Luis Eduardo Carneiro Campos

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"A new rehabilitation protocol for edentulous patients with the use of fixed prosthesis supported by implants - a Retrospective study"

Tese apresentada ao Programa de Pós-graduação da Faculdade de Odontologia da Universidade Federal de Uberlândia, como requisito parcial para obtenção do título de Doutor em Odontologia na Área de Concentração: Clínica Odontológica Integrada

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Orientador: Prof. Dr. Darceny Zanetta-Barbosa
Co-Orientadores: Prof. Dr. Claudio Pinheiro Fernandes
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ATA DE DEFESA - PÓS-GRADUAÇÃO

Programa de Pós-Graduação em:	Odontologia				
Defesa de:	Doutorado				
Data:	Trinta e um de outubro de dois mil e dezenove	Hora de início:	10:00	Hora de encerramento:	14:35
Matrícula do Discente:	11513ODO010				
Nome do Discente:	Luis Eduardo Carneiro Campos				
Título do Trabalho:	Estudo Retrospectivo da Reabilitação do Edentulismo com um Novo Protocolo de Prótese Fixa Implantossuportada				
Área de concentração:	Clínica Odontológica Integrada				
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Reuniu-se no Anfiteatro/Sala 23 Bloco 4L - Anexo A Campus Umuarama, da Universidade Federal de Uberlândia, a Banca Examinadora, designada pelo Colegiado do Programa de Pós-graduação em Odontologia, Professores Doutores: Flávio Domingues das Neves (UFU); Karla Zancopé (UFU); Taís Alves dos Reis (FPM); Israel Chilvarquer (USP) participou da defesa de Tese por meio de vídeo-conferência desde a cidade de São Paulo e Darceny Zanetta Barbosa (UFU) orientador(a) do(a) candidato(a).

Iniciando os trabalhos o(a) presidente da mesa, Dr(a). Darceny Zanetta Barbosa, apresentou a Comissão Examinadora e o candidato(a), agradeceu a presença do público, e concedeu ao Discente a palavra para a exposição do seu trabalho. A duração da apresentação do Discente e o tempo de arguição e resposta foram conforme as normas do Programa.

A seguir o senhor(a) presidente concedeu a palavra, pela ordem sucessivamente, aos(às) examinadores(as), que passaram a arguir o(a) candidato(a). Ultimada a arguição, que se desenvolveu dentro dos termos regimentais, a Banca, em sessão secreta, atribuiu o resultado final, considerando o(a) candidato(a):

Aprovado(a).

Esta defesa faz parte dos requisitos necessários à obtenção do título de Doutor.

O competente diploma será expedido após cumprimento dos demais requisitos, conforme as normas do Programa, a legislação pertinente e a regulamentação interna da UFU.

Nada mais havendo a tratar foram encerrados os trabalhos. Foi lavrada a presente ata que após lida e achada conforme foi assinada pela Banca Examinadora.

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DEDICATÓRIA

Ao Criador,

Agradeço por ter me concedido o sopro da vida, bem como aqueles que de alguma forma me deu a oportunidade de conviver. Por ter me dado a boa e a má sorte, pois com elas aprendi o verdadeiro significado do “Livre Arbítrio”. Presente que somente alguém de tamanha sabedoria, como o Senhor, poderia dar a um filho! Presente que lego a seus “netos”. Obrigado por me guiar até aqui, pois a ciência é um dos melhores caminhos para seguir seus passos e entender seus *landmarks*.

À minha família,

Aos meus pais e avós**, Leônidas e Maria, Selva e Luiz, José e Otília**, que nos mostraram os caminhos e nos deram as ferramentas necessárias para vencermos! Pois acreditavam que um Mundo melhor é construido através do conhecimento. Agradeço aos meus irmãos **Antonio, Augusto e Tatiana** por compartilharem comigo as derrotas e vitórias desta caminhada planetária. A minha esposa, amante e confidente, **Patrícia**. Anjo que entrou em minha vida quando nada mais valia a pena! Aos meus filhos, **Anneliese** e **Leonardo**, que mantém em mim a chama da juventude, e a quem eu posso passar o que foi impresso em meu espírito por meus antepassados. Aos meus segundos pais, **Artur e Magda**, que estiveram e ainda estarão em nossas vidas por todo o sempre!

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A todos vocês, Shalom Adonai – α – Ω

"A vida é um restaurante que serve apenas dois pratos: "bom" e "ruim".
Cabe a você escolher qual deseja."

Luis Eduardo Carneiro-Campos

SUMÁRIO

RESUMO

O edentulismo é um problema de saúde pública, com impacto direto na qualidade de vida. Considerando este fator esta tese de doutorado possui três objetivos específicos: 1 – Avaliar a influência de diferentes desenhos oclusais maxilares nos índices de sobrevivência das próteses mandibulares totais fixas metaloplásticas implantossuportadas por meio de revisão sistemática e meta-análise; 2 – Apresentar um novo desenho de guia multifuncional para procedimentos de carga imediata mandibular, através de relato de caso. 3 – Analisar a sobrevivência de protocolo reabilitador com próteses mandibulares totais fixas metaloplásticas suportadas por 3 implantes opostas à próteses totais convencionais. Em um total de 112 dentições naturais maxilares, 69 implanto-suportadas e 204 removíveis, a prevalência geral de falhas foi: 5,4% (6/112; IC 95% [2,3 a 10,76]), 13,99% (20/69; IC 95% [0,77 a 39,41]) e 4,9% (10/204; IC 95% [0,69 a 12,18]) respectivamente. Não houve diferenças estatísticas nas taxas de sucesso entre naturais e removíveis (Diferença = 0,00 [-0,06,0,06]; P = 0,93; I2 = 27%) ou entre naturais e implanto-suportadas (Risco Diferença = 0,00 [-0,06, 0,07]; P =, 97; I2 = 0%). Com moderada certeza de evidência que o desenho das dentições maxilares, sejam estas naturais ou protéticas, não é determinante no sucesso das metaloplásticas fixas implanto-suportadas mandibulares. A guia multifuncional transferiu com precisão a localização cirúrgica, a impressão, a dimensão vertical e transferência de dados ao laboratório de prótese dentária. Os comprimentos digitais dos cantilevers distais radiográficos variaram de 1,7 mm a 22,9 mm. O Coeficiente de Correlação Intraclasse apresentou resultados acima de 0,9. O teste t pareado retornou valores de p>0,05 para todos os grupos. De um total de 50 próteses mandibulares instaladas sobre 150 implantes houve falha de 10 implantes. As complicações técnicas observadas foram afrouxamento do parafuso do pilar (3,0%), afrouxamento do parafuso protético (17%), fratura do parafuso protético (1%), descolamentos e fraturas da superestrutura (16%), fratura da estrutura metálica (2%), fraturas da prótese maxilar (6%) e perda da prótese mandibular (4%). As taxas de sobrevivência cumulativa de implante e prótese mandibular foram de 93,3% e 96%, respectivamente. As principais complicações peri-implantares foram a formação de biofilme, sangramento à sondagem e dor, que foram controlados durante as visitas de manutenção. Nenhuma das variáveis avaliadas influenciou falhas clínicas e/ou complicações técnicas em níveis estatisticamente significantes. A cirurgia guiada para instalação de implantes mandibulares em região de sínfise mandibular pode ser realizada com guias multifuncionais de baixo custo com previsibilidade. A utilização de próteses totais convencionais maxilares opostas a próteses fixas totais mandibulares implanto-suportadas por três implantes, sendo um em posição vertical em sínfise mandibular e os outros inclinados bilateralmente em

sentido distal é uma modalidade de tratamento confiável e de baixo custo, a ser replicado no combate ao edentulismo em escala mundial.

Palavras-Chaves: boca edêntula, análise de sobrevivência, implante de prótese dentária suportada, carregamento imediato do implante dentário, implante dentário, revisão sistemática, radiografia panorâmica.

ABSTRACT

Edentulism is a public health problem, with direct impact over quality of life. Considering this fact, this Doctoral Thesis will pursue four specific objectives: 1 – Evaluate the influence of different maxillary dentitions on the survival rate of mandibular metal-resin implant-fixed complete denture, by means of systematic reviews and meta-analysis; 2 – Present a new multifunctional template design for immediate loading procedures, by means of a case report and 3 – Analyze rehabilitation protocol survival of mandibular metal-resin implant-fixed complete denture, supported by 3 implants, opposed by conventional dentures. In a total of 112 natural, 69 implant-supported and 204 removable dentitions, the general prevalence of failure was respectively 5.4% (6/112; IC 95% [2.3 a 10.76]), 13,99% (20/69; IC 95% [0.77 a 39.41]) e 4.9% (10/204; IC 95% [0.69 a 12.18]). There were no statistical differences between natural and removable dentitions (difference = 0,00 [-0.06, 0.06]; P = 0.93; I2 = 27%), or not even between natural and implant-supported (difference risk = 0,00 [-0.06, 0.07]; P = 0.97; I2 = 0%). With moderate certainty of evidence it is suggested that natural maxillary dentitions do not affect the survival rate of mandibular mandibular metal-resin implant-fixed complete denture differently from other prosthetic designs. The multifunctional template precisely transferred the surgical implants locations, the impression, the vertical dimension and data transfer to the dental technician. Radiographic cantilever extensions varied from 1.7 mm a 22.9 mm. Intra-Class Correlation (ICC) presented values over 0.9. T-test returned values of $p>0.05$ for all groups. From fifty mandibular prostheses, installed over 150 implants, 10 implants failed. Technical complications observed were abutment screw loosenings (3,0%), prosthetic screw loosenings (17%), prosthetic screw fractures (1%), superstructure detachments (16%), framework fracture (2%), fractures of maxillary dentures (6%) and loss of mandibular prosthesis (4%). Cumulative survival rates of implants and mandibular prosthesis were respectively 93.3% and 96%. Main peri-implant complications were biofilm formation, bleeding on probing and pain, which were controlled during maintenance visits. None of the evaluated variables influenced clinical failures and/or technical complications in statistical significant level. The guided surgery

for the installation of mandibular implants on the mandibular symphysis can be performed with enough predictability, using low cost multifunctional templates. The use of maxillary dentures as opposed mandibular metal-resin implant-fixed complete dentures, supported by three implants, being one in the vertically placed, in the mandibular symphysis, and the other two distally tilted in parasymphisary regions, is a reliable, and should be be encouraged for the treatment of edentulism in global scale.

Key-words: mouth edentulous, analysis survival, dental prosthesis implant supported, immediate dental implant loading, dental implant, systematic review, panoramic radiograph.

1. INTRODUÇÃO E REFERENCIAL TEÓRICO

O edentulismo é uma condição prevalente, e é responsável por um terço das desabilidades relacionadas a desordens orais no mundo (1). Nestas circunstancias a reabsorção óssea se mostra como um processo contínuo (2), diminuindo especialmente em mandíbulas (3) o suporte e a estabilidade das próteses totais convencionais (4). O que faz com que utilização de próteses totais fixas metaloplásticas implantossuportadas seja uma opção viável e previsível em longo prazo (5). Entretanto seus altos custos desencorajam importante parcela da população, especialmente em países com baixa renda (6,7). Nas últimas décadas consideráveis esforços científicos (8–12) têm sido reportado para cumprirem esta demanda social após a introdução do carregamento imediato de implantes (13–15).

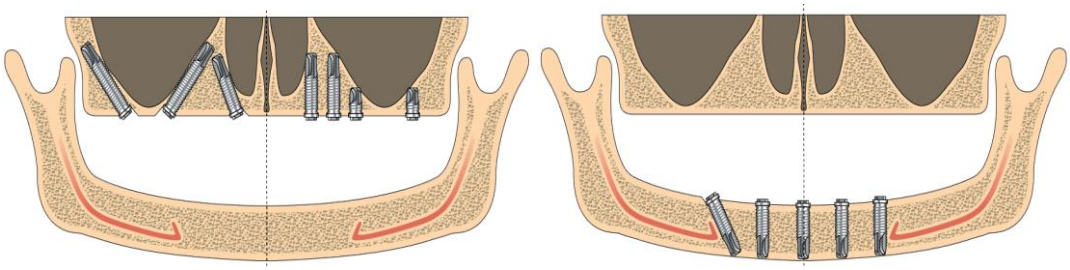
Fonte: Brånemark *et al*., 1999.

Figura 1: Sistema Brånemark Novum®. Conceito "*Teeth in a Day*". O sistema apresentava infraestrutura metálica pré-fabricada que deveria ser recoberta por superestrutura com dentes e resina em acrílico. A presença de extensões cantileveres distais era notada.

No ano de 1999, o conceito cirúrgico e protético, Brånemark Novum® para a reabilitação de mandíbulas edêntulas (Figura 1), contemplava a instalação de três implantes verticalmente posicionados e paralelos entre si em região mentual em carga imediata. A utilização de padrões e guias cirúrgicas pré-fabricadas proporcionaram agilidade na conclusão do tratamento e índice de sobrevivência de 98% (10,16–18). Todavia os altos custos,

associados e os critérios de indicação limitados, impediram a utilização da técnica de maneira mais ampla.

A inclinação de implantes em regiões nasais, mentuais e sinusais (Figura 2) foi proposta por Krekmanov *et al* (2000) a fim de minimizar a morbidade cirúrgica, comum aos enxertos ósseos. Como consequência houve ganho biomecânico, uma vez que prorcionou a redução do comprimento horizontal das extensões cantileveres distais (19).



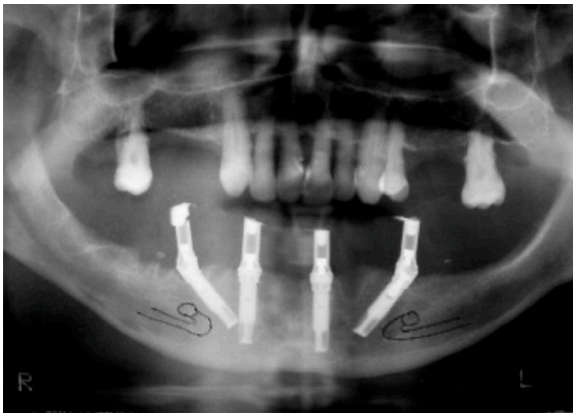
Fonte: Krekmanov *et al.,* 2000.

Figura 2: Implantes inclinados para diminuir morbidade com a utilização de procedimentos de enxertos e aumento da área de suporte distal

Devido às evidências que se construiam, no ano de 2003 foi apresentado o conceito “All-on-Four” (20), que previa a redução do número de implantes associados às inclinações dos mesmos (Figura 3), reduzindo custos, comprimento dos cantileveres distais e ampliando o escopo biomecânico das próteses totais fixas mandibulares (21–23).

Aceitas, porém não desejadas, extensões cantileveres são regiões que apresentam de forma reconhecida uma considerável gama de fragilidades mecânicas para com o sistema (24–26). Comprimentos entre 15mm (27,28) e 20mm (29) são até o momento os parâmetros literários utilizados como aceitáveis para as extensões, entretanto ainda não foram claramente evidenciados (30), mantendo o tema aberto a discussão (31–33). Observa-se na maioria das vezes que mensurações dos comprimentos das extensões cantileveres são realizadas por metodologias de baixa acuidade como imagens analógicas e reguas plásticas. Mesmo estudos que utilizam métodos de maior precisão, como exemplo, paquímetros digitais; desconsideram em sua maioria

a presença de assimetrias comuns as diversas anatomias protéticas (19,26,28), o que impossibilita naturalmente as aferições acuradas.



Fonte: Maló *et al.,* 2003.

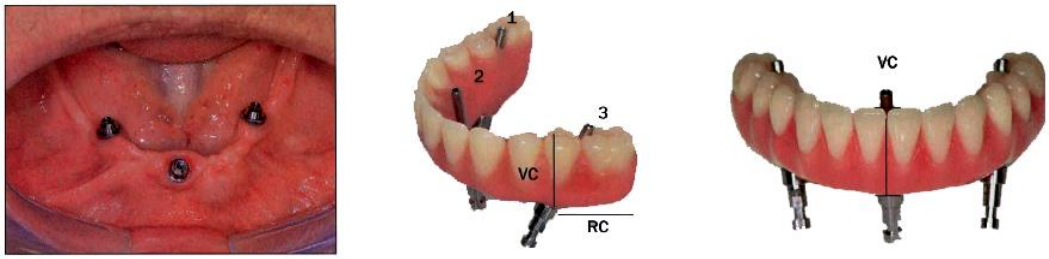
Figura 3: Conceito “All-on-Four”. Implantes inclinados anteriormente aos forames mentuais para diminuir a morbidade de mais eventos cirúrgicos.

Dentre as dificuldades propostas em relação a distribuição de tensões em próteses totais fixas metaloplásticas implantossuportadas e suas limitações mecânicas é relevante reconhecer que o sucesso reabilitador dependerá de fatores como: idade, gênero, número, distribuição e estado de saúde da dentição remanescente (34,35). Além disso, a estabilidade da dentição restaurada é também é influenciada por aspectos funcionais, como força e velocidade mastigatória (36,37). Desta forma, é compreensível que interferências mecânicas influenciem as taxas de sobrevivência (38) das reabilitações orais, tais como o padrão oclusal maxilar (39,40) ou mesmo possível sobrecarga oclusal (41–44).

Em relação às próteses totais fixas metaloplásticas implantossuportadas com extensões cantileveres distais, as complicações clínicas mais comuns são: os afrouxamentos dos parafusos protéticos, fraturas e destacamentos dos dentes artificiais ou do material de revestimento (40,42,45).

Mais recentemente, no início da última década, seguindo os índices de sobrevivência propostos pelo sistema Brånemark Novum® (10,16–18), a redução do número de quatro para três implantes (Figura 4), sendo os implantes distais posicionados com inclinações distais, foi proposta para uso contemporâneo (46). Esta nova abordagem, associada a novos desenhos de guias multifuncionais teve como objetivo a manutenção dos benefícios das técnicas previamente descritas. Entretanto a inovação estava relacionada a redução de custos sem perda de confiabilidade, apresentando taxas de sobrevivência entre 96,7% (47) e 97,1% (12).

Para que sejam considerada previsíveis, novas abordagens e técnicas devem ser desenvolvidas sob diretrizes estritas (48), bem como avaliado sob parâmetros precisos de diagnóstico (49) de acordo com ensaios clínicos de longo prazo bem projetados para produzir protocolos padrão (50).



Fonte: Costa *et al*. 2015.

Figura 4: Utilização de prótese fixa metaloplástica mandibular suportada por três implantes de acordo com da união dos conceitos Brånemark Novum® (1999) e de implantes inclinados (Krekmanov e colaboradores, 2000).

Neste contexto a busca de soluções de baixo custo, reprodutíveis e acessíveis a um maior número de profissionais e pacientes, assim como replicáveis no serviço público de saúde são bem vindas. Sendo assim se faz necessário indagar: 1 – "Próteses totais implantossuportadas metaloplasticas fixas mandibulares com extensões cantileveres distais, opostas a diferentes padrões oclusais maxilares, sejam estes naturais ou protéticos, apresentam diferentes índices de sobrevivência?"; 2 – "Guias multifuncionais não prototipados são capazes de auxiliar, com precisão clínica, a instalação de

implantes em sínfise mentoniana para o carregamento imediato e conclusão da reabilitação protética maxilo-mandibular?"; 3 – "Próteses fixas metaloplásticas mandibulares suportadas por 3 implantes, sendo um deles instalado em sinfise mentoniana e os demais inclinados distalmente em regiões parassinfisárias, opostas a próteses totais convencionais em procedimentos de carregamento imediato, apresentam índices de sobrevivência similares aos demais desenhos descritos na atualidade para o manejo do edentulismo?". Desta forma o objetivo principal desta Tese de Doutorado foi:

Avaliação retrospectiva de protocolo reabilitador de arcos edêntulos sob carregamento imediato desenvolvido com a finalidade de diminuição de custos e alcance social.

Como objetivos específicos teremos:

2.1. Objetivo Específico 1: Analisar a influência de diferentes desenhos oclusais maxilares nos índices de sobrevivência das próteses mandibulares totais fixas metaloplásticas implantossuportadas;

2.2. Objetivo Específico 2: Analisar a aplicação clínica de novo desenho de guia multifuncional não prototipado para procedimentos de carga imediata de próteses mandibulares totais fixas metaloplásticas implantossuportadas;

2.3. Objetivo Específico 3: Analisar os índices de sobrevivência de próteses e implantes de protocolo reabilitador do edentulismo com próteses mandibulares totais fixas metaloplásticas implantossuportadas por 3 implantes opostas à próteses totais convencionais, divididas em três fatores de estudo: perda de osseointegração; complicações técnicas e periimplantares.

2

CAPÍTULOS

CAPÍTULO 1 – ARTIGO 1

Carneiro-Campos, LE; Freitas-Fernandes, LB; Masterson, D; Magno, MB; Fernandes, CP; Maia, LC; Zanetta-Barbosa, D. Does the natural maxillary dentition influence the survival rate of mandibular metal-resin implant-fixed complete dental prostheses in a different way of prosthetic dentitions? A systematic review and meta-analysis

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Does the natural maxillary dentition influence the survival rate of mandibular metal-resin implant-fixed complete dental prostheses in a different way of prosthetic dentitions? A systematic review and meta-analysis

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SYSTEMATIC REVIEW

Does the natural maxillary dentition influence the survival rate of mandibular metal-resin implant-supported fixed complete dentures? A systematic review and meta-analysis

ABSTRACT

Statement of problem. Consensus is lacking regarding the influence of the maxillary dentition on the survival rate of a mandibular metal-resin implant-supported fixed complete denture (MRISFCD) with distal cantilevers.

Purpose. The purpose of this systematic review was to identify whether an opposing natural dentition influences the survival rate of mandibular MRISFCDs.

Material and methods. A literature search was performed, up to February 2018 from MEDLINE/PUBMED, SCOPUS, Web of Science, Cochrane Library, BBO/LILACS databases and non peer-reviewed literature through Open Grey. Clinical studies regarding natural (ND), removable prostheses (RP), and complete-fixed maxillary implant dentitions (ID) with at least a 1-year of follow-up were included. The quality of the included studies was analyzed, and the risk of bias reported. A meta-analysis comparing the survival rate of ND with RP and ND with ID was performed with a confidence interval of 95%, and heterogeneity was tested by an I^2 index. Grading of recommendations, assessment, development, and evaluations (GRADE) was used to determine the certainty of the evidence.

Results, From a total of 112 ND, 69 ID, and 204 RP in the maxillary dentition, the overall prevalence of failures was 5.4% (6/112; 95% CI [2.3 to 10.76]) for ND, 13.99%

(20/69; 95% CI [0.77 to 39.41]) for ID, and 4.9% (10/204; 95% CI [0.69 to 12.18]) for RP. No statistical differences were detected in the success rates between ND and RP (Risk Difference = 0.00 [-0.06,0.06]; *P*=.93; I^2=27%) or between ND and ID (Risk Difference=0.00 [-0.06,0.07]; *P*=.97; I^2=0%), both with moderate evidence.

Conclusion. With a moderate certainty of evidence, it is suggested that natural maxillary dentitions do not affect the survival rate of mandibular MRISFCDs differently from other prosthetic designs.

CLINICAL IMPLICATIONS

Different maxillary dentitions did not influence the survival rates of mandibular metal-resin implant-supported fixed complete dentures. However, adequate treatment planning is important for long-term predictable outcomes.

INTRODUCTION

Complete dentures, especially in the maxilla, are accepted as viable treatments for maintaining the self-esteem and quality of life of most edentulous individuals.[1,2] However, in the mandible,[3] implant-supported restorations should be considered the most predictable alternative.[4] The use of mandibular metal-resin implant-supported fixed complete dentures (MRISFCDs) with distal cantilevers supported by 5 or 6 implants in the mental region, opposed by maxillary complete removable dentures has been well described.[5-8] Favorable results have encouraged the development of alternative approaches, for example, improvements in the number and positioning of implants (upright or tilted), as well as the common clinical use of different opposing dentitions.[5,7-13] However, consensus on the influence of the opposing dentition has still not been reached.[14-17]

Mastication is a mechanical system that depends on factors including the age and sex of the patient and the number, distribution, and status of the remaining dentition.[18,19] The stability of the restored dentition is influenced by other functional aspects, including mastication force and velocity.[20,21] Increased failure rates of mandibular MRISFCDs have been reported to be more frequent when opposed by a natural or fixed dentition than by a removable complete denture.[22,23] Long-term clinical complications are usually of a technical nature, for example, screw loosening, fractures, and loss of the denture teeth or the veneering material.[23-25] Diagnostic errors,[26-28] as well as the presence of overload in the masticatory system have been identified as decisive factors in such complications.[24,29-31] Thus, the effects of individual occlusal forces and loading conditions are factors that may influence treatment survival rate and should be considered.[32]

The purpose of this systematic review was to identify whether the natural or prosthetic maxillary dentition influences the survival rate of mandibular metal-resin implant-fixed complete dentures with distal cantilevers.

MATERIAL AND METHODS

The review was conducted to answer the following question: "Does the natural maxillary dentition influence the survival rate of MRISFCD in a different way to other prosthetic maxillary dentitions?". This study fulfilled the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[33] and was registered at the International Prospective Register of Systematic Reviews (PROSPERO) database under CRD 42017061075.

Studies were selected according to the population, intervention, comparison, outcome (PICO) strategy[34] as follows: population - edentulous patients rehabilitated

with MRISFCD; intervention - any modality of prosthetic maxillary rehabilitation; comparison - natural dentition or natural dentition with some partial fixed maxillary restorations; outcome - the evaluation of the survival rate of MRISFCD; and study design - only retrospective and prospective clinical studies in humans. Studies evaluating dental records were also accepted. All studies had at least a 1-year of follow-up. Also, the maxillary dentition was as functional as possible.

The presence of all natural teeth in the maxilla and combinations with partial fixed restorations (teeth and/or implants) were considered a natural dentition (ND).[35,36] Complete dentures, removable partial dentures (RPDs), and teeth or implant-retained dentures (implant overdentures) were considered removable prostheses (RP). Complete-fixed implant-supported prostheses were considered an implant dentition (ID) with implants placed in the mental region.[6,37] Variations of the original Brånemark protocol, such as the number and placement (upright or tilted) of the implants were accepted. Immediate bone loading and immediate placement of implants at fresh extraction sites were acceptable if a horizontal plateau was obtained after the osteotomy of the implantation site.[13] Studies conducted for the evaluation of both maxillary and mandibular arches were also accepted, but the results of the mandibular arch were only considered for the present systematic review. However, those that did not distinguish the types of failures that occurred in the maxilla and mandible were excluded.

Animal studies, case reports, in vitro studies or reviews, studies that did not record the opposing dentition, including the natural and at least one other and those conducted in patients with uncontrolled acute, chronic, or autoimmune diseases, as well as neurological diseases, skeletal, genetical or pathological abnormalities that needed to be treated with adverse maxillofacial approaches for implant placement, poor oral

hygiene, and lack of motivation were also excluded, as well as studies in children or adolescents.[38,39] Studies that included patients diagnosed with parafunction[37,40] and implants which failed in the first year of service[25,41] were also excluded.

An electronic search was conducted up to February 2018, on the MEDLINE/PUBMED, SCOPUS, Web of Science, Cochrane Library, and BBO/ LILACS databases and also in the non peer-reviewed literature through Open Grey.

Medical Subjects Headings (MeSH) and other free terms related to "Dental Prosthesis, Implant-Supported", "Denture, Complete", "Denture, Complete, Immediate", "Denture, Complete, Lower", "Denture, Complete, Upper", "Denture, Partial, Fixed", "Denture, Partial, Removable" and "Dentition" were used with "Boolean operators" ("AND", "OR", "NOT") to combine and perform the searches according to the syntax rules of different databases. A search strategy was developed in the English language by a librarian (D.M). Database alerts were created, and a manual search was also performed. Articles found in more than 1 database were considered duplications and were removed. Selected titles were evaluated and judged after the abstracts and full texts were read. Two independent investigators (L.E.C-C, L.B.F-F) extracted the data. Disagreements were evaluated and resolved by discussion with a third author (L.C.M). In cases of remaining doubt, the authors were contacted to explain details and for data clarification.

Quality assessment and risk of bias was performed using 6 guidelines for critical appraisal of published research.[42] The first guideline was that the study design must be in accordance with the PICO strategy.[34] The other 5 are represented in Table 1. The evaluation of each study was performed using "no problem" (0), "minor problem" (+), and major problem (++) markings. When the question was not adequate to produce

useful information, an answer of not applicable (NA) was recorded. Three summary questions were asked to explain biased results: "Is there a trend to the error in some direction?"; "Are there confounding factors that could lead to serious confusion?"; "Is there a chance that the results could lead to random errors?". In cases of negative responses, the study was considered as consistent and justified.

Five meta-analysis were performed by MedCalc 18.2.1 (MedCalc Software BVBA) and RevMan (Review Manager, v5.3; The Cochrane Collaboration) software. Stable and functional prostheses supported by implants, or even those requiring minimal restoration in situ, were considered as survival.[9,12] In the first, second, and third meta-analysis, each design of the maxillary arch (ID, ND, and RP) was considered as a different outcome. The number of failures and the total number were evaluated in each study for each type of maxillary dentition and included calculating the pooled prevalence with a 95% confidence interval (CI).

In the fourth and fifth meta-analysis, the prevalence of survival rates (events) and the total number of individuals who had implant dentition versus the control group (natural dentition) were included. In the second meta-analysis, the prevalence of survival rates (events) and the total number of individuals who had removable prostheses versus the control (natural dentition) group were included. In both analyses, the risk difference (RD) was calculated with a 95% CI. The heterogeneity of effect size was assessed by the I^2 test. As the studies were not functionally equivalent, with different aspects in the characteristics of the participants and methodology, the meta-analysis was performed using a random-effect model. Sensitivity analyses were further conducted to estimate and verify the influence of studies, one by one or grouped, on the pooled results if the heterogeneity was substantial or considerable (50 to 100%).[43] The

certainty of the evidence was determined using the grading of recommendations, assessment, development, and evaluations (GRADE) approach.[44] Observational studies started as low evidence, and the quality of or certainty in the body of evidence decreased to low or very low quality if serious or very serious issues related to the risk of bias, inconsistency, indirectness, imprecision and publication bias were present. The quality of the evidence was upgraded if the magnitude of the effect was large or very large, or if the effect of all plausible confounding factors reduced the effect or suggested a spurious effect. The quality of the evidence can vary from very low to high and was generated for the association meta-analysis (fourth and fifth analysis).

RESULTS

The search identified 9751 titles and abstracts: MEDLINE/PUBMED (n=5402), SCOPUS (n=966), Web of Science (n=2351), Cochrane Library (n=809) and BBO/LILACS (n=144), and the Open Grey literature (n=79), 2 from manual searching, and 1 from the alerts (Fig. 1). After duplicates were removed, 6017 titles and abstracts were screened. From the 382 full texts checked for eligibility, 29 were read in full. After readings, 23 full-text articles were excluded (Table 2).[5,24,25,28,29,32,45-62] Six studies were included in the meta-analysis (Table 3),[7-9,12,13,63] all with low risk of biased results (Table 4). Four studies were retrospective and 2 were prospective. Four hundred and four MRISFCDs were placed over 2163 implants (dropouts were 8.16%). The mean age was 62.07 (±5.6 to 8.6) years. The number of natural dentitions (ND) were 112 (29%), followed by 204 (53%) removable prostheses (RP), and 69 (18%) implant-supported dentures (ID). Three, 4, 5, or 6 implants supported the prosthesis, and implants were upright and tilted. Metal frameworks were made by Brånemark Novum titanium framework, computer-aided design and computer aided manufacturing (CAD-CAM)

titanium, gold alloy, electro-eroded cast titanium, prefabricated milled titanium, and cobalt-chromium, all metallic materials. Among the included studies, 3 reported implant and prosthesis failures.[7,13,63] The other 3 reported a 100% survival rate over a period ranging from 6 to 84 months for implants and prostheses.[8,9,12] Prosthetic failures were related to implant loss, not to prosthetic failures. Forty-five implants were lost, as well as 4 prosthetic failures. The main failures were resin teeth fractures in 5 patients,[9,12] and prosthetic and abutment screw loosening in the other 3.[9] All the failures were easily repaired, leading to a 100% prosthetic survival rate.

Six studies were included in the meta-analysis for the prevalence of failures of MRISFCD versus ND. The heterogeneity was not extensive (I^2=1%). Of the total MRISFCD with a maxillary natural dentition (n=112), 5.4% (n=6) presented failures, with a CI range from 2.3 to 10.76 (Fig. 2A). Six studies were included in the prevalence of failures of MRISFCD versus RP. The heterogeneity was substantial (I^2=70%). Of the total MRISFCD with maxillary removable dentures (n=204), 4.9% (n=10) presented failures, with a CI range from 0.69 to 12.18 (Fig. 2B). To the evaluation of the prevalence of failures in MRISFCD versus ID, Accocela et al[63] was not included because of a lack of data for each outcome group. Therefore, only 5 studies were used. The heterogeneity was considerable (I^2=81%). Of the total MRISFCD with maxillary implant dentition (n=69), 13.99% (n=20) presented failures, with a CI range from 0.77 to 39.41 (Fig. 2C). Regarding MRISFCD failures related to ND versus RP, the heterogeneity was not extensive (I^2=27%) and not significant (I^2 *P*=.23). Therefore, no sensitivity analysis was conducted. Of the total number of individuals with maxillary removable prostheses (n=204), 93.6% (n=191) did not present failures, whereas 94.6% (n=106) of the individuals with a maxillary natural dentition (n=112) did not present

failures. No statistically significant difference was observed between these 2 maxillary dentitions (RD 0.00 [-0.06, 0.06], *P*=.93, I^2=27%) (Fig. 3). For the MRISFCD failures related to ND versus ID, in the first meta-analysis, the heterogeneity was considerable (I^2=87%). To reduce heterogeneity, sensitivity analysis was conducted, and during this stage the I^2 ranged from 0% to 91%. To reduce heterogeneity, van Steenberghe et al[13] was excluded from this analysis. Therefore, 4 studies were included in this meta-analysis. Of the total number of individuals with a maxillary implant dentition (n=69), 91.3% (n=63) did not present failures, whereas 95.4% (n=83) of the individuals with a maxillary natural dentition (n=87) did not present failures. No statistically significant difference was observed between these 2 maxillary dentitions (RD 0.00 [-0.06, 0.07], *P*=.97, I^2=0%) (Fig. 3). This evidence was assessed and qualified as moderate (Table 5).

DISCUSSION

The search for the influence of opposing dentitions on implant-supported restorations has been assessed without clear evidence.[14-17] In the present study, only retrospective and prospective studies were used. Longitudinal clinical studies in uncontrolled environments appear to replicate private practice and also address the study question; therefore, a preliminary search was carried out. Because of the small number of relevant studies found, the search was enlarged with a substantial increase in the number of studies found, and consequently exclusions. Meta-analysis, analysis of bias, detailed checklist and subsequent judgment were performed. A critical evaluation was performed using the guidelines of Fowkes and Fulton.[42] Strict control of exclusion factors in the selected studies was difficult to assess, since parafunctional habits cannot always be observed before the rehabilitation of edentulous patients[40] and is one of the major causes of technical complications.

No long-term studies reported, with a moderate certainty of evidence, that the opposing dentition had a detrimental effect on the survival rate of implants. Also, no such effect was found in the frameworks or veneering materials that were not easily repaired when they were opposed to natural, removable maxillary dentitions, or implant maxillary dentitions.[8,9,12] After 13 years, clinical changes in the rehabilitation of edentulous mandibles with MRISFCD appear to have been partially responsible for the increase in the survival rate and should be considered in contemporary approaches. Such findings included variables such as the number and position of implants,[7,9,12,13] the type of maxillary dentition,[7–9,12,13,63] and the framework material.[8,9,12,13]

The prevalence of MRISFCD failures when in opposition to ND was 5.4%, 4.9% for the RP and 14.0% for ID. When RP and ID maxillary dentitions were individually compared with ND, the results showed no differences in relation to the outcome measures. Long-term survival is a complex challenge and depends on clinical practice. Most of the reported prosthetic failures occurred because of loss of implants[7,13] during the preliminary stages of immediate implant loading.[10,30] Such outcomes can be caused by wrong diagnosis and the criteria for immediate loading.[26-28] Other factors may be relevant to explain implant failure, including systemic and/or local risks like placement in oncologic patients, clenching, and smoking.[7,13] Studies with healthy individuals who were heavy smokers and presented signs of severe clenching had multiple implant failures during the first year of observation.[7,12,63] These issues are not in the focus of this systematic review and meta-analysis and would be better discussed in other studies.

The presence of prosthetic technical complications was consistent with previous findings.[23] Further development of veneering materials with improved loading capacity

should facilitate stress distribution in the prosthetic/tissue interface. In the challenge to face disability imposed by edentulism on a global scale, oral health professionals should carefully consider a patient's clinical history as well as biomechanical conditions in order to avoid unexpected events and improve the long-term clinical outcome.

CONCLUSIONS

Based on the findings of this systematic review and meta-analysis, the following conclusion was drawn:

1. With a moderate certainty of evidence, natural maxillary dentitions opposed by MRISFCDs do not affect the long-term survival rate differently than other maxillary prosthetic designs.

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TABLES

Table 1. Study question checklist based on Fowkes and Fulton[42]

Guidelines	Checklist .(0)	(+)	(++)
− Study sample			
1) Source of samples	More than 40 Subjects	≅30-39 patients	Less than 30 patients
2) Sampling Method	Randomic and ordinary population (males and females), Good health conditions; smoke and alcoohol (admitted)	Not clear	Not quoted
3) Sample size	Calculation method	Not clear	Not quoted
4) Entry criteria and exclusions	Consistent data about clinical health, as well as occlusal conditions	Not clear	Not quoted
− Control group characteristics			
1) "Definition of control	Presence of a minimum of 2 maxillary dentitions, including an ND, without parafunction	Not clear	Not quoted
2) Source of control	Subjects with compatibylity in social and health. Remarkable research institution.	Not clear	Not quoted
− Quality of measurements			
1) Validity	Follow-up records under specialized supervision	Not clear	Not quoted
2) Reproducibility	Outcomes evaluated by a team of specialists (minimum two)	Not clear	Not quoted
3) Blindness	Follow-up team is not the same as the surgical and/or prosthetic team	Not clear	Not quoted or accepted
− Completeness			
1) Dropouts and deaths	Must be quantified	Less than 20%	More than 20%
− Distorting influences			
1) Extraneous treatment	o extensive repairs of critical prosthetic failure	Not clear	Not cited or accepted
2) Changes over time	No modification of parameters during the observation period	Statistic analysis	Only qualitative analysis
3) Confounding factors	Prosthetic failures after implant loss in the first weeks after loading should not be computed	Not clear	Accepted
4) Distortion by the analysis	When counfounding factors were adjusted by statistics	Not clear	Not adjusted

(++) = Major problem; (+) = Minor problem; .(0) = No problem; (NA) = Not applicable. ND - Natural dentition.

Table 2. Exclusion of 23 full-text articles based on exclusion criteria

Author and year of publication	Reason of exclusions
Krennmair et al., 2013	Confused data regarding the influence of the maxillary arch
De Smet et al., 2007	Maxillary and mandibular archs does not match
Francetti et al., 2008	
Davis, Packer, Watson, 2003	Natural dentition in mandible
Eliasson et al., 2000	Inclusion of mandibular implant-fixed complete dental prostheses made by ceramics
Peñarrocha-Oltra et al., 2015	
Henry, Bower, Wall, 1995	Acceptance of parafunction
Tolman, Laney, 1993	Maxillary and mandibular dentitions quantified in the same analysis
Zarb, Schmitt, 1996	
Ji et al., 2012	
Dhima, 2014	
Maló et al., 2015	
Balshi et al., 2016	
Maló et al., 2016	
Ventura, 2016	
De Bruyn, Vand de Veld, Collaert, 2008	Maxillary dentitions cited but not quantified as factors causing failure
Friberg, Jemt, 2010	
Krennmair et al., 2016	
Schwarz, 2010	Natural dentition not found in the study
Cid, 2014	Mandibular implant-fixed complete dental prostheses with and/or without cantilever
Ganeles et al., 2001	
Colomina, 2001	Full and partial prostheses in the same analysis
Priest, Smith, Wilson, 2014	Acceptance of subjects under 18 years old

Table 3. Data extraction from six included studies

Author, Year, Country	Institution	Type of study	Patients (n)	Mean Age (Range)	Dropouts	Follow Up Months	Implants (n /	Mandibular MRIFCDP Framework
van Steenberghe et al., 2004, Belgium	Catholic University, Leuven	Prospective	50	56.5	5	3,6 and12	150 (3)	50 Brånemark Novum® titanium framework
Friberg, Henningsson and Jemt, 2005, Sweden	The Brånemark Clinic - Gotemburg	Retrospective	152	66	10	12	750 (4, 5, 6)	147 CAD/CAM titanium, 5 Cast in gold alloy
Friberg, Jemt, 2008, Sweden	The Brånemark Clinic - Gotemburg	Retrospective	90	70.7	14	12	450 (5)	90 CAD/CAM Titanium
Acocella et al., 2012, Italy	University of Florence	Retrospective	45	56.7	0	6 to 6 until 48	225 (5)	45 Electroeroded cast titanium
Sannino et al., 2017, Italy	University of Rome	Retrospective	51	63.4	0	6, 12 and 24	136 (4)	51 Titanium prefabricated precision milled bar
Ayub et al., 2017, Brazil	University of São Paulo	Prospective	16	59.1	4	12,24 and 84	48 (4)	Cobalt-cromium

Author, Year, Country	Status of maxilla ND (n)	Status of maxilla Others	Failures	Prosthetic Survival Rates	Prosthetic failures (n)	Implant Survival Rates	Implant failures (n)
van Steenberghe et al., 2004, Belgium	9	38 RP, 3 ID	ID > RP > ND	95%	Lost because implant failure (2)	92.7%	Loss (11) RP (8) ID (3) ND (0)
Friberg, Henningsson and Jemt, 2005, Sweden	38	82 RP, 30 ID, 2*	RP > ND > ID	99.3%	One remade because implant loss (1)	97.5%	Loss (12) RP (5) ID (3) ND (4)
Friberg, Jemt, 2008, Sweden	21	45 RP, 24 ID	0	100%	Two remades because adaptation (0)	100%	0
Acocella et al., 2012, Italy	25	20 RP	ND > RP	97.8%	One remade because implant loss (1)	99.1%	Loss ND (2)
Sannino et al., 2017, Italy	16	13 RP, 9 ID	0	100%	Minimally repairs (0)	100%	0
Ayub et al., 2017, Brazil	3	6RP, 3 ID	0	100%	Minimally repairs (0)	100%	0

* Lost data

Table 4. Quality assessment of selected studies based on Fowkes and Fulton[42] critical appraisal of published research

Authors and year of publication	Study design appropriate to objective? Objective and Common design				Study sample representative?					Control group acceptable?			
	Prevalence Cross sectional	Prognosis Cohort	Treatment Controlled trial	Cause CH, CC, CS*	Source of sample	Sampling method	Sample size	Entry criteria/exclusions	Non-respondents	Definition of controls	Source of controls	Matching / randomization	Comparable characteristics
van Steenberghe et al, 2004	NA	0	NA	NA	0	0	(++)	(+)	NA	(+)	0	NA	NA
Friberg, Henningsson, Jemt, 2005	NA	0	NA	NA	0	0	(++)	(+)	NA	(+)	0	NA	NA
Friberg, Jemt, 2008	NA	NA	NA	0	0	0	(++)	(+)	NA	(+)	0	NA	NA
Acocella et al, 2012	NA	0	NA	NA	0	0	(++)	0	NA	(++)	0	NA	NA
Sannino et al, 2017	NA	0	NA	NA	0	0	(++)	0	NA	0	0	NA	NA
Ayub et al, 2017	NA	0	NA	NA	(++)	0	(++)	0	NA	0	0	NA	NA

Authors and year of publication	Quality of measurements and outcomes?				Completeness?				Distorting influences?				
	Validity	Reproducibility	Blindness	Quality control	Compliance	Dropouts	Deaths	Mising data	Extraneous treatments	Contamination	Changes over time	Counfounding factors	Distortion reduced by analysis
van Steenberghe et al, 2004	0	(+)	(+)	NA	NA	0	0	0	0	NA	0	0	0
Friberg, Henningsson, Jemt, 2005	0	0	(+)	NA	NA	0	0	0	0	NA	0	0	0
Friberg, Jemt, 2008	0	0	(+)	NA	NA	0	0	0	0	NA	0	0	0
Acocella et al, 2012	0	0	(+)	NA	NA	0	0	0	0	NA	0	0	0
Sannino et al, 2017	0	(+)	(+)	NA	NA	0	0	0	0	NA	0	0	0
Ayub et al, 2017	0	(+)	(+)	NA	NA	(+)	(+)	0	0	NA	0	0	0

*CH - Cohort; CC - Case-control; CS - Cross-sectional; (++) Major problem; (+) minor problem; (0) no problem; (NA) not applicable. **Quality assessment according to the guidelines described by Fowkes and Fulton (1991) for appraising a medical article

Table 5. Certainty of evidence: Survival rate of MRISFCD according to maxillary dentition

Certainty assessment							Summary of findings				
Number of participants (studies) Follow-up	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Overall certainty of evidence**	**Study event rates (%)**		**Relative effect (95% CI)**	**Anticipated absolute effects**	
							With maxillary natural dentition	**With maxillary implant dentition / removable prostheses**		**Risk maxillary natural dentition**	**Risk difference with maxillary implant dentition / removable prostheses**
Maxillary implant dentition versus natural dentition											
144 (4 studies)	not serious	not serious	not serious	serious [a]	very strong association	⊕⊕⊕○ MODERATE	74/78 (94.9%)	63/66 (95.5%)	not estimable	949 per 1.000	**949 fewer per 1.000** (949 fewer to 949 fewer)
Maxillary removable prostheses versus natural dentition											
316 (6 studies)	not serious	not serious	not serious	serious [a]	very strong association	⊕⊕⊕○ MODERATE	106/112 (94.6%)	191/204 (93.6%)	not estimable	946 per 1.000	**946 fewer per 1.000** (946 fewer to 946 fewer)

CI: Confidence interval
a. Sample size lower than 300

FIGURES

Figure 1. Study design.

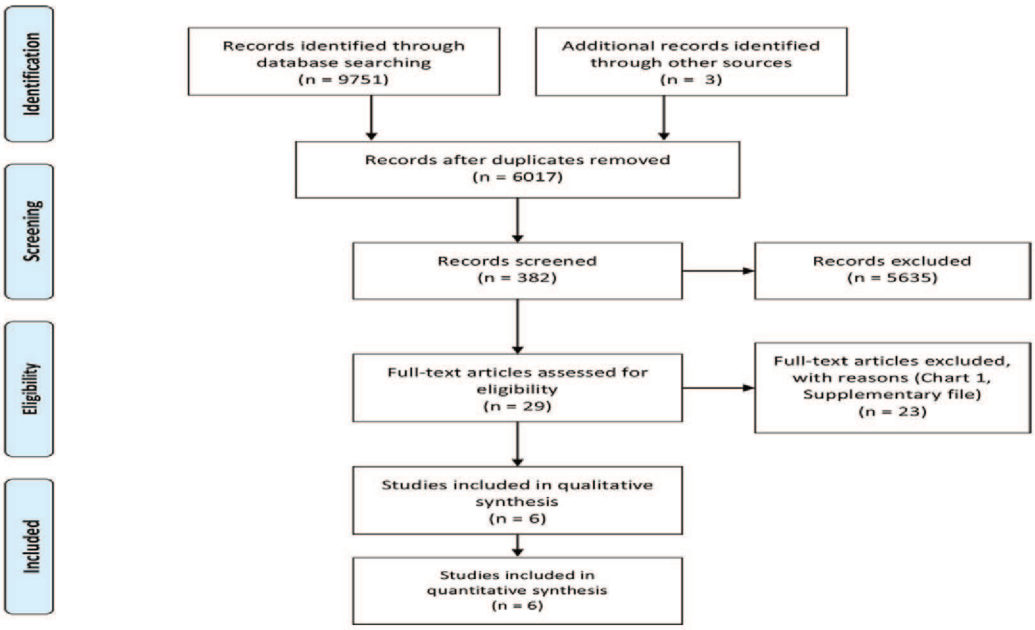


Figure 2. Forest plots. A, Prevalence of failures of mandibular MRISFCD versus maxillary natural dentition. B, Prevalence of failures of ,mandibular MRISFCD versus maxillary removable dentures. C, Prevalence of failures of mandibular MRISFCD versus maxillary implant dentition. MRISFCD, metal-resin implant-supported fixed complete denture.

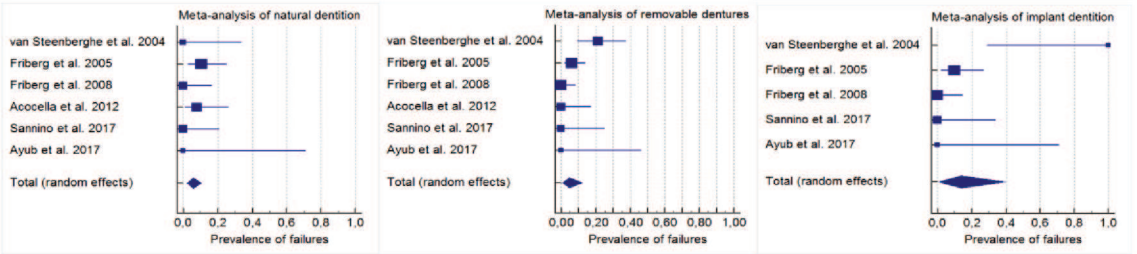
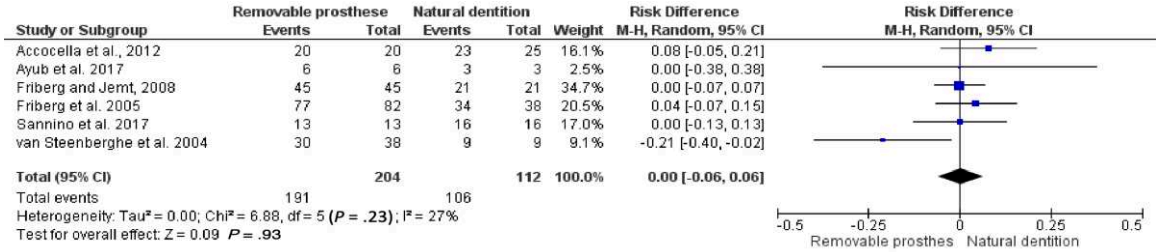
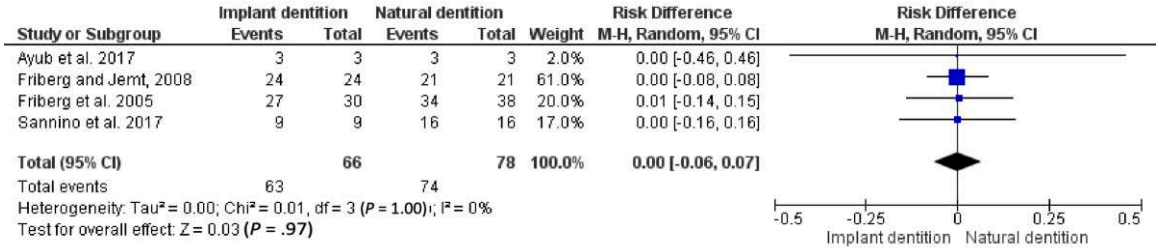


Figure 3. Forest plot of MRISFCD survival rate related to: A, Maxillary removable prostheses versus natural dentition. B, Maxillary implant dentition versus natural dentition. MRISFCD, metal-resin implant-supported fixed complete denture.





CAPÍTULO 2 – ARTIGO 2

Carneiro-Campos, LE; Fernandes, CP; Freitas-Fernandes, LB; Zanetta-Barbosa, D. A multifunctional approach for edentulous patients with immediate implants. A 2.8-year follow-up case report.

A multifunctional approach for the treatment of edentulous patients with immediate implant loading. A 2.8-year follow-up case report

Running head: A multifunctional implant protocol

ABSTRACT

Dental implants have become widely recognized as a safe therapy for oral health rehabilitation. But, are still considered an expensive treatment modality for most people around the world. In order to meet social demands and improve access to implant supported prosthodontics, it is necessary to reduce treatment costs and facilitate the clinical management. This article describes the rehabilitation of a full mouth edentulous fifty-seven-year-old, who was ASA II, a smoker and female. The patient had the placement of three implants in the mandibular mental region for a full mouth immediate loading fixed rehabilitation, following a new concept of a multifunctional approach, the article discusses the results after 2 years of observation. Implant placement and functional characteristics, such as vertical dimension and occlusal pattern were accurately transferred to the mandibular site using a transparent rigid template, used during the surgical procedures, along with a simultaneous impression and occlusal registration. The technique was developed for the rehabilitation of edentulous subjects in 48 hours under careful rehabilitation planning in relation to health conditions and local anatomy. After 2 years, the mandibular metal-resin implant-fixed complete denture as opposed to a conventional denture was kept in function without complications, indicating that the proposed technique seems to be an alternative option for the treatment of edentulous jaws. It is a cost-effective procedure that decreases treatment time and morbidity, allowing increased access to an improved quality of life.

Keywords: management of edentulism, surgical template, oral rehabilitation, dental implants, fixed prosthesis.

INTRODUCTION

Immediate implant loading represents a reliable alternative for the treatment of edentulous jaws. A reduction in treatment time, cost and morbidity, as well as a gain in the quality of life, are some of the benefits reported (1).

The loss of natural teeth has functional and psychosocial consequences (2), that often, are not fully reconciled with the placement of conventional complete dentures. Moreover, different of the past, the new generation of elderly people are growingly concerned with the possibility of tooth loss, the transition to the edentulous state, complaints and its upsetting (3).

Since the beginning of the 21st century, the prediction of population growth and a skewed income distribution has been suggested to have a complex effect on public health systems in the coming years and decades (4). In fact, the largest analysis of global burden of diseases provided a comprehensive and alarming description of the morbidity levels around the world (5). The number of health disabilities is increasing, due to an ageing population as the consequence of a slower decline in disability rates compared to the levels of mortality. In this scenario, the edentulous condition appears as the third oral health-related disability, affecting 16% of the world population, with social determinants intimately related to poverty levels (5). Therefore, the methods of promoting oral health with social outreach and cost-effective techniques are needed. For example, in relation to the mandible, where the approach of the mental region is generally facilitated by good quality and quantity of bone, the use of hand-made acrylic templates supported by panoramic images could remain a long-lasting and reliable approach (6). In addition, a reduction in the number of implants in mandibular implant-supported fixed dentures may be considered an alternative for reducing treatment costs, especially in public health settings, to face the management of the edentulous condition around the world (7).

This clinical report aims to present a surgical and prosthetic approach for the treatment of edentulous patients with the placement of three implants in the mental region with immediate loading of a mandibular metal-resin implant-fixed complete denture (MMRIFCD) as opposed to a conventional denture, followed up over two years and 8 months.

CASE REPORT

This report is part of a retrospective study conducted at the P-I Brånemark Institute (Bauru, SP, Brazil) during the years of 2008 and 2016. All procedures were fully explained to the patient who signed an informed consent form in accordance with the World Medical Association (8), approved by the Human Research Ethic Committee of the Federal University of Uberlandia, MG, Brazil, under the CNS 466/12 resolution.

Diagnosis

A 57-year-old fully edentulous female patient (E.M.S.), who smoked, was referred to the P-I Brånemark Institute for treatment with a mandibular implant-supported fixed resin complete denture as opposed to a conventional maxillary denture. The patient's medical history placed her in the American Society of Anesthesiologists (ASA) status II classification (9). After a comprehensive evaluation and data collection, a treatment plan was developed for guided surgery with implant placement under immediate loading.

The multifunctional template

The rehabilitation protocol started with the preparation of conventional dentures (10). The maxillary denture was taken used until the final acrylic stage, while the mandibular denture waxed tooth set up was processed to produce a duplicate in packed self-polymerizing transparent acrylic resin (VIPI Flash. VIPI Produtos Odontológicos, Pirassununga, SP, Brazil). The original tooth set up waxing was kept in the laboratory waiting for the manufacture of the MMRIFCD.

After duplication, several modifications were made to build the template into its multifunctional condition. All clinical characteristics to allow for the best implant position, inter-arch space and cranio-mandibular relationship were considered in the template. The template is described in Fig 1. The main features follow the device proposed by Vedovato and Cols (11), the devices included to ensure template rigidity - “tuberosity wing” (a), “palatal support” (b), space for implant surgery and impression taking - “operational window” (c), precise location of vertical dimension and centric occlusion - “incisal support” (d), “occlusal support” (e), to ensure locked relationship when the template is occluding with the maxillary prosthesis. Modifications of the original template design were made to include an indicator for the minimal distance between the implant head and bridge cylinder – the “mental plateau wear guide” (f) was included to guarantee the appropriate dimensions for the mucosa and prosthetic materials, and bilateral restraining bases - “digital surgical support” (g) were added to facilitate the positioning of the device by the operator and/or assistant.

Therefore, it is expected that the design will transfer to the surgical site an ideal position of the implants associated with the maxillary-occlusal relationship, facilitating

the impression procedure and occlusal registration. It is important to bear in mind that the template was designed to only be used with the rehabilitation of fully edentulous patients with MMRIFCD as opposed to maxillary dentures.

Before surgery, the multifunctional guide and the maxillary denture were checked to verify occlusion and vertical dimension (Fig. 2a). they were disinfected with sodium hypochloride solution at 1% for 2 hours.

Surgical procedure

One hour before surgery a single 2 g dose of amoxicillin (Amoxil 500mg, GlaxoSmithkline, Rio de Janeiro, RJ, Brazil) dose was administered and 500 mg every 8 hours, for 7 days thereafter. The anesthetic procedure was induced using an injection of articaine 4% with epinephrine 1:100,000 (Nova DFL, Rio de Janeiro, RJ, Brazil) under venous sedation with midazolam 0.5 mg/kg (Dormonid – Injectable, ROCHE Brazil, São Paulo, SP, Brazil), after previous mouthwashes with chlorhexidine digluconate 0.2% (Periogard, Colgate Palmolive-Company, São Paulo, SP, Brazil) for biofilm control, which was continued for 10 days postoperatively.

Horizontal and distal vertical mid-crestal incisions were made to raise flaps and reveal the access to the mandibular bone. After this, the template was inserted and the "mental plateau wear guide" was used to guide bone shaping. Mental ridges were flattened near 5 mm, aiming at an ideal preparation of the site and the space for the placement of the mini-conical prosthetic abutments (Fig. 2b, dot lined). The surgical site was re-checked after drilling 2.0 mm. Metallic guide pins were positioned through the "operative window" (Fig. 2c). After the drilling procedures, the first implant was vertically positioned in the mental midline and the two others were distally tilted in the parasymphysis regions, at least 2 mm away from the mental foramen. The distal implants should be distally angled in approximately 30 degrees, considering the mandible anatomy and the location of the mental foramina. All the implants used were 3.75 x 15 mm machined surface implants (P-I Brånemark Philosophy^{TM}, Exopro, Bauru, Brazil). After the placement of the implants, all insertion torques were measured as 40 N.cm and three straight mini-conical abutments were placed and screwed at 32 N.cm over the hexagonal platforms for immediate loading (Fig. 3a). The flaps were gently

positioned over the residual bone and sutured with a single thread (Catgut, Ethicon, ©Johnson & Johnson, São Paulo, SP, Brazil). After approximately 30 minutes of post-surgical rest, the patient was submitted to impression taking.

Prosthetic reconstruction

Immediately after surgery, the template was seated on the site with impression transfer cylinders connected to the abutments in position to verify the precise emergence of the prosthetic screw openings (Fig. 3b). Before the pick-up impression, the template was removed and the impression transfer cylinders were splinted with an acrylic resin bar to prevent movement during the impression procedure with polyvinylsiloxane (3M-Express, 3M, Fairmont, MN, USA) (Fig. 3c). During the elastomer setting, the patient was asked to keep their mouth closed with the template occluded against the maxillary denture to guarantee the accuracy of the vertical dimension and the occlusion registration (Fig. 4a). The template was rigidly connected to the resin acrylic bar with cold cure acrylic. Again, the patient was asked to keep their mouth closed in firm occlusion with the template and the complete denture during acrylic resin self-curing. The template-acrylic resin bar set was unscrewed from the abutments and sent to the laboratory after the plaster model was cast. No further occlusal registration was done, as the template already caries this information. The metal framework cast in CoCr (Wironit, Bego Bremen, Germany) was tried in the next day and the passive fit was controlled by periapical x-rays. The tooth set up was transferred from the previously prepared mandibular denture and 48 h after the surgery, the maxillary complete denture and the MMRIFCD were placed (Fig. 4b). Occlusal adjustments, torque control at 15 N.cm of the bridge screws and the sealing with composite resin were performed and the patient was informed about hygiene control and the upcoming control visits.

Post-operative follow-up

The current guidelines for the recall regimen and maintenance of implant supported rehabilitations are poorly defined and most often based on natural dentition protocols (12). The P-I Brånemark Institute recall regimen and maintenance protocol to verify implant and peri-implant health as well as prosthetic evaluation after implant surgery is as follows: one week, one month, 3 months, 12 months, and yearly thereafter.

All follow up exams were made removing the MMRIFCD and checking the occlusion, as well as the maxillary denture integrity. The implant peri-implant health status was recorded for the presence of biofilm, pain, bleeding, suppuration, mobility, and probing depth (13). After these procedures, the prosthesis was retained with the use of new prosthetic screws.

DISCUSSION

Implant therapy fulfilled the predictable esthetics and function, it is considered a primary choice for the rehabilitation of edentulous individuals. However, it remains an expensive technique for most people around the world. Treatment approaches that reduce the treatment components and processing time may minimize costs and morbidities, increasing access to an improved quality of life, also for lower income populations.

The case report presents the result after 2 years and 8 months of evaluation of a new approach for immediate loading procedures and is not intended to replace more sophisticated techniques such as prototyped templates following CT scans, but rather to be a simplified, yet, reliable tool for clinical care. Different to the original Branemark 6 implant two-stage protocol (14), the present case report placed three implants, immediately loaded in the mental region in front of the mental foramina, the first was vertical and the two other implants were tilted to avoid injuries to the alveolar nerve. In this case report, the number of implants placed was three, but the technique does not limit the installation of four or more implants according to the treatment plan. The current approach to tilt the distal implants decreases the cantilever horizontal extensions in length, improving the biomechanical stability, through an increased polygonal support area for the seating of a MMRIFCD (15). The design, ease of use, optimal position of the implants, and balancing of the prosthesis was achieved due to the characteristics of the template. The multifunctional approach assists free hand surgical and prosthetic procedures while keeping the spatial and maxillo-mandibular relationship without the use of anchor pins or other stabilization systems commonly used in prototyped templates. As the mental region frequently presents sufficient bone for implant surgery in quantity and quality (6), the operator is easily reassured of the selected positions to confirm the intended distances and prosthetic support polygon, and

can reassess the surgical field whenever necessary. The structure rigidity of the multifunctional template ensures a high dimensional stability in the impression procedure, reducing it to almost zero, the need for solder, with a passive fit is confirmed by periapical x-rays.

Regarding the cost-effectiveness of the technique, the main aspects are the reduction of implant components and the reduction of the treatment time to approximately 10 clinical hours. Mental regions submitted to open flap implant surgery may rely on easily accessible panoramic radiographs, dismissing more sophisticated CT scans. Passive fit was easily obtained and should be considered due to the use of the multifunctional template during the surgical procedure. It facilitated an overview of the site, as well as a better implant placement, with an angulation of 30° in relation to the mental and distal implants. Therefore, the use of a small number of implants, together with straight abutments, promoted accuracy, while not requiring welding points. Also, the streamlined clinical/laboratory steps facilitated by the multifunctional template eliminate the need for more expensive techniques and processes. Simplified labor and low-cost materials are required, which facilitates the increased access of the technique to universal public health policies around the world.

During the observation period, no relevant mechanical failures have been observed, neither in the MMRIFCD, neither in the maxillary complete denture. The exception was the loosening of the prosthetic screws on three implants, at the same time, after 18 months, which can be expected in the longterm (Pjetursson, Asgeirsson, Zwahlen, & Sailer, 2014). As a guideline, it is recommended that, during the maintenance visits, prosthetic screws are checked and retightened accordingly. In the present study, the screws that were prematurely loosened, failed due to individual behavior and parafunctional habits. Therefore, to avoid potential problems, it is advised that maintenance and retightening be performed every six months. No other occurrences were noted during the evaluation period. The depth of probing during the evaluation period ranged from 1 mm to 3 mm. The presence of 38.9% of biofilm formation and 11% of bleeding was noted. No mobility or bone loss was observed after two years and eight months.

The current patient had normal mouth opening, however individuals with opening limitations should be carefully evaluated during treatment planning, due to the dimensions of the template and the need to be used in synergy with the maxillary denture throughout the oral rehabilitation procedure.

The proposed multifunctional approach loading technique seems to be a reliable alternative of fully edentulous patients with a cost-effective procedure, decreasing treatment time, morbidity, and improving access to an improved quality of life.

RESUMO

Os implantes dentários tornaram-se amplamente reconhecidos como uma terapia segura para a reabilitação da saúde bucal. Mas ainda são consideradas uma modalidade de tratamento de alto custo para a maioria das pessoas ao redor do mundo. Para atender às demandas sociais e melhorar o acesso à prótese dentária implantada, é necessário reduzir os custos do tratamento e facilitar o manejo clínico. Este artigo descreve a reabilitação de uma paciente do sexo feminino, paciente edêntula total, com 57 anos de idade, ASA II, fumante, com a instalação de três implantes na região mentual mandibular em carga imediata seguindo um novo conceito de abordagem multifuncional e discute os resultados após 2 anos de observação. A localização dos implantes e as características funcionais, como dimensão vertical e padrão oclusal, foram transferidas com precisão para o sítio mandibular por um guia multifuncional de acrílico rígido transparente, utilizado durante os procedimentos cirúrgicos, ao longo do procedimento de moldagem e do simultâneo registro oclusal. A técnica foi exclusivamente desenvolvida para a reabilitação de indivíduos desdentados em 48 horas sob planejamento cuidadoso de reabilitação em relação às condições de saúde e anatomia local. Após 2 anos, a prótese fixa total implanto suportada metaloplástica foi mantida em funcionamento em oposição a uma prótese convencional sem complicações, sugerindo que a técnica proposta parece ser uma opção alternativa para o tratamento de mandíbulas edêntulas. É um procedimento de baixo custo que diminui o tempo de tratamento e a morbidade, permitindo maior acesso a melhor qualidade de vida.

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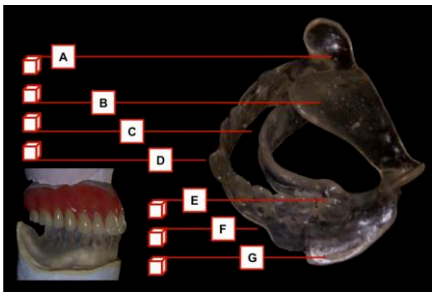

Figure 1. Left side at the bottom: A maxillary denture as opposed to a lower denture waxing duplication in transparent acrylic resin for the manufacture of the multifunctional template. On the right, the template and its features are as follows: “tuberosity wing” (a), “palatal support” (b), “operative window” (c), “incisal support” (d), “occlusal support” (e), “mental plateau wear guide” (f), and “digital surgical support” (g).

Figure 2a. Maxillary denture and template in occlusion to verify the vertical dimension and stability; b. View of the "mental plateau wear guide" placed on the flattened mental bone (dot lined); c. Metallic guide pins placed after drilling 2.0 mm to check the correct orientation of the implants through the “operative window” of the template.

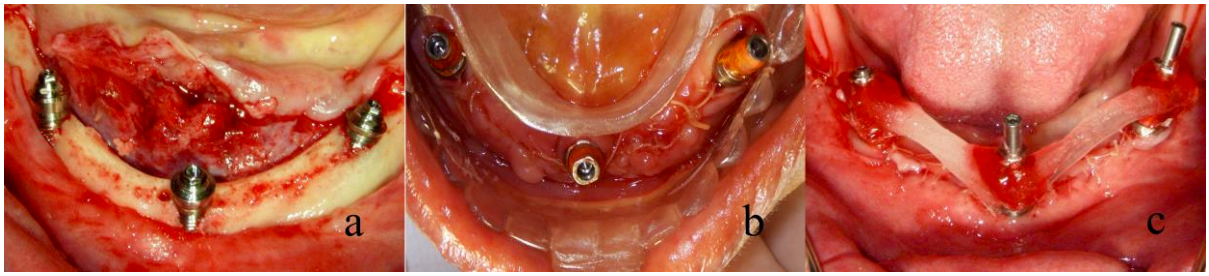

Figure 3a. Mini conical abutments placed over the implant's hexagonal platforms for immediate loading; b. Impression abutments placed to check the precise position of the prosthetic screw emergencies; c. Impression abutments attached with acrylic resin bars to prevent movement and increase accuracy during the impression procedure.

Figure 4a. Maxillary denture and the multifunctional template in occlusion during the elastomer polymerization, maintaining centric occlusion and vertical dimension; b. Rehabilitation placed during the preliminary adjustments; c. Radiographic control of the passive fit.

CAPÍTULO 3 – ARTIGO 3

Carneiro-Campos, LE; Fernandes, CP; Freitas-Fernandes, LB; Zanetta-Barbosa, D. Clinical evaluation of mandibular implant-supported fixed complete dentures supported by three straight and tilted implants. A retrospective study.

Clinical evaluation of mandibular implant-supported fixed complete dentures supported by three straight and tilted implants. A retrospective study.

Running title: Mandibular implant-fixed prosthesis survival

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ABSTRACT

Objectives: To evaluate the survival rate of fixed complete dental prostheses supported by three immediately loaded implants as opposed to maxillary dentures.

Materials and Methods: A retrospective study was conducted from 2.2 up to 8 years. Fifty subjects were rehabilitated with conventional maxillary dentures and mandibular metal-resin implant-supported fixed complete dentures supported by three immediately loaded implants, using a multifunctional template in a 48-h clinical protocol. Fifty-one machined and 99 rough-surface dental implants, connected with straight mini conical abutments, were selected. Implant loss, peri-implant outcomes, and technical complications were assessed considering the influence of implant surface type, cantilever length, as well as age, gender, health status, smoking, alcoholism, schooling, and social-economic status.

Results: Four machined and six rough surface implants failed (6.7%). Cantilevers measured from 3.3 to 22.9 mm. Technical complications were abutment screw loosening (3.0%), prosthetic screw loosening (17%), prosthetics screw fracture (1%), superstructure detachments and fractures (16%), metallic framework fracture (2%), maxillary denture fractures (6%), and mandibular prosthesis loss (4%). The cumulative implant and mandibular prosthesis survival rates were 93.3% and 96%, respectively. The main peri-implant complications were biofilm formation, bleeding on probing, and pain, which were controlled during the maintenance visits. None of the assessed

variables were found to influence clinical failures and/or technical complications to statistically significant levels.

Conclusions: The clinical management approach may be considered as an alternative to conventional techniques to extent lower financial costs and treatment time.

Keywords: mouth edentulous, analysis survival, dental prosthesis implant supported, immediate dental implant loading, dental implant.

Abstract Word count: 234

1 INTRODUCTION

Edentulism is a public health issue, accounting for one-third of the disabilities related to oral disorders worldwide (Global Burden of Disease Study 2013 Collaborators, 2015). Bone resorption induced by tooth loss (Allen & McMillan, 2003) impacts the supporting alveolar morphology and the prosthetic stability of conventional dentures (Emami, de Souza, Kabawat, & Feine, 2013), particularly in the mandible (Tallgren, 2003). The use of implant-supported overdentures is a highly successful method, while being the least expensive alternative. Nevertheless, it has the same limitations often imposed by local conditions for dentures, such as interocclusal space, limited attached mucosa (Chaimattayompol & Arbree, 2003; DeBoer, 1993), as well as patient satisfaction (De Kok, Chang, Lu, & Cooper, 2011). The most predictable treatment in these cases is the metal-resin implant-fixed complete dental prostheses (Critchlow & Ellis, 2010). However, high costs have discouraged low-income patients worldwide and prevented access to the treatment benefits (Al-Dwairi, 2010; Nagaraj, Mankani, Madalli, & Astekar, 2014). Following the development of immediate loading implant protocols (Balshi & Wolfinger, 1997; Randow, Ericsson, Nilner, Petersson, & Glantz, 1999; Schnitman, Wöhrle, Rubenstein, DaSilva, & Wang, 1997), the Brånemark Novum®, was introduced (Brånemark et al., 1999; Engstrand et al., 2003) with survival rates of 98% for mandibular fixed complete prostheses on three straight and parallel implants (Brånemark et al., 1999; De Smet, Duyck, Vander Sloten, Jacobs, & Naert, 2007; Friberg, Henningsson, & Jemt, 2005; van Steenberghe et al., 2004). However, associated high costs and limited indication criteria still prevented wider use. Tilted distal implants reduced surgical morbidity associated with bone grafts and limited distal

cantilever segments (Krekmanov, Kahn, Rangert, & Lindström, 2000). The "All-on-4" concept (Maló, Rangert, & Nobre, 2003), for example, confirmed the long-term success rate of tilted implants (Ayub et al., 2017; Francetti, Corbella, Taschieri, Cavalli, & Del Fabbro, 2015; Hopp, de Araújo Nobre, & Maló, 2017; Taruna, Chittaranjan, Sudheer, Tella, & Abusaad, 2014). A reduced number of implants were also tested by Hatano, et al. in a study with overall survival rates of 96.7% (Hatano, Yamaguchi, Yaita, Ishibashi, & Sennerby, 2011), while Rivaldo, et al. reported 97.1% success (Rivaldo, Montagner, Nary, da Fontoura Frasca, & Brånemark, 2012). Both studies placed three implants on the mental region; one vertically and two distally tilted, located mesial to the mental foramina. However, the influence of systemic conditions and external factors, such as socioeconomic status, on the survival rate of this approach have still not been reported.

Thus, considering the importance of producing sufficient evidence for optimal clinical decision-making, the aim of this retrospective study was to evaluate the long-term survival rate for treating edentulous patients with maxillary dentures and mandibular metal-resin implant-supported fixed complete dentures supported by three implants.

2 MATERIALS AND METHODS

This retrospective study was conducted in accordance with the STROBE guidelines (Strengthening the Reporting of Observational Studies in Epidemiology) (von Elm et al., 2014) and the World Medical Association ("WMA - The World Medical Association-Declaration of Helsinki," n.d.). The study was approved by the human research ethics committee of the Federal University of Uberlandia, MG, Brazil, under the CNS 466/12 resolution. Each subject received a detailed description of the proposed treatment and signed their consent to the agreements. Original data were extracted from the patient records (L.E.C-C and L.B.F-F).

Fifty subjects referred to the P-I Brånemark Institute in Bauru, São Paulo, Brazil, were selected by the staff members to be rehabilitated with conventional maxillary dentures and mandibular metal-resin implant-supported fixed complete dentures (MRISFCD) by a volunteer team. A retrospective study from 2.2 up to 8-years was performed from April 10, 2008, up to May 24, 2016. Table 1 shows the parameters followed during the study period. Demographic data were accessed by a descriptive

analysis of gender and age. The health status was divided into five groups. Some subjects were included in one or more groups. Smoking and alcoholism were computed in yes/no hazardous habits categories. Schooling was determined by assessing the status of the participants in the categories of illiterate, incomplete elementary school, elementary school, high school, and graduate. Social-economic status was assessed according to the Brazilian Criteria of Economic Classification – BCEC (BCEC, 2016).

The inclusion criteria were healthy edentulous subjects of both genders who received conventional maxillary dentures and MRISFCD. Subjects with controlled local or systemic diseases, those with limited hazardous habits were accepted. Exclusion criteria were people that did not present a capacity for adequate hygiene practice (Levin, 2008).

2.1 The multifunctional template

Maxillary and mandibular wax dentures were fabricated (Fig 1a). The maxillary dentures were finished, and mandibular wax dentures were duplicated to produce multifunctional templates in clear resin (Fig. 1b), while the original mandibular tooth set up was reserved for the MRISFCD. The multifunctional template was used for surgical and prosthetic procedures (Figs 1 and 2) and was designed to secure craniomandibular vertical and horizontal relationship.

2.2 Surgical procedures

Surgical procedures were carried out in a surgical room under antibiotic prophylaxis. After raising flaps to access the mandibular bone, mental ridges were flattened 5 mm below the template (Fig 2a dotted) (Adell, Lekholm, Rockler, & Brånemark, 1981). Three implants were placed using the template (Fig 2b). The midline implants were straight, while posterior ones were mesial to the mental foramina and tilted distally up to 30^{o}, considering the mandible anatomy and the location of mental foramina. Insertion torques were measured at each implant (minimal of 35 N.cm), and the mini-conical straight abutments were screwed at 32 N.cm over the external hex platforms (Fig 2c). Flaps were then gently positioned over the residual bone and sutured.

2.3 Prosthetic procedures

Prosthetic procedures were performed immediately after surgery. Impression transfer cylinders connected to the abutments were splinted to fit the template “operative area”. During the elastomer setting (3M- Express, 3M, Fairmont, MN), to guarantee the accuracy of occlusion features, subjects kept their mouth closed (Fig 3a). Forty-eight hours after surgery, the MRISFCD were installed (Fig 3b) following occlusion check, and radiographic passive fit control (Fig 3c) with a panoramic radiograph taken according to manufacturer's instructions for the evaluation of passive fit.

2.4 Follow up protocol

The follow-up protocol included appointments at 1 week, 1 month, 3 months, 12 months, and yearly thereafter. Clinical exams were made by removing the MRISFCD and checking the occlusion, as well as the integrity of the maxillary denture. The peri-implant health status was evaluated, recording the absence/occurrence of biofilm, bleeding on probing, pain, suppuration, and measuring the probing depth at six sites of each implant. Implant mobility was examined individually (Todescan, Lavigne, & Kelekis-Cholakis, 2012). Additional visits were on demand. In the presence of mucositis or peri-implantitis, scaling and polishing were performed. In cases of mobility, the implants were removed, and the prostheses revised. Survival was based on stability, comfort, and absence of suppuration of implants supporting a functional prosthesis during the observation time (Albrektsson & Zarb, 1993; Ayub et al., 2017).

2.5 Cantilever evaluations

Cantilever lengths were measured on the panoramic X-Rays taken for passive fit control. X-Rays were scanned (HP Scanjet G2410, Hewlett- Packard, Palo Alto, CA, USA) with plastic rulers. Photoshop CS 2017 (Adobe Systems Incorporated, San Jose, CA, USA) was used to assess the cantilever segment lengths, applying the "rectangular marquee" tool calibrated at a fixed ratio (1×1) to check the precision of the obtained images. Two investigators measured right and left cantilever segments, from the distal limits of the bridge cylinder to the metal edges of the distal cantilever on two occasions, in order to increase the accuracy of measurements.

2.6 Statistics

The results were analyzed using the Statistical Package for Social Sciences, IBM® SPSS® 21 (SPSS Inc., IL, USA). Descriptive analysis of the data set was followed by the Chi-squared test ($\alpha = 0.05$) to evaluate the association of implants loss with gender, health status, smoking, alcoholism, schooling, and social-economic status. Influence of age on implant losses was evaluated using Student's t-test. The Mann-Whitney U test was used to assess the association of health impairments on implant losses. Exact Fischer's test ($\alpha = 0.05$) was used to evaluate the influence of technical failures and surface types on implant loss. Cantilever measurements were assessed using Student's t-test and Cronbach's α intra-class correlation coefficient to verify the intra and inter-examiner agreement. Peri-implant outcomes were evaluated using absolute and relative frequencies while the binomial test was applied to verify the occurrence/absence of periodontal variables. Two investigators were previously trained and calibrated for peri-implant parameters, and checked by Kappa coefficient for inter-rater reliability assessment. Statistically significant differences were considered when $p < 0.001$.

3 RESULTS

3.1 Demographic conditions and implant failures

Fifty subjects, 33 women and 17 men (mean age of 60.1 ± 8.78 years), were enrolled in this retrospective study (Table 1). One-hundred-fifty external hex implants were placed. Fifty-one machined surfaces (P-I Brånemark Philosophy™, Exopro LA, Bauru, SP) and 99 rough surfaces (96 Brånemark System MK IV TiUnite, Nobel Biocare™, Kungsgatan, Gothenburg and Osseotite, and 3 Biomet 3I™, Palm Beach Gardens, FL). Implants with diameters of 3.75 and 4.0 mm and lengths of 11.5, 13, 15, and 18 mm were used according to site characteristics. One-hundred-forty-seven implants were immediately loaded. Three implants placed in one subject were left to heal for 3 months as the insertion torque did not meet the required 35 N.cm for immediate loading. Table 1 also shows the mean, standard deviation, and range of cantilever radiographic lengths. The two-tailed paired t-test showed no differences between the investigators ($p > 0.05$). No statistical differences were found for intra or inter-investigations. Cronbach's α intra-class correlation coefficient was 0.9991 to the left and 0.9994 to the right cantilever segments.

After the 8-year follow-up, no deaths or withdrawals were noted. Six participants were removed from the peri-implant sample evaluation due to regular absence during the evaluation period. The mean observation time was 26.1 ± 12.01 months. In relation to subjects referred for treatment, more than 50% did not complete elementary school and were classified as C1 according to the BCEC, with an annual income of around 8.000 USD. Most of them had metabolic diseases, followed by inflammatory diseases, heart diseases, and cancer. Smokers and alcoholics were also observed.

No associations were found between the loss of osseointegration and gender ($p = 0.42$), schooling ($p = 0.84$), socioeconomic status ($p = 0.63$), and health conditions [group 1 ($p = 0.41$); group 2 ($p = 1.00$); group 3 ($p = 0.06$); group 4 ($p = 1.00$); or alcoholism ($p = 0.11$) and smoking ($p = 1.00$)]. Also, no statistical differences ($p = 0.97$) were found in relation to the loss of implants and age. The cumulative survival rate (CSR) of implants was 93.3%. All subjects presented one or more co-morbidities as depression, hypertension, gastric reflux, hypothyroidism, arthritis, osteoporosis, diabetes, and chronic kidney disease. Table 2 shows all detailed description of the implant failures. In relation to implant outcomes, one female subject, who used oral bisphosphonates, lost all immediately loaded Nobel Biocare™ implants at 4.4 months postoperatively, also showing three other signs of parafunction. Regarding implant surfaces, no significative differences were found in implant loss for machined or rough surfaces ($p = 0.54$ to the left side implants; $p = 0.54$ to the midline; and $p = 0.21$ to the right side).

3.2 Technical failures

Table 3 shows the detailed description of the technical failures found for 21 subjects, during the evaluation time. All complications were easily solved, except for the subject that lost all the implants. This sibject received 3 new implants, a new MRISFCD and had to have one prosthesis remade, due to a framework fracture. The prostheses cumulative survival rate was calculated at 96%.

3.3 Peri-implant outcomes

The Kappa coefficient was assessed (KIA = 0.942). Peri-implant outcomes and statistics are presented in Table 4. According to the binomial test ($\alpha = 0.05$), for the right-side implants, there was no statistical significance in the occurrence of biofilm and pain. But the absence of bleeding, suppuration, and mobility was proven to be statistically significant. For the midline implants, the absence of peri-implant complications was statistically significant in all recorded variables. The periodontal outcomes of the implants placed on the left side were similar to the midline, except the biofilm formation that did not show statistically significant differences. The range of peri-implant depth after the observation period was 1.67 ± 0.68 mm for the mandible right side, 1.61 ± 0.64 mm for the mental region, and 1.79 ± 0.65 mm for the left implants.

4 DISCUSSION

The retrospective study revealed a CSR of 93.3% for implants and 96% for the prostheses supported by three implants, as opposed to maxillary dentures in one-stage surgery. The clinical approach proposed in this retrospective study aimed to increase efforts in reducing treatment time and morbidity, through the reduction of surgical and prosthetic supplies, while maintaining high-quality treatment. Cost-effectivity ratios also proved favorable, when considering some limitations related to implant-supported overdentures. The multifunctional template guides, used to position the tilted implants, provide for the variation of a 30^{o} angle between distal and medial implants, as required to achieve a passive fit of the prosthetic infrastructure. Different from the “All-on-4” technique (Taruna et al., 2014), this study used straight abutments to avoid risks of stress concentrations (Arun Kumar et al., 2013; Cardelli et al., 2009) and to improve the cost-effectiveness of the process. As proposed by the cited technique, distally implants were tilted, aiming to reduce cantilevers in length. However, it is not always clinically feasible. It is important to consider, that the anatomic conditions of bone volume and the position of the mental foramina have a direct influence on the inclination capacity of the distal implants and, therefore, on the length of the cantilever segments. The need for the reduction in the length of cantilevers (Drago, 2017; Real-Osuna, Almendros-Marqués, & Gay-Escoda, 2012; Romanos, Gupta, Gaertner, & Nentwig, 2014; Semper, Heberer, & Nelson, 2010; Suedam, Moretti Neto, Sousa, & Rubo, 2016) is related to

biomechanical studies, which suggest that stress concentrations closer to the arms are proportional to the occlusal force exerted on the extension area (Osier, 1991).

Most implants in this study were lost in late failures, suggesting there may be a correlation to peri-implantitis (Robertson, Shahbazian, & MacLeod, 2015) or to overload. The latter is usually associated with parafunctional behaviors (De Angelis et al., 2017; Papi et al., 2017). Accuracy in parafunction diagnosis is a limitation in edentulous patients (Levin, 2008). However, gender, anxiety, nervous reactions, psychological responsibility, smoke, snoring, restless sleep, noise in the room, less than 8 hours sleep, headache, biting objects and others, can be considered as risk factors (Guo et al., 2018). Signs of parafunctional behavior, such as extensive wear, were observed in some subjects that had implant loss. Among them, two male and one female subjects were alcoholics, who also developed other complications such as loosening of the prosthetic screws and fracture of acrylic teeth. One of them, a male addicted, presented framework fracture. In addition, all subjects that lost implants had at least one, or even a combination of health impairments and hazardous habits. In regard to the patient who lost all three implants, he was an user of oral biphosphonates (de-Freitas et al., 2016; Tella & Gallagher, 2014), which is considered to be related to disorders in bone remodeling and, in some cases, osteonecrosis of the jaw (Lorenzo-Pouso et al., 2019). Nevertheless, although no statistical evidence was found, these findings were carefully considered, once it is well-known that patients with uncontrolled diabetes (Chrcanovic, Albrektsson, & Wennerberg, 2014) and smoking habits (Buhara & Pehlivan, 2018) present higher risks.

Considering that some failures occurred in subjects without signs of parafunctions and that mechanical complications are expected (Acocella et al., 2012; Ayub et al., 2017; Goodacre, Bernal, Rungcharassaeng, & Kan, 2003; Hinze, Thalmair, Bolz, & Wachtel, 2010; Sannino, Bollero, Barlattani, & Gherlone, 2017), one other point to be discussed, in relation to overload, was the number of implants in the support. In these cases the majority of failures are related to screw loosening (Chrcanovic et al., 2014). In our study, the same behavior has been observed, however, the percentage of loosen screws were high (17%). This could be explained due to the fact that the reduced implants in the support causes an increase in stress forces in screw regions (Simamoto

Júnior et al., 2014; Sousa et al., 2016). However, in our study, none of the variables influenced screw loosening. Nevertheless, as it is an expected failure, we recommend that the maintenance period should be carefully observed and, if necessary, reduced accordingly. Clinical trials are encouraged, in order to determine optimal maintenance intervals, considering the reduction of failures versus the increase in long-term costs.

After the follow-up period, none of the subjects evaluated showed any signs of infection. However, the presence of a biofilm and pain, especially in right side implants, were noted. In our study, oral care has been reinforced during the maintenance visits, but low schooling and the advanced age of many subjects could be a reasonable cause for this scenario. Furthermore, as expected, a larger biofilm accumulation was found in the distally tilted implants (Hopp et al., 2017; Narvaja et al., 2018). After the observation period, the low average probing depth and standard deviation found in the sample studied are in accordance with the expected long-term measurements for both straight and tilted implants (Menéndez-Collar et al., 2018). Current guidelines for recall policy and for maintenance of implant-supported rehabilitations are poorly defined, and are most often based on natural dentition protocols (Bidra et al., 2016).

Regarding the occlusal design of the maxilla, there is moderate evidence of its influence on MRISFCD survival rates, regardless of the number of implant support points (Carneiro-Campos et al., 2019). However, there is still a considerable lack of long-term studies on the behavior of MRISFCD supported by three implants. To confirm the findings described here, it is important that other studies, with longer observation periods and larger data sets are carried out, considering strict guidelines and precise diagnostic parameters (Balogh et al., 2015; Lachin, 2004). Nevertheless, the technique can be widely used in public health policies, with direct impact on the quality of life of low-income people, as long as the proposed risk mitigating measures are carefully taken.

CONCLUSIONS

The results of this retrospective study indicated that the clinical management approach were acceptable, and should be considered as alternative approach for conventional

techniques, extent to lower financial costs and treatment time. However, further research is needed.

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Table 1. Study group descriptive analysis

Subjects			Health, Smoking and Alcoholism status				Schooling		Social-Economics		Implant Brand and Surface - N (%)			Radiographic Cantilever Lenght	
Gender	N (%)	Age (Years) Mean_StdDev	Groups	N (%)*	Accumulative status** N (%)		Schooling	N (%)	Status***		Biomet 3I (Rough)	PI Brånemark Philosophy (Machined)	Nobel Biocare (Rough)	Rigth Side (cm) Min/Max (Mean/StdDev)	Left side (cm) Min/Max (Mean/StdDev)
Male	17 (34)	58.80 ± 7.72	0	6 (35.30)	Healthy	3 (17.60)	Illiterate	2 (11.70)	B2	7 (41.10)	-	21 (41.18)	30 (58.82)	3.3 / 22.9 (11.67 ± 4.69)	1.7 / 19.3 (10.87 ± 4.54)
			1	1 (5.90)	Single	9 (53.00)	Incomplete Elementary School	8 (47.10)	C1	4 (23.60)					
			2	1 (5.90)	Double	1 (5.90)	Elementary School	4 (23.60)	C2	2 (11.80)					
			3	5 (29.40)	Triple	4 (23.50)	High School	3 (17.60)	D	4 (23.50)					
			4	5 (29.40)											
			Smoking	4 (23.50)											
			Alcoholism	7 (41.20)											
Female	33 (66)	60.80 ± 9.32	0	7 (21.20)	Healthy	5 (15.20)	Illiterate	1 (3.00)	B1	2 (6.10)	1 (1.01)	30 (30.30)	68 (68.69)		
			1	2 (6.10)	Single	13	Incomplete Elementary School	18	B2	5 (15.20)					
			2	-	Double	(39.40)	Elementary School	(54.50)	C1	18					
			3	16 (48.50)	Triple	12	High School	5 (15.20)	C2	(54.50)					
			4	19		(36.40)	Graduate	7 (21.20)	D	4 (12.10)					
			Smoking	4 (12.10)		3 (9.00)		2 (6.10)		4 (12.10)					
			Alcoholism	5 (15.20)											

N=number; %=percentage; cm = centimeters; Min=minimum; Max=maximum; StdDev=standard deviation; *Frequency of subjects/groups; **Frequency of subjects according to accumulative occurrence of health and behavior status; ***BCEC Classification - Social-Economics is divided into A1, A2, B1, B2, C1, C2, D, and E, where "A" is the highest level and "E" related to the poverty band.

Table 2. Detailed analysis of implants losses during the study period.

Subjects	1	2	3	4	5	6	7	8
Gender	M	M	M	F	F	F	F	M
Age - years	55	55	57	49	64	70	71	59
Health status *	G3	G1 G3	G4	G3	G3 G4	G4	G3 G4	G3
Smoking	No	Yes	No	No	No	No	No	Yes
Alcoholism	Yes	No	No	Yes	No	No	No	Yes
Schooling	Mid	IES	ES	ES	IES	IES	IES	IES
Social-economics	C1	B2	D	C2	C1	C2	C1	D
Implant brand	PIB	PIB	NB	PIB	NB	PIB	3I	NB
Implant location	L	L	L	L	R M L	L	L	R
Implant dimensions - mm	3.75 x 15.00	3.75 x 10.00	3.75 x 15.00	4.00 x 15.00	3.75 x 15.00 3.75 x 13.00 3.75 x 15.00	3.75 x 15.00	4.00 x 18.00	3.75 x 15.00
Elapsed time for implant loss - months	22.00	12.60	13.30	17.90	4.40	3.50	12.40	15.00
Rigth cantilever length - cm	17.00	7.80	16.80	21.40	9.40	4.10	7.50	3.20
Left cantilever length - cm	19.00	2.90	11.70	19.30	9.90	6.10	7.00	3.40

M= male; F= female; G= health impairment group; Mid= middle school; IES= incomplete middle school; PIB= P-I Brånemark PhilosophyTM ; NB = Nobel BiocareTM; 3I= Biomet 3ITM; R= rigth side; M= midline; L= left side; Social-Economics is divided into A1, A2, B1, B2, C1, C2, D, and E, where "A" is the highest level and "E" related to the poverty band.

Table 3. Detailed analysis of technical failures during the study period.

Events	Subjects (N)	Events (N)
Abutment screw loosening	2	3 (3.00%)
Prosthetic screw loosening	13	25 (17.00%)
Prosthetics screw fracture	1	1 (1.00%)
Teeth fracture or detachment	6	7 (14.00%)
Superestructure failure	1	1 (2.00%)
Framework failure	1	1(2.00%)
Maxillary denture failure	3	3 (6.00%)
MMRIFCDP loss	2	2 (4.00%)

Table 4. Detailed analisys of periimplant outcomes during the study period

Peri-implant outcomes	Right side implant (tilted)			Midline implant (not tilted)			Left side implant (tilted)		
	Yes (N/%)	Not (N/%)	Missing data (N/%)	Yes (N/%)	Not (N/%)	Missing data (N/%)	Yes (N/%)	Not (N/%)	Missing data (N/%)
Biofilm	21 / 42%	23 / 46%	6 / 12%	30 / 60%	14 / 28%	6 / 12%	17 / 34%	26 / 54%	6 / 12%
Pain	20 / 40%	24 / 48%	6 / 12%	2 / 4%	42 / 84%	6 / 12%	3 / 6%	40 / 82%	6 / 12%
Bleeding	13 / 26%	31 / 62%	6 / 12%	9 / 18%	35 / 70%	6 / 12%	10 / 20%	33 / 68%	6 / 12%
Suppuration	0 / 0%	44 / 88%	6 / 12%	0 / 0%	44 / 88%	6 / 12%	0 / 0%	43 / 88%	6 / 12%
Mobility	0 / 0%	44 / 88%	6 / 12%	0 / 0%	44 / 88%	6 / 12%	0 / 0%	44 / 88%	6 / 12%

Right side implant	Occurrence	N (Subjects)	Quantity (%)	Binomial test	
Biofilm	Yes	21	48	0.88	No
	No	23	52		
Pain	Yes	20	45	0.65	No
	No	24	55		
Bleeding	Yes	13	30	0.01	Yes
	No	31	70		
Suppuration	Yes	0	0	p<0.001	Yes
	No	44	100		
Mobility	Yes	0	0	p<0.001	Yes
	No	44	100		

Midline implant	Occurrence	N (Subjects)	Quantity (%)	Binomial test	
Biofilm	Yes	30	68	0.02	Yes
	No	14	32		
Pain	Yes	2	4	p<0.001	Yes
	No	42	95		
Bleeding	Yes	9	20	p<0.001	Yes
	No	35	80		
Suppuration	Yes	0	0	p<0.001	Yes
	No	44	100		
Mobility	Yes	0	0	p<0.001	Yes
	No	44	100		

Left side implant	Occurrence	N (Subjects)	Quantity (%)	Binomial test	
Biofilm	Yes	17	39	0.17	No
	No	27	61		
Pain	Yes	3	7	*p<0.001*	Yes
	No	41	93		
Bleeding	Yes	10	23	p<0.001	Yes
	No	34	77		
Suppuration	Yes	0	0	p<0.001	Yes
	No	44	100		
Mobility	Yes	0	0	p<0.001	Yes
	No	44	100		

44/50 subjects evaluated (missing data-6); N=number; %= percentage

Figure 1. a. Denture wax try-in; b. On the bottom right, the maxillary denture finished and the mandibular wax duplication to build the template. b. Multifunctional template features: A – "tuberosity wing"; B – "occlusal support"; C – "palatal support"; D – "operative window"; E – "incisal support"; F – "metal plateau wear guide"; G – "digital surgical support".

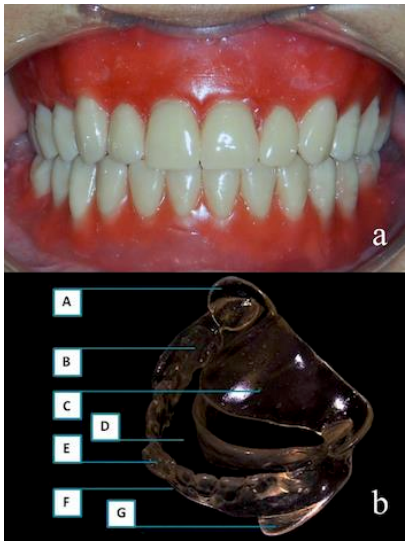

Figure 2. a. "Mental plateau wear guide" in position and mental bone flatten (dot-lined); b. Implants placed in the mental region. On the right the mental nerve can be seen distally of the implant; c. Mini-conical abutments placed for immediate loading.

Figure 3. a. Maxillary denture in occlusion with the template during the impression procedure; b. Rehabilitation in position for preliminary adjustments and occlusal check; c. Panoramic image for passive fit control.

3. DISCUSSÃO

Com moderada certeza de evidência observou-se que, diferentes desenhos oclusais maxilares, sejam dentições naturais, próteses fixas ou removíveis, não influenciaram a sobrevivência de próteses mandibulares totais fixas metaloplásticas implantossuportadas em longo prazo. Entretanto, embora não tenha sido o objetivo do estudo, há indícios de que a parafunção deva ser a maior causa de fracassos, não somente de próteses, bem como de implantes em médio e longo prazo. Hábitos parafuncionais são reconhecidamente deletérios, tanto às dentições artificiais, bem como às naturais (51,52). Entretanto, a investigação da parafunção em pacientes totalmente edêntulos nem sempre é favorável, ou mesmo acessível (53), sendo um limite a ser considerado na abordagem do planejamento do tratamento edêntulo total. A busca de materiais e tratamentos que sejam capazes de suportar cargas parafuncionais, ou mesmo a facilitação da distribuição de tensões nas interfaces duras e moles é lacuna aberta à indústria medico-odontológica.

Próteses totais convencionais maxilares, ao contrário das mandibulares, apresentam melhor performance funcional, devido às condições de suporte, retenção e estabilidade traduzidas pela area chapeável (4,5). Desta forma modelos reabilitadores que priorizem próteses fixas mandibulares implantossuportadas opostas às próteses totais convencionais devem ser objetivados para aumento do alcance social. O modelo apresentado neste estudo também reduziu o número de implantes no suporte e realizou carga imediata guiada por um modelo acrílico multifunctional não prototipado. Foi transferida com precisão a localização cirúrgica dos implantes, as moldagens, as dimensões verticais e consequente envio de dados ao laboratório de prótese dentária de cinquenta pacientes tratados no P-I Brånemark Institute em Bauru, São Paulo, entre os anos de 2008 e 2016. A abordagem proporcionou a redução dos comprimentos distais dos cantilevers, que variaram de 1,7 mm a 22,9 mm (cantilever radiográfico), com a utilização de implantes inclinados nestas regiões. Foram obsevados 93,3% de sobrevivência de implantes e 96%

das próteses, além aumento do polígono de apoio protético, menor tempo e consequente custo.

O guia multifuncional possibilitou a instalação dos implantes distais a uma inclinação de 30º em relação aos implantes sinfissários, o que proporcionou passividade para o assentamento protético. Diferente da técnica "All-on-4" (22), este estudo usou pilares retos para evitar riscos de concentrações de tensão (54,55) e melhorar a relação custo-eficácia.

As diretrizes atuais para o regime de manutenção de reabilitações implantossuportadas não estão bem definidas, baseando-se na maioria das vezes em protocolos utilizados na dentição natural (56). A maioria dos implantes deste estudo foi perdida devido a falhas tardias, sugerindo que poderia estar relacionada à periimplantite (57) ou sobrecarga, possivelmente associada a hábitos parafuncionais (51,52). Após o período de manutenção, nenhum dos sujeitos da pesquisa apresentou sinais de infecção. No entanto, a presença de um biofilme e dor, especialmente em nas regiões direitas, foram notados. Em nosso estudo, o cuidado oral foi reforçado durante as visitas de manutenção, entretanto a baixa escolaridade e a idade avançada de muitos sujeitos podem ser respostas plausíveis a estes achados. Além disso, como esperado, foi encontrado um maior acúmulo de biofilme nos implantes distalmente inclinados (21,58). Após o período de observação, a baixa profundidade média de sondagem e o desvio padrão encontrados na amostra estudada estão de acordo com as medidas de longo prazo esperadas para implantes retos e inclinados (59).

Extensões cantileveres são comumente um risco reabilitador (24,25). Desta maneira devem ser evitadas sempre que possível, especialmente os comprimentos horizontais entre 15 mm (26,28), ou mesmo acima de 20 mm (29). Esta problemática reside ao fato de que a concentração de tensões na região dos implantes distais tende a ser proporcional à força oclusal exercida nesta região (60). De acordo com estudos anteriores (19,20) a redução do comprimento horizontal das extensões cantileveres foi observada com a abordagem apresentada. Entretanto, é necessário se ter em mente que as

condições anatômicas do volume mandibular, bem como a posição de emergência do forame mentoniano são fatores que influenciam diretamente a capacidade técnica de inclinação dos implantes distais. Portanto, o comprimento dos cantileveres embora possa ser reduzido, ainda assim não pode ser previsto.

As complicações mecânicas observadas neste estudo foram semelhantes aos demais protocolos convencionais (8,9,61–63). Sinais de parafunção, como desgaste extenso, foram observados em alguns indivíduos perderam implantes. Dentre estes, três etilistas, dois do sexo masculino e um do sexo feminino, que também desenvolveram outras complicações, como afrouxamento dos parafusos protéticos e fratura dos dentes acrílicos. Todos os indivíduos que tiveram perdas de implantes apresentavam um ou mais comprometimentos sistêmicos, além de hábitos viciosos. No entanto, não houve evidência que correlacionasse os mesmos, provavelmente devido ao pequeno número da amostra. Todavia, estes achados devem ser cuidadosamente analisados, uma vez que é reconhecida a influência do diabetes (64) e também do tabagismo (65) na remodelação óssea e manutenção da interface osseointegrada. O uso mais amplo de bisfosfonatos em medicina (66,67) e a osteonecrose relacionada da mandíbula também é um importante tema a ser considerado em terapia cirúrgica, sendo passível de estar relacionado a um dos casos de insucessos apresentados (68).

Como considerações finais orienta-se que estudos futuros comparem abordagens tradicionais para a reabilitação da mandíbula edêntula e o protocolo apresentado, o que pode ser apontado como uma limitação deste trabalho. Todavia, ainda há carência de estudos de longitudinais com o desenho apresentado. Para confirmar os achados aqui descritos, é importante que períodos de observação mais longos e maiores conjuntos de dados sejam realizados com diretrizes rígidas e parâmetros diagnósticos precisos (49,50).

4. CONCLUSÕES

1. Com moderada certeza de evidência, dentições maxilares naturais opostas a próteses mandibulares totais fixas metaloplásticas implantossuportadas não afetam em longo prazo a sobrevivência de maneira diferente de modelos protéticos;

2. A utilização de guias multifuncionais não prototipadas com desenhos capazes de transferir a região cirúrgica precisão, serem ainda capazes de transferir a moldagem ao laboratório e manter as relações oclusais se mostraram eficazes em médio e longo prazo.

3. A sobrevivência de próteses e implantes de protocolo reabilitador do edentulismo com próteses mandibulares totais fixas metaloplásticas implantossuportadas por 3 implantes opostas à próteses totais convencionais mostrou-se inicialmente, semelhante aos protocolos reabilitadores com maior número de implantes no suporte.

De acordo com as evidências apresentadas o manejo clínico proposto se mostra viável e deve ser considerado como alternativa as técnicas convencionais para o tratamento do edentulimo maxilo-mandibular, reduzindo custos e tempo de tratamento. Entretanto, a limitação do número de indivíduos atendidos requer que estudos multicêntricos possam elucidar de forma mais efetiva as questões propostas.

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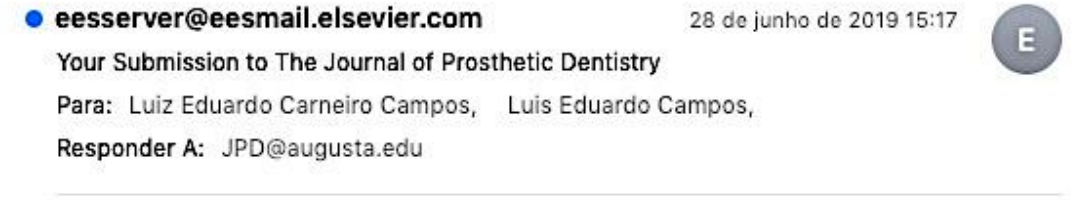
ANEXOS



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Your Submission to The Journal of Prosthetic Dentistry

Para: Luiz Eduardo Carneiro Campos, Luis Eduardo Campos,

Responder A: JPD@augusta.edu

Jun 28, 2019

Re: Manuscript # JPD-D-18-00859R3

Dear Eduardo,

Thank you for submitting your manuscript # JPD-D-18-00859R3, entitled "Does the natural maxillary dentition influence the survival rate of mandibular metal-resin implant-supported fixed complete dentures? A systematic review and meta-analysis."

I am pleased to inform you that your paper has been accepted for publication in The Journal of Prosthetic Dentistry.

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Thank you for submitting your work to The Journal of Prosthetic Dentistry.

Yours sincerely,

Stephen F Rosenstiel, BDS, MSD
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