in human subjects and therefore was approved by this committee on Sep 20, 2016.

**Prof. Jacks Jorge Junior**

Coordenador  
 CEP/FOP/UNICAMP

Nota: O título do protocolo aparece como fornecido pelos pesquisadores, sem qualquer edição.  
 Notice: The title of the project appears as provided by the authors, without editing.

## ANEXO 2 – Protocolo de Submissão Minerva Stomatologica.

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## ANEXO 3 – Relatório de Originalidade

Mayara, 2020

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