Lívia Bonjardim Lima

# Avaliação do impacto do número de implantes empregados para reabilitação tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados.

*Impact assessment of implant number used to support full-arch fixed prostheses on quality of life, patient satisfaction and implant and prosthesis success.*

Tese apresentada à Faculdade de Odontologia
da Universidade Federal de Uberlândia,
para obtenção do Título de Doutor em
Odontologia na Área de
Clínica Odontológica Integrada.

Uberlândia, 2019

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Orientador: Prof. Dr. Paulo Cézar Simamoto Júnior

Banca Examinadora:
Prof. Dr. Paulo Cézar Simamoto Júnior
Prof. Dr. Lair Mambrini Furtado
Prof. Dr. Luiz Carlos Gonçalves
Profa. Dra. Fabiane Maria Ferreira
Prof. Dr. João Paulo Silva Servato

Uberlândia, 2019

Ficha Catalográfica Online do Sistema de Bibliotecas da
UFU com dados informados pelo(a) próprio(a) autor(a).

L732
2019

Lima, Lívia Bonjardim, 1989-
Avaliação do impacto do número de implantes empregados para reabilitação tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados. [recurso eletrônico] / Lívia Bonjardim Lima. - 2019.

Orientador: Paulo Cézar Simamoto Júnior.
Tese (Doutorado) - Universidade Federal de Uberlândia, Pós-graduação em Odontologia.
Modo de acesso: Internet.
Disponível em: http://doi.org/10.14393/ufu.te.2019.2589
Inclui bibliografia.
Inclui ilustrações.

1. Odontologia. I. Simamoto Júnior, Paulo Cézar ,1977-, (Orient.). II. Universidade Federal de Uberlândia. Pós-graduação em Odontologia. III. Título.

CDU: 616.314

Bibliotecários responsáveis pela estrutura de acordo com o
AACR2: Gizele Cristine Nunes do Couto - CRB6/2091
Nelson Marcos Ferreira - CRB6/3074

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# ATA DE DEFESA - PÓS-GRADUAÇÃO

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|---|---|---|---|---|---|
| Programa de Pós-Graduação em: | Odontologia | | | | |
| Defesa de: | Tese | | | | |
| Data: | Vinte e três de dezembro de dois mil e dezenove | Hora de início: | 08:00 | Hora de encerramento: | 12:00 |
| Matrícula do Discente: | 11713ODO010 | | | | |
| Nome do Discente: | Lívia Bonjardim Lima | | | | |
| Título do Trabalho: | Avaliação do impacto do número de implantes empregados para reabilitação tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados | | | | |
| Área de concentração: | Clínica Odontológica Integrada | | | | |
| Linha de pesquisa: | Implantodontia e Prótese sobre implantes | | | | |
| Projeto de Pesquisa de vinculação: | Implantodontia e Prótese sobre implantes | | | | |

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Iniciando os trabalhos o(a) presidente da mesa, Dr(a). Paulo Cézar Simamoto Junior, 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.

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Documento assinado eletronicamente por **Luiz Carlos Gonçalves**, **Professor(a) do Magistério Superior**, em 23/12/2019, às 12:00, conforme horário oficial de Brasília, com fundamento no art. 6º, § 1º, do Decreto nº 8.539, de 8 de outubro de 2015.

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Documento assinado eletronicamente por **João Paulo Silva Servato**, **Usuário Externo**, em 23/12/2019, às 12:25, conforme horário oficial de Brasília, com fundamento no art. 6º, § 1º, do Decreto nº 8.539, de 8 de outubro de 2015.

Documento assinado eletronicamente por **Fabiane Maria Ferreira**, **Usuário Externo**, em 23/12/2019, às 12:27, conforme horário oficial de Brasília, com fundamento no art. 6º, § 1º, do Decreto nº 8.539, de 8 de outubro de 2015.

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**Referência:** Processo nº 23117.108087/2019-79 SEI nº 1765209

# DEDICATÓRIA

Dedico esta tese à memória do meu amado irmão Danilo Bonjardim Lima, que acredito, de onde estiver, está olhando por mim e vibrando a cada graça alcançada.

.

# AGRADECIMENTOS ESPECIAIS

A **Deus,** que tem me conduzido e protegido até aqui. Que não me abandona e que derrama suas bençãos sobre minha vida, me fortalecendo nos momentos difíceis e me orientando nas ocasiões de dúvidas, que me fez forte para vencer os obstáculos que surgiram e que me ajudou a crescer frente às adversidades vividas. Que é fonte de todo Amor e em quem minha fé repousa.

Aos meus pais **Orlando e Rosilane,** que me criaram com todo Amor e disciplina e plantaram em mim a semente da busca por uma vida melhor, sempre com a memória da minha origem e gratidão por todo seu sacrifício.

À **toda minha família**, em especial aos meus **avós Walter Figueiredo e Neuza Brito** pelo amor, pelas orações e suporte de sempre. Amo vocês!

Ao meu companheiro **Luiz Fernando**, que partilha dos meus momentos de aflição, sempre buscando uma forma de abrandar meu coração. Que me motiva a seguir meus sonhos e compartilha seu caminho comigo.

À **Tainá Nascimento** por ser minha eterna dupla! Que mesmo na distância não me deixa sozinha e sempre esteve ali para um telefonema de 2 horas para desabafar sobre as dificuldades da vida e comemorar as vitórias alcançadas.

Aos meus sogros o senhor **Ronan** e a dona **Leila** que me acolheram como filha e sempre estiveram na torcida pelas vitórias que eu almejava.

Aos **amigos,** que de perto ou longe foram apoios durante as fases difíceis de formação longe de casa e, em especial, à **Fabiane Maria**, que desde 2017, quando me aventurei a ir para Rio Verde, vem me mostrando um carinho e cuidado que foram muito importantes para meu fortalecimento pessoal e profissional.

# AGRADECIMENTOS

Ao meu orientador **Prof. Dr. Paulo Cézar Simamoto-Júnior**, muito obrigada pela amizade, por todos os ensinamentos e especialmente por ter me proporcionado a oportunidade do mestrado e doutorado, onde tanto cresci. Obrigada pelo tratamento sempre tão cordial e pela valorização da minha atuação como profissional, sempre com a confiança em meu trabalho.

Ao meu amigo **Marcos Boaventura,** que foi um presente que o mestrado meu deu e sem o qual este doutorado e tese não teriam sido possíveis.

Ao **Prof. Dr. Luiz Carlos Gonçalves**, que tem sido fonte de inspiração e ensinamentos desde a época de minha residência. Com quem aprendi a apreciar ainda mais a reabilitação e o cuidado em entregar o melhor trabalho. Em quem me espelhei ao tentar ser melhor. Sem o qual minha formação na Universidade Federal de Uberlândia não teria sido a mesma. Obrigada ainda por estar na torcida pelo meu sucesso.

Ao **ILAPEO,** pela parceria no desenvolvimento do projeto de avaliação clínica dos pacientes usuários de protocolo maxilar.

Aos **professores da banca,** Prof. Dra. Fabiane Maria Ferreira, Prof. Dr. João Paulo Silva Servato, Prof. Dr. Lair Mambrini Furtado e Prof. Dr. Luiz Carlos Gonçalves obrigada por terem aceito o convite, contribuírem com o trabalho e participarem desse momento.

Aos **professores da Faculdade de Odontologia da Universidade Federal de Uberlândia (FOUFU)** pela dedicação, amizade e ensinamentos transmitidos a mim ao longo destes anos.

Aos ***funcionários da FOUFU,*** em especial à Bethânia, cujo sofá da sala foi muitas vezes um divã e se tornou uma verdadeira amiga neste tempo de UFU. Muito obrigada pela amizade e disponibilidade de ajuda sempre que precisei.

À **Universidade Federal de Uberlândia** e **Faculdade de Odontologia – FOUFU**, obrigada pela oportunidade de cursar minha residência, mestrado e doutorado. Em 2012 cheguei como uma forasteira e desde então tenho sido acolhida por tantas pessoas gentis que aqui estão.

À **Coordenação de Aperfeiçoamento de Pessoal de Nível Superior** (CAPES), pelo apoio financeiro por meio da bolsa de Doutorado.

À **Fundação de Amparo à Pesquisa do estado de Minas Gerais** (FAPEMIG), pelo apoio financeiro por meio da bolsa de Mestrado.

***A todos que torceram por mim e que de alguma forma contribuíram para a realização deste trabalho!!!***

# SUMÁRIO

# *RESUMO*

**RESUMO**

A reabilitação de rebordos desdentados com próteses totais fixas implanto-suportadas é um tratamento estabelecido, no entanto ainda se busca a simplificação desse tratamento a fim de redução de custos e menos trauma para o paciente. Estudos têm avaliado a condição de sobrevivência dos implantes empregados em número reduzido, no entanto o foco também deveria se voltar para a manutenção das próteses e a percepção do paciente quanto a seu tratamento. Assim, esta tese teve finalidade de avaliar o impacto do número de implantes empregados para reabilitação tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados**.** Foi dividido em três objetivos específicos. **Objetivo específico 1:** Impacto do número de implantes empregados em protocolos mandibulares – Revisão sistemática. Revisar se o número de implantes empregados para suportar prótese tipo protocolo mandibular influencia a taxa de sobrevivência dos implantes, perda óssea marginal e sobrevivência das próteses. **Objetivo específico 2:** Número de implantes empregados para reabilitações totais fixas maxilares: Revisão sistemática. Avaliar se o número de implantes empregados para suportar reabilitações totais tipo protocolo maxilar influencia a taxa de sobrevivência dos implantes, perda óssea marginal e sobrevivência das próteses. **Objetivo específico 3:** Reabilitação total implanto-suportada em maxila com diferentes números de implantes. Relato de 3 casos. Relatar 3 casos de pacientes reabilitados com próteses tipo protocolo maxilar, empregando diferente número de implantes e discutir o impacto desta reabilitação sobre a qualidade de vida e a satisfação destes pacientes. Após análise dos dados obtidos, pôde-se concluir que: protocolos mandibulares suportados por três implantes demonstraram sobrevivência de implantes e perda óssea marginal no primeiro ano satisfatórios, no entanto a sobrevivência de próteses foi inferior aos demais grupos e isto sugere um maior acompanhamento de tais reabilitações; a taxa de sobrevivência de implantes e próteses, bem como a perda óssea marginal nos protocolos maxilares suportados por 4 implantes foram satisfatórios comparados com diferente número de implantes. Quanto ao impacto sobre a qualidade de vida e satisfação do paciente, os casos apresentados

demonstraram escores satisfatórios, independente do número de implantes instalados.
**Palavras-chave:** Implantes dentários; prótese dentária fixada por implante; qualidade de vida.

# *ABSTRACT*

**ABSTRACT**

Rehabilitation of edentulous arches with implant-supported full-arch fixed protheses is a settled treatment, however simplification of this treatment is sought in order to reduce the costs and trauma to the patient. Studies have evaluated the survival of dental implants when they are used in reduced number, nevertheless the focus should also be on maintaining the prostheses and the patient's own perception of their treatment. Thus, this thesis aimed to assess the impact of the number of implants used to support full-arch fixed prostheses upon quality of life, patient satisfaction and the success of installed implants and prostheses. This work was divided in three specific objectives. **Objective 1:** Impact of Implant Number on Mandibular Implant-Supported Profile Prostheses: A Systematic Review. To review whether the number of implants used to support a mandibular profile prosthesis does influence the implant survival rate, marginal bone loss and prosthesis survival rate. **Objective 2:** Number of implants used in full fixed implant supported prostheses in maxilla: systematic review. To evaluate if the number of implants used in full fixed implant supported prostheses in maxilla does influence the implant survival rate, marginal bone loss and prosthesis survival rate. **Objective 3:** Maxillary Implant supported full-arch rehabilitation using different number of implants: three cases report. To report three cases of patients rehabilitated with Implant supported full-arch fixed prostheses, using different number of implants, and discussed the impact of this rehabilitation on quality of life and patient's satisfaction. After the data analysis, the authors concluded that: mandibular profile prosthesis supported by three implants showed satisfactory implant survival rate and marginal bone loss in the first year, however the prosthesis survival rate was inferior to other groups and this suggests a longer follow-up for these rehabilitations; the implant and prosthesis survival rate, as the marginal bone loss of full-arch fixed prostheses supported by four implants were satisfactory compared to different number of implants. Concerning to the oral health quality of life impact and patient's satisfaction, the presented cases showed satisfactory scores, regardless the number of implants installed.

**Key-words:** Dental implants; dental prosthesis, implant-supported; quality of life.

# *INTRODUÇÃO E REFERENCIAL TEÓRICO*

# 1. INTRODUÇÃO E REFERENCIAL TEÓRICO

As últimas décadas têm sido marcadas por um crescimento demográfico de pessoas idosas e tem sido registrado um aumento da expectativa de vida da população (Lunenfeld & Stratton, 2013). Assim, faz-se necessário que os profissionais da área de saúde acompanhem as mudanças solicitadas com esta nova face da população atendida, inclusive os cirurgiões-dentistas que necessitam voltar-se às demandas apresentadas por um grupo representativo de pacientes de idade avançada e que buscam não somente função, como também qualidade de vida.

Embora em países de caráter socio-econômico mais desenvolvido o edentulismo parece não mais figurar entre os principais problemas que acometem a saúde de sua população (Sussex, 2008), quando o quadro é analisado em aspecto global, nota-se que a saúde bucal ainda é pobre entre pessoas de idade avançada, o que é demonstrado pelas altas taxas de cárie, perdas dentárias e doença periodontal (Petersen & Yamamoto, 2005). Abordando especialmente o edentulismo total, este não parece estar estabilizado ou diminuindo e mesmo com a redução gradual das perdas dentárias nas novas gerações, o aumento da expectativa de vida associado à característica da presença de excesso de açúcar na alimentação ocidental, contribui para a manutenção do número de edêntulos ao redor do mundo (Cooper, 2009). Como mostra a Pesquisa Nacional de Saúde Bucal do Brasil, em 2010, que observou a necessidade de prótese total em um maxilar em 17,9% dos indivíduos examinados (entre 65 e 74 anos de idade) e uma proporção de 15,4% de pessoas que necessitavam de prótese total nos dois maxilares dentro da mesma faixa etária. (Ministério da Saúde, 2012).

A opção de tratamento menos invasiva para que a reabilitação de pacientes totalmente edêntulos seja possível é a confecção de próteses totais removíveis, entretanto a reabsorção óssea pela ausência dentária gera um prejuízo de sua retenção, causando dificuldade quanto à função mastigatória e fonética, assim como gera estado de tensão no usuário da prótese removível, que mostra-se receoso de que o dispositivo protético possa soltar-se durante a função (Blomberg & Lindquist, 1983). A utilização de implantes dentários pode

melhorar a estabilidade percebida pelo paciente por meio do tratamento com próteses removíveis tipo overdenture ou mesmo próteses totais fixas do tipo protocolo (Allen & McMillan, 2003), que têm o potencial de melhorar a habilidade mastigatória dos pacientes que antes possuíam prótese convencionais. (Allen & McMillan, 2002)

A previsibilidade das reabilitações totais fixas implanto-suportadas está consolidada na literatura (Brånemark *et al.,* 1995; Ekelund *et al*., 2003; Astrand *et al.*, 2008). Originalmente, Brånemark et al. (1977) definiram o conceito de utilização de 6 implantes endósseos para reabilitação fixa de arcos completamente edêntulos em caráter de carga convencional. Anos mais tarde, em 1995, Brånemark *et al.,* em um estudo retrospectivo de acompanhamento de 10 anos, relataram uma série de 156 pacientes consecutivos reabilitados com prótese tipo protocolos mandibulares e maxilares, utilizando 4 ou 6 implantes. Uma reduzida disponibilidade óssea foi a razão principal para emprego de 4 implantes em alguns dos casos. Embora tenha sido encontrado uma ligeira tendência para maior falha de implantes nos casos reabilitados com 4 implantes, as taxas de sobrevivência de implantes e próteses foram semelhantes para ambos os grupos no período de 10 anos de acompanhamento. Os autores sugeriram, desta forma, que números excessivos de implantes deveriam ser evitados nas reabilitações.

Então, novos protocolos de tratamento vêm sendo desenvolvidos, por meio de estudos (Agliardi *et al*., 2008; Hatano *et al*., 2011; Babbush *et al*., 2014; Piano *et al*., 2016), com a intenção de reduzir o número de implantes empregados, visando a redução do custo final do tratamento e especialmente facilitar o procedimento de higiene pelo paciente, na medida em que haverá um maior espaçamento entre os implantes. Este último ponto a ser considerado já foi previamente citado por pacientes como motivo para escolha de próteses removíveis em detrimento de próteses fixas implanto-suportadas e não deve ser negligenciado, em vista da característica de idade e dificuldade motora dos pacientes a serem reabilitados (Rodriguez *et al.*, 2000).

Bruyn e colaboradores (2001), em um estudo prospectivo, avaliaram o sucesso dos implantes e da reabilitação protética de pacientes tratados com

prótese fixa tipo protocolo mandibular em carga imediata sobre 3 implantes de plataforma regular (4,1mm). A perda óssea observada no primeiro ano manteve-se dentro dos limites aceitáveis de 1,5mm. No entanto, as altas taxas de falhas de implantes em função (9,5%) e de próteses instaladas (15%) no primeiro ano levaram os autores a fazer considerações acerca da cautela em relação a este tipo de tratamento, sugerindo que mais altas taxas de sucesso deveriam ser apresentadas antes que este protocolo seja seguido. Estes mesmos autores advertem para o fato de que a busca por tratamentos com menor número de implantes, com menor custo, não deveria levar a complicações e problemas técnicos ao longo do tempo (Bruyn *et al*., 2001).

Kok e colaboradores (2011) avaliaram em seu estudo piloto controlado aleatorizado, dentre outros fatores, taxas de sobrevivência dos implantes e complicações protéticas observadas em pacientes reabilitados com protocolo mandibular sobre 3 implantes de 4mm de diâmetro, comparando-os a overdentures suportadas por 2 implantes. Os implantes foram reabilitados em caráter de carga convencional e outra variação para a prótese fixa a partir do conceito Brånemark Novum foi a angulação dos implantes distais a fim de aumentar a distribuição dos implantes, melhorando o suporte da prótese. 100% de sobrevivência dos implantes e próteses foram relatados no primeiro ano de acompanhamento. Deste modo, os autores consideram que esta forma de tratamento pode ser empregada, porém ressaltam que períodos de maior acompanhamento são necessários para validação desta modalidade.

Em 2016, Piano e seus colaboradores examinaram, por 2 anos, 21 pacientes, tratados com próteses totais maxilares suportadas por 4 implantes. Eles avaliaram parâmetros clínicos da condição periodontal destes pacientes e concluíram que a carga imediata destes implantes posicionados anteriormente ao seio maxilar pode ser um procedimento de tratamento confiável para apoiar reabilitações completas fixas.

Agliardi e sua equipe, em 2008, relataram os resultados de um estudo em que avaliaram 21 pacientes tratados com a técnica “V-II-V”, em que quatro implantes são instalados em posição inclinada de maneira a fugir da região do seio maxilar e dois implantes são posicionados retos na região anterior da

maxila. Cento e vinte e seis implantes foram instalados e tiveram tempo médio de acompanhamento de vinte meses. Os autores concluíram que a técnica é uma modalidade viável para reabilitação de maxilas atróficas, evitando, desta maneira, procedimento de enxertos ósseos e levantamento de seio maxilar.

Como mencionado, em diversas situações, por fatores biológicos como a perda óssea acentuada, o cirurgião se depara com a necessidade de realização de procedimentos cirúrgicos para aumento do rebordo alveolar atróficos (Gunne *et al*., 1995), de maneira que um número adequado de implantes seja instalado para posterior reabilitação protética. Entretanto, a busca por formas de tratamento simplificadas como alternativa a esse tratamento demorado e de custo oneroso tem sido conduzida (Asawa *et al.*, 2015; Piano *et al.,* 2016). Autores sugeriram a utilização de implantes trans-sinusais para quando a altura óssea não se fazia adequada (Jensen *et al.,* 2012) ou mesmo a inclinação de implantes em maxila a fim de evitar procedimento de levantamento de seio maxilar (Jensen & Adams, 2009).

Desta maneira, estudos vêm sendo realizados a fim de determinar se a redução do número de implantes utilizados para tais tratamentos pode ser uma opção viável a longo prazo, com o adicional benefício da redução dos custos, bem como a possível facilitação da higiene oral pelo paciente, sem que haja prejuízo do sucesso dos implantes (Rodriguez *et al.,* 2000; Babbush *et al.,* 2014; Passoni *et al.,* 2014; Bhering *et al.,* 2016; Niedermaier *et al*., 2016; Hopp *et al.,* 2017).

A maioria das pesquisas relacionadas à reabilitação com próteses totais implanto-suportadas direciona sua investigação para as taxas de sucesso e sobrevivência dos implantes, além da perda óssea marginal apresentadas. Análises das taxas de sucesso das próteses nem sempre são encontradas na literatura (Engquist *et al*., 2005; Rivaldo *et al.,* 2012; Scala *et al.*, 2012). No entanto esta análise faz-se justificada como parte importante da demonstração do sucesso de uma determinada modalidade de tratamento (Rodriguez *et al*., 2000).

Além dos quesitos biológicos, questões como o impacto da reabilitação com próteses implanto-suportadas na qualidade de vida do paciente

e a percepção do próprio paciente sobre o tratamento recebido deveriam ser parâmetros ao se buscar demonstrar o real mérito de uma modalidade de tratamento frente a outra (Martín-Ares *et al.,* 2016; Topçu *et al.,* 2017; Nagahisa *et al.,* 2018), visto que a aprovação do resultado final do tratamento consiste não somente em adaptação funcional, como também na aceitação psicossocial pelo paciente (Cibirka *et al.,* 1997).

As expectativas, cada vez maiores, de pacientes candidatos à reabilitação com implantes dentários tornam as avaliações baseadas no paciente ainda mais relevantes. (Brennan *et al.*, 2010) Assim, medidas de impacto da saúde oral sobre qualidade de vida, bem como satisfação do paciente quanto ao tratamento estão cada vez mais incluídas nos processos de avaliação (Martín-Ares *et al.,* 2016; Topçu *et al.*, 2017; Nagahisa *et al.,* 2018). Estas mensurações englobam usualmente questionários de qualidade de vida e pesquisa do tipo Likert ou escala visual analógica (VAS) e geralmente focalizam o impacto da saúde bucal na qualidade de vida dos pacientes e são desenvolvidas através da análise de preocupações, atitudes e percepções destes (Topçu *et al.,* 2017; Paul *et al.,* 2018)

Diante do exposto, a hipótese deste trabalho é que o número de implantes utilizados para reabilitações tipo protocolo tem influência nas características de sucesso destes implantes, no sucesso clínico das reabilitações protéticas, bem como afeta a qualidade de vida do paciente tratado e a satisfação deste frente ao tratamento.

# *OBJETIVOS*

## 2. OBJETIVO GERAL

Avaliar o impacto do número de implantes empregados para reabilitação tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados.

**2.1. Objetivo específico 1:** *Impacto do número de implantes empregados em protocolos mandibulares – Revisão sistemática.*

Revisar, por meio de revisão sistemática, se o número de implantes empregados para suportar prótese tipo protocolo mandibular influencia a taxa de sobrevivência dos implantes, perda óssea marginal e sobrevivência das próteses.

**2.2. Objetivo específico 2:** *Número de implantes empregados para reabilitações totais fixas maxilares: Revisão sistemática.*

Avaliar se o número de implantes empregados para suportar reabilitações totais tipo protocolo maxilar influencia a taxa de sobrevivência dos implantes, perda óssea marginal e sobrevivência das próteses.

**2.3. Objetivo específico 3:** Reabilitação total implanto-suportada em maxila com diferentes números de implantes. Relato de 3 casos.

Relatar 3 casos de pacientes reabilitados com próteses tipo protocolo maxilar, empregando diferente número de implantes, e discutiu o impacto desta reabilitação sobre a qualidade de vida e a satisfação destes pacientes.

# *CAPÍTULOS*

## 3. CAPÍTULOS

Serão apresentados nesta sessão três artigos, sendo cada um correspondente a um capítulo.

**3.1. Capítulo 1:** Artigo 1 - Impact of Implant Number on Mandibular Implant-Supported Profile Prostheses: A Systematic Review
Lívia Bonjardim Lima; Nayara Ribeiro de Freitas; Veridiana Resende Novais; Paulo Cézar Simamoto Júnior

**3.2. Capítulo 2:** Artigo 2 - Impact of Implant Number on Maxillary Implant-Supported Profile Prostheses: A Systematic Review
Lívia Bonjardim Lima; Andressa Ramos Silva; Paulo Cézar Simamoto-Júnior

**3.3. Capítulo 3:** Artigo 3 - Maxillary Implant supported full-arch rehabilitation using different number of implants: three cases report
Lívia Bonjardim Lima; Marcos Boaventura de Moura; Flávia Noemy Gasparini Kiatake Fontão; Geninho Thomé Dercelino Bittencourt Júnior; Paulo Cézar Simamoto-Júnior

### 3.1. Capítulo 1

Impact of Implant Number on Mandibular Implant-Supported Profile Prostheses: A Systematic Review

Lívia Bonjardim Lima; Nayara Ribeiro de Freitas; Veridiana Resende Novais; Paulo Cézar Simamoto Júnior

DOI: 10.11607/jomi.6243

# Impact of Implant Number on Mandibular Implant-Supported Profile Prostheses: A Systematic Review

Lívia Bonjardim Lima, MSc[1]/Nayara Ribeiro de Freitas, DDS[2]/
Veridiana Resende Novais, PhD[3]/Paulo Cézar Simamoto Júnior, PhD[4]

***Purpose:*** *To assess studies on edentulous patients rehabilitated using mandibular implant-supported profile prostheses and analyze the impact of different numbers of implants used on the implant survival rate, peri-implant bone loss, and prosthesis survival rate.* ***Materials and Methods:*** *This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement and was registered on PROSPERO. The PubMed/MEDLINE database was searched for articles published before July 18, 2016. The study attempted to answer the following PICO question: In edentulous patients, do full-arch fixed prostheses supported by three implants have a satisfactory implant survival rate, marginal bone loss, and prosthesis survival rate compared with those supported by different numbers of implants? Evidence levels of each study were evaluated using the Oxford Centre for Evidence-Based Medicine (OCEBM); methodologic quality was evaluated using the Methodological Index for Nonrandomized Studies (MINORS) scale and Cochrane Risk of Bias Tool. Descriptive statistics were performed when applicable. Implant survival curves were constructed using the Kaplan-Meier method, and marginal bone loss was analyzed using the Kruskal-Wallis, Dunn's, and Mann-Whitney tests.* ***Results:*** *This analysis included 21 published studies of 4,712 implants and 1,245 mandibular implant-supported profile prostheses in 1,245 patients. The patients were grouped by the number of implants used: group 1 (three implants) had an implant survival rate of 90%; group 2 (four implants) had a rate of 95%; and group 3 (five implants) had the lowest rate, 74%. Groups 1 and 3 had the lowest first-year bone losses (median: 0.73 and 0.70 mm, respectively), and were significantly different from group 2 (median: 1.31 mm; P < .001).* ***Conclusion:*** *Despite the limitations in the studies with low levels of evidence and the methodology of MeSH term research, it was concluded that the implant survival rate and first-year bone loss of full-arch fixed prostheses supported by three implants were satisfactory. However, the prosthesis survival rate was inferior to that of other groups, which suggests a longer follow-up of these rehabilitations.* Int J Oral Maxillofac Implants 2018;33:795–807. doi: 10.11607/jomi.6243

**Keywords:** *dental implants, implant-supported dental prosthesis, survival rate*

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An increase in the elderly population and an increase in life expectancy have occurred in recent decades.[1] Therefore, it is necessary for dental health professionals to adapt their actions, which attempt to reestablish masticatory function, esthetics, and phonation ability, as well as self-esteem and confidence, to changes in the population. Edentulism remains a challenge as the world's population ages.[2] Considering the social characteristics of edentulism in a low-income population,[3] there is a need for clinical protocols that can achieve wider population coverage through reduced costs and less-invasive surgical procedures.[4]

The rehabilitation of the mandibular arch with dental implants supporting a fixed full-arch prosthesis is a good treatment that may provide better chewing performance, improved stability and comfort, and better

speech capacity in patients who have problems with complete dentures.[5,6]

Studies with long-term follow-up periods have reported successful treatment with mandibular implant-supported profile prostheses.[7,8] Initially, six dental implants were required to support a fixed mandibular full-arch denture.[9] Later, Brånemark et al (1995)[10] investigated the use of four and six implants to completely rehabilitate edentulous patients. Although they found a slightly increased failure rate in cases with a reduced number of implants, implant and prosthesis survival rates were satisfactory for both groups. In 1999, the new Novum protocol was introduced, based on the implantation of three large-diameter implants in the anterior mandible using a prefabricated set of guides and bars. Results after 6 months to 3 years showed that 98% of implants and prostheses were successful.[11]

Several studies[12–14] have since examined reductions in the number of implants to reduce the final cost of the treatment,[15] and to facilitate improved hygiene procedures[16] due to the larger spaces between the implants. Most of those studies only highlighted the implant survival rate and marginal bone loss; the prosthesis survival rate was not always reported.[17,18] Therefore, it seems worthwhile to analyze this topic to determine the overall success of the rehabilitation treatment.[16]

This review analyzed studies that included edentulous patients rehabilitated using mandibular implant-supported profile prostheses and compared the impact of the different numbers of implants used on implant survival, peri-implant bone loss, and the prosthesis survival rate. The following P = patient problem/population, I = Intervention, C = Comparison, O = Outcome (PICO) question was used to guide this review: "In edentulous patients, do full-arch bridges supported by three implants have a satisfactory implant survival rate, marginal bone loss, and prosthesis survival rate compared to those supported by different numbers of implants?"

## MATERIALS AND METHODS

This review is registered on PROSPERO (http://www.crd.york.ac.uk/PROSPERO/), with the following registration number: CRD42016048523.

### Search Strategy

The PubMed/MEDLINE database was electronically searched for articles published before July 18, 2016. The search strategy included MeSH terms and entry terms related to or describing the intervention. The terms were combined with PubMed/MEDLINE filters for clinical trials of interventions and studies published in English. There were no restrictions on the date of publication. A manual search was also conducted to find additional relevant articles.

The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement was used in this study.[19] The PICO of this study was as follows: P, mandibular edentulous patients; I, mandibular full-arch fixed prostheses supported by three implants; C, mandibular full-arch fixed prostheses supported by different numbers of implants; and O, implant survival rate, marginal bone loss, and prosthesis survival rate. The clinical question in PICO format was: "In edentulous patients, do full-arch bridges supported by three implants have a satisfactory implant survival rate, marginal bone loss, and prosthesis survival rate compared to those supported by different numbers of implants?"

The following Medical Subject Heading (MeSH) terms were used: "Jaw, Edentulous"; "Dental Implants"; "Dental Prosthesis, Implant-Supported"; "Mandibular Prosthesis"; and "Mandibular Prosthesis Implantation", and their related entry terms were used in different combinations with the Boolean operators "AND" and "OR":

- ((((“Jaw, Edentulous”[Mesh] OR “Edentulous Jaw” OR “Edentulous Jaws”OR“Jaws,Edentulous”)) AND (“Dental Implants”[Mesh] OR “Implants, Dental” OR “Dental Implant” OR “Implant, Dental” OR “Dental Prostheses, Surgical” OR “Dental Prosthesis, Surgical” OR “Surgical Dental Prostheses” OR “Surgical Dental Prosthesis” OR “Prostheses, Surgical Dental” OR “Prosthesis, Surgical Dental”))) AND (* AND “Mandibular Prosthesis Implantation”[Mesh] OR “Implantation, Mandibular Prosthesis” OR “Implantations, Mandibular Prosthesis” OR “Mandibular Prosthesis Implantations” OR “Prosthesis Implantation, Mandibular” OR “Prosthesis Implantations, Mandibular”
- ((((“Jaw, Edentulous”[Mesh] OR “Edentulous Jaw” OR “Edentulous Jaws” OR “Jaws, Edentulous”)) AND (“Dental Implants”[Mesh] OR “Implants, Dental” OR “Dental Implant” OR “Implant, Dental” OR “Dental Prostheses, Surgical” OR “Dental Prosthesis, Surgical” OR “Surgical Dental Prostheses” OR “Surgical Dental Prosthesis” OR “Prostheses, Surgical Dental” OR “Prosthesis, Surgical Dental”))) AND (AND “Mandibular Prosthesis”[Mesh] OR “Mandibular Prostheses” OR “Prostheses, Mandibular” OR “Prosthesis, Mandibular”
- ((((“Jaw, Edentulous”[Mesh] OR “Edentulous Jaw” OR “Edentulous Jaws” OR “Jaws, Edentulous”)) AND (“Dental Implants”[Mesh] OR “Implants, Dental” OR “Dental Implant” OR “Implant, Dental” OR “Dental Prostheses, Surgical” OR “Dental Prosthesis, Surgical” OR “Surgical Dental Prostheses” OR “Surgical Dental Prosthesis” OR “Prostheses, Surgical Dental” OR

"Prosthesis, Surgical Dental"))) AND ("Dental Prosthesis, Implant-Supported"[Mesh] OR "Dental Prosthesis, Implant Supported" OR "Implant-Supported Dental Prosthesis" OR "Dental Prostheses, Implant-Supported" OR "Implant Supported Dental Prosthesis" OR "Implant-Supported Dental Prostheses" OR "Prostheses, Implant-Supported Dental" OR "Prosthesis, Implant-Supported Dental" OR "Denture, Implant-Supported" OR "Denture, Implant Supported" OR "Implant-Supported Denture" OR "Dentures, Implant-Supported" OR "Implant Supported Denture" OR "Implant-Supported Dentures" OR "Prosthesis Dental, Implant-Supported" OR "Dental, Implant-Supported Prosthesis" OR "Dentals, Implant-Supported Prosthesis" OR "Implant-Supported Prosthesis Dental" OR "Implant-Supported Prosthesis Dentals" OR "Prosthesis Dental, Implant Supported" OR "Prosthesis Dentals, Implant-Supported")

Terms relevant to the comparisons conducted in this study, such as the number of implants and the outcome, were not used to avoid restricting the initial search. In addition, each investigator randomly conducted a manual search of PubMed/MEDLINE and of the references of the eligible articles.

### Inclusion Criteria

The inclusion criteria of this study were as follows: *(1)* studies enrolling patients who underwent mandibular rehabilitation with implant-supported profile prostheses; *(2)* articles presenting data on the implant survival rate; *(3)* articles presenting data on the number of implants placed per patient; *(4)* randomized clinical trials; *(5)* prospective studies; and *(6)* retrospective studies.

### Exclusion Criteria

The exclusion criteria of this study were as follows: *(1)* articles published in a language other than English or Portuguese; *(2)* studies that focused on a comparison of the length, surface, or connection of implants, bone grafts, and guide surgery; *(3)* systematic and literature reviews; *(4)* a follow-up time of less than 1 year; *(5)* full-text articles that were not available on the database searched; *(6)* single case reports; *(7)* duplicated articles; *(8)* letters to the editor; *(9)* commentaries; and *(10)* articles with missing or unclear data.

When more than one publication reported results for the same group of patients, only the report containing the most comprehensive data was included to avoid the duplication of information.

### Screening and Eligibility

Two independent reviewers (L.B.L., N.R.F.) screened the titles retrieved by this search based on the defined inclusion criteria. Disagreements were resolved by discussion. Following the screening, the abstracts of all titles agreed on by both investigators were obtained and screened again for adherence to the inclusion criteria. If the title and abstract did not provide sufficient information to determine adherence to the inclusion criteria, the full text was obtained and read. Disagreements were again solved by discussion. Finally, data were collected from the full text of the articles that met the inclusion criteria. The two reviewers extracted data independently using a data extraction table. Disagreements regarding data extraction were resolved by a simultaneous reading of the text by the two reviewers.

### Data Extraction

Information on the survival rates of each type of implant, prosthetic survival, peri-implant bone loss, and complications of the surgery and prostheses were collected from all included studies. Additional data collected included the author(s), year of publication, type of study, number of patients, number of implants placed in each patient, details of the implants placed, moment of loading, details of surgical complications, and follow-up time.

### Quality Assessment

The quality of the included studies was assessed using the Oxford Centre for Evidence-Based Medicine (OCEBM) levels of evidence.[20]

### Methodological Index for Nonrandomized Studies

The quality of the articles was also assessed according to the Methodological Index for Nonrandomized Studies (MINORS).[21] The items were scored on the MINORS scale as 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate). The maximum score was 16 for noncomparative studies and 24 for comparative studies. Therefore, the study quality of noncomparative studies was defined as poor (≤ 5), fair (6 to 10), or good (≥ 11); that of comparative studies was defined as poor (≤ 8), fair (9 to 16), or good (≥ 17).

### Cochrane Risk of Bias Tool

The Cochrane Risk of Bias Tool[22] was used to assess the quality of the randomized clinical trials included in this study. The response to each criterion was reported as Yes (low risk of bias), No (high risk of bias), or Unclear (unclear risk of bias). The final score was based on the number of domains that showed a risk of bias. A low risk of bias indicated that four or more domains were free of bias; moderate risk indicated that three domains did not present a risk of bias; and high risk indicated that two or fewer domains did not present a risk of bias. The reviewers resolved discrepancies through discussion.

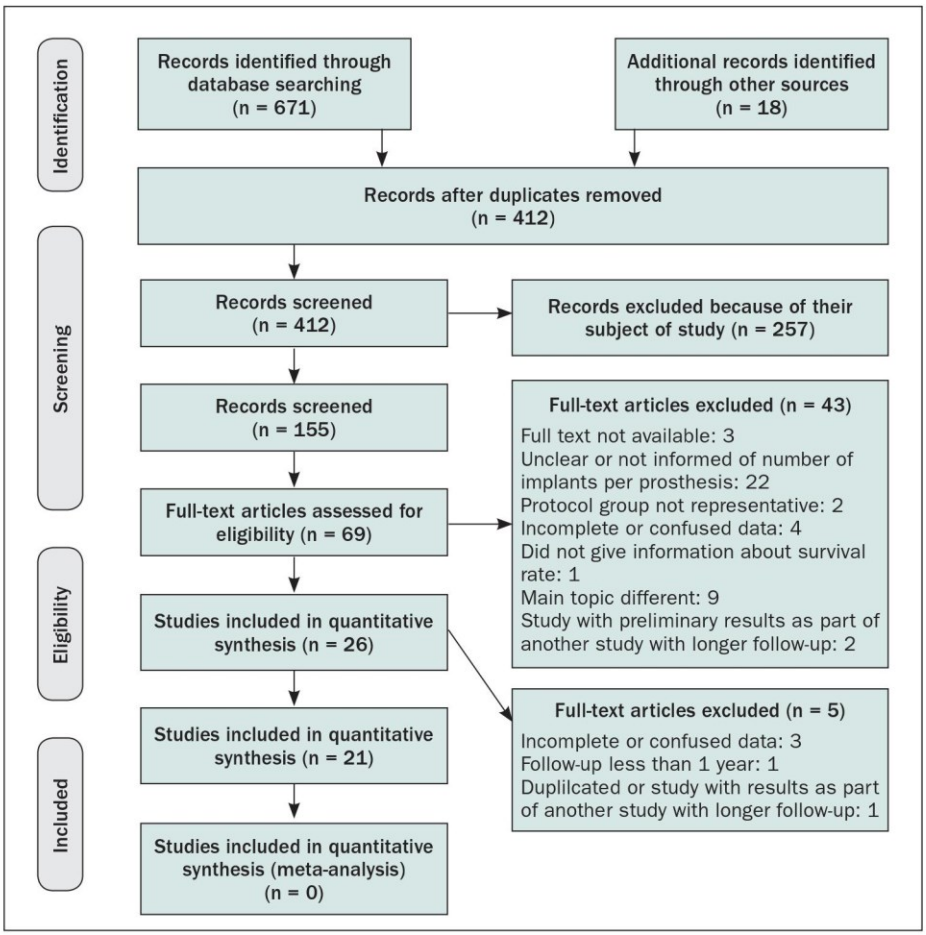


**Fig 1** Flow diagram of the search processes and results.

### Synthesis of Results and Statistical Analysis

Initially, the gathered data were depicted using descriptive statistics. Overall survival curves were constructed using the Kaplan-Meier method and compared using the log-rank test. Pairwise multiple-comparisons procedures were conducted using the Holm-Sidak method. The cumulative implant survival rate was determined with the patient as the unit of analysis by considering the first incidence of an implant loss, and again with the implant itself as the unit of analysis by considering all implants lost during follow-up. The enrolled studies were grouped into categories based on the number of implants placed in each patient, as follows: group 1, three implants per patient; group 2, four implants; and group 3, five implants. Time Zero was defined in all included studies as the time of dental prosthesis placement (baseline). Statistical analyses were performed using SigmaPlot 12.0 software with a 95% confidence interval and $\alpha = 5\%$.

Studies describing first-year bone loss were divided into the categories mentioned previously. The Kruskal-Wallis and Dunn's multiple-comparisons tests were used to analyze the bone loss in the described groups. A comparison of first-year bone loss between axial and angled implants was performed using the Mann-Whitney test. These analyses were performed with a 95% confidence interval and $\alpha = 5\%$. Column statistics were developed with GraphPad Prism 6.0 (GraphPad Software).

### Risk of Bias Across Studies

An analysis of the risk of bias across the included studies could not be performed because the review did not include a significant number of randomized clinical trials (RTCs). Thus, a funnel plot could not be created.

## RESULTS

### Search Results and Characteristics

The literature search using MeSH and entry terms found 671 articles. The process of identification, screening, eligibility, and inclusion of the articles is shown on the flow diagram (Fig 1). Twenty-one articles were included in the data extraction and analysis (Table 1, Fig 1). This analysis included one randomized controlled trial pilot,[14] four prospective multicenter studies,[13,24,30,37]

11 clinical prospective studies,[17,18,23,27–29,31,33–35,38] one prospective single-cohort study,[32] and four clinical retrospective studies.[12,25,26,36]

### Quality Assessment and Risk of Bias

***OCEBM.*** The quality assessment of the articles according to the levels of OCEBM evidence[11] is shown in Table 2. Most studies[13,14,17,18,23,24,27–35,37,38] were classified as 1b, which corresponds to individual randomized controlled trials and individual inception cohort studies with > 80% follow-up. Four articles[12,25,26,36] were classified as 2b, corresponding to retrospective cohort studies.

***MINORS.*** The analysis of quality using MINORS[12] was applied to 20 articles that were not RCTs. Eleven studies were comparative, and nine were noncomparative. Their classifications are shown in Table 3. All but one of the comparative studies[13,17,18,23,29–32,35,37] were defined as good quality; Crespi et al (2012)[28] was classified as fair. Among the noncomparative studies, five[12,25,26,33,34] were defined as fair and four[24,27,36,38] were considered to be good quality.

### Cochrane Risk of Bias Tool

One study[14] was an RCT, and its quality was assessed using the Cochrane Risk of Bias Tool. The study was classified as having a moderate risk of bias, as three of seven domains had a low risk of bias, two domains were unclear, and the remaining two had a high risk of bias. The detailed analysis is shown in Table 4.

### Synthesis of the Results

In all, 4,712 implants and 1,245 implant-supported full-arch fixed prostheses in 1,245 patients were examined. Group 1 included seven studies[12,13,23–27] of 1,068 implants placed in 356 patients. Group 2 included 11 studies[14,17,28–36] of 3,204 implants placed in 801 patients. Group 3 included three studies[18,37,38] of 440 implants placed in 88 patients.

Data related to the diameter and length of the placed implants were extracted from the selected studies (Table 1). In group 1, the implant diameter was 3.75 to 5.0 mm, and the length was 8.5 to 20 mm. Group 2 used implants with a diameter of 3.5 to 5.0 mm and length of 7 to 21 mm. Group 3 implants were 3.5 to 4.8 mm in diameter and 10 to 18 mm in length. Capelli et al (2007)[30] did not present the dimensions of the implants placed in their study. Francetti et al (2012)[29] presented only the diameters of the implants used, while Engquist et al (2005),[17] Eliasson et al (2000),[34] and Maló et al (2015)[36] only reported data on implant length.

Most studies reported immediate loading of implants (≤ 7 days after placement of the implant).[12,14,18,24–33,36] Five studies[13,17,27,37,38] reported early loading (≤ 2 months after placement of the implant). Only three studies[17,23,35] reported the use of the conventional loading moment (≥ 2 months after implant placement).

Group 1 studies reported 57 implant losses (5.33%) during a maximum follow-up period of 120 months; group 2 studies reported 47 implant losses (1.46%) in 132 months; and group 3 studies reported 27 implant losses in 60 months. Three group 1 studies[12,23,26] had implant survival rates of > 95%, and four studies[13,24,25,27] had rates of 90% to 95%. In group 2, only one study[17] reported a rate of < 95% between groups; the other studies[14,28–36] in this group reported survival rates of > 97%. One group 3 study[38] had an implant survival rate of 89.7%, and two[18,37] had implant survival rates of > 94%.

The following surgery complications were reported: paresthesia, minor flap dehiscences, and local mucosal inflammation (group 1); peri-implantitis, light hypoesthesia of the lower lip, paresthesia, implant removed due to pain, mucositis, gingival hyperplasia, recession, and fistula (group 2); and persistent pain, fistula, and peri-implantitis (group 3). The prosthetic intercurrences reported in group 1 studies were dental adjustment, prosthetic screw loosening, prosthetic screw fracture, fracture of hybrid prostheses or teeth fractures, problems related to vertical occlusal dimension and abrasion, mobile primary bars, and loss of access-hole fillings. Group 2 reported occlusal screw loosening, fracture of the acrylic prosthesis, metal framework not fitting, occlusion needing to be adjusted, abutment screw loosening, resin tooth detachment/fracture, framework fractures, fractures in the artificial resin, and technical in-office teeth renewing due to abrasion/fracture and discoloration of the prosthesis. Group 3 reported abutment screw loosening, complete failure of the prosthesis, fractures of the framework, and prostheses that had to be adapted or modified.

### Additional Analysis

***Implant Survival Rate.*** An additional analysis using the patient as the unit of analysis (first incidence of implant loss) was conducted. The following studies were included. Group 1 included Hatano et al (2011),[12] De Kok et al (2011),[23] Gualini et al (2009),[25] and Engstrand et al (2003).[27] Group 2 included Cannizzaro et al (2013),[14] Engquist et al (2005),[17] Francetti et al (2012),[29] Capelli et al (2007),[30] Weinstein et al (2012),[31] Francetti et al (2008),[32] Degidi et al (2010),[33] Krennmair et al (2016),[35] and Maló et al (2015).[36] Group 3 included Raghoebar et al (2003)[37] and Schwarz et al (2010).[38]

Table 5 presents implant survival data for the patients in the included studies. Group 1 included 252 patients and reported 25 implant losses that occurred during 120 months of follow-up, for an implant survival rate of 90%. Group 2 included 662 patients and

**Table 1 General Characteristics of Included Studies**

| Author, year | No. of patients | No. of implants/ patient | Details of implants (mm) | Time of loading | Implant survival rate (%) |
|---|---|---|---|---|---|
| De Kok et al, 2011[23] | 10 | 3 | 4.0 × 11 or 13 | Conventional | 100 |
| Henry et al, 2003[24] | 51 | 3 | 5.0 × 11.5 | Immediate | 90.7 |
| Gualini et al, 2009[25] | 15 | 3 | 5.0 × 11.5 or 13 | Immediate | 91.1 |
| Rivaldo et al, 2012[26] | 33 | 3 | 4.1 × 10; 13; 15; 18 | Immediate | 97.97 |
| Engstrand et al, 2003[27] | 95 | 3 | 5.0; 4.5; 4.0 × 11.5 or 13 | Immediate (67.4%); Early (32.6%) | 93.7 |
| Hatano et al, 2011[12] | 132 | 3 | 3.75 or 4.5 × 8.5; 10; 11.5; 13; 15; 18; 20 | Immediate | 96.7 |
| De Bruyn et al, 2001[13] | 20 | 3 | 3.75 or 4.0 × 15 or 13 | Early | 90 |
| Crespi et al, 2012[28] | 20 | 4 | 3.75 or 4.0 × 13 or 15 | Immediate | 97.5 |
| Francetti et al, 2012[29] | 33 | 4 | 4.0 (diameter) | Immediate | 100 |
| Cannizzaro et al, 2013[14] | 30 | 4 | 4.0 or 5.0 × 10; 11.5; 13; 15 | Immediate | 100 |
| Capelli et al, 2007[30] | 24 | 4 | Not reported | Immediate | 100 |
| Weinstein et al, 2012[31] | 20 | 4 | 4.0 × 11.5 to 15 | Immediate | 100 |
| Francetti et al, 2008[32] | 62 | 4 | 4.0 × 11.5; 13; 15 | Immediate | 100 |
| Degidi et al, 2010[33] | 20 | 4 | 3.5 or 4.5 × 11 or 14 | Immediate | 100 |
| Engquist et al, 2005[17] | 108 | 4 | 10; 13; 15; 18; 21 (length) | Conventional (A,B,C); Early (D) | 97.5 (B); 93.3 (A,D); 93.2 (C) |
| Eliasson et al, 2000[34] | 119 | 4 | 7; 10; 13; 15; 18; 20 (length) | Not reported | 99.36 |
| Krennmair et al, 2016[35] | 41 | 4 | 3.8 or 4.3 × 11; 13; 16 | Conventional | 100 |
| Maló et al, 2015[36] | 324 | 4 | 10 to 18 (length) | Immediate | 98.61 |
| Raghoebar et al, 2003[37] | 10 | 5 | 3.75 × 10; 11.5; 13; 15; 18 | Early | 94 |
| Scala et al, 2012[18] | 41 | 5 | 3.7 or 4.8 × 12; 13; 14 | Immediate | 97.6 |
| Schwarz et al, 2010[38] | 37 | 5 | 3.5 or 4.0 × 10; 13; 15 | Early | 89.7 |

No. = number; A = group A; B = group B; C = group C; FDP = fixed dental prosthesis; SD = standard deviation; y = year;
[a]Clinical follow-up. [b]Radiographic follow-up.

| Prosthesis survival rate (%) | Surgery complications | Mean marginal bone loss (No. of implants)[mm] | Follow-up (No. of patients) |
|---|---|---|---|
| 100 | None | Not reported | 1 y |
| 94 | Paresthesia | 0.4 ± 0.9 (43) | 1 y (49) |
| 86.7 | None | No bone loss below the first thread (33); averaged loss 0.1 over the 6 sites (3); mean remodeling 0.5 (3) | 4 y |
| Not reported | Not reported | Central implants (33): 0.92 ± 0.61;<br>Distal implants (66): 0.74 ± 0.52 | 1.5 y |
| 99 | Dehiscence; temporary paresthesia; mucosal inflammation | 1 year: 0.73 ± 0.64 (83) | 2 y (65)<br>5 y (9) |
| 92.4 | None | Not reported | 2 y (119)<br>5 y (77) |
| 85 | Not reported | 0.9 ± 1.1 | 1 y (15)<br>3 y (5) |
| 100 | None | 1 year: axial 1.4 ± 0.30; angled 1.05 ± 0.32/ 3 years: axial 1.06 ± 0.41; angled 1.12 ± 0.35 | 3 y |
| 100 | Peri-implantitis | 1 year: axial 0.57 ± 0.42; angled 0.48 ± 0.23 | 3 y (33)<br>5 y (12) |
| 100 | None | 1.31 ± 0.71 | 1 y |
| 100 | Not reported | 1 year: axial 0.82 ± 0.62 (32);<br>angled 0.75 ± 0.55 (32) | 1 y (23)<br>3 y (20) |
| 100 | None | 1 year: axial 0.6 ± 0.3 (36);<br>angled 0.7 ± 0.4 (36) | 2 y (20)<br>4 y (3) |
| 100 | Light hypoesthesia | 1 year: axial 0.7 ± 0.4 (60);<br>angled 0.7 ± 0.5 (60) | 1 y (62)<br>4 y (10) |
| Not reported | Not reported | 1 year: −0.07<br>2 years: −0.21 ± 0.25 | 2 y (20) |
| Not reported | Not reported | A: 1.27 ± 0.14 (30)<br>B: 1.60 ± 0.09 (42)<br>C: 1.34 ± 0.12 (62)<br>D: 1.14 ± 0.12 (42) | 3 y (102) |
| 100 | Paresthesia and implant removed because of pain | 5 years: Mesial implants: 0.6;<br>Distal implants: 0.3 | 1 y (119)<br>3 y (105) |
| 100 | Mucositis, gingival hyperplasia, recessions, and fistula | 1 year: axial 1.13 ± 0.36; angled 1.00 ± 0.5 | 3 y (37) |
| 99.7 | Not reported | 5 years: 1.81 ± 0.06; axial 1.74 ± 0.05;<br>angled 1.76 ± 0.05 | 7 y (247)[a];<br>5 y (235)[b] |
| Unclear | Pain and fistula | 1 year: 0.36 ± 0.60 (44);<br>3 years: 0.47 ± 0.62 (39) | 3 y (9) |
| Not reported | Not reported | Direct technique: 0.8 ± 0.7;<br>Indirect technique: 0.7 ± 0.8 | 1 y (40)<br>3 y (11) |
| 89.2 | Peri-implantitis | Not reported | 3 y (28)<br>5 y (25) |

**Table 2 Study Hierarchy of Evidence**

| Author/year | Type of study | Levels of evidence (OCEBM 2011) |
|---|---|---|
| Cannizzaro et al, 2013[14] | Randomized controlled trial pilot | 1b |
| De Bruyn et al, 2001[13] | Prospective multicenter study | 1b |
| Capelli et al, 2007[30] | Prospective multicenter study | 1b |
| Henry et al, 2003[24] | Prospective multicenter study | 1b |
| Raghoebar et al, 2003[37] | Prospective multicenter study | 1b |
| Francetti et al, 2008[32] | Prospective single-cohort clinical trial | 1b |
| Crespi et al, 2012[28] | Clinical prospective study | 1b |
| Degidi et al, 2010[33] | Clinical prospective study | 1b |
| Eliasson et al, 2000[34] | Clinical prospective study | 1b |
| Engquist et al, 2005[17] | Clinical prospective study | 1b |
| Engstrand et al, 2003[27] | Clinical prospective study | 1b |
| Francetti et al, 2012[29] | Clinical prospective study | 1b |
| De Kok et al, 2011[23] | Clinical prospective study | 1b |
| Krennmair et al, 2016[35] | Clinical prospective study | 1b |
| Scala et al, 2012[18] | Clinical prospective study | 1b |
| Schwarz et al, 2010[38] | Clinical prospective study | 1b |
| Weinstein et al, 2012[31] | Clinical prospective study | 1b |
| Gualini et al, 2009[25] | Clinical retrospective study | 2b |
| Hatano et al, 2011[12] | Clinical retrospective study | 2b |
| Maló et al, 2015[36] | Clinical retrospective study | 2b |
| Rivaldo et al, 2012[26] | Clinical retrospective study | 2b |

**Table 3 Study Quality Assessment by MINORS Scale**

| | Methodologic items for nonrandomized studies | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Author, year | A | B | C | D | E | F | G | H | I | J | K | L | Score |
| **Comparative studies** | | | | | | | | | | | | | |
| De Bruyn et al, 2001[13] | 2 | 2 | 2 | 2 | 1 | 2 | 0 | 2 | 1 | 2 | 2 | 2 | 20 |
| Capelli et al, 2007[30] | 2 | 0 | 1 | 2 | 0 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 18 |
| Crespi et al, 2012[28] | 2 | 0 | 0 | 1 | 0 | 2 | 0 | 1 | 2 | 2 | 2 | 1 | 13 |
| Engquist et al, 2005[17] | 2 | 2 | 2 | 2 | 0 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 20 |
| Francetti et al, 2008[32] | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 1 | 2 | 2 | 2 | 2 | 21 |
| Francetti et al, 2012[29] | 2 | 0 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 2 | 20 |
| De Kok et al, 2011[23] | 2 | 1 | 2 | 2 | 0 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 20 |
| Krennmair et al, 2016[35] | 2 | 0 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 20 |
| Raghoebar et al, 2003[37] | 2 | 1 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 21 |
| Scala et al, 2012[18] | 2 | 2 | 2 | 2 | 0 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 21 |
| Weinstein et al, 2012[31] | 2 | 0 | 2 | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 20 |
| **Noncomparative studies** | | | | | | | | | | | | | |
| Degidi et al, 2010[33] | 2 | 2 | 2 | 2 | 0 | 2 | 0 | 0 | # | # | # | # | 10 |
| Eliasson et al, 2000[34] | 2 | 0 | 2 | 1 | 0 | 2 | 0 | 1 | # | # | # | # | 7 |
| Engstrand et al, 2003[27] | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | # | # | # | # | 14 |
| Gualini et al, 2009[25] | 2 | 2 | 1 | 2 | 0 | 2 | 0 | 0 | # | # | # | # | 9 |
| Hatano et al, 2011[12] | 2 | 1 | 1 | 1 | 0 | 2 | 1 | 0 | # | # | # | # | 8 |
| Henry et al, 2003[24] | 2 | 0 | 2 | 2 | 1 | 2 | 2 | 0 | # | # | # | # | 11 |
| Maló et al, 2015[36] | 2 | 1 | 2 | 2 | 2 | 2 | 1 | 2 | # | # | # | # | 14 |
| Rivaldo et al, 2012[26] | 2 | 0 | 2 | 2 | 1 | 2 | 0 | 1 | # | # | # | # | 10 |
| Schwarz et al, 2010[38] | 2 | 0 | 2 | 2 | 1 | 2 | 0 | 2 | # | # | # | # | 11 |

A = clearly stated aim; B = inclusion of consecutive patients; C = prospective collection of data; D = appropriate endpoints; E = unbiased assessment; F = a follow-up period; G = losses to follow-up of < 5%; H = prospective calculation of the study size; I = adequate control group; J = contemporary groups; K = baseline equivalence of groups; L = adequate statistical analyses.

**Table 4 Study Quality Assessment by Cochrane Risk of Bias Tool**

| | Quality of randomized clinical trial | | | | | | |
|---|---|---|---|---|---|---|---|
| | Selection | | Performance | Detection | Attrition | Reporting | |
| Randomized controlled trial, year | Sequence generation | Allocation concealment | Blinding of participants and personnel | Blinding of outcome assessors | Incomplete outcome data | Selective outcome reporting | Other sources of bias |
| Cannizzaro et al, 2013[14] | Yes/ low risk | Yes/ low risk | Unclear/ unclear risk | Yes/ low risk | Unclear/ unclear risk | No/ high risk | No/ high risk |

**Table 5 Implant Survival Ratio in Retrieved Patients**

| Groups | Total | Loss | Survival rate (%) | *P* value |
|---|---|---|---|---|
| G1 | 252 | 25 | 90 | < .001* |
| G2 | 662 | 30 | 95 | |
| G3 | 47 | 12 | 74 | |
| Overall | 986 | 66 | 93 | |

*Statistically significant difference; log-rank test; Holm-Sidak method: G1 × G2, $P = .00358$; G1 × G3, $P = .00188$; G2 × G3, $P = .00000000444$.

**Table 6 Implant Survival Ratio in Retrieved Implants**

| Groups | Total | Loss | Survival rate (%) | *P* value |
|---|---|---|---|---|
| G1 | 1068 | 57 | 95 | < .001* |
| G2 | 3204 | 47 | 99 | |
| G3 | 440 | 27 | 94 | |
| Overall | 4712 | 131 | 97 | |

*Statistically significant difference; log-rank test; Holm-Sidak method: G1 × G2, $P < .001$; G1 × G3, $P = .530$; G2 × G3, $P < .001$.

reported 30 failures in 84 months of follow-up, for an implant survival rate of 95%. Group 3 included 47 patients and reported 12 implant losses in 60 months, for the lowest implant survival rate of 74%. Figure 2 demonstrates that group 2 showed the highest survival of all groups (log-rank test, $P < .001$).

Table 6 shows the cumulative implant survival rate using the implant as the unit of analysis. All 21 articles in this review were included in this analysis. Group 1 included 1,068 implants and reported 57 implant losses during 120 months of follow-up, for a survival rate of 95%. Group 2 included 3,024 implants and reported 47 losses in 132 months of follow-up, for a survival rate of 99%. Group 3 included 440 implants and reported 27 implant losses in 60 months, for a survival rate of 94%. Group 2 had the best survival compared with the other groups (log-rank test, $P < .001$) (Fig 3). There was no significant difference between groups 1 and 3 ($P = .530$).

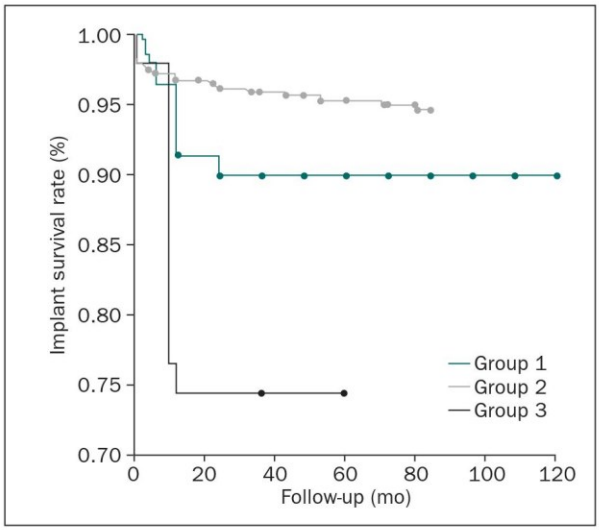


**Fig 2** Implant survival rate using the Kaplan-Meier method with patient as the unit of analysis (first incidence of implant loss).

## Peri-implant Bone Loss

Bone loss analysis included 14[13,14,17,18,24,27–33,35,37] of the 21 articles, as only these studies reported the necessary information. Bone loss was analyzed using two perspectives. First (Fig 4), the mean first-year bone loss of each study was determined, and the articles were grouped as described earlier. Eight studies were included in both this and in the second analysis. Group 1 included De Bruyn et al (2001),[13] Henry et al (2003),[24] and Engstrand et al (2003)[27]; group 2 included Cannizzaro et al (2013),[14] Engquist et al (2005),[17] and Degidi et al (2010)[33]; and group 3 included Scala et al (2012)[18] and Raghoebar et al (2003).[37] The median first-year bone loss for group 1 was 0.73 mm (range, 0.40 to 0.90). In group 2, the median first-year loss was 1.31 mm (range, –0.07 to 1.33). In group 3, the median first-year bone loss was 0.55 mm (range, 0.36 to 0.75). The number of samples in this analysis was considered too small, and the Kruskal-Wallis test revealed no significant difference between these groups ($P = .7571$).

Second, the studies were grouped as mentioned earlier (groups 1, 2, and 3), and the first-year mean bone loss of the study was considered valid for all

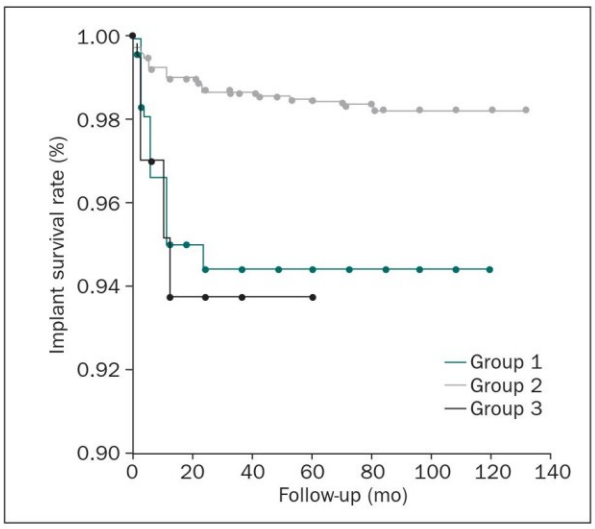


**Fig 3** Implant survival rate using the Kaplan-Meier method with implant as the unit of analysis.

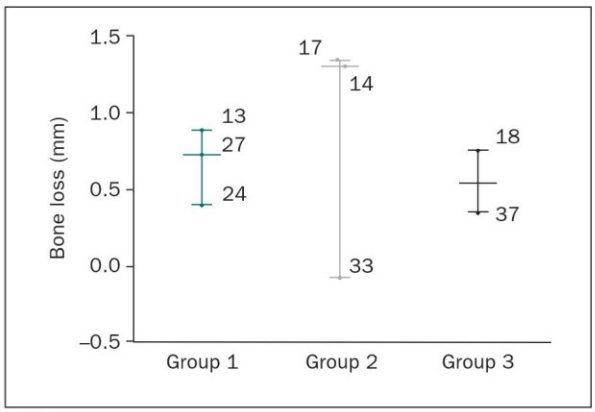


**Fig 4** First-year bone loss of each study grouped according to the number of implants placed per patient. Results are presented in median with range. No statistically significant difference was seen between these groups ($P = .7571$).

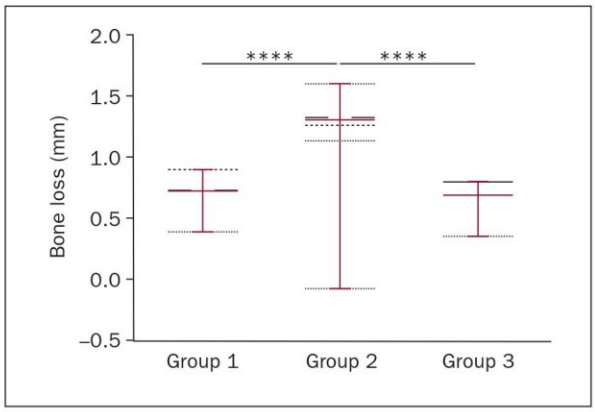


**Fig 5** First-year bone loss of all implants placed in the study. The number of all implants placed in each study was considered. Results are presented in median with range. ****Statistically significant difference between the groups ($P < .0001$).

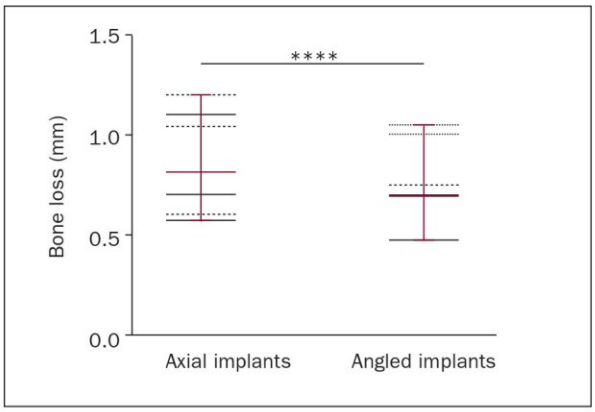


**Fig 6** A comparison between the first-year bone loss of axial and angled implants. All placed in group 2. Results are presented in median with range. ****Statistically significant difference between the groups ($P < .0001$).

implants placed. The analysis considered the number of implants used in each study. Group 1 studies included information on first-year mean bone loss for 319 implants, with a median of 0.73 mm (range, 0.40 to 0.90). In group 2, 376 implants were considered, and had a median first-year bone loss of 1.31 mm (range, –0.07 to 1.60). Group 3 included 249 implants, with a median first-year bone loss of 0.70 mm (range, 0.36 to 0.80). As shown in Fig 5, fixed full-arch prostheses supported by four implants (group 2) had the highest bone loss (Kruskal-Wallis test, $P < .0001$). The Dunn's test revealed that there was a significant difference between groups 1 and 2 and between groups 2 and 3. However, there was no significant difference between groups 1 and 3.

Finally, six studies[28–32,35] reported bone loss in angled versus axial implants, and these values were analyzed. The analysis included 352 axial implants and 272 angled implants; all were placed in group 2 patients. As shown in Fig 6, the axial group had higher bone loss (median = 0.82; range, 0.57 to 1.20) than the angled group (median = 0.70; range, 0.48 to 1.05). The Mann-Whitney test revealed a significant difference between these groups ($P < .0001$).

## Prosthesis Survival Rate

Three articles[13,25,38] reported a prosthesis survival rate of < 90%. One[25] group 1 study lost two of 15 prostheses; both were due to the loss of two distal implants. De Bruyn et al,[13] also in group 1, reported the loss of three of 20 prostheses. One was lost after the loss of all implants; another was lost after the loss of a distal implant, and a third was lost due to the loss of two implants. Schwarz et al,[38] in group 3, reported the loss of one prosthesis after the loss of all implants;

three prostheses were substantially modified after the loss of two or more implants. Nine studies presented 100% survival rates of the placed prostheses. Among them were one study[23] in group 1 and eight studies[14,28–32,34,35] in group 2. Five studies[17,18,26,33,37] either did not present prosthesis survival data, or the data were unclear.

## DISCUSSION

Cost is widely discussed as the primary reason to reduce the number of implants used to support implant-supported profile prostheses. Nevertheless, decreased surgical trauma and the facilitation of patient hygiene are additional benefits.[12,14,15,29] This is especially important considering that older patients most often receive total rehabilitation treatments, and these patients often have greater motor difficulties. This systematic review investigated whether the mandibular implant-supported profile prosthesis supported by three implants had a satisfactory implant survival rate, peri-implant bone loss, and prosthesis survival rate compared with different numbers of implants.

The quality of the selected studies indicates limitations due to the lack of articles related to the subject under investigation with a high level of evidence. There was a lack of randomized controlled studies, which compromises the quality of the included publications. Twenty-one articles were included in this analysis, and most were classified as good quality.[13,14,17,18,23,24,27,29–32,35–38] However, among them, only one study[14] was an RCT, which reinforces the need for additional RCTs to reduce the risk of bias and enhance the level of evidence of the results. Among the selected articles, missing or unclear numerical data about patients, interventions, and complications, and a lack of detail about losses during follow-up are issues that limit the quality of the results and suggest details to be considered for future studies, especially the improvement of documentation of medical records.

When the results of this review were synthesized, the surgical complications in each group were similar, and were usually related to the surgical procedure itself, the manual ability of the surgeon, and the oral care performed by the patient during the postoperative period. Thus, no special effect of the number of implants was observed. Screw loosening and resin fractures of the teeth or fracture of the hybrid prostheses were the most commonly reported complications, even though framework and screw fractures were also similarly distributed among the groups. The exact number of these events in all articles could not be accessed; thus, a statistical comparison among the groups was not conducted. Nevertheless, it is suggested that individual occlusal forces and the closing pressure are possible causative factors for veneer problems and acrylic tooth fractures.[35] In addition, the type of opposite dentition should be considered in order to analyze the indication of fabricating retentions on the synthetic veneers, or to reinforce them to avoid possible fractures.[35] Eliasson et al[34] corroborated the idea of opposite dentition, and reported that patients who underwent rehabilitation of both arches with fixed implant-supported prostheses experienced greater numbers of resin tooth fractures of the mandibular implant-supported prostheses compared with patients who used total removable superior prostheses, due to the increase in masticatory force. Furthermore, long-term follow-ups are fundamental to determine the success and survival of prosthetic rehabilitation, considering that intercurrences usually appear with use (fatigue). This differs from surgical intercurrences, which do not require long follow-up periods to manifest.

A comparison between the analysis using the patient and the analysis using the implant as the unit of measure revealed that, with the exception of group 3, the first analysis presented the higher rate of implant loss. However, in the second analysis, even though group 2 had a better implant survival rate, all groups reported rates of at least 94%, which was similar to results reported in other studies.[39,40] A possible explanation for the high rate of loss in the first analysis of group 3 is that several patients experienced unitary implant loss. This can be confirmed by the second analysis of group 3, which revealed an implant loss rate similar to the other groups. Still, the methodologic quality of the study of Schwarz et al (2010),[38] which reported the worst implant survival rate, can be questioned because their results were significantly lower than those of previous studies[8,41] with equal numbers of placed implants.

The groups of studies that placed three or five implants registered the lowest values of peri-implant bone loss. However, the median of all groups was satisfactory, considering the acceptable limit of 1.5 mm in the first year of function.[42] Still, some group 2 implants showed a mean bone loss of slightly more than 1.5 mm. The study[17] that reported these values also reported a tendency of additional bone resorption in the group that underwent two-stage surgery, and discussed individual variations such as medical conditions and loading circumstances as reasons for the observed bone loss.

A significant difference was observed in the first-year marginal bone loss between axial and angled implants in the group 2 studies. The tilted implants showed the lowest bone loss, which one study[43] explains is due to posterior areas receiving vertical forces and the anterior region (the location of the axial implants) receiving

oblique forces. Thus, biomechanical force distribution and the thinner bone in the anterior region are possible explanations for this difference, as agreed by Eliasson et al (2000),[34] who also found more bone loss in mesially placed implants than in angled implants placed in the posterior region.

In contrast, other studies[26,36,44–46] did not report significant differences in bone loss around axial and angled implants. This outcome may be related to the biomechanical advantages of angled implants, such as the extension of the supporting zone and consequent reduction of prosthesis extension,[44] good anchorage of the posterior implant,[28] and reduction of the cantilever length.[44] In fact, single angulated implants may increase the stress on the surrounding bone.[47] However, when the angled implants are splinted, as in a fixed implant-supported prosthesis, the spread of the implants and rigidity of the prosthetic structure should reduce bending,[44] thus favoring survival of the prosthesis.

Finally, the analysis demonstrated that in group 2, the loss of a prosthesis was due to the loss of all implants. However, in group 1, the loss of a prosthesis occurred even when only one or two implants were lost. This difference highlights the disadvantage of placement of three implants to support a fixed full-arch prosthesis, as the failure of a single implant can result in the loss of the mandibular profile prosthesis.[12,13]

The primary limitation of this review was the lack of RCTs comparing the number of implants supporting mandibular profile prostheses, thus increasing the risk of bias of the analysis. In addition, attempts to contact the authors of the included studies did not result in satisfactory answers. The search using MeSH terms was incomplete and hindered the search for relevant articles, even when few filters were applied. Yet, the authors conducted the review and analyzed all appropriate items, even though a meta-analysis could not be performed.

Factors such as the length of the cantilever, inclination of the implants, opposite dentition, surface, diameter and length of the implants, and moment of loading can also influence the clinical outcomes. In addition, the authors believe that the difficulty patients have performing necessary hygiene increases when more implants are used, which could affect the longevity of the rehabilitation. However, a correlation between these factors and the results of the treatment could not be performed in this study because the included articles did not report the necessary data.

## CONCLUSIONS

Within the limitations of this work, it is possible to conclude that mandibular profile prostheses using three implants have shown a satisfactory implant survival rate and peri-implant bone loss during the first year of function. Meanwhile, the prosthesis survival rate was inferior compared with mandibular profile prostheses supported by a higher number of implants. This suggests that controlled studies with a long-term follow-up period are necessary to clarify the reason for this condition and resolve this issue. Moreover, clinicians must be aware that the loss of a single implant can compromise the rehabilitation when only three implants are used, and this should be discussed with the patient during treatment planning.

## ACKNOWLEDGMENTS

This work was supported by Fapemig – Fundação de Amparo à Pesquisa do Estado de Minas Gerais – Brazil. The authors would like to thank Dr João Paulo Silva Servato for furnishing them with valuable contributions about the methodologic process of the systematic review. The authors reported no conflicts of interest related to this study.

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## 3.2. Capítulo 2

Impact of Implant Number on Maxillary Implant-Supported Profile Prostheses: A Systematic Review

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Artigo a ser submetido para o periódico International Journal of Oral and Maxillofacial Implants

# Impact of Implant Number on Maxillary Implant-Supported Profile Prostheses: A Systematic Review

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## ABSTRACT

**Purpose:** To assess studies on edentulous patients rehabilitated using full fixed implant supported prostheses in maxilla and analyze the impact of different numbers of implants used on the implant survival rate, peri-implant bone loss, and prosthesis survival rate. **Materials and Methods:** This systematic review adhered to PRISMA statement and was registered on PROSPERO. PubMed/MEDLINE database was searched for articles published before January 07, 2019. The study attempted to answer the PICO question: "In edentulous patients, do maxillary full arch bridges supported by four implants, compared with different numbers of implants, show satisfactory implant survival rates, marginal bone loss, and prosthesis survival?" Methodological quality was evaluated using the MINORS scale and Cochrane Risk of Bias Tool. Descriptive statistics were performed when applicable. Implant survival curves were constructed using Kaplan-Meier method, and marginal bone loss was analyzed using the Kruskal-Wallis and Dunn's tests. **Results:** This analysis included 26 published studies of 3466 implants and 663 maxillary full fixed implant supported prostheses in 663 patients. The patients were grouped by the number of implants used: Group 1 (two or three implants), Group 2 (4 implants), Group 3 (five or six implants) and Group 4 (more than six implants). Concerning to the implant survival rate, the groups presented 99%, 99%, 97% and 99%, respectively. So, there was no statistically significant difference between the groups ($p = 0,078$). The bone loss was statistically different between G1 and G2, G1 and G3, G2 and G3, G2 and G4, G3 and G4, but not between G1 and G4. The G1 presented the lowest median of bone loss (0.54mm) in the first year of function and the G2 the highest one (1.05mm). **Conclusion**: Despite the work limitations, it was concluded that the implant survival rate, first-year bone loss and prosthesis survival rate of maxillary full fixed implant supported prostheses supported by four implants were satisfactory compared to different number of implants.

**Key words**: dental implants, implant-supported dental prosthesis, survival rate.

## INTRODUCTION

The increase of elderly population and of the life expectancy have occurred in recent decades.[1] Therefore, it is important that dental health professionals adapt their works, which attempt to reestablish masticatory function, aesthetics, and phonation ability, as well as self-esteem and confidence, to the changes seen in population. Edentulism still figures as a challenge to the dentist as the world's population ages.[2] Taking into consideration the social aspects of edentulism in a low-income population,[3] there is a need for clinical protocols that can provide wider population coverage through reduced costs and less invasive surgical procedures.[4]

The rehabilitation of the maxillary arch with dental implants supporting a full fixed implant supported prostheses is a good treatment that may provide better chewing performance, improved stability and comfort, as well as improved quality of life in patients who have problems with complete dentures.[5-8]

Long-term follow-up studies have reported successful rehabilitation of edentulous patients with implant-supported profile prostheses.[7,9] Initially, six dental implants were required to support a fixed full-arch bridge.[10] Later, Branemark et al. (1995)[9] investigated the use of four and six fixtures to completely rehabilitate edentulous patients. They have found a slightly higher failure rate in cases with a reduced number of fixtures. However, implant and prosthesis survival rates were satisfactory for both groups.

Thus, studies have been conducted with the aim to determine whether the reduced number of implants used to support the fixed prostheses could be a long-term viable option, with the additional benefits of reducing the final cost of the treatment, and to facilitate improved hygiene procedures due to the larger spaces between the implants.[11-14] Besides the implant survival rate and marginal bone-loss, it is worthwhile to analyze the prostheses survival rate to actually determine the overall success of the rehabilitation treatment.

This review analyzed studies that included edentulous patients rehabilitated using full fixed implant supported prostheses in maxilla and compared the impact of the different numbers of implants used on implant survival, peri-implant bone loss, and the prosthesis survival rate. The P = patient problem/population, I = Intervention, C = Comparison, O = Outcome (PICO) question "In edentulous patients, do maxillary full arch bridges supported by four implants, compared with different numbers of implants, show satisfactory implant survival rates, marginal bone loss and prosthesis survival?" was used to guide this review.

## MATERIALS AND METHODS

This review is registered on PROSPERO (http://www.crd.york.ac.uk/PROSPERO/), with the following registration number: CRD42019126482.

### Search strategy

The PubMed/MEDLINE database was electronically searched for articles published before January 07, 2019. The search strategy included MeSH terms and entry terms related to or describing the intervention. The terms were combined with PubMed/MEDLINE filters for clinical trials of interventions. There were no restrictions on the date of publication. A manual search was also conducted to find additional relevant articles.

The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement was used in this study.[15] The PICO of our study were as follows: P: maxillary edentulous patients; I: maxillary full arch bridges supported by four implants; C: maxillary full arch bridges supported by different numbers of implants; and O: implant survival rate, marginal bone loss, and prosthesis survival rate. The clinical question in PICO format was: "In edentulous patients, do maxillary full arch bridges supported by four implants,

compared with different numbers of implants, show satisfactory implant survival rates, marginal bone loss, and prosthesis survival?"

The following Medical Subject Heading (MeSH) terms were used: "Jaw, Edentulous", “Maxilla”, “Maxillary Prosthesis”, "Dental Implants", "Bone Remodeling", “Survival Rates” and their related entry terms were used in different combinations with the Boolean operators “AND” and “OR”:

- "Jaw, Edentulous"[Mesh] OR “Edentulous Jaw” OR “Edentulous Jaws” OR “Jaws, Edentulous”
- "Maxilla"[Mesh] OR “Maxillas” OR “Maxillary Bone” OR “Bone, Maxillary” OR “Bones, Maxillary” OR “Maxillary Bones” OR “Maxillae”
- “Maxillary Prosthesis” [Mesh] OR “Maxillary Prostheses” OR “Prostheses, Maxillary” OR “Prosthesis, Maxillary”
- "Dental Implants"[Mesh] OR “Implants, Dental” OR “Dental Implant” OR “Implant, Dental” OR “Dental Prostheses, Surgical” OR “Dental Prosthesis, Surgical” OR “Surgical Dental Prostheses” OR “Surgical Dental Prosthesis” OR “Prostheses, Surgical Dental” OR “Prosthesis, Surgical Dental” OR "Dental Implantation, Endosseous"[Mesh] OR “Implantation, Endosseous Dental” OR “Endosseous Dental Implantation” OR “Osseointegrated Dental Implantation” OR “Implantation, Osseointegrated Dental” OR “Dental Implantation, Osseointegrated” OR “Implantation, Endosseous” OR “Endosseous Implantation” OR "Dental Prosthesis, Implant-Supported"[Mesh] OR “Dental Prosthesis, Implant Supported” OR “Implant-Supported Dental Prosthesis” OR “Dental Prostheses, Implant-Supported” OR “Implant Supported Dental Prosthesis” OR “Implant-Supported Dental Prostheses” OR “Prostheses, Implant-Supported Dental” OR “Prosthesis, Implant-Supported Dental” OR “Denture, Implant-Supported” OR “Denture, Implant Supported” OR

"Implant-Supported Denture" OR "Dentures, Implant-Supported" OR "Implant Supported Denture" OR "Implant-Supported Dentures" OR "Prosthesis Dental, Implant-Supported" OR "Dental, Implant-Supported Prosthesis" OR "Dentals, Implant-Supported Prosthesis" OR "Implant-Supported Prosthesis Dental" OR "Implant-Supported Prosthesis Dentals" OR "Prosthesis Dental, Implant Supported" OR "Prosthesis Dentals, Implant-Supported" OR "Dental Implantation"[Mesh] OR "Dental Prosthesis Implantation" OR "Prosthesis Implantation, Dental" OR "Implantation, Dental" OR "Implantation, Dental Prosthesis" OR "Dental Prosthesis Implantations" OR "Implantations, Dental Prosthesis" OR "Prosthesis Implantations, Dental"

- "Bone Remodeling"[Mesh] OR "Remodeling, Bone" OR "Bone Turnover" OR "Bone Turnovers" OR "Turnover, Bone" OR "Turnovers, Bone"
- "Survival Rate"[Mesh] OR "Rate, Survival" OR "Rates, Survival" OR "Survival Rates" OR "Mean Survival Time" OR "Mean Survival Times" OR "Survival Time, Mean" OR "Survival Times, Mean" OR "Time, Mean Survival" OR "Times, Mean Survival" OR "Cumulative Survival Rate" OR "Cumulative Survival Rates" OR "Rate, Cumulative Survival" OR "Rates, Cumulative Survival" OR "Survival Rate, Cumulative" OR "Survival Rates, Cumulative"

Terms relevant to the comparisons conducted in this study, such as the number of implants were not used to avoid restricting the initial search. In addition, each investigator randomly conducted a manual search of PubMed/MEDLINE and on the references of the eligible articles. The last manual search was conducted in August 10, 2019.

**Inclusion criteria**

The inclusion criteria of this study were as follows: (a) studies enrolling patients who underwent maxillary rehabilitation with implant-supported full arch bridges; (b) articles presenting data on the implant survival rate; (c) articles presenting data on the number of implants placed per patient; (d) randomized clinical trials; (e) prospective studies; and (f) retrospective studies.

**Exclusion criteria**

The exclusion criteria of this study were as follows: (a) all the subjects of the study being systemic compromised like diabetics, patients suffering osteoporosis, smokers, in use of bisphosphonates; (b) zygomatic implants; (c) studies in which all the patients were rehabilitated in grafted areas; (d) systematic and literature reviews (e) a follow-up time of less than 1 year; (f) single case reports; (g) duplicated articles; (h) letters to the editor; (i) commentaries; and (j) articles with missing or unclear data.

When more than one publication reported results for the same group of patients, we included only the report containing the most comprehensive data to avoid the duplication of information.

**Screening and eligibility**

Two independent reviewers (LBL and ARS) screened the titles retrieved by this search based on the defined inclusion criteria. Disagreements were resolved by discussion. Following the screening, the abstracts of all titles agreed on by both investigators were obtained and screened again for adherence to the inclusion criteria. If the title and abstract did not provide sufficient information to determine adherence to the inclusion criteria, the full text was obtained and read. Disagreements were again solved by discussion. Finally, data were collected from the full text of the articles that met the inclusion criteria. The two reviewers extracted data

independently using a data extraction table. Disagreements regarding data extraction were resolved by a simultaneous reading of the text by the two reviewers.

**Data extraction**

Information on the survival rates of each type of implant, prosthetic survival, peri-implant bone loss and biological and prosthetic complications were collected from all included studies. Additional data collected included the author(s), year of publication, type of study, number of patients, number of implants placed in each patient, details of the implant placed, moment of loading and follow-up time.

**Quality assessment**

*Methodological Index for Nonrandomized Studies*

The quality of the articles was also assessed according to the Methodological Index for Nonrandomized Studies (MINORS).[16] The items were scored on the MINORS scale as 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate). The maximum score was 16 for non-comparative studies and 24 for comparative studies. Therefore, the study quality of non-comparative studies was defined as poor (≤ 5), fair (6-10), or good (≥ 11); that of comparative studies was defined as poor (≤ 8), fair (9-16), or good (≥ 17).

*Cochrane Risk of Bias Tool*

The Cochrane Risk of Bias Tool[17] was used to assess the quality of the randomized clinical trials included in this study. The response to each criterion was reported as Low risk of bias, High risk of bias or Unclear risk of bias. The final score was based on the number of domains that showed a risk of bias. A low risk of bias is indicated if the majority of the information was classified as low risk of bias; moderate risk is defined if most of the items were labeled as low risk or unclear; and high risk of bias indicated that the proportion of high

risk is enough to affect the interpretation of the results. The reviewers resolved discrepancies through discussion.

**Synthesis of results and statistical analysis**

Initially, the gathered data were depicted using descriptive statistics. Overall survival curves were constructed using the Kaplan-Meier method and compared using the log-rank test. Pairwise multiple-comparisons procedures were conducted using the Holm-Sidak method. The cumulative implant survival rate was determined with the implant itself as the unit of analysis by considering all fixtures lost during follow-up. The enrolled studies were grouped into categories based on the number of fixtures placed in each patient, as follows: Group 1 (two or three implants), Group 2 (four implants), Group 3 (five or six implants) and Group 4 (more than six implants). Time Zero was defined in all included studies as the time of dental prosthesis placement (baseline). Statistical analyses were performed using SigmaPlot 12.0 software with a 95% confidence interval and $\alpha = 5\%$.

Studies describing first-year bone loss were divided into the categories mentioned previously. The Kruskal-Wallis and Dunn's multiple-comparisons tests were used to analyze the bone loss in the described groups. These analyses were performed with a 95% confidence interval and $\alpha = 5\%$. Column statistics were developed with GraphPad Prism 6.0 (GraphPad Software, San Diego, CA, USA).

**RESULTS**

**Search results and characteristics**

The literature search using MeSH and entry terms found 3155 articles. The process of identification, screening, eligibility and inclusion of the articles is shown on the flow diagram (Figure 1). Twenty-six articles were included in the data extraction and analysis (Table 1, Figure 1). This analysis included six randomized controlled trial,[20-23,30,40] sixteen

prospective studies[8,18,19,24,25,27-29,31,32,34,36,38,39,41,42] and four clinical retrospective studies.[26,33,35,37]

**Quality assessment and risk of bias**

*MINORS*

The analysis of quality using MINORS was applied to 20 articles that were not RTCs. Twelve[18,24,26,27,29,32,34-37,39,42] studies were non-comparative and eight[8,19,25,28,31,33,38,41] were comparative. Their classifications are shown in Table 2. Among the non-comparative studies, three[27,29,36] were defined as fair and the other nine[18,24,26,32,34,35,37,39,42] were considered to be good quality.

All but two[8,25,28,31,33,41] of the comparative studies were defined as good quality. The studies of Agnini et al, 2014[19] and Ostman et al, 2005[38] were classified as fair.

*Cochrane Risk of Bias Tool*

Six studies[20-23,30,40] were RTCs, and their quality was assessed using the Cochrane Risk of Bias Tool. One study[23] was classified as having a high risk of bias, as just one of seven domains had a low risk of bias, and the remaining six had a high risk of bias. The other five studies[20-22,30,40] were defined as low risk of bias. The detailed analysis is shown in Table 3.

**Synthesis of the results**

In all, 3466 implants and 663 implant-supported full-arch bridges in 663 patients were examined. Group 1 included four studies[21,22,23,37] of 236 implants placed in 82 patients. Group 2 included 10 studies[8,19,25,26,28,31,32,34,36,40] with 908 implants placed in 227 patients. Group 3 included 13 studies[8,18-20,26,30,35,36,38,39,40-42] enrolling 1499 implants placed in 251

patients. Finally, Group 4 enrolled 07 studies[19,24,27,29,33,36,38] with 823 implants placed in 103 patients.

Data related to the diameter and length of the installed implants were extracted from the selected studies (Table 1). In Group 1, the implant diameter varied from 3.8-5.0 mm and the length were 8.5-15 mm. Group 2 used implants with a diameter of 3.3- 4.5 mm and length of 10-20 mm. In Group 3 implants were 3.3- 6 mm in diameter and 5- 20 mm in length. Group 4 used implants with 3.5- 4 mm in diameter and 8- 20 mm in length. Five studies[19,26,33,34,41] did not present the dimensions of the implants placed in their study. Francetti et al. (2012)[28] presented only the diameters of the implants used, while Gallucci et al. (2004)[29] and Ostman et al. (2005)[38] only reported data on implant length.

Most studies[18-26,28,29,31-36,38-42] reported immediate loading of implants (≤ 7 days after placement of the implant. Four studies[23,27,30,37] reported early loading (≤ 2 months after placement of the implant). Only three studies[8,27,38] reported the use of the conventional loading moment (≥ 2 months after implant placement).

Group 1 studies reported 2 implant losses (1%) during a maximum follow-up period of 60 months; Group 2 studies reported 12 implant losses (1%) in 60 months; Group 3 studies reported 38 implant losses (3%) in 60 months. And Group 4 studies reported 12 implant losses (1%) during a maximum follow-up period of 108 months; Of all articles included in the quantitative synthesis, thirteen[19,20,22,25-27,29,34,35,38,40-42] have shown implant survival rate below 100%. Among these, only two articles presented implant survival rate less than 95%, being Hinze et al. (2010)[34] (92.1%) part of the Group 2 and Toljanic et al. (2016)[42] (93.5%) as part of the Group 3.

The following biological complications were reported: Post-implantation hemorrhage; implant protruding into the nasal cavity (Group 1); Pain and swelling without suppuration; implantitis; mucositis; mobility (Group 2); non-integration; mobility; pain,

swelling without suppuration; peri-implantitis; gingivitis; candidiasis; peri-implant bone loss associated with a partial implant fracture of the implant neck (Group 3); gingivitis; candidiasis and facial hematoma (Group 4). The prosthetic intercurrences reported in Group 1 studies were temporomandibular joint problems; prostheses screw loosening; soft tissue prosthesis induced ulcer; prosthetic teeth detached; functional and aesthetic complaint for missing molars when smiling; and porcelain chipping. Group 2 reported prosthetic screws loosening; fracture of the veneering material of the definitive implant-supported complete fixed dental prostheses (FDP); fractures of their acrylic resin provisional restorations; denture redesign because of air escape; acrylic resin denture base fracture; teeth fracture; excessive tooth wear; discoloration of acrylic resin; sore spots and loss of the screw access hole restoration. Group 3 reported fracture of denture tooth; framework fracture; abutment screw loose; abutment fracture; food impaction; hard occlusal contacts; inaccurate seating of angled abutment; construction too bulky; fractured resin provisional denture; irregularities; phonetic problems; fracture of the veneering material of the definitive implant-supported complete FDP; provisional prostheses had to be remade because did not fit; excessive tooth wear; discoloration of acrylic resin; sore spots; hyperplastic soft tissue with ulcers; detachment prosthetic teeth; And Group 4 showed fracture of the provisional bridge; screw loosening; provisional glass fiber-reinforced restorations fractured and breaking of esthetic veneering of the temporary prostheses, as the prosthetic complications observed.

**Additional analysis**

*Implant survival rate*

Figure 2 shows the cumulative implant survival rate using the implant as the unit of analysis. All 26 articles in this review were included in this analysis. Group 1 included 236 implants and reported 2 implant losses during 60 months of follow-up, with a survival rate of

99%. Group 2 included 908 implants and reported 12 losses in 60 months of follow-up, with a survival rate of 99%. Group 3 included 1499 implants and reported 38 implant losses in 60 months, with a survival rate of 97%. And Group 4 included 823 implants and reported 12 losses in 108 months of follow-up, with a survival rate of 99%. Table 4 demonstrates that there was no statistically significant difference between the Groups *(p* = 0.078).

*Marginal bone loss*

Bone loss analysis included 15[18-20,22-25,28,32,33,35,38,40-42] of the 26 articles, as only these studies reported the necessary information.

The studies were grouped as mentioned above (Groups 1, 2, 3 and 4), and the first-year mean bone loss of the study was considered valid for all implants placed. The analysis considered the number of implants used in each study. Group 1 studies[22,23] included information on first-year mean bone loss for 150 implants, with a median of 0.54 mm (range of 0.47 to 0.88). In Group 2,[19,25,28,32,40] 316 implants were considered, and had a median first-year bone loss of 1.05 mm, (range of 0.32 to 1.42). Group 3[18-20,35,38,40-42] included 1239 implants, with a median first-year bone loss of 0.9 mm (range of 0.15 to 1.66). And Group 4 studies[19,24,33,38] included information on first-year mean bone loss for 316 implants, with a median of 0.6 mm (range of 0.11 to1.37). As shown in Figure 3, bridges supported by three or two implants (Group 1) had the lowest bone loss (Kruskal-Wallis test, $p < 0.0001$). The Dunn's test revealed that there was a significant difference between Groups 1 and 2, Groups 1 and 3, groups 2 and 3, Groups 2 and 4 and between Groups 3 and 4. However, there was no significant difference between Groups 1 and 4.

*Prosthesis survival rate*

Twenty-one articles[8,18,19,23-26,28-41] reported 100% of prothesis survival rate. Of the remain, four studies[20-22,27] have shown prosthesis survival rate between 95% and 96.7%. Only one study[42] presented a significant low rate of prostheses survival (76.5%). This study belongs to the Group 3. Between the four articles which reported prosthesis survival rate equal or above 95%, Cannizzaro et al. (2016)[21] and Cannizzaro et al. (2017)[22] belonged to Group 1, Cannizzaro et al. (2015)[20] belonged to Group 3 and Ferrigno et al. (2002)[27] to Group 4.

## DISCUSSION

The time and the costs spent in the edentulous patient's rehabilitation are widely pointed as the main reason to reduce the number of implants installed to support a full fixed implant supported prosthesis. Besides, improve the healing period for patients by decreasing surgical trauma and to facilitate the hygiene process for them are additional benefits.[21,22,40] These considerations are especially relevant considering that older patients most often receive total rehabilitation treatments and these patients deserve better attention during the surgical moment and often have greater motor difficulties. This systematic review investigated whether the maxillary implant-supported full arch bridge supported by four implants had a satisfactory implant survival rate, marginal bone loss, and prosthesis survival rate compared to different numbers of implants.

The quality of the group analysis performed with the selected studies indicates limitations due to the lack of articles related to the subject under investigation. There is a lack of randomized controlled studies comparing the influence of implant number variations on the rehabilitation outcome. Regarding the quality of work and article itself, twenty-six articles were included in this analysis, and most were classified as good quality.[8,18,20-22,24-26,28,30-35,37,39,40-42] However, among them, only six studies were RTCs,[20-23,30,40] and one[23] of them was classified as high risk of bias, with significant methodological problems. Which reinforces the need for

additional RTCs to reduce the risk of bias and enhance the level of evidence of the results. Among the selected articles, missing or unclear numerical data about patients, interventions, and complications, and a lack of detail about losses during follow-up are issues that limit the quality of the results and suggest details to be considered for future studies, especially the improvement of documentation of medical records. Besides, it would be preferable to analyze the studies in groups, if the research developed by them were actually related to number comparisons of installed implants.

Concerning to biological complications, the studies do not present sufficient data to run a statistic analysis. Nevertheless, the described complications do not seem relevant to affect the survival rates analyzed here. The groups reported similar complications, which apparently are more related to the surgeon ability and technique, nevertheless the studies usually mentioned that the surgeons were experienced professionals; and also appears that the care taking by the patients with their oral hygiene was more related to these than the number of fixtures installed.

Since the sample size of the groups vary from each other, and the exact number of complications events are not available, it does not seem valid to affirm that one group actually had more prosthetic complications than others. Although it was possible to observe that prostheses screw loosening, fracture of acrylic resin provisional and definitive prostheses; teeth fracture, prosthetic teeth detached and porcelain chipping were the most common complications identified. Agnini et al. (2014)[19] suggest that adequate occlusal analysis and planning must be done since the provisional phase of the rehabilitation. Crespi et al. (2012)[25] advocate for the use of non–metal-reinforced acrylic resin restorations which could reduce the stress transmission to the bone-implant interface, however affirm that more long term prospective clinical trials are needed to confirm their effectiveness. Hinze et al. (2010)[34]

considered such complications as minor events and did not find correlation between them and the opposite dentition of the patients.

The analysis of implant survival has shown that all groups presented satisfactory rate, above 97%, with significative follow-up time varying from 60 to 108 months. There was no statistically significant difference between the Group 2, with four implants installed per patient, to the others. Thus, in this point is valid to say that regardless the number of implants used to support the rehabilitation of edentulous maxilla with full fixed prostheses, all groups have successfully played their roles.

The groups of studies that installed less than four implants or more than six implants (G1 and G4) registered the lowest values of peri-implant bone loss. Though, it is important to notice that the sample size of the groups was not equivalent, and the values analyzed are median and not mean values of bone loss. The group of interest (G2) presented median bone loss values and range satisfactory, likewise the other groups, considering the acceptable limit of 1.5 mm in the first year of function.[43]

Finally, in the Group 1, the prostheses had to be remade because of mechanical problems[21] in a bridge supported by two implants or after the loss of one implant in a bridge supported by three implants[22]. This should capture the clinician's attention for the disadvantage of installation of three or less implants to support a fixed full-arch bridge, as the failure of a single implant can result in the loss of the bridge. In the group 3, one prosthesis was lost because the patient lost two left implants inserted with a torque lower than 50 Ncm in soft bone.[20] In the work of Toljanic et al. (2016)[42], belonging to Group 3, in the first year, 3 patients lost all together 10 implants and were not able to use fixed restoration anymore and 1 patient was lost of follow up. At the end of a 5-year analysis, only 40 patients were evaluated, and among them, one prosthesis had failed. The reason for this was not mentioned. So, the prothesis survival rate of 76,5% considered the initial amount of 51 patients, but the authors of the article considered

a value of 97.5% of prosthesis survival rate (39/40). At last, Ferrigno et al. (2002),[27] in Group 4, lost 2 prostheses after the loss of 3 implants each. The authors suggest a possible relation between the prosthetic rehabilitation performed and the implant lost by the patients.

The primary limitation of this review was the lack of randomized clinical trials comparing the number of implants supporting maxillary profile prosthesis, thus increasing the risk of bias of the analysis. Besides, attempts to contact the authors of the enrolled articles did not result in satisfactory answers. The search using MeSH terms seems to be incomplete and unsatisfactory and have hindered the search for relevant articles, even with few filters applied. Yet, the authors conducted the review and analyzed all appropriate items, even though a meta-analysis could not be performed.

Factors such as the length of the cantilever, opposite dentition, surface, diameter and length of the fixtures could also influence the clinical outcomes. It is the authors opinion that the difficulty patients have performing necessary hygiene increases when more implants are used, which could affect the health and longevity of the rehabilitation. Nevertheless, an analysis of this relation could not be performed in this study because the included articles did not report the necessary data.

## CONCLUSIONS

Within the limitations of this work, it is possible to conclude that maxillary full fixed implant supported prostheses using four implants have shown a satisfactory implant survival rate and marginal bone loss during the first year of function. Moreover, the prosthesis survival rate was 100% in the group of four implants installed per patient. This suggests that the use of four implants to support a maxillary full fixed implant supported prosthesis is a predictable and stable modality of treatment for edentulism, since the patient's anatomy and systemic condition allow the adequate procedures.

## ACKNOWLEDGMENTS

This work was supported by CAPES – Coordenação de Aperfeiçoamento de Pessoal de Nível Superior- Brazil.

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## FIGURES LEGENDS

Figure 1. Flow diagram of the search processes and results.

Figure 2. Implant survival rate using the Kaplan-Meier method with implant as the unit of analysis.

Figure 3. First-year bone loss of all implants installed on the study. The number of all implants installed in each study was considered. Results are presented in Median with range. The different capital letters mean statistically significant difference between the groups ($p < 0.0001$).

**Figure 1.**

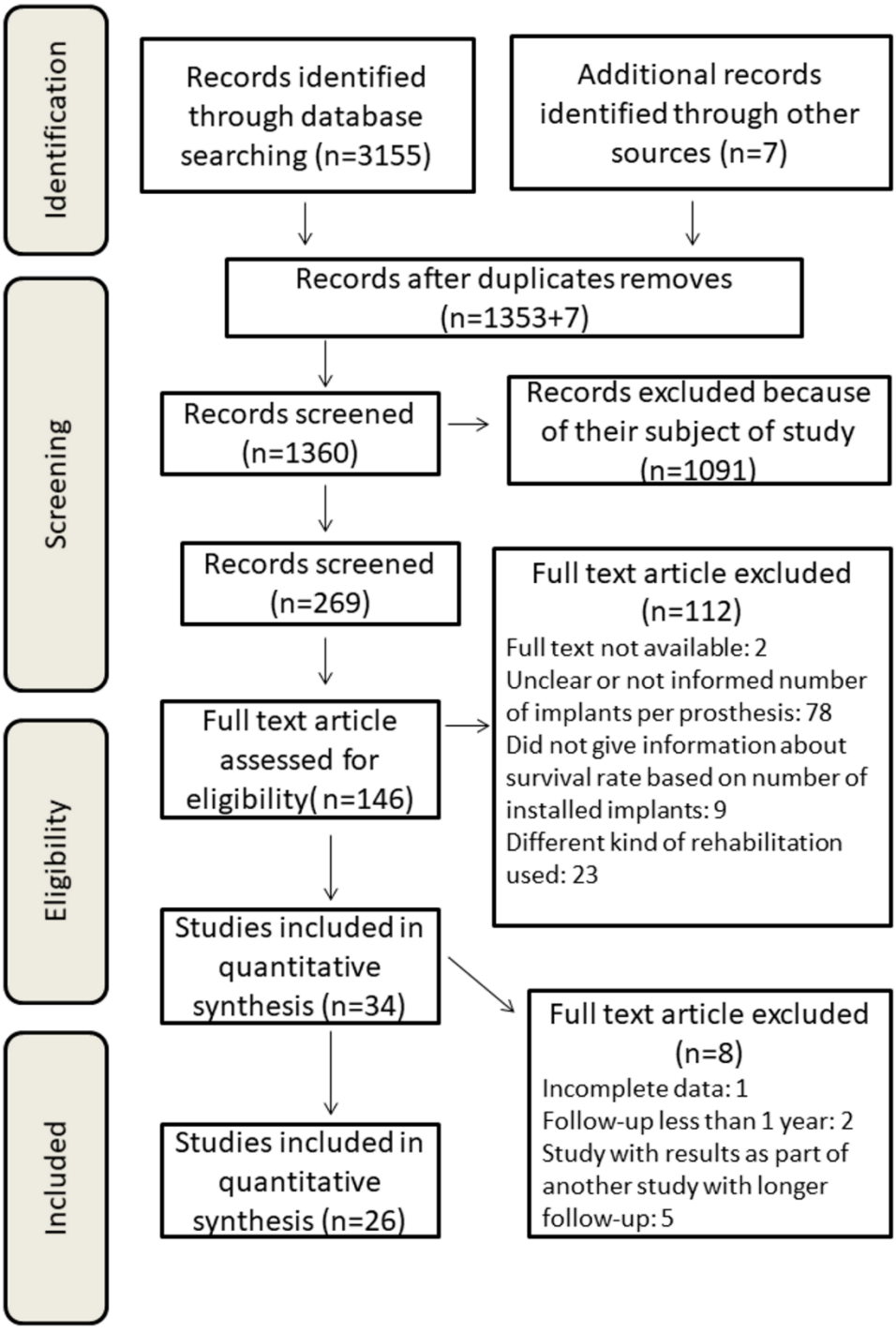
Identification
Screening
Eligibility
Included
Records identified through database searching (n=3155)
Additional records identified through other sources (n=7)
Records after duplicates removes (n=1353+7)
Records screened (n=1360)
Records excluded because of their subject of study (n=1091)
Records screened (n=269)
Full text article excluded (n=112)
Full text not available: 2
Unclear or not informed number of implants per prosthesis: 78
Did not give information about survival rate based on number of installed implants: 9
Different kind of rehabilitation used: 23
Full text article assessed for eligibility( n=146)
Studies included in quantitative synthesis (n=34)
Full text article excluded (n=8)
Incomplete data: 1
Follow-up less than 1 year: 2
Study with results as part of another study with longer follow-up: 5
Studies included in quantitative synthesis (n=26)

**Figure 2.**

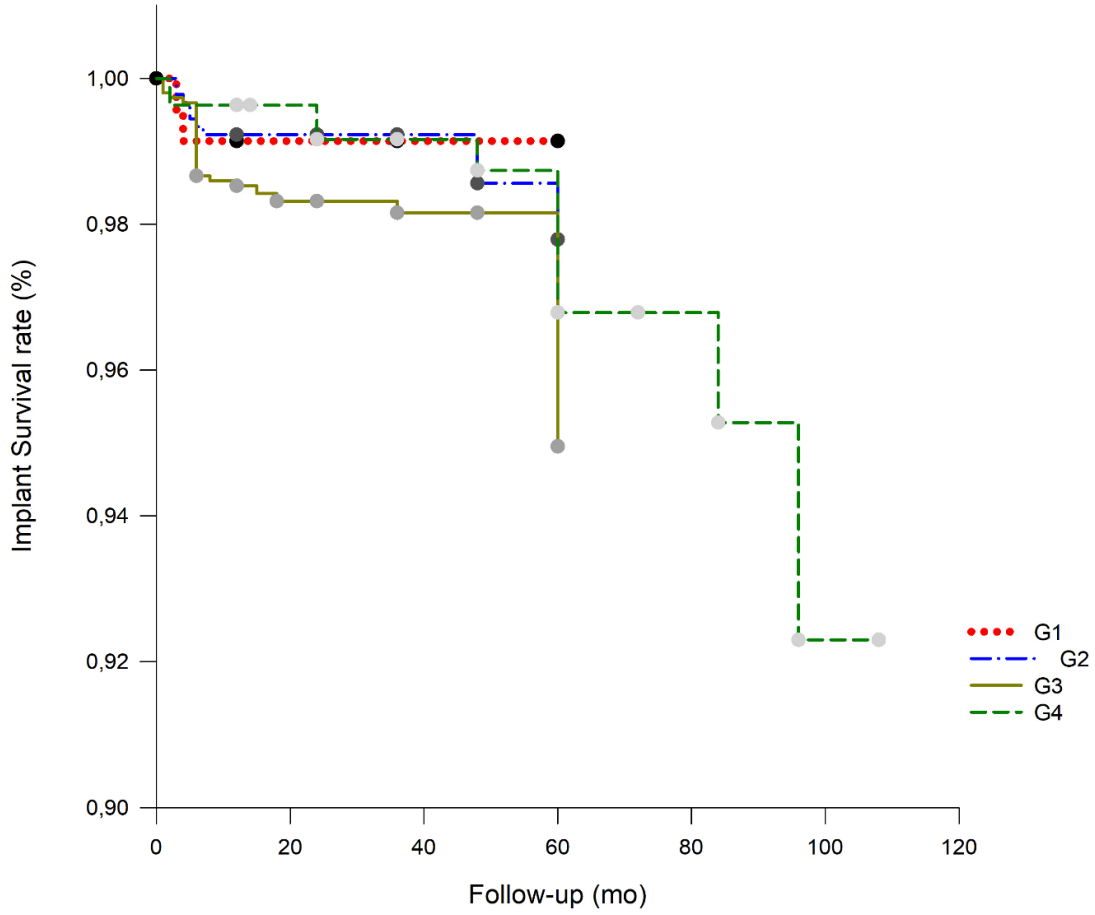
1,00
0,98
0,96
0,94
0,92
0,90
Implant Survival rate (%)
0
20
40
60
80
100
120
Follow-up (mo)
G1
G2
G3
G4

**Figure 3.**

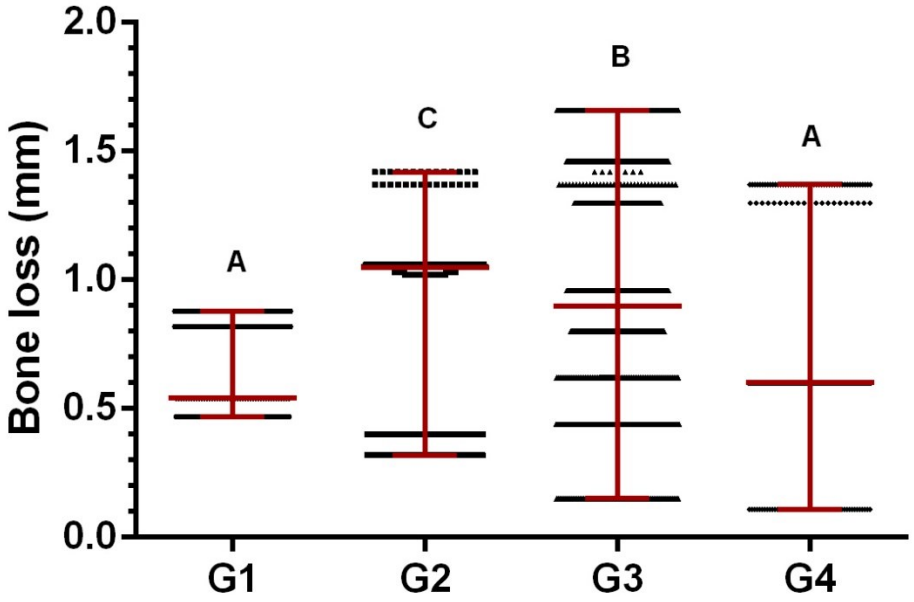

**Table 1.** General Characteristic of Included Studies

| Author, year | Type of study | Number of patients | N. of implants per patient [N. of patients] | Details of implants | Time of loading | Implant survival rate | Prostheses survival rate | Mean marginal bone loss (mm) | Follow-up (months) [N. of patients] |
|---|---|---|---|---|---|---|---|---|---|
| **Agliardi et al., 2009**[18] | Prospective | 20 | 6 | 4.0mm x 11.5m to 15mm | Immediate | 100% | 100% | **Axial:** 0.8 ± 0.4 / **Tilted:** 0.9 ± 0.5 | 12 |
| **Agnini et al., 2014**[19] | Prospective | 20 | 4[7], 6[7], 8[6] | Not reported | Immediate | 97.5% | 100% | **Axial**: 1.37 ± 0.14 / **Tilted:** 1.42 ± 0.14 | 12 |
| **Canizzaro et al., 2015**[20] | RCT | 30 | 6 | 4.1 to 6mm x 5 or 11.5mm | Immediate | 98.9% | 96.7% | **Short:** 0.15 ±0.04 / **Long:** 0.62±0.12 | 12 |
| **Canizzaro et al., 2016**[21] | RCT | 20 | 2[10]/ 3[10] | 3.80 to 5 mm x 8.5 to 13.0 mm | Immediate | 100% | 95% | Not reported | 12 |
| **Canizzaro et al., 2017**[22] | RCT | 20 | 3 | 3.8 to 5 mm x 8.5 to 15 mm | Immediate | 96.7% | 95% | **Machined:** 0.82 ±0.06 / **roghness:** 0.88 ± 0.06 | 12 |
| **Chowdhary and Kumararama 2018**[23] | RCT | 30 | 3 | 4.0 mm x 13 mm | Immediate and early | 100% | 100% | **Early loading:** 0.47 ± 0.24 / **immediate loading:** 0.54 ± 0.27 | 36 [29] |
| **Collaert and Bruyn 2008**[24] | Prospective | 25 | 7 [6], 8 [18] 9 [1] | 3.5 to 4mm x 8 to 15mm | Immediate | 100% | 100% | 0.6 | 36 [22] |
| **Crespi et al., 2012**[25] | Prospective | 24 | 4 | 3.75 or 4.0mm x 15 or 13 mm | Immediate | 98.9% | 100% | **Axial:**1.02 ± 0.35/ **Tilted:** 1.05 ± 0.29 | 36 |
| **Drago 2016**[26] | Retrospective | 112 | 4 [110], 5[2] | Not reported | Immediate | 99.5% | 100% | Not reported | 48 |
| **Ferrigno et al., 2002**[27] | Prospective | 55 | 8 | 3.3 or 4.1mm x 8.6, 10 or 12mm | Conventional and early | **1y:** 100% / **2y:** 99.5% / **10y:** 97.9% | 96.4% | Not reported | 12[55] /24 [46] / 108[1] |
| **Francetti et al., 2012**[28] | Prospective | 16 | 4 | 4 mm of diameter | Immediate | 100% | 100% | **Axial:** 0.40 ± 0.27 / **Tilted:** 0.32± 0.28 | 36 [16] / 48 [7] |
| **Galluci et al., 2004**[29] | Prospective | 5 | 10 [2], 8[3] | 8.0, 10 or 12mm long | Immediate | 95,4% | 100% | Not reported | 12 |
| **Gastaldi et al., 2017**[30] | RCT | 2 | 5[1], 6[1] | 4.0 mm x 10 or 11.5 mm | Early | 100% | 100% | Not reported | 60 |
| **Gherlone et al., 2016**[31] | Prospective | 17 | 4 | 3.75 or 4.3mm x 12 or 15.5mm | Immediate | 100% | 100% | Not reported | 12 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Gherlone et al., 2018**[32] | Prospective | 12 | 4 | 4.5 or 3.8mm x 13 or 15mm | Immediate | 100% | 100% | **Axial**:1.03 ± 0.33 / **Tilted:** 1.06 ± 0.50 | 60 |
| **Heinemann et al., 2012**[33] | Retrospective | 6 | 8[3],9 [2], 10[1] | Not reported | Immediate | 100% | 100% | 0.11 | 24 |
| **Hinze et al., 2010**[34] | Prospective | 19 | 4 | Not reported | Immediate | 92.1% | 100% | Not reported | 12 |
| **Katsoulis et al., 2011**[8] | Prospective | 13 | 4[1], 5[2], 6[10] | 4.3mm x 10 to 16mm | Conventional | 100% | 100% | Not reported | 24 |
| **Meloni et al., 2010**[35] | Retrospective | 15 | 6 | 4.3 or 5 mm x 10 to 13 mm | Immediate | 97.8% | 100% | 1.66 ± 0.20 | 18 |
| **Nikellis et al., 2004**[36] | Prospective | 14 | 4[1], 5[2], 6[8],7[1], 8[2] | 3.75mm x 10 to 20mm | Immediate | 100% | 100% | No bone loss below the first thread | 24 |
| **Oliva et al., 2012**[37] | Retrospective | 12 | 3 | 4.1 to 4.8 mm x 10 to 14 mm | Early | 100% | 100% | Not reported | 60 |
| **Ostman et al., 2005**[38] | Prospective | 20/20 | 6[17], 7[3] / 6 [20] | 10 to 18mm long | Immediate and Conventional | 99.2%/ 100% | 100% | 1.30 ± 1.06 / 1.46 ± 1.07 | 12 [20] [20] / 36 [14] 12] |
| **Ostman et al., 2010**[39] | Prospective | 4 | 6 | 4.0 or 5 mm x 8.5 to 15 mm | Immediate | 100% | 100% | Not reported | 12 |
| **Tallarico et al., 2016**[40] | RCT | 40 | 6[20], 4[20] | 3.3 and 4mm x 10, 11.5 or 13mm | Immediate | **6 impl:** 95%/ **4 impl:** 98.7% | 100% | **1y: 4 impl:** 1.05 ± 0.35 / **6 impl:** 0.96 ± 0.29 / **5y: 4 impl:** 1.71±0.42 / **6 impls:**1.51 ± 0.36 | 60 |
| **Testori et al., 2008**[41] | Prospective | 41 | 6 | Not reported | Immediate | 97.9% | 100% | **Axial:**0.9 ± 0.4 / **Tilted:** 0.8 ± 0.5 | 12[36] / 18 [30] |
| **Toljanic et al., 2016**[42] | Prospective | 51 | 6 | 3.5 to 5mm x 8 to 17mm | Immediate | 93.5% | 76.47% | **1y**: 0.44± 0.79 / **5y** 0.44± 1.25 | 12 [47] / 60[40] |

1 N. = number; Y = year; 4 impl: four implants per patient; 6 impl: six implants per patient.

**Table 2.** Studies quality assessment by MINORS scale

| METHODOLOGICAL ITEMS FOR NON-RANDOMIZED STUDIES | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Author, year** | **1A** | **2B** | **3C** | **4D** | **5E** | **6F** | **7G** | **8H** | **9I** | **10J** | **11K** | **12L** | **Score** |
| **NON-COMPARATIVE STUDIES** | | | | | | | | | | | | | |
| Agliard et al., 2009[18] | 2 | 2 | 2 | 2 | 0 | 2 | 1 | 0 | - | - | - | - | **11** |
| Collaert and Bruyn 2008[24] | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 0 | - | - | - | - | **12** |
| Drago 2016[26] | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | - | - | - | - | **14** |
| Ferrigno et al., 2002[27] | 2 | 2 | 2 | 2 | 0 | 2 | 0 | 0 | - | - | - | - | **10** |
| Gallucci et al., 2004[29] | 2 | 1 | 0 | 2 | 0 | 2 | 2 | 0 | - | - | - | - | **9** |
| Gherlone et al., 2018[32] | 2 | 2 | 2 | 1 | 0 | 2 | 2 | 0 | - | - | - | - | **11** |
| Hinze et al., 2010[34] | 2 | 1 | 2 | 2 | 0 | 2 | 2 | 0 | - | - | - | - | **11** |
| Meloni et al., 2010[35] | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 0 | - | - | - | - | **13** |
| Nikellis et al., 2004[36] | 2 | 1 | 1 | 2 | 0 | 2 | 2 | 0 | - | - | - | - | **10** |
| Oliva et al., 2012[37] | 2 | 1 | 2 | 2 | 0 | 2 | 2 | 0 | - | - | - | - | **11** |
| Ostman et al., 2010[39] | 2 | 1 | 2 | 2 | 0 | 2 | 2 | 0 | - | - | - | - | **11** |
| Toljanic et al., 2016[42] | 2 | 2 | 2 | 2 | 0 | 2 | 1 | 0 | - | - | - | - | **11** |
| **COMPARATIVE STUDIES** | | | | | | | | | | | | | |
| Agnini et al., 2014[19] | 2 | 1 | 2 | 1 | 2 | 2 | 1 | 0 | 2 | 2 | 0 | 2 | **16** |
| Crespi et al., 2012[25] | 2 | 1 | 2 | 2 | 0 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | **19** |
| Francetti et al., 2012[28] | 2 | 2 | 2 | 2 | 0 | 2 | 1 | 0 | 2 | 2 | 2 | 2 | **19** |
| Gherlone et al., 2016[31] | 1 | 1 | 2 | 2 | 0 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | **18** |
| Heinemann et al., 2012[33] | 2 | 1 | 2 | 2 | 0 | 2 | 2 | 0 | 2 | 2 | 0 | 2 | **17** |
| Katsoulis et al., 2011[8] | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | **20** |
| Ostman et al., 2005[38] | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 0 | 2 | 0 | 2 | 2 | **16** |
| Testori et al., 2008[41] | 2 | 2 | 2 | 2 | 1 | 0 | 1 | 0 | 2 | 2 | 2 | 2 | **18** |

A: clearly stated aim; B: inclusion of consecutive patients; C: prospective collection of data; D: appropriate endpoints; E: unbiased assessment; F: a follow-up period; G: losses to follow-up of < 5%; H: prospective calculation of the study size I: adequate control group; J: contemporary groups; K: baseline equivalence of groups; L: adequate statistical analyses.

**Table 3.** Study quality assessment by Cochrane risk of bias tool

| QUALITY OF RANDOMIZED CLINICAL TRIAL | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | SELECTION | | PERFORMANCE | DETECTION | ATTRITION | REPORTING | | FINAL SCORE |
| Randomized controlled trial, year | Sequence generation | Allocation Concealment | Blinding of participants and personnel | Blinding of outcome assessors | Incomplete outcome data | Selective outcome reporting | Other sources of bias | |
| Canizzaro et al., 2015[20] | LR | LR | LR | LR | LR | LR | U | **LR** |
| Canizzaro et al., 2016[21] | LR | LR | LR | LR | LR | LR | LR | **LR** |
| Canizzaro et al., 2017[22] | LR | LR | LR | LR | LR | LR | LR | **LR** |
| Chowdhary and Kumararama 2018[23] | HR | HR | HR | HR | LR | HR | HR | **HR** |
| Gastaldi et al., 2017[30] | LR | LR | LR | LR | LR | LR | LR | **LR** |
| Tallarico et al., 2016[40] | LR | LR | LR | LR | LR | LR | LR | **LR** |

LR: low risk of bias; U: unclear; HR: high risk of bias

**Table 4.** Implant survival ratio in the retrieved implants.

| Group | Total | Loss | Survival Rate | p- value |
|---|---|---|---|---|
| **G1** | 236 | 2 | 99 | 0,078* |
| **G2** | 908 | 12 | 99 | |
| **G3** | 1499 | 38 | 97 | |
| **G4** | 823 | 12 | 99 | |
| **Overall** | 3466 | 64 | 98 | |

*: log rank statistic for the survival curves is not great enough to exclude the possibility that the difference is due to random sampling variability; there is not a statistically significant difference (p =0,078).

### 3.3. Capítulo 3

Maxillary Implant supported full-arch rehabilitation using different number of implants: three cases report

Lívia Bonjardim Lima; Marcos Boaventura de Moura; Flávia Noemy Gasparini Kiatake Fontão; Geninho Thomé Dercelino Bittencourt Júnior; Paulo Cézar Simamoto-Júnior

Artigo a ser submetido para o periódico International Journal of Implant Dentistry

**Maxillary Implant supported full-arch rehabilitation using different number of implants: three cases report**

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## ABSTRACT

**Background:** For a long time, the rehabilitation of maxillary edentulous arches with implant supported full-arch prostheses was conducted with the installation of a significant large number of implants. Nevertheless, these rehabilitation cases can be challenging if the bone availability is restricted. The alternatives for this situation could be bone graft procedures, maxillary sinus elevation or the use of a reduced number of implants in strategic positions. **Case presentation:** This work describes and discuss three cases of patients with edentulous maxillae which were rehabilitated with full fixed prostheses supported by six, five and four implants respectively. After two years of follow-up, the three patients were invited to answer oral health-related quality of life questionnaires and visual analogic scale of satisfaction. **Conclusions:** All patients presented good clinical and radiographic aspects at their returns. The quality of life did not seem to be reduced, regardless the number of implants used to support the prostheses. All patients presented satisfactory scores of satisfaction with their treatment.


**Keywords:** Dental Implants, Dental Prosthesis, Implant-Supported, Quality of life, Patient Satisfaction

## BACKGROUND

Although the edentulism do not seem to play a major role on the oral health in developed countries populations [1], when the global aspect of the elderly people is analyzed it can be noted that high levels of caries, tooth loss and periodontal diseases remain present as a problem of oral health [2].

Taking into account the bone resorption caused by teeth loss along with the resulted poor removable prosthesis retention on the jaws, it is observed a constant feeling of insecurity by the patient that uses this kind of rehabilitation device [3]. The implant supported full fixed prosthesis is consolidated as a reliable method to provide for the edentulous patient better stability [4] and masticatory function [5], as well as a potential to positively impact on oral health quality of life [4,6].

Reports of large numbers of implants used to fully rehabilitate edentulous maxilla with implant supported protheses are found on the literature [7-9], however studies have been conducted with the aim of determine whether the reduction of the number of implant installed to support a full fixed prothesis could be a reasonable option for the patient, without prejudice in terms of implant and prostheses survival [10-14].

The reduced number of installed implants can afford for the patient a less invasive procedure, decreased treatment cost and besides a possible facilitation of oral hygiene procedures [10,11,14]. In fact, the process of bone resorption suffered by the jaws after the tooth loss can actually makes more difficult a fixed rehabilitation with implants if a large number of these are the intention. Thus, in order to escape from bone grafts surgical procedures and searching for simplified methods, studies are being developed [15,16].

Beyond the biological requirements, understanding the impact of implant supported rehabilitation on quality of life and self-perception of the patient should be taken as parameters for the final measurement of treatment quality [17-19]. The success of a rehabilitation consists

of not only the functional aspects, but in a special way the psychosocial self-acceptation by the patient [20].

Thus, this article intends to demonstrate and discuss three cases of patients with edentulous maxillae which were rehabilitated with full fixed prostheses supported by six, five and four implants respectively. They all complete two years of follow-up and the three patients answered oral health-related quality of life questionnaires and visual analogic scale of satisfaction after they signed the informed consent term. (Ethical approval number: 09005419.8.0000.5152).

## CASES PRESENTATION

### Case 1

A 61-year-old woman presented at the Oral Implant Dentistry Department of the Faculty Ilapeo, Curitiba, Brazil. The same showed partial edentulism, with unsatisfactory unitary crowns at the upper jaw (Figure 1). At the first moment, anamnesis and radiographic examination were performed. No systemic diseases were reported by the patient. At the time of the clinical and radiographic examination was noted the presence of periapical disease in several teeth, associated with bone loss and unsatisfactory endodontic treatments. It was suggested the extraction of the remain dental elements and installation of dental implants to supported full-arch fixed prosthesis in both arches. Once patient was prepared and the surgical planning was established, six dental implants (Helix, GM Acqua, Neodent, Curitiba, Brazil) were inserted in the upper jaw, two of them with 3.75mm x 11.5mm of dimension, two with 3.5mm x 11.5mm, one with 3.75mm x 13mm and the another with 4mm x 13mm of dimension, immediately after the extraction of the remain teeth. Primary implant stability (insertion torque above 45N) was obtained and definitive titanium abutments were inserted on the implants with

torque of 20N. During the same week, prosthetic procedures were conducted and the patient received the definitive implant supported full-arch prothesis (Figure 2).

Panoramic radiograph was taken at this time, indicating satisfactory positioning of the implants and prosthetic adaptation. Clinical follow-up visits occurred at 4, 8 and 12 months (Figure 3) after loading. Radiographic evaluation was repeated at the 12 months return with a panoramic radiograph (Figure 4). By that time no biologic neither prosthetic complications were noted. At the 24 months follow-up visit, the patient was invited to answer an oral health-related quality of life questionnaire and visual analogic scale of satisfaction. At this time the patient presented full-arch implant supported prostheses in both arches. After signing the informed consent form, the questionnaires were applied.

**Case 2**

A 69-year-old man presented at the Oral Implant Dentistry Department of the Faculty Ilapeo, Curitiba, Brazil. At the clinical evaluation, the patient presented partial edentulism, with unsatisfactory multiple fixed prostheses and unitary crown at the upper jaw (Figure 1). Anamnesis and radiographic examination were performed. At the radiographic examination was observed bone loss around the pillar teeth of the fixed protheses, misfit and caries infiltration of the fixed prostheses, besides periapical diseases in the inferior teeth. Arterial hypertension, diabetes and previous heart attack were reported by the patient, but after medical evaluation the surgical procedure was allowed. Extraction of the remain dental elements and placement of dental implants to supported full-arch fixed prostheses was the suggested treatment. Once patient was prepared and the surgical planning was established, five dental implants (Helix, GM Acqua, Neodent, Curitiba, Brazil) were inserted in the upper jaw, two of them with 4.0mm x 16mm of dimension and three with 3.75mm x 16mm of dimension, immediately after the extraction of the remain teeth. Primary implant stability (insertion torque

above 32N) was obtained and definitive titanium abutments were inserted on the implants with torque of 20N. Within four days, prosthetic procedures were conducted and the patient received a definitive implant supported full-arch prothesis (Figure 2).

A panoramic radiograph was taken, indicating satisfactory positioning of the implants and prosthetic adaptation. Clinical follow-up visits also occurred at 4, 8 and 12 months (Figure 3) after loading. Radiographic evaluation was repeated at the 12 months return with a panoramic radiograph (Figure 4). No biologic neither prosthetic complications were noted during the visits. At the 24 months follow-up visit, the patient was invited to answer an oral health-related quality of life questionnaire and visual analogic scale of satisfaction. At this time the patient presented full-arch implant supported prostheses in the upper and lower jaw. After signing the informed consent form, the questionnaires were applied.

**Case 3**

A 61-year-old woman presented at the Oral Implant Dentistry Department of the Faculty Ilapeo, Curitiba, Brazil. The patient presented total edentulism in the upper jaw (Figure 1) and a full-arch implant supported prosthesis in the mandible. Anamnesis and radiographic examination were performed. At the radiographic examination was observed adequate bone dimensions on the right side of the maxilla, but reduced bone availability and sinus pneumatization on the left side. Cardiac alteration was reported by the patient, but after medical evaluation the surgical procedure was allowed. Placement of dental implants to supported a full-arch fixed prosthesis was the suggested treatment. Once patient was prepared and the surgical planning was established, four dental implants (Helix, GM Acqua, Neodent, Curitiba, Brazil) were inserted in the upper jaw, two of them with 3.75mm x 16mm of dimension and two with 3.75mm x 13mm of dimension, immediately after the extraction of the remain teeth. Primary implant stability (insertion torque of 60N) was obtained and definitive

titanium abutments were inserted on the implants with torque of 20N. During the four next days, prosthetic procedures were conducted and the patient received the definitive implant supported full-arch prothesis (Figure 2).

A panoramic radiograph was taken, indicating satisfactory positioning of the implants and prosthetic adaptation. Clinical follow-up visits also occurred at 4, 8 and 12 months (Figure 3) after loading. Radiographic evaluation was repeated at the 12 months return with a panoramic radiograph (Figure 4). At the four months visit it was necessary to adjust the acrylic portion of the prosthesis to reduce the compression on the soft tissue. At the 12 months visit new adjust was made and new hygiene orientation was presented to the patient. At the 24 months follow-up visit, the patient was invited to answer an oral health-related quality of life questionnaire and visual analogic scale of satisfaction. After signing the informed consent form, the questionnaires were applied.

**Oral health-related quality of life and patient satisfaction**

The Oral Health Impact Profile 14 (OHIP-14Br) [21] was applied to measure the influence of oral health on the well-being of individuals on 2 years follow-up returns after implant placement. OHIP-14 is divided into the following items: functional limitation (items 1 and 2), physical pain (items 3 and 4), psychological discomfort (items 5 and 6), physical disability (items 7 and 8), psychological disability (items 9 and 10), social disability (items 11 and 12) and social disadvantage (items 13 and 14). Questions were scored on a scale: 0 indicates never; 1 rarely; 2 sometimes; 3 constantly and 4 always. The highest score represents the worst quality of life and vice versa. The score of each patient was 4. All but one of the items were answered as “never”, with a score of “0”. Only the item 5, which refers to psychological discomfort and asks the patient about the self-conscience of their prostheses, was reported as “always”, giving a final score of “4” for each patient.

Factors with the potential to affect patient satisfaction (eg, quality of perception, aesthetic perception, ease of cleanliness, etc.) were analyzed using a Visual Analog Scale similar to that employed by a study [18] which evaluated both the implant site-related and patient-based factors with the potential to affect the extent of patients' satisfaction. The scale is graded from 0 to 100, with 0 being "totally dissatisfied" and 100 "fully satisfied". Values above 70 are considered to be satisfied. Patient completion of the scale were performed at follow-up returns of 2 years after implant installation. The patients presented on case 1 and 2, answered "100" (fully satisfied) for fourteen of fifteen questions. Only the question about the cost of the treatment was marked in "90". The patient presented on case 3, answered "100" (fully satisfied) for eight of fifteen questions (items about speech, surgical act, time between surgery and rehabilitation, cost, future implant surgery and recommendation of the procedure to a friend). Three questions were graded as "90", they were about the esthetic of the prosthesis, self-expectations and daily activities like bite and chew. Another three questions were graded as "80", they enrolled satisfaction with the prosthesis, pre-operatory information's about the treatment and fear concerning to the hygiene of the implants. Finally, the question about the cleaning of the prosthesis received the score "70".

## DISCUSSION

The installation of six or more implant to support a full-arch fixed prosthesis in the maxilla is known to be an adequate and reliable treatment modality for edentulous patients [8,9]. The presented case 1 is a good representation of this rehabilitation. In the two years of follow-up it was not seen any biologic or prosthetic complication or complaining by the patient.

Some aspects like the treatment cost [10, 22], the inter-implant distance for hygiene process by the patient [11] and the bone availability [22] should be considered by the oral

surgeon before determine the number of implants to be installed for support a full-arch fixed prosthesis in maxilla.

Besides, with the aging process occurring on population [23], it seems reasonable that the oral surgeon evaluates carefully the systemic condition of the patient, and plans a less traumatic surgical procedure. Besides, in cases where bone availability is restricted, the reduction of number of implants should be considered rather than more complex surgical procedures as bone grafts [24] and maxillary sinus augmentation [25], or zygomatic implants [26]. The "all-on-four" modality is an attempt to obtain a treatment with reduced time and cost through immediate implant-supported prostheses, allowing relatively simple and predictable therapy for edentulous patients with atrophic jaws [22].

This work reports cases of maxillary full-arch rehabilitations supported by six, five and four implants. All patients were treated with immediate loading of the implants. In two years of follow-up, it was not seen any clinical or radiographic signs suggesting a possible failure or even minor problem with none of the prosthesis. Other studies have presented good results with immediate loading in full arch implant supported prostheses [9,13, 22, 27]. Some authors [13] suggest that patients being treated with immediately loading protocol need to be enlightened and encouraged to follow a continuous follow-up program including the treatment of a dental hygienist. This is exactly one of the aspects that these three cases well instance, since all patients were evaluated at 4, 8, 12 and 24 months post-loading, until now.

In two (case 1 and 2) of the treated patients, the implants were installed in fresh sockets. Although it was not seen any biologic complication during the follow-up is important to be aware that the association of immediate implantation, poor quality of bone found in maxilla and immediate loading require attention during the osseointegration phase. A group of authors [28] suggest that immediate implant placement associate with immediate loading in upper jaw could result in increase of failure rate. It is worthwhile to say that to allow immediate

rehabilitation, it is suggested [22] that the implants should be inserted with a final torque of between 30-50 N. In our report, all implants were installed with torque of at least 32N.

Concerning to the hygiene process, the authors agree with the study [29] which affirmed that the dentist should prevent peri-implantitis instead of treat it. These authors also emphasize that the dental professional should continually encourage the patient to adhere to consistent home care in order to prevent peri-implantitis. Other study [30] even suggest that electric toothbrush use may be an effective part of a self-performed cleaning protocol for patients with All-on-4 concept to facilitate plaque removal.

Regardless the number of installed implants in these three cases and despite the fact that periapical radiographs were not available for the two years evaluation, the one- year panoramic radiograph and the clinical parameters do not suggest any significant marginal bone loss. However, new radiographic exams must be done to confirm this affirmation.

Prosthetic complications including interim prosthesis (denture base) fracture, denture tooth debonding/delamination, denture tooth fracture, prosthetic and/or abutment screw loosening, usually reported as seen in full arch implant supported rehabilitations [31], were not observed in these patients. The patient shown in case 3 had to have her acrylic base of the prosthesis adjusted because of soft tissue compression. Only a minor inflammation was noted at the region and improved after. Certainly, continuous clinical returns must happen to preserve the good function and esthetic of the prostheses.

The oral health-related quality of life is an important aspect to be considered when the dentist wants to determine the success of the treatment. Among the cases reported here, the greater score obtained with the OHIP-14Br was “4”. That indicates a lower impact of the treatment modality on quality of life. The only negative aspect that was constant among the patients was the self-conscience about the rehabilitation used. A previous study [20] about patient's subjective feelings after implant-supported rehabilitations, has found in the domain of

comfort the great impact on the responses. The authors [20] state that this factor is really difficult to determine irrespective of the excellence of the prosthesis, but should be considered to determine the success of the treatment. In general, the three patients were satisfied about speech, esthetic and function obtained, regardless the number of implants used.

All three patients have shown scores of satisfaction of “70” or more, which indicates that they are satisfied with the treatment received. Among the patients with five or six implants installed, the factor cost was the only one reported with less than “100” score, even though it received a “90” score, which indicates that it is issue to be considered when a treatment is proposed for the patient [18]. Only the patient which received four implants to support the fully rehabilitation has shown values between “70” and “100” among the items evaluated. Although the values still mean overall satisfaction, it is important to notice that four of fifteen items were scored with “80” or “70”. They enrolled satisfaction with the prosthesis, pre-operatory information’s about the treatment and fear concerning to the hygiene of the implants. Finally, the question about the cleaning of the prosthesis received the score “70”. Other study [18] has presented a similar information, and says that patients with bridges were less satisfied with the pretreatment information and cleanability of their prosthesis, than patients with single restoration. Although this is one case report and the information cannot be extrapolated to population, it can be at least an indication of factors to be well discussed with the patient before determine the treatment.

Finally, despite the number of patients presented, it could be noted that all three were adequately rehabilitated. The full-arch prosthesis supported by four implants did not presented worst clinical neither radiographic aspects compared to the others. The overall oral health-related quality of life was good and none of the patients was unsatisfied with the treatment received. Clinical prospective studies should be conducted enrolling not only the biologic and

prosthetic aspects, but the self-perception of the patients in order to fully understand the success of implant-supported full-arch rehabilitations.

## DECLARATIONS


### Acknowledgements

The authors report no acknowledgement related to this report.

### Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.


### Availability of data and materials

All data generated or analyzed during this study are included in this published article.

### Authors' contributions

All authors were involved with the literature review and/or the performance of the surgery and prosthetic procedures. All authors read and approved the final manuscript.

### Ethics approval and consent to participate

The work was submitted and approved by the research ethics committee- CEP and is identified by the number 3.342.159 and the patients gave informed consent for all surgical and prosthetic procedures.

## Consent for publication

Written informed consent was obtained from the patients for publication of this case report and accompanying images.

## Competing interests

Marcos Boaventura de Moura and Geninho Thomé work at Neodent, Curitiba, Brazil.

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## FIGURE TITLES

**Figure 1: A.** Initial clinical aspect of patient 1; **B.** Initial clinical aspect of patient 2; **C.** Initial clinical aspect of patient 3; **D**. Initial radiograph of patient 1; **E**. Initial radiograph of patient 2; **F**. Initial radiograph of patient 3.

**Figure 2: A.** Clinical aspect of prosthetic rehabilitation in patient 1; **B.** Clinical aspect of prosthetic rehabilitation in patient 2; **C.** Clinical aspect of prosthetic rehabilitation in patient 3; **D**. Initial radiograph after prosthesis installation in patient 1; **E**. Initial radiograph after prosthesis installation in patient 2; **F**. Initial radiograph after prosthesis installation in patient 3.

**Figure 3**: **A, D and G**: One-year clinical aspect of patient 1; **B, E and H:** One-year clinical aspect of patient 2; **C, F and I:** One-year clinical aspect of patient 3.

**Figure 4**: **A**: One-year radiograph aspect of patient 1; **B**: One-year radiograph aspect of patient 2; **C**: One-year radiograph aspect of patient 3.

**Figure 1:**

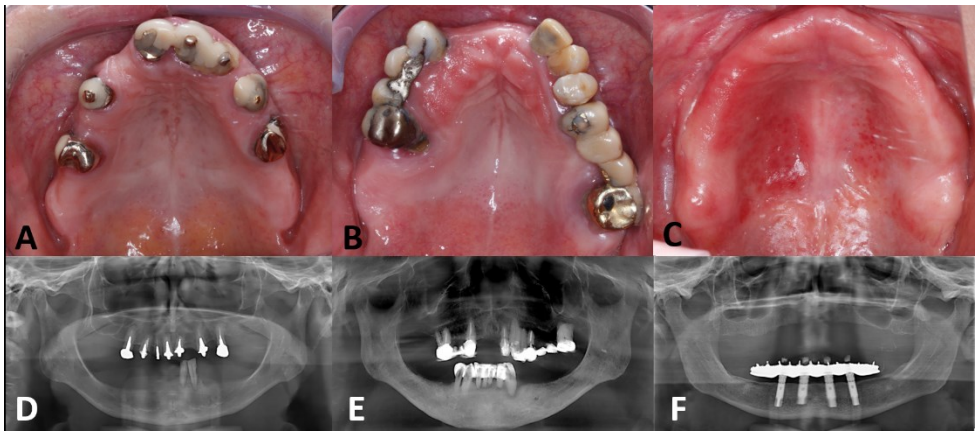



**Figure 2:**

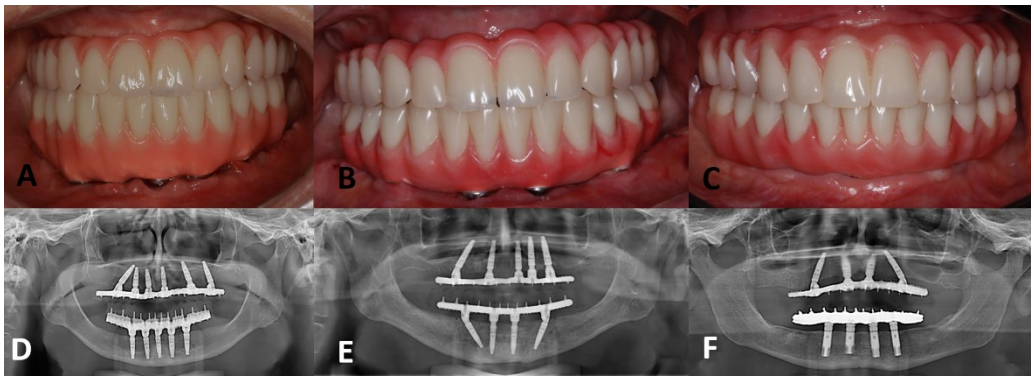


**Figure 3:**

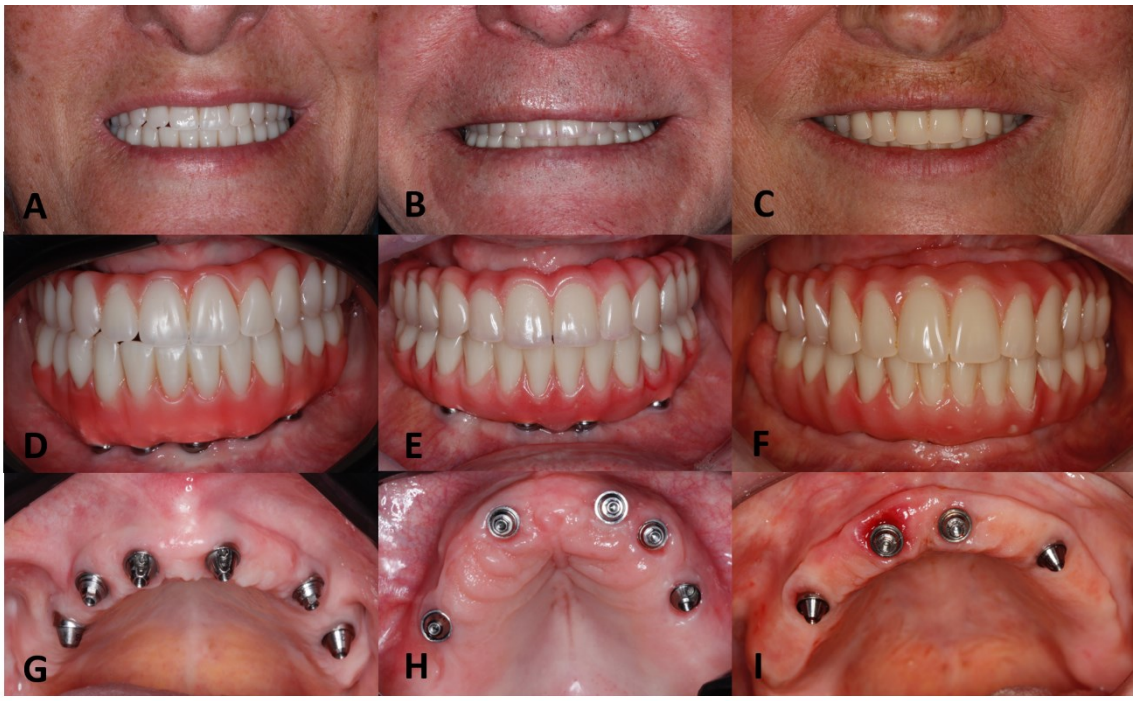
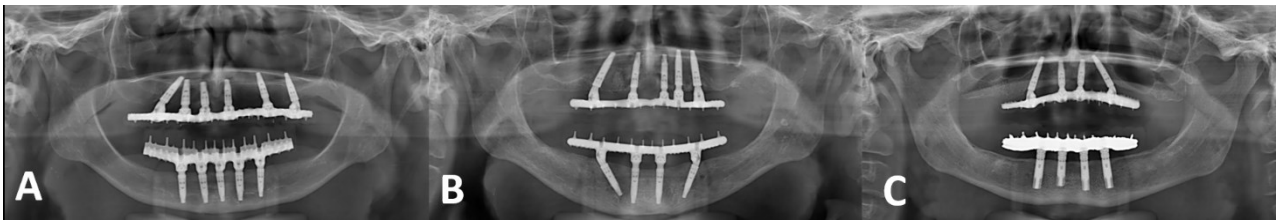



**Figure 4:**



# *CONSIDERAÇÕES FINAIS*

## 4. CONSIDERAÇÕES FINAIS

Considerando as limitações deste estudo, pôde-se concluir que: protocolos mandibulares suportados por três implantes demonstraram sobrevivência de implantes e perda óssea marginal no primeiro ano satisfatórios, no entanto a sobrevivência de próteses foi inferior aos demais grupos e isto sugere um maior acompanhamento de tais reabilitações; a taxa de sobrevivência de implantes e próteses, bem como a perda óssea marginal nos protocolos maxilares suportados por 4 implantes foram satisfatórios comparados com diferente número de implantes. Quanto ao impacto sobre a qualidade de vida e satisfação do paciente, os casos apresentados demonstraram escores satisfatórios, independentemente do número de implantes instalados. Estudos clínicos prospectivos, que englobem tanto os aspectos biológicos e protéticos quanto percepção do paciente quanto ao tratamento, deveriam ser desenvolvidos.

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* De acordo com a Norma da FOUFU, baseado nas Normas de Vancouver. Abreviaturas dos periódicos com conformidade com Medline (Pubmed).

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* De acordo com a Norma da FOUFU, baseado nas Normas de Vancouver. Abreviaturas dos periódicos com conformidade com Medline (Pubmed).

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# *ANEXOS*

**ANEXO 1.** Normas da revista do artigo 2.

JOMI
The International Journal of
ORAL & MAXILLOFACIAL IMPLANTS

## GUIDELINES FOR AUTHORS

### MANUSCRIPT SUBMISSION

**Submit manuscripts via JOMI's online submission service:**
**www.manuscriptmanager.com/jomi**
Manuscripts should be uploaded as a Word (doc) file with tables and figures preferably embedded at the end of the document.
*No paper version is required.*

**Acceptable material.** Original articles are considered for publication on the condition they have not been published or submitted for publication elsewhere (except at the discretion of the editors). Articles on implant or tissue engineering (TE) basic or clinical research, clinical applications of implant/TE research and technology, proceedings of pertinent symposia or conferences, quality review papers, and matters of education related to the implant/TE field are invited.

**Number of authors.** Authors listed in the byline should be limited to four. Secondary contributors can be acknowledged at the end of the article. (Special circumstances will be considered by the editorial chairman.)

**Review/editing of manuscripts.** Manuscripts will be reviewed by the editorial chairman and will be subjected to blind review by the appropriate section editor and editorial staff consultants with expertise in the field that the article encompasses. The publisher reserves the right to edit accepted manuscripts to fit the space available and to ensure conciseness, clarity, and stylistic consistency, subject to the author's final approval.

**Adherence to guidelines.** Manuscripts that are not prepared in accordance with these guidelines will be returned to the author before review.

### ONLINE ONLY ARTICLES

All technology and case reports will appear in online format only. Articles are listed in the issue's Table of Contents and abstracts are printed in the issue. Full text of articles is available online.

### MANUSCRIPT PREPARATION

- The journal will follow as much as possible the recommendations of the International Committee of Medical Journal Editors (Vancouver Group) in regard to preparation of manuscripts and authorship (Uniform requirements for manuscripts submitted to biomedical journals. Ann Intern Med 1997;126:36–47). See http://www.icmje.org
- **Manuscripts** should be double-spaced with at least a one-inch margin all around. Number all pages. Do not include author names as headers or footers on each page.
- **Title page.** Page 1 should include the title of the article and the name, degrees, title, professional affiliation, and full address of all authors. Phone, fax, and e-mail address must also be provided for the corresponding author, who will be assumed to be the first-listed author unless otherwise noted. If the paper was presented before an organized group, the name of the organization, location, and date should be included.
- **Abstract/key words.** The abstract should include a maximum of 350 words. A list of key words should be provided, not to exceed six. Abstracts for basic and clinical research articles must be structured with the following four sections: Purpose, Materials and Methods, Results, and Conclusions. Abstracts of short communications should also be structured but should be a maximum of 250 words. For all other types of articles (ie, literature reviews, technical and case reports), abstracts should not exceed 250 words and need not be structured.
- **Article text.** Currently there is no article page limit (within reason).
- **Acknowledgments.** Persons who have made substantive contributions to the study can be acknowledged at the end of the article. Also specify grant or other financial support, citing the name of the supporting organization and grant number.
- **Legends.** Figure legends should be typed as a group at the end of the manuscript. Detailed legends are encouraged. For photomicrographs, specify original magnification and stain.
- **Tables.** Each table should be logically organized, typed on a separate page at the end of the manuscript, and numbered consecutively. Table title and footnotes should be typed on the same page as the table.
- **Abbreviations.** The full term for which an abbreviation stands should precede its first use in the text unless it is a standard unit of measurement.
- **Trade names.** Generic terms are to be used whenever possible, but trade names and manufacturer name should be included parenthetically at first mention.
- **Numbers.** Per SI convention, authors are requested to use decimal points rather than commas for fractional numbers.

### REFERENCES

- All references must be cited in the text, numbered in order of appearance.
- The reference list should appear at the end of the article in numeric sequence.
- Do not include unpublished data or personal communications in the reference list. Cite such references parenthetically in the text and include a date.
- Avoid using abstracts as references.
- Provide complete information for each reference, including names of all authors (up to six). If the reference is to part of a book, also include title of the chapter and names of the book's editor(s).

***Journal reference style:***

1. Waasdorp J, Reynolds MA. Allogeneic bone onlay grafts for alveolar ridge augmentation: A systematic review. Int J Oral Maxillofac Implants 2010;25:525–531.

***Book reference style:***

1. Wikesjo UME, Hanisch O, Sigurdsson TJ, Caplanis N. Application of rhBMP-2 to alveolar and periodontal defects. In: Lynch SE, Genco RJ, Marx RE (eds). Tissue Engineering: Applications in Maxillofacial Surgery and Periodontics. Chicago: Quintessence, 1999:269–286.

### ARTICLE ACCEPTANCE

Article acceptance is pending receipt of images judged to be of sufficient quality for publication (see the guidelines below). Once a manuscript is accepted, authors should submit high-resolution digital image files (by email or on disk) to:

**Managing Editor**
**JOMI**
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The disk/package should be labeled with the first author's name, shortened article title, and article number.

### DIGITAL IMAGES/ACCEPTED ARTICLES

When preparing final images to send, consider the following points:

- Resolution must be at least 300 dpi when the image is 3 inches wide.
- Images saved in TIFF format are preferred, but JPG or EPS files are acceptable.
- Images grouped together must be saved as individual files.
- Images containing type should either be saved as a layered file or provided along with a second file with type removed.
- Line art (graphs, charts, drawings) should be provided as vector art (AI or EPS files)
- Please do not embed images into other types of documents (eg, Word, Excel, PowerPoint, etc).

### MANDATORY SUBMISSION FORM

The Mandatory Submission Form (accessible at www.quintpub.com) must be signed by all authors and can be uploaded as a separate document with the article submission, or it can be mailed (see address above) or faxed (630-736-3634) to the JOMI Managing Editor.

### PERMISSIONS AND WAIVERS

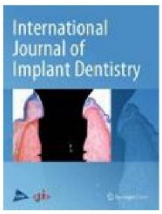
- Permission of author and publisher must be obtained for the direct use of material (text, photos, drawings) under copyright that does not belong to the author.
- Waivers must be obtained for photographs showing persons, otherwise faces will be masked to prevent identification.
- Permissions and waivers should be faxed along with the Mandatory Submission Form to the JOMI Managing Editor (630-736-3634).

### REPRINTS

Reprints can be ordered from the publisher. Authors receive a 40% discount on quantities of 100 or 200.

**ANEXO 1.** Normas da revista do artigo 3.






## Submission Guidelines



# Case Reports

## Criteria

We encourage the publication of original and interesting case reports that contribute significantly to medical knowledge.
Manuscripts must meet one of the following criteria:

1. Unreported or unusual side effects or adverse interactions involving medications.
2. Unexpected or unusual presentations of a disease.
3. New associations or variations in disease processes.
4. Presentations, diagnoses and/or management of new and emerging diseases.
5. An unexpected association between diseases or symptoms.
6. An unexpected event in the course of observing or treating a patient.
7. Findings that shed new light on the possible pathogenesis of a disease or an adverse effect.

- Case reports should include an up-to-date review of all previous cases in the field.
- Authors should seek written and signed consent to publish the information from the patients or their guardians prior to submission. Authors will be asked to confirm informed consent was received as part of the submission process. The submitted manuscript must include a statement to this effect in the 'Consent' section, as follows: "Written informed consent was obtained from the patient for publication of this case report and accompanying images". The editorial office may request copies of the informed consent documentation upon submission of the manuscript.
- Appropriate institutional review board (IRB) review and approval should accompany all studies involving human participants or research material derived from human participants. This information should be clearly stated in the Method section of the manuscript including the date of the IRB approval and duration of the trial/study. If the study was exempted from IRB approval, that information should be indicated in the Method section.

**Note to authors:** Regardless of below information, Case Report for *International Journal of Implant Dentistry* should be divided into three sections;"Background", "Case presentation", and "Discussion". Please refrain from using 'Conclusion'.

# Preparing your manuscript

### Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
  - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review, A case report etc."
  - or, for non-clinical or non-research studies: a description of what the article reports
- list the full names and institutional addresses for all authors
- if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below
- indicate the corresponding author

### Abstract

The abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. The abstract must include the following separate sections:

- **Background:** why the case should be reported and its novelty
- **Case presentation:** a brief description of the patient's clinical and demographic details, the diagnosis, any interventions and the outcomes
- **Conclusions:** a brief summary of the clinical impact or potential implications of the case report

### Keywords

Three to ten keywords representing the main content of the article.

### Background

The Background section should explain the background to the case report or study, its aims, a summary of the existing literature.

### Case presentation

This section should include a description of the patient's relevant demographic details, medical history, symptoms and signs, treatment or intervention, outcomes and any other significant details.

### Conclusions

This should state clearly the main conclusions and include an explanation of their relevance or importance to the field.

### List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

## Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and material
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

**Ethics approval and consent to participate**

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived)
- include the name of the ethics committee that approved the study and the committee's reference number if appropriate

Studies involving animals must include a statement on ethics approval.

See our editorial policies for more information.

If your manuscript does not report on or involve the use of any animal or human data or tissue, please state "Not applicable" in this section.

**Consent for publication**

If your manuscript contains any individual person's data in any form (including individual details, images or videos), consent to publish must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent to publish.

You can use your institutional consent form if you prefer. You should not send the form to us on submission, but we may request to see a copy at any stage (including after publication).

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If your manuscript does not contain data from any individual person, please state "Not applicable" in this section.

**Availability of data and materials**

All manuscripts must include an 'Availability of data and materials' statement. Data availability statements should include information on where data supporting the results reported in the article can be found including, where applicable, hyperlinks to publicly archived datasets analysed or generated during the study. By data we mean the minimal dataset that would be necessary to interpret, replicate and build upon the findings reported in the article. We recognise it is not always possible to share research data publicly, for instance when individual privacy could be compromised, and in such instances data availability should still be stated in the manuscript along with any conditions for access.

Data availability statements can take one of the following forms (or a combination of more than one if required for multiple datasets):

- The datasets generated and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS]

- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
- All data generated or analysed during this study are included in this published article [and its supplementary information files].
- The datasets generated and/or analysed during the current study are not publicly available due [REASON WHY DATA ARE NOT PUBLIC] but are available from the corresponding author on reasonable request.
- Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.
- The data that support the findings of this study are available from [third party name] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [third party name].
- Not applicable. If your manuscript does not contain any data, please state 'Not applicable' in this section.

More examples of template data availability statements, which include examples of openly available and restricted access datasets, are available here.

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Hao Z, AghaKouchak A, Nakhjiri N, Farahmand A. Global integrated drought monitoring and prediction system (GIDMaPS) data sets. figshare. 2014. http://dx.doi.org/10.6084/m9.figshare.853801

With the corresponding text in the Availability of data and materials statement:

The datasets generated during and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS].[Reference number]

**Competing interests**

All financial and non-financial competing interests must be declared in this section.

See our editorial policies for a full explanation of competing interests. If you are unsure whether you or any of your co-authors have a competing interest please contact the editorial office.

Please use the authors' initials to refer to each authors' competing interests in this section.

If you do not have any competing interests, please state "The authors declare that they have no competing interests" in this section.

**Funding**

All sources of funding for the research reported should be declared. The role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript should be declared.

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The individual contributions of authors to the manuscript should be specified in this section. Guidance and criteria for authorship can be found in our editorial policies.

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**Acknowledgements**

Please acknowledge anyone who contributed towards the article who does not meet the criteria for authorship including anyone who provided professional writing services or materials.

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This section is optional.

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

**Footnotes**

Footnotes should be designated within the text using a superscript number. It is not allowed to use footnotes for references/citations.

## References

Examples of the Vancouver reference style are shown below.

See our editorial policies for author guidance on good citation practice.

**Web links and URLs:** All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. http://tumor.informatics.jax.org/mtbwi/index.do. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

**Example reference style:**

*Article within a journal*

Smith JJ. The world of science. Am J Sci. 1999;36:234-5.

*Article within a journal (no page numbers)*

Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition.

BMC Medicine. 2013;11:63.

*Article within a journal by DOI*

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. Dig J Mol Med. 2000; doi:10.1007/s801090000086.

*Article within a journal supplement*

Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. Blood 1979;59 Suppl 1:26-32.

*Book chapter, or an article within a book*

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic; 1980. p. 251-306.

*OnlineFirst chapter in a series (without a volume designation but with a DOI)*

Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. Top Curr Chem. 2007. doi:10.1007/128_2006_108.

*Complete book, authored*

Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science; 1998.

*Online document*

Doe J. Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. 1999. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999.

*Online database*

Healthwise Knowledgebase. US Pharmacopeia, Rockville. 1998. http://www.healthwise.org. Accessed 21 Sept 1998.

*Supplementary material/private homepage*

Doe J. Title of supplementary material. 2000. http://www.privatehomepage.com. Accessed 22 Feb 2000.

*University site*

Doe, J: Title of preprint. http://www.uni-heidelberg.de/mydata.html (1999). Accessed 25 Dec 1999.

*FTP site*

Doe, J: Trivial HTTP, RFC2169. ftp://ftp.isi.edu/in-notes/rfc2169.txt (1999). Accessed 12 Nov 1999.

*Organization site*

ISSN International Centre: The ISSN register. http://www.issn.org (2006). Accessed 20 Feb 2007.

*Dataset with persistent identifier*

Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (Sorghum bicolor). GigaScience Database. 2011. http://dx.doi.org/10.5524/100012.

## General formatting information

Manuscripts must be written in concise English. For help on scientific writing, or preparing your manuscript in English, please see Springer's Author Academy.

Quick points:

- Use double line spacing
- Include line and page numbering
- Use SI units: Please ensure that all special characters used are embedded in the text, otherwise they will be lost during conversion to PDF
- Do not use page breaks in your manuscript

## File formats

The following word processor file formats are acceptable for the main manuscript document:

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- Rich text format (RTF)
- TeX/LaTeX (use either BioMed Central's TeX template)

**Please note:** editable files are required for processing in production. If your manuscript contains any non-editable files (such as PDFs) you will be required to re-submit an editable file if your manuscript is accepted.

For more information, see 'Preparing figures' below.

## Additional information for TeX/LaTeX users

Please use either BioMed Central's TeX template and BibTeX stylefile if you use TeX format. Submit your references using either a bib or bbl file. When submitting TeX submissions, please submit both your TeX file and your bib/bbl file as manuscript files. Please also convert your TeX file into a PDF (please do not use a DIV file) and submit this PDF as a supplementary file with the name 'Reference PDF'. This PDF will be used by our production team as a reference point to check the layout of the article as the author intended. Please also note that all figures must be coded at the end of the TeX file and not inline.

The Editorial Manager system checks for any errors in the Tex files. If an error is present then the system PDF will display LaTex code and highlight and explain the error in a section beginning with an exclamation mark (!).

All relevant editable source files must be uploaded during the submission process. Failing to submit these source files will cause unnecessary delays in the production process.

TeX templates:

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- article (part of the standard TeX distribution)
- amsart (part of the standard TeX distribution)

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For all manuscripts, information about data availability should be detailed in an 'Availability of data and materials' section. For more information on the content of this section, please see the Declarations section of the relevant journal's Instruction for Authors. For more information on SpringerOpen's policies on data availability, please see our editorial policies.

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# Preparing figures

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- Table titles (max 15 words) should be included above the table, and legends (max 300 words) should be included underneath the table.
- Tables should not be embedded as figures or spreadsheet files, but should be formatted using 'Table object' function in your word processing program.
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**ANEXO 3.** Aprovação pelo Comitê de Ética.

UNIVERSIDADE FEDERAL DE UBERLÂNDIA/MG

## PARECER CONSUBSTANCIADO DO CEP

**DADOS DO PROJETO DE PESQUISA**

**Título da Pesquisa:** Avaliação do impacto do número de implantes empregados para reabilitação de maxila com prótese tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados.

**Pesquisador:** Paulo Cézar Simamoto Júnior

**Área Temática:**

**Versão:** 2

**CAAE:** 09005419.8.0000.5152

**Instituição Proponente:** Universidade Federal de Uberlândia/ UFU/ MG

**Patrocinador Principal:** Financiamento Próprio

**DADOS DO PARECER**

**Número do Parecer:** 3.342.159

**Apresentação do Projeto:**

Trata-se da análise às respostas de pendências, segundo o parecer consubstanciado 3.263.802, de 13 de abril de 2019.

Trata-se de um estudo retrospectivo em pacientes que receberam, nos anos de 2017 e 2018, implantes em maxila e reabilitação com prótese total fixa implanto-suportada tipo protocolo, com 4, 5 ou 6 implantes instalados e suportando a prótese. O objetivo é avaliar o impacto do número de implantes empregados para reabilitação de maxila com prótese tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados, e, para isso, serão avaliados prontuários de pacientes do ILAPEO. Estes, estando de acordo com os critérios de inclusão, serão selecionados, as imagens radiográficas e tomográficas serão avaliadas e um questionário será aplicado para coleta de informações. Os dados coletados serão avaliados qualitativamente e quantitativamente.

**Objetivo da Pesquisa:**

OBJETIVO GERAL

Avaliar o impacto do número de implantes empregados para reabilitação de maxila com prótese tipo protocolo sobre a qualidade de vida, satisfação do paciente e sobre o sucesso dos implantes e da prótese instalados.

**Endereço:** Av. João Naves de Ávila 2121- Bloco "1A", sala 224 - Campus Sta. Mônica
**Bairro:** Santa Mônica **CEP:** 38.408-144
**UF:** MG **Município:** UBERLANDIA
**Telefone:** (34)3239-4131 **Fax:** (34)3239-4335 **E-mail:** cep@propp.ufu.br

OBJETIVOS ESPECÍFICOS:

Objetivo específico 1: Avaliar o comportamento clínico de próteses tipo protocolo suportadas por diferente número de implantes em maxila;

Objetivo específico 2: Acompanhar a perda óssea ao redor dos implantes que suportam a prótese tipo protocolo em maxila, por meio de imagens radiográficas e comparar a perda apresentada pelos implantes levando em consideração o número de implantes que suportam a prótese (4, 5 ou 6 implantes);

Objetivo específico 3: Avaliar a satisfação de pacientes reabilitados com prótese tipo protocolo em maxila e comparar a satisfação apresentada pelos pacientes levando em consideração o número de implantes que suportam sua prótese (4, 5 ou 6 implantes), com uso da Escala Visual Analógica (EVA);

Objetivo específico 4: Avaliar o impacto da saúde oral sobre a qualidade de vida do paciente reabilitado com prótese tipo protocolo em maxila, por meio do questionário de impacto de saúde oral sobre qualidade de vida OHIP-14Br e comparar o valor do impacto apresentado pelos pacientes levando em consideração o número de implantes que suportam sua prótese (4, 5 ou 6 implantes).

**Avaliação dos Riscos e Benefícios:**

Segundo os pesquisadores:

RISCOS:

Não há riscos evidentes que estejam relacionados com este projeto de pesquisa que comprometam a saúde dos pacientes. No momento da avaliação dos prontuários dos pacientes que receberam reabilitações implanto-suportadas tipo protocolo em maxila, por ser esta análise retrospectiva, não há risco cirúrgico aos pacientes, bem como não há riscos quanto à análise radiográfica, visto que este estudo somente avaliará exames de imagem já realizados pelos pacientes, não os submetendo a novas tomadas radiográficas. O único risco adicional refere-se à possibilidade de identificação do indivíduo quando da aplicação dos questionários e da escala visual analógica, no entanto cada participante será identificado apenas por um número nos questionários preenchidos, assim quando a informação coletada for utilizada não haverá nome ou imagem que exponha o paciente e desta maneira será mantido sigilo sob todas as informações pessoais dos participantes.

BENEFÍCIOS:
Os benefícios relacionados a este projeto de pesquisa estão relacionados à melhoria dos planejamentos de reabilitação utilizados em futuros tratamentos, por meio da verificação da eficiência da reabilitação estudada (implanto-suportadas tipo protocolo em maxila), oportunizando maior evidência clínica sobre as vantagens de utilização deste protocolo terapêutico. Os pacientes terão como principal benefício o acompanhamento adequado e periódico de seu tratamento recebido e reparo de possíveis intercorrências, visto que sua reabilitação protética já foi realizada e está sendo acompanhada retrospectivamente.

**Comentários e Considerações sobre a Pesquisa:**
As pendências listadas no Parecer Consubstanciado, seguem abaixo, bem como a resposta da equipe de pesquisa e a análise de atendimento ou não da pendência feita pelo CEP/UFU.

PENDÊNCIA 1: A forma de recrutamento é avaliação inicial de prontuários dos pacientes. Estes, estando de acordo com os critérios de inclusão, serão abordados por contato telefônico. O CEP esclarece que esta forma não pode ser utilizada, e os pesquisadores devem propor outra metodologia de abordagem do participante.

RESPOSTA DO PESQUISADOR: Entendemos que a abordagem por telefone aos pacientes realmente poderia não ser a forma ideal. Desta maneira, como os pacientes que receberam as próteses totais fixas implanto-suportadas em maxila tipo protocolo mantém acompanhamento de rotina a cada 6 meses na clínica do ILAPEO (por ser este um procedimento habitual e recomendado a pacientes que possuem próteses implanto-suportadas), entendemos que a melhor forma será usar tal momento de retorno do paciente para esclarecê-lo sobre o projeto de pesquisa, e apresentação do TCLE. Somente a partir de então, mediante aceitação e assinatura do TCLE, os dados serão coletados e os questionários aplicados aos pacientes.

ANÁLISE DO CEP: Pendência atendida
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PENDÊNCIA 2: SOBRE O TCLE

a) coloca-se como benefícios ao participante "Os benefícios serão o acompanhamento adequado e periódico do tratamento recebido e reparo de possíveis intercorrências.". Esse não é benefício da pesquisa, uma vez que o acompanhamento nas consultas ocorrerá mesmo que o paciente não participe da pesquisa. O trecho pode induzi-lo a pensar que só terá direito ao acompanhamento se participar do estudo. Corrigir o trecho no TCLE, lembrando que os benefícios devem ser os mesmos no TCLE, no projeto completo e na Plataforma Brasil.

RESPOSTA DO PESQUISADOR: No TCLE bem como no corpo do texto do projeto foi realizada a alteração devida. Observamos que o trecho acima realmente não estava condizente, visto que, por ser um estudo não intervencional, os benefícios são indiretos, desta forma foi realizada correção, estando da seguinte maneira no corpo do texto: Os benefícios gerados com este estudo, por não ser intervencional, serão indiretos e estão relacionados à melhoria dos planejamentos de reabilitação utilizados em futuros tratamentos, por meio da verificação da eficiência da reabilitação estudada (implanto-suportadas tipo protocolo em maxila) e do impacto deste tipo de tratamento na qualidade de vida do paciente, além da observação do quanto o paciente se mostra satisfeito com o tratamento recebido. Desta maneira, oportunizando maior evidência clínica sobre a utilização deste protocolo terapêutico na comunidade científica. No TCLE também foi realizada a alteração: Os benefícios gerados com este estudo serão indiretos, ao participar deste estudo o(a) senhor(a) estará auxiliando na melhoria dos planejamentos de reabilitação utilizados em futuros tratamentos, por meio da verificação da eficiência do tratamento recebido pelo paciente e do impacto deste tipo de tratamento na qualidade de vida do paciente além da observação do quanto o paciente se mostra satisfeito com o tratamento recebido.

ANÁLISE DO CEP: Pendência atendida

b) Em riscos ao participante, destaca-se o trecho "Os riscos estão relacionados com os materiais empregados em seus atendimentos clínicos de acompanhamento, que seriam realizados mesmo que não estivesse participando desta pesquisa, e estes materiais serão descartáveis e os instrumentais serão esterilizados". Se a pesquisa propõe apenas avaliação de prontuário, de imagens, visual e aplicação de questionário, este risco não é compatível com o estudo proposto. Revisar o TCLE e fazer as adequações também no projeto completo e na Plataforma Brasil.

RESPOSTA DO PESQUISADOR: Observamos que esta parte do texto realmente não estava correta e as correções foram feitas no TCLE pois no texto do projeto de pesquisa não havia erro.
Desta forma, no TCLE a alteração seguinte foi realizada: Os riscos desta pesquisa estão somente relacionados à possibilidade de identificação do participante, no entanto, cada participante será identificado apenas por um número nos questionários preenchidos, assim quando a informação coletada for utilizada não haverá nome ou imagem que exponha o paciente.

ANÁLISE DO CEP: Pendência atendida.

**Considerações sobre os Termos de apresentação obrigatória:**
Todos os termos devidamente apresentados.

**Conclusões ou Pendências e Lista de Inadequações:**
As pendências apontadas no parecer consubstanciado número 3.263.802, de 13 de abril de 2019, foram atendidas.

De acordo com as atribuições definidas na Resolução CNS 466/12, o CEP manifesta-se pela aprovação do protocolo de pesquisa proposto.
O protocolo não apresenta problemas de ética nas condutas de pesquisa com seres humanos, nos limites da redação e da metodologia apresentadas.

**Considerações Finais a critério do CEP:**
Data para entrega de Relatório Final ao CEP/UFU: Janeiro de 2021.

OBS.: O CEP/UFU LEMBRA QUE QUALQUER MUDANÇA NO PROTOCOLO DEVE SER INFORMADA IMEDIATAMENTE AO CEP PARA FINS DE ANÁLISE E APROVAÇÃO DA MESMA.

O CEP/UFU lembra que:
a- segundo a Resolução 466/12, o pesquisador deverá arquivar por 5 anos o relatório da pesquisa e os Termos de Consentimento Livre e Esclarecido, assinados pelo sujeito de pesquisa.
b- poderá, por escolha aleatória, visitar o pesquisador para conferência do relatório e documentação pertinente ao projeto.
c- a aprovação do protocolo de pesquisa pelo CEP/UFU dá-se em decorrência do atendimento a Resolução CNS 466/12, não implicando na qualidade científica do mesmo.

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Orientações ao pesquisador :

• O sujeito da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (Res. CNS 466/12 ) e deve receber uma via original do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado.

• O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado e descontinuar o estudo somente após análise das razões da descontinuidade pelo CEP que o aprovou (Res. CNS 466/12), aguardando seu parecer, exceto quando perceber risco ou dano não previsto ao sujeito participante ou quando constatar a superioridade de regime oferecido a um dos grupos da pesquisa que requeiram ação imediata.

• O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo (Res. CNS 466/12). É papel de o pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.

• Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprobatório do CEP, para serem juntadas ao protocolo inicial (Res.251/97, item III.2.e).

**Este parecer foi elaborado baseado nos documentos abaixo relacionados:**

| Tipo Documento | Arquivo | Postagem | Autor | Situação |
|---|---|---|---|---|
| Informações Básicas do Projeto | PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1288525.pdf | 06/05/2019 08:01:02 | | Aceito |
| Outros | resposta_ao_parecer.docx | 06/05/2019 08:00:28 | Paulo Cézar Simamoto Júnior | Aceito |
| Projeto Detalhado / Brochura Investigador | Projeto_pesquisa.pdf | 06/05/2019 07:58:13 | Paulo Cézar Simamoto Júnior | Aceito |
| TCLE / Termos de Assentimento / Justificativa de Ausência | TCLE.pdf | 06/05/2019 07:57:59 | Paulo Cézar Simamoto Júnior | Aceito |

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|---|---|---|---|---|
| Folha de Rosto | Folha_de_Rosto.pdf | 24/02/2019 18:32:42 | Paulo Cézar Simamoto Júnior | Aceito |
| Outros | Lattes_dos_pesquisadores.pdf | 24/02/2019 18:31:13 | Paulo Cézar Simamoto Júnior | Aceito |
| Declaração de Pesquisadores | Equipe_executora.pdf | 24/02/2019 18:24:39 | Paulo Cézar Simamoto Júnior | Aceito |
| Outros | EVA.pdf | 01/02/2019 09:54:31 | Paulo Cézar Simamoto Júnior | Aceito |
| Outros | OHIP.pdf | 01/02/2019 09:54:13 | Paulo Cézar Simamoto Júnior | Aceito |
| Declaração de Instituição e Infraestrutura | Instituicao_coparticipante.pdf | 01/02/2019 09:40:14 | Paulo Cézar Simamoto Júnior | Aceito |

**Situação do Parecer:**
Aprovado

**Necessita Apreciação da CONEP:**
Não

UBERLANDIA, 22 de Maio de 2019

**Assinado por:**
**Karine Rezende de Oliveira**
**(Coordenador(a))**